REPORT

2013

HAEMOVIGILANCE IN CATALONIA

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INTRODUCTION

The report on haemovigilance in Catalonia for 2013 includes:

1. Transfusion reactions and errors in blood transfusion and blood components.
2. Adverse reactions in blood donation.
3. Adverse reactions related to the quality and safety of blood and blood components.

1
REACTIONS AND ADVERSE EFFECTS OF BLOOD TRANSFUSION

1.1 Participation index and index of components under haemovigilance.

In this edition, 97 centres have transfused blood components, and a total of 54 (55.7%) have sent notifications (Table 1).
The total number of transfused components was 300,089, and the number of components that were transfused in the notifying centres was 264,535 (88.1%) (Table 1). The centres that did not send notifications of any complication confirmed that the lack of notifications was due to the absence of any complications with the transfusions in 2013.

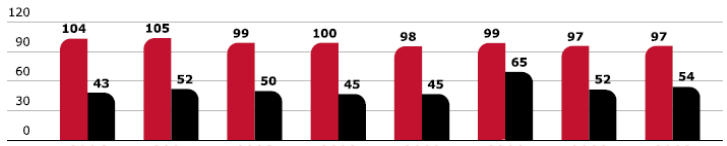
Table 1
Participation and notification data

The 43 non-notifying centres confirmed that they did not have any complications.

Centres	2013	%	2012	%	Transfused components	2013	% 2013	% 2012
Total centres	97	-	97		Total components	300,089	-	-
Participating centres	97	100	97	100	In participating centres	300,089	100	100
Notifying centres	54	55.7	52	53.6	In notifying centres	264,535	88.1	92.5

Figure 1 shows the changes in the number of transfusion centres that have notified any adverse effects to the haemovigilance registry in Catalonia over the period 2006-2013.

Figure 1
Changes to the number and percentage of notifying centres compared to that of transfusion centres



Transfusion centres
Centres that have made a notification

	2006	2007	2008	2009	2010	2011	2012	2013
% NC	41	49.5	51.5	45	45.9	65.5	53.6	57.7

Table 2 confirms the relationship between the percentage of notifying centres and the number of components transfused. The higher the number of components transfused, the higher the percentage of centres sending notifications. 100% of the centres that transfuse more than 5,000 components sent a notification.

No. of transfused components	Transfusion centres	Notifying centres	%
< 500	35	10	28.6
501 - 1,000	7	4	57.1
1,001 - 3,000	30	17	56.7
3,001 - 5,000	10	8	80
5,001 - 10,000	8	8	**100**
10,001 - 20,000	5	5	**100**
> 20,000	2	2	**100**

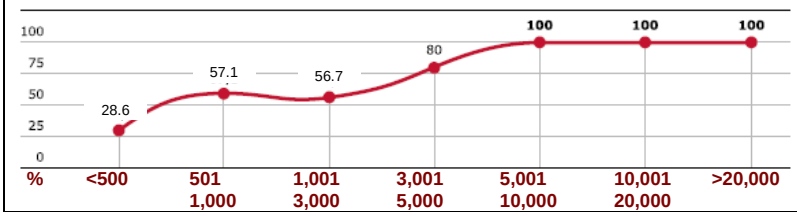


Table 2
Percentage of notifying centres compared to the number of transfused components

All the centres with more than 5,000 transfused components sent notifications.

The centres that carry out more transfusion send notifications.

1.2 Number of notifications related to blood transfusion

1,064 notifications were sent in 2013. 99% of them were sent electronically using the software for notifying reactions and adverse effects of transfusion. Figure 2 shows the changes to the number of notifications over the last 11 years. In particular, the higher number of incidents and near-misses that were notified contributed to the rise in the number of notifications in 2013.
Regarding the near-misses, the rise was due to small number of transfusion centres (n=3) that have persistently searched for this type of error.

The rate of notifications for every thousand transfused components also increased again in this edition, reaching 3.54‰, the highest rate since the haemovigilance programme was created in Catalonia.

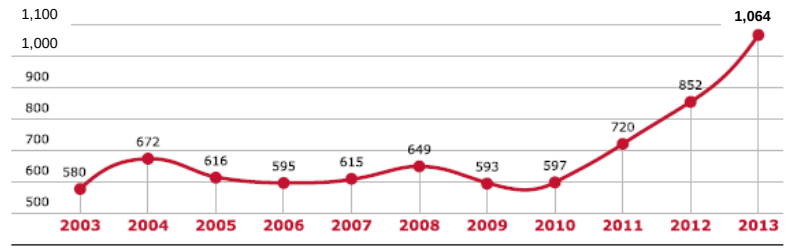


Figure 2
Number of notifications related to transfusions
Period 2003-2013

Rate of notifications per 1,000 components (‰)

2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
1.52	1.71	1.54	1.66	1.59	1.92	1.78	1.83	2.25	2.61	**3.54**

1.3 Distribution of reactions and transfusion errors

96.2% of the notifications sent were finally included. The rest (3.8%) were notifications with a final degree of imputability of 0 (20 cases).
45.7% of the notifications were adverse reactions and 54.3% were transfusion errors with the distribution as shown in Table 3.

Table 3
Adverse reactions and errors related to blood transfusion

Notifications sent: **1,106**
Included: **1,064**

	n	%		n	%
Adverse reactions	**486**	**45.7**	**Transfusion errors**	**578**	**54.3**
Immune reactions	412	84.8	Incidents (the component was transfused)	95	16.4
TR Discomfort	35	7.2			
Cardiovascular/metabolic complications	29	5.9	Near-misses (the component was not transfused)	483	83.6
Hemosiderosis	9	1.9			
Infectious complications	1	0.2			

1.4 Adverse immune reactions to blood transfusion

Of all the adverse reactions to transfusion, immune reactions were the most frequent (84.8%), and among them, allergic reactions and febrile reactions made up for 97.5% of the total (Figure 3). However, only 9.4% of the allergic reactions and none of the febrile reactions were classified with any degree of imputability or seriousness of ≥2. 47% of the serious allergic reactions were investigated and a possible IgA deficit was ruled out (Table 4).

The 4 acute haemolytic reactions were due to errors in administering ABO incompatible red blood cells, and 2 were considered serious. Among the 4 delayed haemolytic reactions 2 stand out, which were caused by antibodies with anti-Jka specificity with are still the most common of this type of reaction.

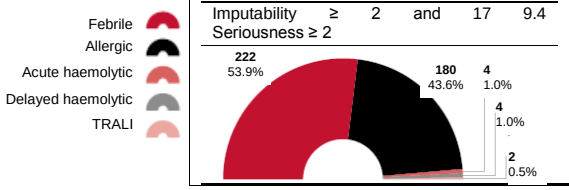
The percentage of notifications of transfusion-related acute lung injury (TRALI) was 0.5%, the same as in the previous year.

