Near miss errors in transfusion medicine: the experience of the *G. Gaslini* Transfusion Medicine Service

Diego Ardenghi, Marina Martinengo, Laura Bocciardo, Paola Nardi, Gino Tripodi

Servizio di Immunoematologia e Medicina Trasfusionale, Istituto Giannina Gaslini, Genova, Italy

Backgroung. The monitoring of *near miss errors,* in other words events that cannot be classified as substantial errors, but whose occurrence suggests that there is probably a critical point in a working procedure, can be useful in order to prevent these 'almost errors' from occurring again or to prevent them evolving into 'relevant errors'.

Study design and methods. The methods for picking up and studying near miss errors use widely tested systems that have recently also been applied to medicine. These systems are based on the process of identifying the risk through spontaneous notifications of events *(incident reporting).* In our Service of Immunohaematology and Transfusion Medicine (SIMT) these reports were assessed using *root cause analysis,* allowing us to introduce *corrective actions* to eliminate or reduce the risk.

Results. We report the distribution, type and frequency of near miss errors, divided according to the stage of the working procedure in which they occurred, and for each of them describe the possible causes and corrective actions identified. We show how the possibility of an error, with potentially harmful consequences for the patient, is present throughout the whole transfusion chain. Near miss errors in Transfusion Medicine can be included in the wider field of 'clinical risk, a problem that concerns not only SIMT, but also numerous other sectors of health care.

Conclusion. The instruments identified through this study can lower the threshold of clinical risk in a Transfusion Service.

Key words: incident reporting; near miss; clinical risk; risk management.

Introduction

In the last decade the haemovigilance system has been shown to be an efficient instrument for reducing the "clinical risk" associated with transfusions. The most advanced haemovigilance systems currently in function in Europe are those developed in France (Hemovigilance) and in the United Kingdom (SHOT)[1-4]; in Italy, a Haemovigilance System, co-ordinated by the National Institute of Health, was established in 2004, in order to comply with directive 2002/98/CE. This system processes the reports of adverse events collected at a regional level[5].

The shared aims of these haemovigilance systems are predominantly to monitor and collection information on adverse events in transfusion therapy and to record substantial errors. It is only more recently that the importance of monitoring not only these errors, but also *near miss errors* (avoided errors) has become clear. These near miss errors are events that have no repercussions on the patient, since they are intercepted by the control instruments tested and functioning in the Transfusion Centres. These controls prevent a procedural error from evolving into an substantial error, but the fact that the near miss error

Blood Transfus 2007; 5: 210-216 DOI 10.2450/2007.0010-07
© SIMTI Servizi Srl

has occurred suggests that an analysis is needed to identify a probably critical point in the procedures used in a working system[6-9].

Errors occur because working processes do not take into consideration every possible event: for instance, the presence of critical points in procedures, guidelines not applied, poor co-ordination, organisational weaknesses, inefficient communication systems, and inadequate or no maintenance of equipment. These critical points increase the probability of human error, whereas optimisation of the processes can reduce the risk: the registration and critical analysis of errors can be a useful instrument for this purpose.

Non-medical industries have developed a procedural system based on incident reporting, which provides incentives for spontaneous registration, ensures confidentiality of the data supplied and highlights the possible improvements to systems that can derive from collecting and analysing data and applying the indications gained. Indeed, recording near miss errors has several advantages over registering adverse events that have actually occurred: the higher frequency of near miss errors enables a quantitative analysis, there are fewer obstacles to collecting the information and the responsibility of the staff is more limited.

In the field of medicine an analogous concept is used in the British haemovigilance system, SHOT[4] (Serious Hazards of Transfusion), which monitors *transfusion safety* through voluntary reports of non-infective complications of transfusion therapy, while *blood safety* is controlled through notifications of infective complications to a national surveillance centre.

These principles were used in this study to evaluate the near miss errors recorded in the 2 years 2005-2006 in our Transfusion Service, with the aim of identifying instruments useful for reducing clinical risk. Although there were no errors that caused adverse events in patients undergoing transfusion therapy in this period, we recorded a considerable number of near miss errors. The analysis of these near misses was useful in order to prevent the 'almost errors' from being repeated or from becoming relevant errors.

