Guidelines of the Belgian Hemovigilance Report

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Recommendations of the hemovigilance report 2008 were also formulated in the previous reports and remain valid. The hemovigilance data and recommendations have helped to reduce "wrong blood" transfusions but errors continue to occur. Further reduction of human errors will need to focus on the utilisation of appropriate computerized systems.

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Introduction

Hemovigilance is defined as the set of organized surveillance procedures relating to serious adverse or unexpected events or reactions in donors or recipients of blood and blood components, and the epidemiological follow-up of donors.[1] In Belgium, the organization of hemovigilance is one of the missions of the Federal Agency for Medicines and Health Products (FAMHP). The purpose of hemovigilance (or blood surveillance) is to improve and assure the quality and safety of the complete blood transfusion chain from the donor to the recipient including the safety of the collection and the administration of blood components. To achieve this goal, data on serious adverse reactions and events, that may affect the quality and safety of blood and labile blood components or may put the life of the donor or the recipient in danger are recorded and evaluated. Reporting of serious adverse reactions and events is mandatory. Based on these reports, the hospitals and blood establishments can take appropriate measures to prevent recurrence of events in order to improve the safety of the blood transfusion. At the level of the FAMHP, the obtained data are further evaluated and translated into a number of general recommendations that further contribute to enhance the quality and safety of the blood transfusion chain. Recently the annual hemovigilance report 2008 of the FAMHP was published.[2] This report provides an overview of serious adverse events and reactions identified and reported in 2008 by hospitals and blood establishments, as well as a set of recommendations. In this article the data and the recommendations for hospitals will be discussed and compared with those of some other countries.

Results

In 2008 four hemolytic transfusion reactions due to ABO incompatibility were notified. Interestingly, the number of this type of serious reactions decreased from 10 in 2006 to 7 in 2007 and 4 in 2008 (*Figure 1*). As the hemovigilance system started in November 2005, data on serious reactions before 2006 are not available. However, the total number of notifications of wrong blood transfused to a recipient, including the reports of hemolytic reactions

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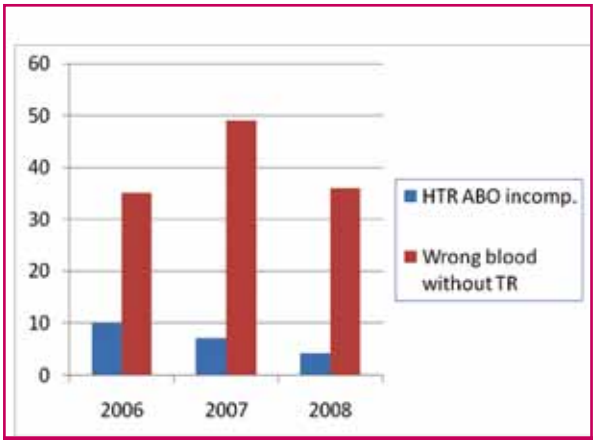

Figure 1. Wrong blood administration: number associated with hemolytic transfusion reactions (HTR) due to ABO incompatibility and number without transfusion reactions (TR).

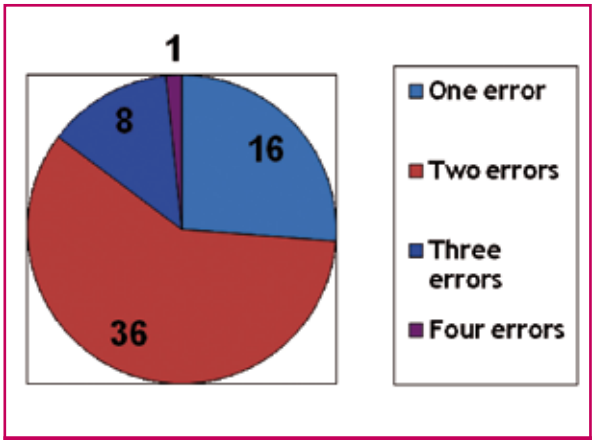

Figure 2. Number of errors/incorrect blood component transfusion (IBCT).