Figure 3
Immune reactions

Notifications sent: **424**
Included: **412**

	n	%
Febrile reactions	**222**	
Imputability ≥ 2	88	39.6
Imputability ≥ 2 and Seriousness ≥ 2	0	0
Allergic reactions	**180**	
Imputability ≥ 2	124	68.8
Imputability ≥ 2 and Seriousness ≥ 2	17	9.4

	n
Acute haemolytic reactions	**4**
Immune	**4**
ABO incompatibility error	**4**
Delayed haemolytic reactions	4
Anti-Jka	2
Anti-Kell	1
Anti-S	1



n	Age	Sex	Component	Clinical disorder	Treatment	IgA Study	S	I
1	5	M	Red Blood Cells	Bronchospasm	Corticosteroids	No	2	3
2	69	M	Red Blood Cells	Anaphylactic shock	Adrenalin	Yes. Negative	2	2
3	80	F	Red Blood Cells	Bronchospasm	Corticosteroids	No	2	2
4	89	F	Red Blood Cells	Anaphylactic shock	Corticosteroids	No	2	2
5	1	M	Platelet Pool	Anaphylactic shock	Adrenalin	Yes. Negative	2	2
6	1	M	Platelet Pool	Anaphylactic shock	Adrenalin	Yes. Negative	2	2
7	1	F	Platelet Pool	Anaphylactic shock	Corticosteroids Admitted to ICU	Yes. Negative	2	2
8	7	F	Platelet Pool	Anaphylactic shock	Corticosteroids	No	2	2
9	10	F	Platelet Pool	Angioneurotic oedema	Corticosteroids	No	2	2
10	13	F	Platelet Pool	Bronchospasm	Corticosteroids	No	2	2
11	21	M	Platelet Pool	Anaphylactic shock	Corticosteroids	No	2	2
12	26	F	Platelet Pool	Anaphylactic shock	Corticosteroids	Yes	2	2
13	38	F	Platelet Pool	Bronchospasm	Corticosteroids	No	2	2
14	61	M	Platelet Pool	Anaphylactic shock	Corticosteroids	Yes. Negative	2	3
15	79	M	Platelet Pool	Anaphylactic shock	Corticosteroids	No	2	2
16	66	M	Plasma (Inactivity with Methylene Blue)	Bronchospasm	Corticosteroids	Yes. Negative	2	2
17	83	M	Plasma (Inactivity with Methylene Blue)	Bronchospasm	Corticosteroids Adrenalin	Yes. Negative	2	2

Table 4
Anaphylactic reactions

Total: **17**

S Seriousness
I Imputability

1.5 Transfusion-related acute lung injury (TRALI)

The two cases meet the clinical criteria for acute lung injury and, furthermore, in both cases anti-HLA class II antibodies were identified in the donor. The first case was caused by a transfusion of a mix of platelets and in a female donor anti-HLA class I antibodies were identified, which correlated with the corresponding antigen that was present in the recipient. The previous existence of pneumonia before the development of the TRALI allows this case to be classified as a possible TRALI. The degree of imputability was considered very low (I=1) due to the generally poor condition of the patient and the bad prognosis before the transfusion. The patient eventually died in hospital (S=4).

The second case was caused by the transfusion of a concentrate of red blood cells. Similarly, anti-HLA class I and II antibodies were identified in a female donor, with the corresponding antigens being present in the recipient (Table 5).

n	Diagnosis	Age	Component	Diagnosis	Immunological Diagnosis	S	I
1	Serious community-acquired pneumonia. Stenosis and Aortic insufficiency. Intubated	48	Platelet Pool	↓ PO2	Anti HLA-II in 1 donor. Ag positive recipient	4	1
2	Neoplasm	73	Red Blood Cells	↓ PO2 X-ray changes	Anti HLA-I and II in Donor. Ag Positive recipient	2	3

Table 5
TR-Acute Lung Injury

Notifications sent: **6**
Included**: 2**

S Seriousness
I Imputability

1.6 Transfusion related discomfort

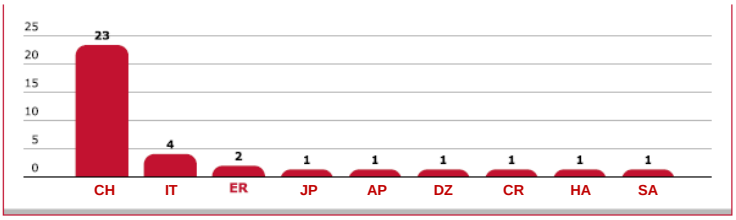
This includes the reactions that were submitted to the haemovigilance programme as unclassifiable reactions (Figure 4).

The majority (65.7%) were chills followed far behind by itching, erythema, joint pains, abdominal pains, dizziness, cramps, headaches and stomach-aches.

Figure 4
Transfusion related discomfort

Notifications sent: **37**
Included: **35**

Chills **CH**
Itching **IT**
Erythema **ER**
Joint Pains **JP**
Abdominal Pains **AP**
Dizziness **DZ**
Cramps **CR**
Headaches **HA**
Stomach-Aches **SA**



1.7 Adverse cardiovascular reactions

In this group (Table 6), cases of cardiogenic pulmonary oedema due to circulatory overload still stand out, amounting to 51.8% of the total, a notably higher percentage than that of 2012 (33.3%).

Table 6
Cardiovascular reactions

Notifications sent: **30**
Included: **29**

	n		n	%
Cardiovascular reactions	29	Cardiogenic pulmonary oedema	15	51.8
		Hypertension	9	31.1
		TR Dyspnoea	3	10.3
		Hypotension	1	3.4
		Bradycardia	1	3.4

Table 7 shows the diagnoses, the type of component transfused and the risk factors of the patients. Although they are predisposing factors, old age, the diagnoses and the present risk factors still mean we should consider whether the prescription of the correct transfusion volume and speed required for the physical and clinical characteristics of these patients is carried out systematically.

Eight cases (53.3%) were considered serious with a probable or certain imputability (≥ 2) in 6 cases.

One 79 year-old female patient died in the hospital with the maximum degree of imputability (I=3).
The patient suffered an advanced neoplasm, was undergoing chemotherapy treatment and required regular transfusions of blood components. She was taken to A&E for dyspnoea and anaemia (Hb 5 g/dl), where she was admitted and the transfusion of two red blood cells concentrates (500ml) was prescribed without the prophylactic measures. When the transfusion was finished, a case of circulatory overload occurred, which did not respond to treatment with diuretics and finally led to her death in the hospital.