Methods

The process adopted in our Transfusion Service to collect and study information on near miss errors uses widely tested criteria:

1- identification and notification of near miss errors (incident reporting)[10] ;
2- evaluation and analysis of the reports (root cause analysis)[11-12];
3- identification of corrective actions (clinical risk management)[13].

Identification and notification of near miss errors

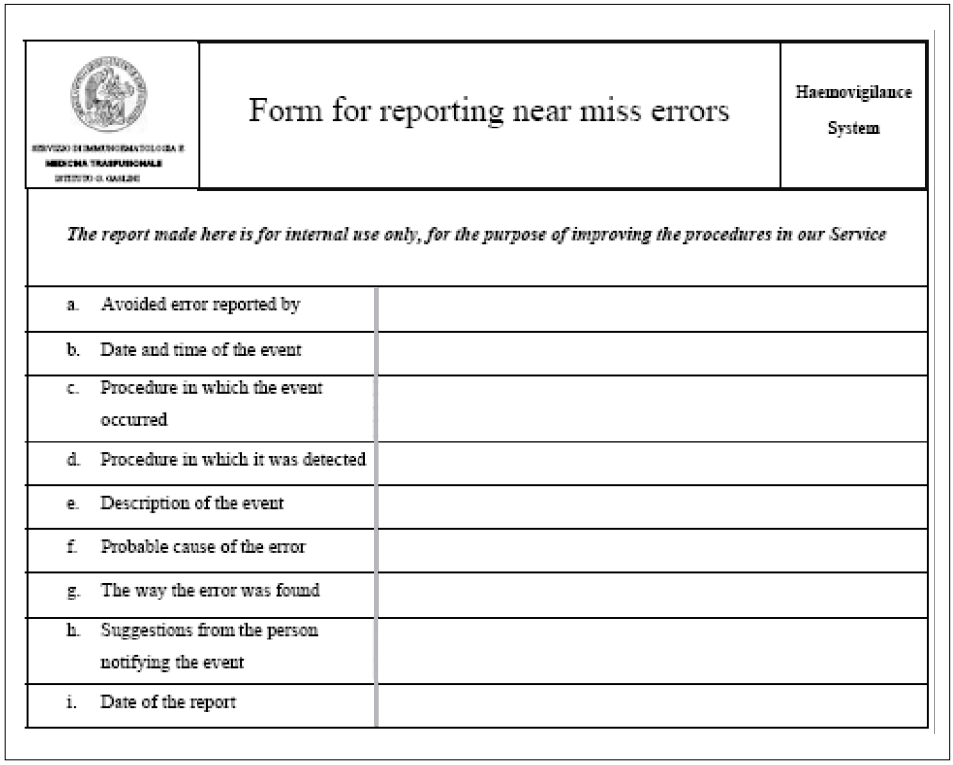
A near miss error is not easily identified, because a distinction must be made between an event that is potentially harmful for the patient, if not corrected before it occurs, and a procedural error that cannot have consequences for the patient. The critical points of the method of analysis are, therefore, precise identification of the events that must be notified and who should notify them.

In our Service of Immunohaematology and Transfusion Medicine (SIMT) we have established that, in a first stage, all notifications are acceptable and that all staff can report events which, in their opinion, could be considered near miss errors. The reports are made by compiling a specific form, in which the members of staff can describe in detail what they saw, at what stage of the working process the event occurred, the timing and the control mechanism that enabled the adverse event to be prevented. Besides allowing a description of the error, the form also includes a space for an immediate evaluation by the person notifying the near miss of the causes of the event and possible solutions to introduce. For these reasons the report form must be easy to fill in and should not include information on the possible causes of the error, which could condition the notification (Figure 1).

Evaluation and analysis of the reports

The report forms are evaluated by the person in charge of the Haemovigilance System: the first aim is to select the incident reports, in order to exclude those not acceptable as near miss errors (a corrupting bias). The reports considered to describe procedural errors rather than "near misses" are recorded as anomalies or non-conformities using the appropriate Quality System documents, while those considered to describe near miss errors are collected by the Haemovigilance System.