due to ABO incompatibility, was only slightly lower in 2008 than the two previous years (*Figure 1*) and did not show the same drop as for the hemolytic reactions. The risk of transfusing a wrong blood component to a patient decreased from 1/14,700 transfused blood components in 2006 to 1/16,100 administered components in 2008. The errors are independent of the type of component (erythrocyte concentrates, platelet concentrates or virus inactivated fresh frozen plasma). The wrong blood components transfused without causing a transfusion reaction were ABO compatible in 73.3% of the cases. However, as could be expected, in 15% of the cases Rhesus D positive units were administered to Rhesus D negative recipients putting these patients at serious risk for developing anti-D antibodies. The transfusion of wrong blood without causing a reaction is part of an entity that is called "incorrect blood component transfusion (IBCT)". The definition of IBCT is broader than the bedside administration errors (blood intended for another patient) or administration of blood with the wrong blood group. It comprises also all reported episodes where a patient was transfused with a blood component that was incorrect in terms of its specification (e.g. not irradiated, expired, laboratory errors, testing and process errors). The total number of IBCT reported in Belgium in 2008 was 48 or 7.1/100,000 units transfused. An overview of the cases of IBCT notified from 2006 to 2008 is given in *Table 1*.

A constant finding during the three years of reporting of hemolytic transfusion reactions due to ABO incompatibility and IBCT is that in most instances the transfusion of incorrect blood components is the consequence of more than one error in the transfusion chain, sometimes up to four errors (*Figure 2*). Errors involve the prescription, the collection of the pre-transfusion blood sample, the laboratory testing, the hospital blood bank delivery of the blood components, the choice of the component for transfusion and the administration of the component. Most cases of IBCT were associated with errors related to the administration of the components (e.g. 85% in 2008) and to the choice of the component at the ward (e.g. 60% in 2008). Laboratory testing errors and blood bank delivery errors counted for 23% and 15% respectively. Very few errors were reported during prescription (2%) and collection of the pre-transfusion blood sample (2%). In 2006, prescription and sampling errors were each still associated with 10 percent of wrong blood transfusions and 2/5 of these sampling errors resulted in acute hemolytic transfusion reactions.[3] The latter types of errors are still occurring, but in 2008 only rarely lead to a case of IBCT.

The analysis of the 2008 notifications lead to the formulation in the annual hemovigilance report of the following recommendations for hospitals: the administration of an incorrect blood component should be avoided by a bedside properly conducted control of the recipient (identity, blood type, special

Table 1. Summary of the incorrect blood components transfused (IBCT) notified from 2006 to 2008.

Incorrect blood component transfused: type	Number of IBCT 2006	2007	2008
• Wrong blood (wrong patient/wrong blood group)	35	49	36
• Expired blood component	2	2	2
• Not irradiated blood component	1	0	0
• Allogeneic blood when autologous blood is available	0	0	1
• Without crossmatch or irregular antibody search result	1	0	0
• After crossmatch result expired	0	1	2
• Crossmatch incompatible, released as compatible	1	1	1
• Crossmatch carried out on wrong sample	0	2	0
• Not antigen negative for a patient with irregular antibodies	2	2	3
• Equipment failure: crossmatch not validated	1	0	0
• Error when registering patient at admission	0	0	2
• Other	0	4	1
Total	**43**	**61**	**48**

requirements), the blood component (blood type, unit number) and the compatibility form (destination, unit number) prior to administration; every hospital needs to have a specific procedure for the administration of blood components and to ensure appropriate training of all those administering blood; a properly conducted identification procedure of the patient prior to the collection of a pre-transfusion blood sample is also needed.

Discussion

The same recommendations were formulated in previous reports and remain valid. The administration of wrong blood may be followed by a transfusion reaction and even a fatal outcome. It became the greatest transfusion risk to patients. However, in all instances it is the consequence of avoidable errors that must be reduced as much as possible. The implementation of hemovigilance systems and the recommendations formulated have reduced the hemolytic transfusion reactions due to ABO incompatibility. Most probably this decrease is due to the fact that this type of preventable reactions and serious adverse events in the hospitals are always investigated in order to know the cause(s) and to define and implement corrective measures. The decrease of the number of hemolytic transfusion reactions due to ABO incompatibility is also noted in other countries, especially in the countries with the longest experience in hemovigilance such as France and the United Kingdom (UK). In France, where reporting is mandatory from the start of the system in 1994, this type of reaction dropped from 28 in 2000 to 11 in 2008 for a not much different number of blood components transfused.[4]

In 26.7% of the cases of "wrong" blood transfusions the blood was ABO incompatible but did not cause a transfusion reaction. In these cases, the absence of a reaction might be due to low titer anti-A/B antibodies in the recipient or in the blood component.