Of the 3 cases of TR-Dyspnoea, only one had a seriousness of ≥2 but with a low imputability (I=1); in another case, considered to be of low seriousness, the imputability was considered to be ≥2, and finally, the third case was given the minimum degrees of seriousness and imputability. In all cases, circulatory overload and TRALI were ruled out (Table 8).

n	Age	Component	Volume transfused (ml)	Diagnosis	Risk factors	S	I
1	28	Red Blood Cells	100	Neoplasm	-	**2**	1
2	32	Platelets	260	Acute haemorrhage	Respiratory failure	**2**	**2**
3	67	Red Blood Cells	200	Kidney failure	Oliguria	1	1
4	67	Red Blood Cells	271	Neoplasm	Respiratory failure	**2**	**2**
5	67	Red Blood Cells	300	Kidney failure	Heart disease	1	1
6	73	Red Blood Cells	300	Liver disease Kidney failure	-	**2**	**2**
7	79	Red Blood Cells	500	Neoplasm	Heart disease	**4**	**3**
8	82	Red Blood Cells	210	Chronic disease	Heart disease	1	1
9	82	Red Blood Cells	100	Chronic disease	Respiratory failure	1	1
10	84	Red Blood Cells	250	Acute haemorrhage	Heart disease	**2**	1
11	87	Red Blood Cells	290	Neoplasm	Respiratory failure	**2**	**3**
12	87	Red Blood Cells	200	Acute haemorrhage	Heart disease	1	**2**
13	90	Plasma	150	Chronic disease	-	1	1
14	91	Red Blood Cells	250	Burns	-	**2**	**2**
15	100	Red Blood Cells	200	Chronic disease	Heart disease	1	**2**

Table 7
Cardiogenic pulmonary oedema
Total: **15**

S Seriousness
I Imputability

n	Age	Component	Volume transfused (ml)	Diagnostic	S	I
1	3	Platelets	150	Neoplasm	1	**2**
2	52	Red Blood Cells	200	Chronic diseases	1	1
3	72	Platelets	10	Liver disease. HIV	**2**	1

Table 8
Transfusion related dyspnoea

Total: **3**

1. Dyspnoea, nausea and vomiting at the end of the transfusion treated with hydrocortisone.

2. Dyspnoea, nausea, vomiting, chills, shivering, hypertension and tachycardia at the end of the transfusion treated with O2, hydrocortisone and diuretics.

3. Dyspnoea, thoracic/abdominal pain, hypertension and erythema at the beginning of the transfusion treated with O2 and hydrocortisone.

S Seriousness
I Imputability

1.8 Hemosiderosis

In this edition, 9 cases of hemosiderosis were notified (Table 9).

n	Start date of transfusion therapy	Number of RCC transfused	Ferritin (ng/ml)	Treatment with iron chelation	S	I
1	15/10/2009	83	1,140	No	2	2
2	26/12/2003	60	2,196	No	2	2
3	14/02/2010	57	1,490	No	2	2
4	23/02/2011	55	4,430	No	2	3
5	26/08/2005	51	1,010	No	2	2
6	13/11/2012	46	2,936	No	2	3
7	14/02/2012	40	1,243	No	2	3
8	14/07/2010	33	1,639	No	2	2
9	21/02/2011	32	1,200	No	2	2

Table 9
Hemosiderosis

Total: **9**

S Seriousness
I Imputability

1.9 Infectious complications

In the infectious complications group, 1 case of bacterial contamination and 5 suspected cases of viral infections transmitted by transfusion were notified (Table 10).

The case of bacterial contamination was in a patient who suffered a febrile reaction after receiving one unit of red blood cell concentrate. In a sample of the unit and in a blood culture taken from the patient *Yersinia*

enterocolitica grew. The germ could not be isolated in the plasma from the donation and the platelet concentrate was not transfused.

The suspected viral infections were related to the hepatitis C virus in 3 cases, and HBV and HTLV-I in the remaining two. At the time of finishing the report, it has been possible to rule out the role of the blood in the transmission of the infection in the 3 suspected cases of the hepatitis C virus and that of HTLV-I; the suspected case of HBV transmission is still underway. Furthermore, it should be added that it was possible to close a case of suspected HIV and another of Babesiosis from 2012. However, 2 suspected cases of HCV transmission from 2011 are still underway.

Table 10
Infectious complications

Total**: 1**

Furthermore, a suspected case of HIV and one of Babesiosis from 2012 have been closed. Two suspected cases of HCV from 2011 are still underway.

	n
Bacterial infection	**1**

In **1** case *Yersinia enterocolitica* was detected in the culture of the red blood cells that was transfused and in the patient.

- Patient suffered high fever and chills.
- Platelets not transfused.
- Plasma culture negative.

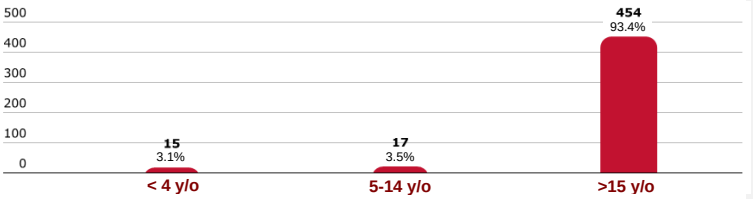
Suspected viral infections	**n**	**Ruled out**	**Underway**
HIV	0	0	0
HBV	1	0	1
HCV	3	3	0
Other suspected infections	**n**	**Ruled out**	**Underway**
HTLV-I	1	1	0

1.10 Adverse reactions by age

Only 32 (6.5%) of the 485 reactions in which the age had been included are from children below the age of 15 (Figure 5). In 15 cases, the age was lower than 4, and in the 17 remaining cases the age was between 5 and 14. In both age groups, allergic reactions stand out (Figure 6). 9.7% of all the components transfused were to children below the age of 15 (29,108 components), and as such the overall notification rate of 3.54‰ should in theory have generated 103 notifications, instead of the 32 that were finally received.

Figure 5
Percentage of notifications of adverse reactions by age

Notifications sent**: 505**
Included**: 486**



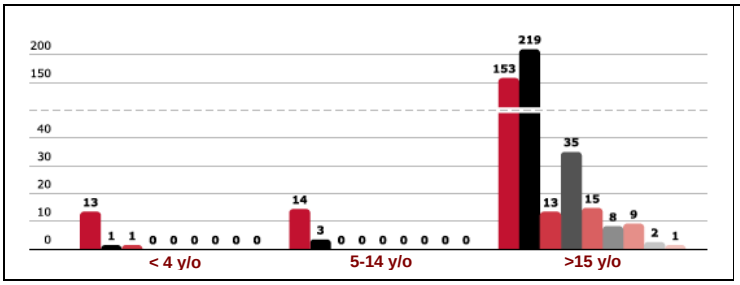


Figure 6
Adverse reactions to blood transfusion by age group

Notifications sent**: 505**
Included**: 486**

- Allergic
- Febrile
- Cardiovascular and metabolic
- TR Discomfort
- Cardiogenic pulmonary oedema
- Haemolytic reactions
- Hemosiderosis
- TRALI
- Bacterial infection

1.11 Seriousness of the adverse reactions to blood transfusion

Figure 7 shows the distribution of the adverse reactions according to the degree of seriousness. It can be seen that the majority (89.9%) of the reactions are a degree of seriousness of 1 (clinical signs without risk of death). 0.45% had no clinical expression, 9.2%, however, caused life threatening conditions for the patient and, two more cases (0.45%) led to the death of the patients. These cases correspond to a TRALI and another to cardiogenic pulmonary oedema due to circulatory overload. In the first case, as was mentioned above, the relationship between the transfusion and the complication was considered to be very low (I=1). However, in the second case the relationship was considered to be certain (I=3).