The accepted reports are then examined using the principles of root cause analysis, a methodology applied to the study of factors causing an adverse event or, more generally, an incident. This instrument is



	Form for reporting near miss errors	Haemovigilance System
The report made here is for internal use only, for the purpose of improving the procedures in our Service		
a. Avoided error reported by		
b. Date and time of the event		
c. Procedure in which the event occurred		
d. Procedure in which it was detected		
e. Description of the event		
f. Probable cause of the error		
g. The way the error was found		
h. Suggestions from the person notifying the event		
i. Date of the report		

Figure 1 - Form for reporting near miss errors

based on an organisational conception of the error and is not limited to simply having detected the error or to searching for the mistakes closest to the event, but has the purpose of analysing the whole process that caused the error –in other words, identifying the *root cause*. This analysis must be based on the system and not on the individual; the priority is to resolve the problem and not to search for the miscreant.

From an operative point of view, in the case of a near miss error, we considered the procedure in which it occurred, verifying the stages of the whole process until identifying the root cause, intended as the *defect in a process, whose elimination prevents the occurrence of a specific adverse event.*

Identifying the corrective interventions

The root causes must be classified in a reference scheme that enables corrective interventions to be identified for each single event or several events that can be grouped together because of their nature, or place or time of occurrence.

The reconstruction of the work flow, from when the Operative Unit sends the request for a blood component until the delivery of a transfusion unit, enabled a chronological classification of the events identified as near miss errors.

In fact, near miss errors can occur throughout the whole chain of the transfusion system, but some critical points can be identified, at which near misses are more frequent or at which groups of different reports can occur; an analysis of the critical points enables the correctable causes to be identified and appropriate interventions to be made.

Results

In the period between January 2005 and December 2006, 318 reports were collected through the incident reporting system; however, the events that stemmed from non-conformities of the requests for blood components (n=215) were considered separately, because these are errors attributable to the Operative Units, although they could lead to other errors in the SIMT. Eighty-two events actually occurred in the Service and were accepted by the person in charge of the Haemovigilance System as near miss errors; this corresponds to about 80% of the reports made by the staff. The reports excluded were evaluated as errors of procedure that would not have had any consequence for the patient (Table I).

Table II shows the distribution, the type and the

Blood Transfus 2007; 5: 210-216 DOI 10.2450/2007.0010-07

Table I - Summary of the reports

Period report's collection	Total n. of reports	Reports of non-conformity of requests for blood components	Reports not accepted as near miss errors	Reports accepted as near miss errors
01/01/2005 to 31/12/2006	318	215	21	82

Table II - Occurrence of near miss errors

Process	Procedure in which the event occurred	Number of actions performed	Number of reports	RPO*	Procedure in which the event was detected
Acceptance of request for blood components	Non-conformity of request	11,271	215	1.9	Control of the request
	Ineffective control of the request	11,271	29	0.25	Attribution of the blood components
Attribution of blood components	Unit with inappropriate antigen profile	11,638	9	0.07	Validation of attribution Delivery of blood components
	Date of collection of the unit not appropriate	11,638	18	0.15	Validation of attribution Delivery of blood components
	Analytic errors in pretransfusion tests	11,638	5	0.04	Validation of attribution
Processing of blood components	Leucocyte depletion not performed	3,430	2	0.05	Delivery of blood components Control of unit in OU
	Irradiation not performed	1,305	5	0.3	Delivery of blood components Control of unit in OU
	Washing/resuspension not performed	1,084	12	1.1	Delivery of blood components Control of unit in OU
Delivery of blood components	Delivery of a unit not assigned to the patient	12,713	2	0.01	Delivery of blood components Control of unit in OU

*RPO: Relative Percentage Occurrence; that is, the percentage of the number of near miss errors with respect to the number of actions performed; OU: Operative Unit.

frequency of the near miss errors, divided on the basis of the stage in the working process in which they occurred, and also the sub-process in which they were identified and thus avoided. The table also shows the total number of actions and the number of reports for each stage of the working process.