In November 2002, in France the notification of the cases of incorrect blood component transfusion (IBCT) not associated with a reaction started and the number of IBCT reported increased from 138 in 2003 to 196 in 2008 (6.8/100,000 units transfused). The ratio of IBCT (7.1/100,000) reported in Belgium compares well with that for France, the Netherlands (8.1/100,000 units transfused) and the UK (6.9 in 2007 and 9.2 in 2008).[4-7] In the UK, apart from IBCT two separate categories were created in 2008: "unnecessary and inappropriate transfusions" (U&I T) and "handling and storage errors" (HSE): an increase of these types of errors was noted from 4.8/100,000 units transfused in 2007 to 7.6/100.000 units transfused in 2008.[6,7] This indicates the need for special attention for these areas in the future. The reporting of IBCT remains quite high and the same types of errors are occurring each year. This is not surprising as the transfusion process is complex and involves a large multi-disciplinary organization with many chances for errors. The Medical Event Reporting System (MERS) for transfusion has shown that near-miss events are 300 times

Key messages for clinical practice

1. The administration of "wrong" blood became the greatest transfusion risk to patients.
2. Most incorrect blood component transfusions can be avoided by a bedside properly conducted control - prior to administration - of the recipient, the blood component and the compatibility form.
3. A formal specific procedure, a wristband and appropriate training of all those administering blood are essential elements for carrying out correctly the bedside check.
4. The pre-transfusion blood grouping (and comparison of the results) of blood samples from two different blood collections is an important procedure to detect sampling errors and consequently to prevent the delivery of ABO incompatible blood.

more common than observed adverse events, with 10% occurring after the issue of the blood component but caught before transfusion.[8,9] This indicates that near-miss events are an interesting area for learning on process failure.

The finding that multiple errors are implicated in many "wrong blood" incidents has also consistently be shown by the SHOT scheme in the UK.[7] As in France and the UK, absent or insufficient verification of the identity of the patient and data of patient and blood component was the main cause of the wrong blood transfusion.[2] Most of the cases of multiple errors included a bedside check error which could have revealed a mistake earlier in the transfusion chain. In more than 80% of the wrong blood transfusions a correctly carried out bedside check could have avoided the erroneous administration. The importance of the procedure is also emphasised by the detection by the bedside check of a number of wrong blood units, erroneously delivered by the hospital blood bank. Planned barriers are important to prevent IBCT and to detect near misses. And the bedside check of the identity and data of the patient with that of the blood component is the essential, final barrier. However, this check is not effective against sampling and laboratory errors and these require appropriate barriers, such as the pre-transfusion blood grouping of two separate blood samples. A formal, accurate, concise and user friendly procedure, a wristband and training are essential elements for correctly carrying out the bedside check.[11] How the bedside check is performed, is critical. Nevertheless, failure to perform the bedside check correctly is surprisingly common indicating the need to minimise this possibility of human error.[12] Machine-readable identification technology is ideally suited to reduce the opportunities for errors at the bedside.[13] The recent call of the Directorate-General for Healthcare facilities organization of the Federal Public Service Health, Food chain safety and Environment for projects regarding an "hemovigilance function" in the hospitals includes the possibility for funding of the development and/or further elaboration of computerized control procedures and computerised traceability. These projects may further help to increase the implementation of appropriate computerised systems.

Three years of hemovigilance reporting showed a clear reduction of prescription and sampling errors leading to a case of IBCT. Most probably this finding is the result of the wide implementation of a barrier, in particular the procedure of pre-transfusion blood grouping (and comparing) of blood samples of two different blood takings. This was a recommendation of the 2006 hemovigilance report and was also an advice published by the Superior Health Council in January 2007.[3,14] The procedure is an important step to detect sampling errors and to prevent the delivery of ABO incompatible blood components.

In conclusion, hemovigilance data and recommen-

dations have helped to reduce avoidable "wrong blood" transfusions but errors continue to occur. Further reduction of human errors will need to focus on the utilisation of appropriate computerized systems.

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