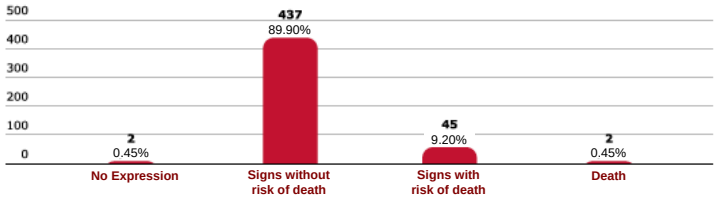


Figure 7
Seriousness of the adverse reactions to blood transfusions

Notifications sent**: 505**
Included**: 486**

Table 11 shows the relationship between the adverse reactions with a degree of seriousness of ≥ 2 (clinical signs with risk of death) with an imputability of ≥ 2 (probable or certain).

The relationship includes 7 cardiovascular complication (6 cases of cardiogenic pulmonary oedema, 1 case of hypertension), 17 anaphylactic reactions, 2 cases of acute immune haemolytic reactions, 1 case of bacterial contamination, 1 case of TRALI and 9 cases of hemosiderosis.

Table 11
Adverse reactions with a seriousness of ≥2 (risk of death) and an imputability of ≥2 (probable or certain)

Notifications sent**: 37**
Included**: 37**

	n%	
Cases with S and I of ≥2	**37**	**100**
Cardiovascular/Metabolic complications	7	18.9
Cardiogenic pulmonary oedema	6*	75.0
Hypertension	1	12.5
Allergic/anaphylactic reactions	17	46.0
Hemosiderosis	9	24.3
Acute immune haemolytic reaction	2	5.4
Septic reaction from bacterial contamination	1	2.7
TRALI	1*	2.7

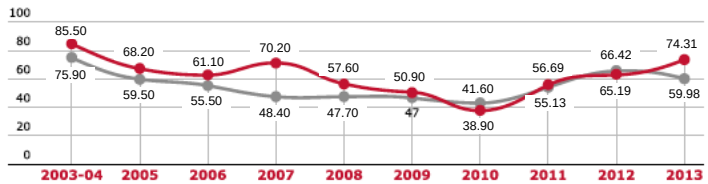
*1 death by cardiogenic pulmonary oedema and 1 by TRALI.

1.12 Trend of the transfusion reactions in the period 2003-2013

Figure 8 shows the development of the allergic and febrile reactions, and allows us to see the rise in the rate of febrile reactions and a fall in the rate of allergic reactions compared to those seen in the previous year.

Figure 8
Trend of febrile and allergic reactions
Period 2003-2013

Rate per 100,000 transfusions



Febrile ---
Allergic ---

Figure 9 shows the development of the acute and delayed haemolytic reactions over the last years, highlighting a small rise in the rate of delayed reactions and a small fall in the rate of acute reactions over the past year.

Figure 9
Trend of haemolytic reactions
Period 2003-2013

Rate per 100,000 transfusions

Acute haemolytic ---
Delayed haemolytic ---

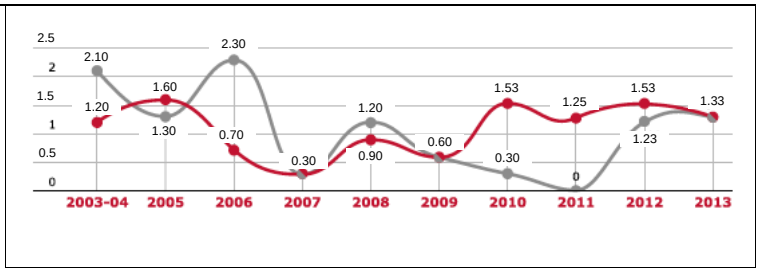


Figure 10 shows the development of cardiogenic and non-cardiogenic pulmonary oedema.
In the first case, a new rise in the rate can be observed. Regarding the development of cases of non-cardiogenic pulmonary oedema or TRALI, a very low rate has been maintained (0.6‰), which shows the effectiveness of the measures not to transfuse plasma from female donors.

Figure 10
Trends in cardiogenic pulmonary oedema and TRALI
Period 2003-2013

Rate per 100,000 transfusions

--- Cardiogenic pulmonary oedema
--- TRALI

1.13 Errors in the transfusion of blood components

Following the recommendations of the International Society of Blood Transfusion (ISBT) and the International Haemovigilance Network (IHN) we have classified transfusion errors as incidents (errors that have not been noticed in time, meaning that the blood components are transfused) and near-misses (having been able to stop the transfusion by detecting the error).

In accordance with this approach, a total of 95 errors were notified in which the blood component was transfused (incidents) with the distribution as shown in Figure 11.

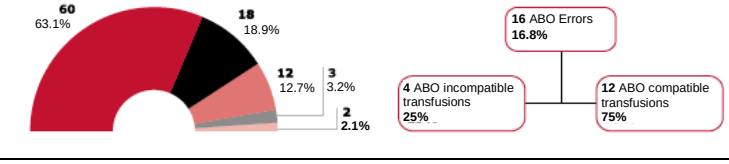


Figure 11
Transfusion errors
Incidents: the component was transfused

Notifications sent: **96**
Included: **95**

Bedside error
Incorrect prescription
Transfusion service error
Extraction error
Preservation/handling error

63.1% of the incidents were errors committed during the administering of the blood components at the patient's bedside, and of these a total of 6 were caused by the incorrect identification of the patient when the transfusion was carried out.
18.9% were errors committed by the transfusion services; 12.7% were caused by incorrect prescriptions; 3.2% by identification errors when carrying out the extraction of the samples and 2.1% by errors in the preservation and/or handling of the blood component.

Of the 16 ABO errors (16.8% of all the errors), an ABO incompatible transfusion was made in 4 cases; the remaining 12 transfusions were ABO compatible but they were not intended for the patient into whom the blood was transfused, or the transfusion was made with a component other than the intended one.

1.14 Consequences of the errors

Table 12 shows the classification of the errors taking their consequences into consideration.

Transfusions with components that did not comply with the necessary requirements (n=15) were due to the causes shown in Table 13.

In neither of the cases in which the patients received non-irradiated components was the notification sent after the appearance of a graft-versus-host disease.