It can be seen from the results that the distribution of reports varied in each working stage. In detail, events that happened with a relative percentage occurrence (RPO, defined as the percentage of the number of near miss errors with respect to the number of actions performed) of greater than 1 were considered as having a high incidence, events with a RPO from 0.1 to 1 as having a medium incidence and those with a RPO less than 0.1 as rare or at low incidence.

The events occurring with a high incidence were sending non-conformed requests (RPO 1.9) and not having washed and resuspended the units (RPO 1.1).

The reports with a medium incidence concerned ineffective controls of the request (RPO 0.25), attribution of units with an unsuitable date of collection (RPO 0.15) and the lack of irradiation of units (RPO 0.3).

Finally, the reports made at a low incidence concerned attribution of units with an inappropriate antigenic profile (RPO 0.07), analytic error in the pretransfusional tests (RPO 0.04), lack of leucocyte removal from the units (RPO 0.05) and, finally, the delivery of a unit not assigned to the patient (RPO 0.01).

Discussion

The results confirm that reporting near miss errors can provide some data that are generally not collected by either the Quality System or the Haemovigilance

system, in that the former records *anomalies*, *non conformities* and *complaints by third parties*[14], while the second records adverse events and substantial errors. We can, therefore, consider incident reporting as a necessary integration of the other two systems.

On the other hand, the fact that there is no evidence that all the near miss errors are reported can be considered a limitation of this method: in the period analysed in this study, only about 60% of the staff made at least one report. It is, therefore, essential for the efficacy of the system that staff are trained and educated about the potential to improve working activities by *learning from errors*.

In our Service, the system of incident reporting allowed us to show that an error, with potentially harmful consequences for the patient, could occur throughout the transfusion chain, even though some events happened repeatedly whereas others were less frequent. It should, however, be stated that frequency of each event is of little relevance for the root cause analysis and does not indicate the danger of the event: in fact, priority must be given to dealing with the potentially more dangerous errors rather than to the more frequent ones.

The analysis of the reports enabled us to identify, in each stage of the working process, the causes of the error and the corrective actions to take.

Non-conforming requests

Errors in personal data and lack of clinical information can be causes of errors, since the attribution and processing of units depends on the accuracy of the information, supplied in the request for blood components.

Greater precision in filling in the data and activation of a computerised system of delivering the requests, with obligatory fields to fill in, will facilitate the introduction of the corrective action.

Ineffective controls of the request

The request for blood components must be controlled at arrival, to detect any errors or omissions.

Computerised delivery of the request could facilitate this procedure, enabling consultation in real time of the computerised transfusion records of each known patient.

Units with an inappropriate antigen profile

A request can be made for units with a specific antigen profile or with a given date of collection. In order to avoid attributing units without these characteristics, the guidelines[15-18], which detail the indications for such units, must be known. The most suitable transfusional support for a patient depends on both the immunohaematological evaluation of the transfusion expert and the clinical information supplied by the doctor.

Consulting the transfusion records of know patients is the best method for reducing the incidence of errors in this area.

Analytic errors during the performance of pre-transfusion tests

Errors can occur during the performance of pre-transfusion tests[19]; these can be detected by the controls and validations set out in the relevant operative procedure.

The introduction of automation during the analytic phase will enable our Service, which up to now has privileged the manual performance of this type of test, to reduce the incidence of analytic errors.

Leucodepletion not performed

There are numerous and consolidated indications for leucodepletion of blood components in transfusion medicine[20], so that it is rare that this process is not performed.

The increase in the production of units leucodepleted pre-storage can contribute to a further decrease in the frequency of this error.

Irradiation not performed

The indications for irradiating blood products are not always unequivocal in the guidelines[21], furthermore, to respect the indications that are given, more clinical details about the patient are required (congenital, acquired or drug-induced immunodeficiency and other primary and secondary disorders).

Guidelines drawn up within our Service have defined more precisely the type of patient to whom irradiated units must be assigned.