Table 12
Results of the incidents by errors committed

Notifications sent**: 96**
Included**: 95**

Classification	n	%
Transfusions with components that did not comply with the necessary requirements (non-irradiated, incorrect phenotype)	15	15.8
Incorrect transfusions (incorrect patient or not the intended component)	13	13.7
Unnecessary or unsuitable transfusions (Incorrect biological parameters: Hb, platelets, coagulation)	8	8.4
Unsafe transfusions (transfusion >4h, very fast, unsuitable handling)	59	62.1
Total	**95**	**100**

Table 13
Transfusion with components that did not comply with the necessary requirements

Total: **15**

Transfusion service errors	n
6	
Selected, delivered and transfused:	
0+ unit to A+ patient	2
Rh(D)+ unit to Rh(D)- patient	1
M+ unit to a patient with anti-M (the sign was understood as anti-S)	1
A different component to the one requested	2

Prescription errors	n
8	
Higher volume and/or dose to children who need fractionated components (hypertransfusion?)	
RCC	3
P	2
Hypertransfusion. Dose of platelets lower than the necessary.	1
It was not indicated that the component needed to be irradiated	2
Extraction errors	**1**
Patient with D+ records with D– results in a new sample, and with anti-D. The previous sample was from another patient and D+ was transfused.	1

Erroneous transfusions (n=13) include cases of patients who received a component other than the intended one, or those of other patients who received transfusions that were not intended for them. The 13 cases were due to 6 errors in identifying the patient at the bedside, 5 transfusion service errors (erroneous selection when delivering the component), and 2 extraction errors. Table 14 explains the reasons and circumstances that led to these errors (Table 14).

Table 14
Erroneous transfusions

Total: **13**

Bedside identification errors	n
6	
ABO Tx. incompatible	2
- The patient was actively identified, but afterwards it was not checked to see if there was a match with the component data.	
ABO Tx. compatible	4
- The protocol was not complied with and nothing was checked.	

Extractions errors	n
2	
ABO Tx. compatible	2
- Correct extraction from patient, sample and request identified with the data of another patient.	

Transfusion service errors	n
5	
ABO Tx. incompatible	2
- Red blood cells intended for another patient were delivered and transfused - In one case the second component was not checked. - Haemolytic reactions were caused.	
ABO Tx. compatible	3
- Components intended for a different patient were delivered and transfused. - 1 case of requests and samples being crossed over from patients coming out of surgery with the same given name and 1st surname	

In the transfusion service errors: The information output was not done in real time. The errors were not detected at the beside

It should be pointed out that the erroneous transfusions due to the erroneous selection and delivery of the components by the transfusion service could have been avoided if the patient had been correctly identified at

the moment of administering the components. However, going against the established protocol, in neither case was the patient actively identified, nor was it checked to see if the data on the bag and those of the patient matched.

Unsuitable or unnecessary transfusions (n=8) were made for the reasons listed in Table 15.

Table 15
Unsuitable or unnecessary transfusions

Total: **8**

	n		n
Prescription errors	**8**	A "reserve" was not requested and red blood cells were transfused on the day	3
		Erroneous amount of haemoglobin	2
		Erroneous amount of platelets	2
		The white blood cell amount and the platelet amount were confused	1

In the unsafe transfusion group we have included 59 examples, as shown in Table 16. The majority were transfusions in which the blood component was transfused at an unsuitable speed (n=37).

Table 16
Unsafe transfusions

Total: **59**

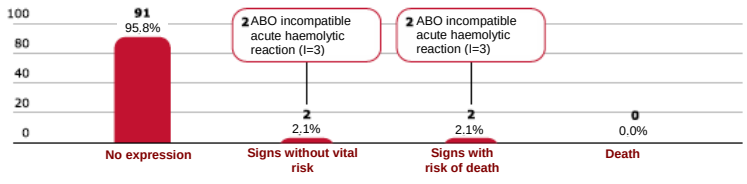
	n		n
Patient bedside errors	**54**	**Preservation/handling errors**	**2**
Transfusion of >4 hours	15	Leakage from bag that was noticed 4 hours later	1
Transfusion of <1 hour (average patient age: 79)	22	AI	1
The transfusion was started >1:30 h after the component was delivered	11	**Prescription errors**	**2**
Breach of blood administering protocol. However, the component was for the correct patient	6	Whole red blood cell concentrate transfused to a child of 15 months	1
		Emergency transfusion requested (without crosshatching) instead of urgent	1
		Transfusion service error	**1**
		A component was selected and prepared on its last day of validity and was delivered and transfused on the following day.	1

1.15 Seriousness of the errors in administering blood components

Figure 12 shows the distribution of the degree of medical seriousness that the notified errors had. In 91 of the cases, no clinical expression was shown and in 2 cases the patients suffered an ABO incompatible acute haemolytic reaction, causing clinical signs without risk of death. In 2 more patients, who also suffered the same reactions for the same reasons, it was serious and put the patients' life at risk.

Figure 12
Seriousness of the incidents in administering blood components

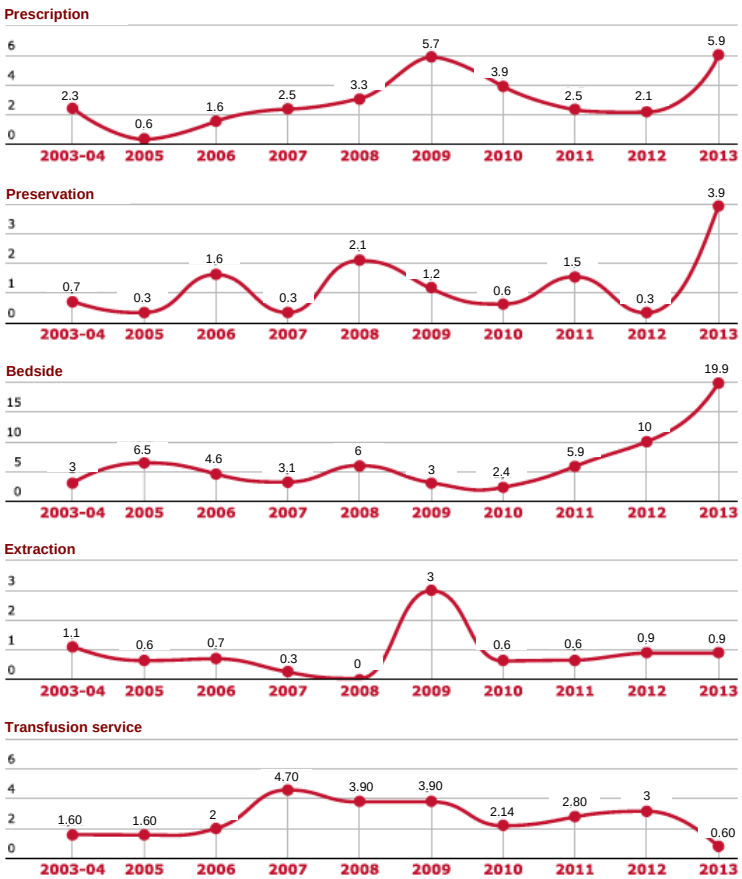
Notifications sent: **54**
Included: **54**



1.16 Trend of the errors in the administering blood components in the period 2003-2013

Figure 13 summarises the different types of errors over the last eleven years.

Figure 13
Incidents in administering components
Trends in the period 2003-2013



There has been a notable rise in prescription errors in this year's edition with a rate of 5.9 errors in every 100,000 transfusions. This rise is also clear in the preservation errors or errors in the handling of the components, which normally result in unsafe transfusions at a rate of 3.9 errors in every 100,000 transfusions. Similarly, there has been a very considerable rise in the errors committed at the bedside, at the time the component was administered, reaching a rate of 19.9 errors in every 100,000 transfusions in 2013. Finally, the rate of errors committed during the extraction of sample has remained stable (0.9/100,000) and the errors committed by the transfusion service have fallen, from 3 to 0.6 in every 100,000 transfusions.

1.17 Near-misses

We include an analysis of the total 483 near-misses, with the distribution as shown in Figure 14.

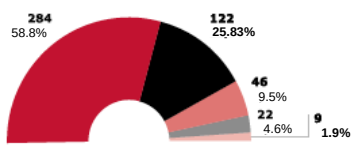


Figure 14
Transfusion errors
Near-misses:
Non-transfused component

Notifications sent: **506**
Included: **483**

- Extraction
- Prescription
- Transfusion service
- Handling/preservation
- Bedside

In this case, it should be pointed out once more that the majority were errors in identifying the patient and/or the samples at the moment of extraction (58.8%). Once again in second place are the prescription errors (25.3%), followed by errors committed by the transfusion service (9.54%) and, after that, component handling/preservation errors with 4.6%, and at 1.9%, errors committed at the patient's bedside at the moment of carrying out the transfusion.

Of the 284 cases that were **near-misses caused by the incorrect identification of the patient and/or the samples at the time of extraction** were completely assessed, in 251 cases the request and/or the sample were wrongly identified, and in the remaining 33 cases, the blood in the vial belonged to another patient. One additional factor that caused these errors to be committed was the pre-printed labels, when it was not checked whether the data printed on them were unmistakeably those of the patient to be transfused.

In the **prescription near-misses** group (n=122) the following should be pointed out:

– In 43 cases, the degree of urgency of the transfusion was not indicated correctly.
– In 28 cases the request was not correctly accompanied by: the lack of the type of component, the number of units and/or volume, the diagnosis, the responsible doctor, etc.
– In 16 cases the amount of haemoglobin was incorrect: sample diluted, haemoglobin amount not updated.
– In 12 cases it was not indicated that the components needed to be irradiated.
– In 7 cases a component was requested other than the one that was really needed.
– In 5 cases more units of red blood cells were requested than were really needed.
– In 4 cases the request was cancelled because the patient was transferred.
– In 3 cases blood components were requested but other laboratory tests were needed.
– In 2 cases the DUI (nursing graduates) were not advised in order to carry out an urgent extraction, causing delays of 6 and 12 hours, respectively.
– In 1 case red blood cells were requested again for a patient who had already had the transfusion.
– In 1 case the amount of platelets was incorrect.

In the **transfusion service near-misses** group (n=46):

– In 16 cases technical errors and/or errors in the transcription of the results were committed, of which 7 cases of erroneous transcription of the ABO group stand out.
– In 15 cases errors in the digital registry of the samples were committed: the identification data of the patient were not correctly registered (n=7); a manual registry error was committed with the unit number (n=3); results were given for an erroneous request (n=2); the record number was duplicated (n=1); the request was not registered on the computer system (n=1) and the reserve data were not correctly registered (n=1).
– In 15 cases component selection and delivery errors were committed: attempted administering of components intended for another patient (n=4); attempted delivery of badly labelled units (n=4), or else more units delivered than envisioned (n=2); or red blood cells instead of plasma (n=2), or red blood cells instead of platelets (n=1), or red blood cells of phenotype D positive for a D negative patient (n=1), and in the last case a reserve of O positive red blood cells was made for an A positive patient (n=1).

The **near-misses related to preservation/handling** (n=22) were made up of the following:

– Blood components stored in fridges not belonging to the transfusion service, without control over the temperature for more than 2 hours (n=14).
– Units lost in the pneumatic tube for more than 2 hours (n=4)
– Bags blocked by coagulants (n=2).
– Bag ripped when put on the infusion equipment (n=1).
– Error in positioning the catheter valve that enabled the contrast supply (n=1).

The ongoing use of systems to improve patient identification has caused new examples of **near-misses at the patients' bedside** to arise (n=9):

– In 6 cases, in going to carry out the transfusion, a change to the bracelet was detected that meant the transfusion could not happen.
– In 2 cases they attempted to carry out the transfusion on the patient on the neighbouring bed. In one case the patient refused to receive the transfusion, and in the other, the transfusion service nurse noticed that she was preparing the wrong patient for transfusion.
– In one case the patient's ABO group was not checked, but that of the bag was.

The handling of the bag made the blood spill out and the transfusion service was advised.

1.18 Trends in near-misses in the period 2003-2013

Figure 15 presents the trends that the different types of near-misses were following in the aforementioned period. The important rise in prescription near-misses should be pointed out, as well as that of the incidents committed at the time the samples were extracted. On a lesser scale, the near-misses detected at the bedside and the preservation/handling of blood components have also increased and, far behind, those committed by the transfusion services.

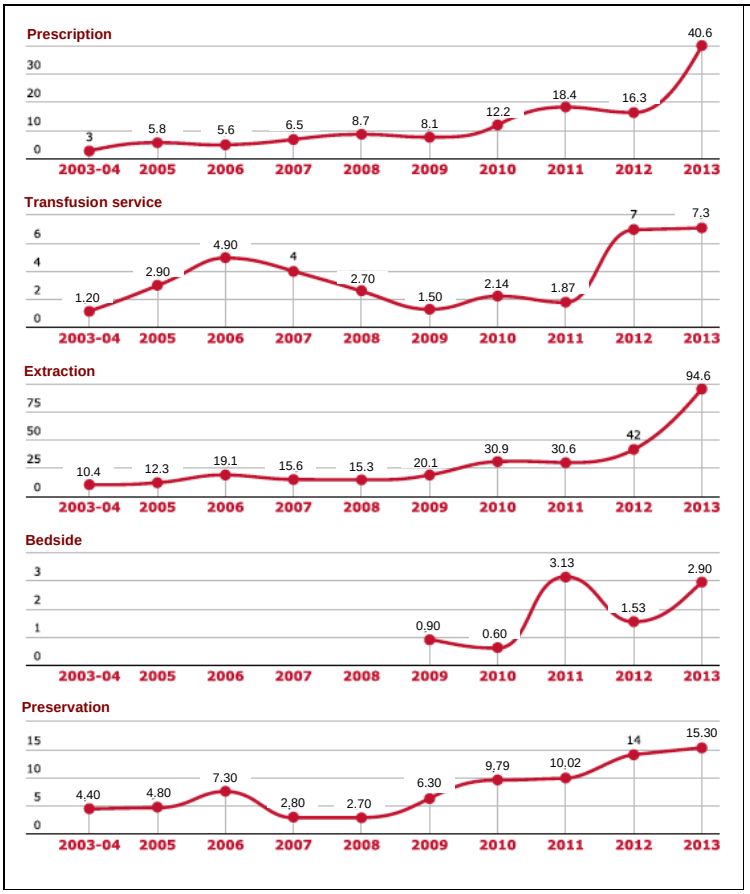


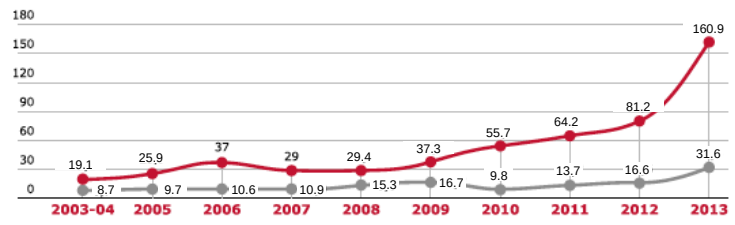
Figure 15
Near-misses
Trends in the period 2003-2013

1.19 The upward trend in transfusion errors (Incidents and Near-misses) in the period 2003-2013

Errors in administering the blood components showed a very sharp increase in 2013, due to the effort made by a small number of hospitals that have designed strategies to identify all of these errors: both the incidents and especially the near-misses. This explains the rates of 31.6 incidents and 160.9 near-misses in every 100,000 transfused components (Figure 16).