Washing or resuspension of blood components not performed

The cause of the high incidence of reports of this event can be related to the transitory nature of the indication for this process, in that washing and

Blood Transfus 2007; 5: 210-216 DOI 10.2450/2007.0010-07

resuspension of blood components are indicated in temporary clinical conditions such as ABO haemolytic disease of the newborn, T activation, bone marrow transplantation from an ABO-non-identical donor, and allergic-type transfusion reactions.

Since these situations are known by the transfuison specialist who made the diagnosis or who has managed the transfusion support, transfusion clinical records are useful for reducing the incidence of this error.

Delivery of units not attributed to the patient

In the rare cases in which units were delivered to a patient who had not been attributed them, the error was avoided by the control carried out in the Operative Units. Since this type of error could have serious consequences, we have set up a procedure which requires a form to withdraw the transfusion units and a control system, which, through the use of a bar code, allows the documentation to be produced only after the stages preceding the computerised delivery process have been checked.

From the foregoing, it can be seen that in our Service, besides frequently occurring events, there were also more rare, but potentially more dangerous events, such as analytic errors in pretransfusion tests or the delivery of units not assigned to a patient. For this reason we decided to apply root cause analysis since this method of investigation is indicated in cases of major incidents or when an event, albeit not serious, occurs at a high frequency.

Transfusion medicine procedures are still associated with a certain risk, which can be set in the wider context of *clinical risk,* a problem that concerns not only Transfusion Services, but also numerous other sectors of health care[22].

As already started at an international level (Agency for Healthcare Research and Quality in the USA, National Patient Safety Agency in the United Kingdom and the Australian Patient Safety Foundation in Australia), a system for managing clinical risk is now being developed in Italy, thanks to the Protocol of Sentinel Events, produced by the Ministry of Health[23]. Numerous risk management projects have also been started at a regional level; these projects are underpinned by some fundamental principles such as accountability, efficacy-appropriateness and the organisational safety of quality. These principles can be identified in the transparency and traceability of the data, in the autonomy and responsibility of the staff (clinical governance) and in the organizational capacity based on standardised processes. These conditions are, therefore, indispensable for lowering clinical risk also in the context of a SIMT with the aim of making transfusion procedures safer and guaranteeing the safety of the patient[24].

In our SIMT, we identified some instruments suitable for this purpose and have shown that each of these could be a corrective action even for different causes. Some of these improving actions, such as the use of *transfusion clinical records* and the introduction of *guidelines for paediatric transfusions*, are already consolidated in our Service, whereas others, such as *computerised delivery of the request for blood components* and *automation of pretransfusion blood tests,* will be introduced in the near future.

It is, however, necessary to emphasize that the reliability of these instruments in no way exonerates the staff from carrying out controls, since the habitual use of complex automated procedures can lead to other errors.

We deliberately did not include in this study an analysis of errors not directly dependent on procedures of the Transfusion Service, because the rare notifications, often verbal, of near miss errors occurring after the delivery of a unit were considered not sufficiently representative of all the events occurring at the patients' bedside. Furthermore, the substantial incidence of transfusion errors that occur in Operative Units both at the time of taking the sample or filling in the sample's label, and at the time of the transfusion, is well known. Communication between the Operative Unit and the SIMT is indispensable also in this case in that only after having learnt of an error can the staff of the Service look for instruments aimed at reducing the risk of such incidents.

A bar code system can be used for this purpose. This system is based on the use of an identifying wrist band[24], and request forms and labels with a unique identification code for the patient. Radiofrequency identification (RFID)[25] technology is under development: radiofrequencies can be exploited to provide unequivocal identification of a transfusional unit and of a patient, guaranteeing traceability of the process.

We can, therefore, conclude that the solutions for reducing transfusion risk already adopted in our SIMT,

and those that can be planned in the Operative Units, were in part suggested by the analysis of near miss errors, in that the change in the conception of an error, no longer considered as an individual failure, but as an occasion to improve the whole organisation, has led to the production of solutions aimed at preventing the error from recurring.