Figure 16
Transfusion errors: Incidents and near-misses
Trends in the period 2003-2013

Rate per 100,000 transfusions



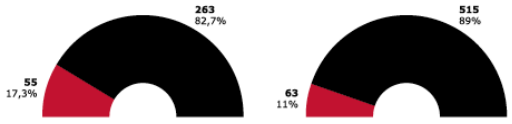
Near-misses ---
Incidents ---

1.20 Comparison of the percentage of errors committed by the transfusion service compared to persons from outside

The overall analysis of the errors committed (incidents plus near-misses) shows that, out of the total of 578 errors, 89% were committed by persons from outside of the transfusion service (Table 17).

Table 17
Comparison of the percentage of errors committed by the transfusion service vs. outside persons
2003-2013

	2012			2013		
	Incidents %	N.M. %	Total	Incidents %	N.M. %	Total
TX service	9 16.7	46 17.5	55	17 17.9	46 9.5	63
Outside	45 83.3	218 82.5	263	78 82.1	437 90.5	515
Total	54	264		95	483	



Transfusion service
Outside of the transfusion service

1.21 Comparative rates of the primary adverse effects of transfusion

Table 18 shows the rates of the primary adverse effects of transfusion in Catalonia during 2013 compared with those recorded since 2003.

The rate of errors in administering blood components has risen again in this edition (1 error in every 3,200 transfusions). The TRALI rate has remained stable and within the levels obtained in previous years. The rate of delayed haemolytic reactions has risen slightly. After 4 years in which no infections complications happened, 1 case out of 300,089 components transfused appeared. In the case of the possible deaths, or the probable/certain deaths, a rate was achieved of 1 in every 300,089 components transfused.

Table 18
Changes in the rates of primary adverse effects of transfusion in Catalonia over the last 11 years

	2003-2008	2009	2010	2011	2012	2013
Errors in administering components	1/9,750	1/6,000	1/10,200	1/7,400	1/6,000	1/3,200
ABO incompatible transfusion	1/62,500	1/37,000	1/40,800	1/63,900	1/65,000	1/75,000
TRALI	1/43,000	1/111,000	1/81,600	1/159,650	1/162,600	1/150,000
Acute haemolytic reactions	1/98,000	1/111,000	1/63,500	1/80,000	1/65,000	1/75,000
Delayed haemolytic reactions	1/95,500	1/167,000	1/326,559	0	1/81,300	1/75,000
Infection transmitted by transfusion	1/646,180	1/333,000	0	0	0	1/300,089
Deaths possibly caused by transfusion	1/274,038	0	0	0	0	1/300,089
Deaths probably/certainly caused by transfusion	1/479,568	0	1/326,559	0	1/325,219	1/300,089

Table 19 compares the rates of the primary adverse effects of transfusion in Catalonia compared with those obtained in other European countries.

Table 19
Comparison of the rates of the main adverse effects of transfusion in other countries

	Catalonia 2013	Spain 2012	France 2012	United Kingdom 2012
Errors in administering components	1/3,200	1/11,000	1/20,000	1/11,000
ABO incompatible transfusion	1/75,000	1/94,000	1/267,000	1/288,000
TRALI	1/150,000	1/100,000	1/55,000	1/262,000
Cardiogenic pulmonary oedema	1/20,000	1/60,000	1/11,000	1/35,000
Acute haemolytic reactions	1/75,000	1/37,000	1/120,000	1/68,500
Infection caused by transfusion	1/300,089	1/640,000	1/247,000	1/950,000
Possible, probable or certain deaths caused by transfusion	1/150,000	1/500,000	1/247,000	1/320,000
Number of components transfused	**300,089**	**1,922,065**	**3,206,778**	**2,878,912**
Rate of notifications/1000 (‰)	**3.54**	**1.55**	**2.42**	**1.23**

Spain: 4 hospitalised deaths: 2 CPO, 1 AHR due to ABO incompatibility and 1 TRALI.
France: 13 hospitalised deaths: 5 CPO, 1 TRALI, 2 bacterial infections, 4 acute haemolytic reactions and 1 case with an uncertain diagnosis
United Kingdom: 9 hospitalised deaths: 6 CPO, 2 AHR (IVIG, Jka) and 1 patient with TR-graft-vs.-host disease (intrauterine transfusion).

Our notification rate for every 1,000 components transfused (3.54‰) compared to the rates seen across the entire Spanish State as a whole (1.55‰) reflects the degree to which the persons connected to haemovigilance in Catalonia are involved; these people participate actively and have gotten into the habit of notifying both the reactions and transfusion errors that they detect. In this case, a high rate such as our own need not be interpreted as a reflection of more reactions and errors, but rather as the expression of the good functioning of the programme. This explains why the rate is closer to that of the French programme and why it is aligned with the English programme, which only notifies serious complications.

However, a more specific analysis of the rates for the more serious complications shows that our error rates in administering components and ABO incompatible transfusions are higher than those obtained in France or in the United Kingdom. On the other hand, the TRALI rate is lower than that of the Spanish State as a whole and France, but it is still higher than that of the United Kingdom.

The different rates for cardiogenic pulmonary oedema confirm that we are looking at a problem that is still growing and that requires special attention in order to avoid it.
The appearance in 2013 of one case of infection caused higher rate of this type of complication given that the number of blood components transfused in Catalonia is obviously lower than the number of components transfused in the Spanish State as a whole, France or the United Kingdom. The same could be said for the rate of deaths that are possibly, probably or certainly related to transfusion.

2
ADVERSE REACTIONS IN BLOOD DONATION

In 2013, 257,018 blood donations were carried out in Catalonia and 3,195 notifications were sent. Of these, a total of 3,167 came from whole blood donations, and 28 from aphaeresis donations (Table 20). The rate of notification was 12.57‰. 1,096 of all the complications notified were from stationary extraction units and 2,099 from mobile units. 69.2% of the complications were found in new or occasional donors.