References

1) Recommendation n° R (95) 15 of the Council of Ministers of the Council of Europe. Il Sangue. Italian edition, Sapere 2001.
2) Rouger P, Noizat-Pirenne F, Le Pennec PY. Haemovigilance and transfusion safety in France. Vox Sang 2000; **78** (Suppl 2): 278-9.
3) Debeir J, Noel L, Aullen JP, et al. The French haemovigilance system. Vox Sang 1999; **77:** 77-81.
4) Williamson LM, Love EM. Reporting serious hazard of transfusion: the SHOT program. Transfus Med Rev 1998; **12:** 28-35.
5) Decreto Legislativo n° 191 del 19 agosto 2005 capo V. Gazzetta Ufficiale Serie Generale n.221 del 22/09/2005
6) Reason JT. Human error models and management. BMJ 2000; **320**: 768-70.
7) Walshe K. Understanding and learning from organisational failure. Qual Saf Health Care 2003; **12**: 81-2.
8) Vincent C. Understanding and responding to adverse events N. Engl J Med 2003; **348**: 1051-6.
9) Brennan TA, Leape LL, Laiard NM, et al. Incidence of adverse events and negligence in hospizalized patients. Result of the Harvard Medical Practice Study I. N Engl J Med 1991; **324**: 370-6.
10) CERT Coordination Center Incident Reporting Guidelines. Available at: http://www.cert.org/tech_tips/incident_reporting.html
11) Livingston AD, Jackson G, Priestley K. Root causes analysis: literature review. Research Report n°325/2001 Health & Safety Executive 2001, Warrington UK.
12) JCAHO Conducting a Root Cause Analysis in Response to a Sentinel Event 1996. Available at: http://www.jointcommission.org
13) Cinotti R "Clinical" risk. Strategies for its management in health care organisations. Blood Transfusion 2006; **4**: 285-95.
14) UNI. Ente Nazionale di Unificazione: UNI EN ISO 9001. Sistemi di gestione per la qualità. Requisiti. December 2000.
15) Agence Francaise de Securitè de Produits de Santè, Transfusion de globules rouges homologues, produits, indications, alternatives 2002. Thérapie 2004; **59 :** 349-73.
16) Hume HA, Kronick JB, Blanchette VB. Review of the literature on allogenic red blood cells and plasma transfusion in children. CMAJ 1997; **156**: S41-S49.
17) The Stationary Office. *Guidelines for the Blood Transfusion Services in the United Kingdom,* 7th ed. The Stationary Office UK 2005.
18) British Committee for Standards in Haematology. Transfusion guidelines for neonates and older children. Br J Haematol 2004; **124**: 433-53.
19) British Committee for Standards in Haematology. Guidelines for compatibility in blood transfusion laboratories. Transfus Med 2004; **14**: 59-73.
20) British Committee for Standards in Haematology. Blood Transfusion Task Force. Guidelines on the clinical use of leucocyte-deplete blood components. Transfusion Med 1998; **8**: 59-71.
21) British Committee for Standards in Haematology. Blood Transfusion Task Force. Guidelines on gamma-irradiation of blood components for the prevention of transfusion-associated GVHD. Transfusion Med 1996; **6**: 261-71.
22) Wolff AM, Bourke J, Campbell IA, Leembruggen D. Detecting and reducing hospital adverse events: outcomes of the Wimmera clinical risk management program. Med J Aust 2001; **174**: 621-5.
23) Protocollo degli Eventi Sentinella del Ministero della Salute. Available at: http://www.ministerosalute.it/programmazione/qualita/qualita.jsp
24) Dzik WH. New technology for transfusion safety. Br J Haematol 2007; **136**: 181-90.
25) Rossini S, Bianchessi A, Brambillaschi G, et al. Sicurezza trasfusionale mediante tecnologia RFID: Sperimentazione per la gestione dell'autotrasfusione (abstract). XXXVII Convegno Nazionale di Studi di Medicina Trasfusionale. 4-7 October 2006 –Paestum. Volume of Abstracts ABS 388 p.257.

Received: 4 April 2007 –Revision accepted: 11 July 2007
Correspondence: Dr. Diego Ardenghi
SIMT, Istituto Gaslini, Genova, Italy
e-mail: diego.ardenghi@libero.it