	Donations	Adverse reactions reported	0/00
Classification by type of donation			
Whole blood	254,162	3,167	12.46
Aphaeresis	2,856	28	9.80
Total	**257,018**	**3,195***	**12.43**
Origin of the notification according to the location of the donation			
Stationary bank	92,877	1,096	11.80
Mobile unit	161,285	2,099	13.01
Total	**254,162**	**3,195**	**12.57**

Table 20
Adverse reactions related to blood donation

Notifications sent: **3,252**
Included: **3,195**

*69.2% from first-time or irregular donors.

Figure 17 shows the development in the number of notifications of adverse reactions within the whole blood donation framework in the period 2005-2013.

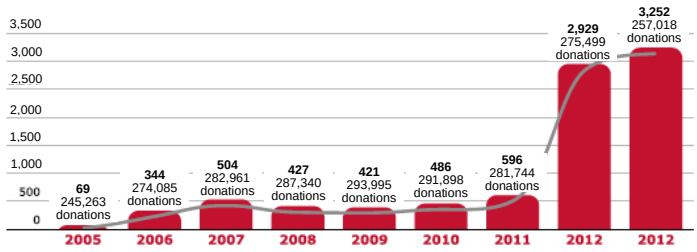


Figure 17
Number of notifications related to blood donation

We have only taken into consideration the figures starting from the HV-05 report, as this was when the adverse reactions/effects of donation started to be reported.

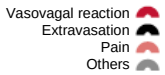
This important rise in the number of notifications began in 2012 and is even more evident in 2013. It is the result of a change to the criteria for collecting these types of complications and after having insisted that all of them should be reported, from the most minor to the most serious. This change in strategy is in line with the addition of the new definitions provided by the International Society of Blood Transfusion (ISBT) and the International Haemovigilance Network (IHN). The change has been most evident for the mobile units, which up until now have been receiving the most serious complications in particular.

Figure 18 shows the new distribution of the adverse reactions seen in the whole blood donations. Vasovagal reactions stand out (86.9%), the large majority of them minor.

Table 21 provides more exact information regarding the type of vasovagal reactions and their degree of seriousness.

Figure 18
Adverse reactions related to whole blood donations

Notifications sent: **3,167**
Included: **3,167**

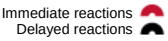


	n	%
Others	4	0.1
Thrombophlebitis	2	0.05
Localised allergy	2	0.05

Table 21
Vasovagal reactions

Notifications sent: **2,753**
Included: **2,753**

Type of reaction	n	%	Seriousness	n	%
Immediate	2,152	78.20	Loss of consciousness	5	0.23
			With injuries (tongue biting)	1	
Delayed	601	21.80	Loss of consciousness	12	1.99
			With injuries (bruising from falling on the ground)	6	



Of the immediate vasovagal reactions (78.2%), 5 cases of loss of consciousness stand out, and one of those caused the donor to bite his own tongue.
The delayed vasovagal reactions (21.9%) are considered to be potentially more serious, as they happen outside of the donation area; out of these, 12 cases caused the loss of consciousness, which in 3 cases caused various types of bruising from falling to the ground. All of the donors' injuries were healed without leaving any kind of scarring. It is possible that the true number of delayed reactions may be higher and many may go unnoticed if there is no proactive action that **causes** them to show. Therefore, the transfusion centre currently contacts all the first-time donors in order to find out about their impression of the donation and whether or not there were any possible complications.

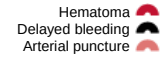
Comentario [JRS1]: Les reaccions vagals retardades (21,9%) són considerades potencialment més greus, ja que es produeixen fora de l'àrea de donació i, d'aquestes, en 12 casos es van produir pèrdues de consciència acompanyades en 3 d'ells de diferents tipus de contusions per caiguda a terra.

SEGONS LA GRÀFICA SÓN 6 I NO 3

Figure 19 shows the distribution of the cases of extravasation.

Figure 19
Extravasation

Included: **310**



The cases of extravasation were mainly related to hematomas (93.9%) followed by delayed bleeding (5.5%) and arterial punctures (0.6%). Tables 22, 23 and 24 show the distribution of the hematomas according to the degree of seriousness, age, sex, type of donor (first-time or regular) and the place where the donation was carried out.

Seriousness	n	%
Minor	240	83.3
Moderate	48	16.7
Serious	0	0.0

Table 22
Extravasation reactions: hematomas (Degree of seriousness)

Included: **288**

The majority of the hematomas were considered minor (83.3%) if not moderate (16.7%).

Age	n	%
From 18 to 30 years old	129	44.3
From 31 to 50 years old	122	41.9
Older than 51 years old	40	13.7

Sex	n	%
Male	121	41.6
Female	170	58.4

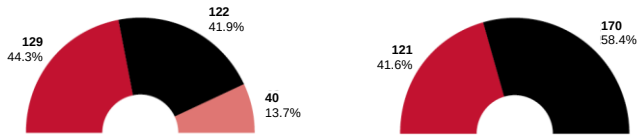


Table 23
Extravasation reactions: hematomas

Included: **291**

The distribution is very similar between the 18 to 30 and the 31 to 50 age groups, but in the above-51 age group the proportion was found to be a lot less (13.7%). Regarding sex, the proportion is slightly higher in female donors (58.4%).

Type of donor	n	%
First-time	222	77.6
Occasional	13	4.5
Regular	51	17.8

Based on 286 cases

Place of donation	n	%
Stationary centre	117	41.3
Equipped premises	76	26.9
Mobile unit	90	31.8

Based on 283 cases

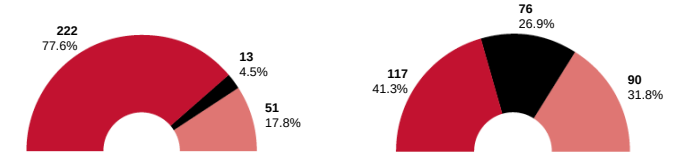


Table 24
Extravasation reactions: hematomas

Included (donor type): **286**
Included (place of donation): **283**

First-time donors experience more hematomas (77.6%); and regarding the place of donation, the stationary centres (41.3%) had a higher result than the equipped premises (26.9%) and the mobile units (31.8%).

Figure 20 shows the distribution of the cases of pain.

The cases of pain correspond to: pain in the arm (93%), nerve irritation (5%) and nerve damage (2%).

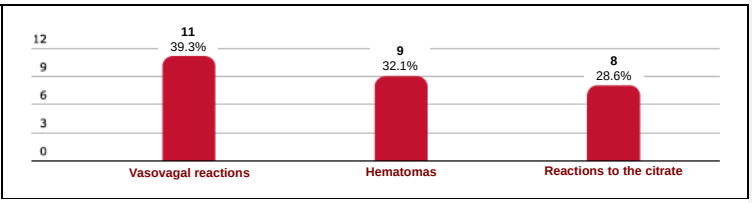
Figure 20
Pain

Included: **100**

Figure 21 shows the distribution of the different types of adverse reaction to the aphaeresis donations. In this section vasovagal reactions also stand out (39.3%), followed by hematomas (32.1%) and reactions to the citrate (28.6%).

Figure 21
Adverse reactions related to donation through aphaeresis

Notifications sent: **28**
Included: **28**



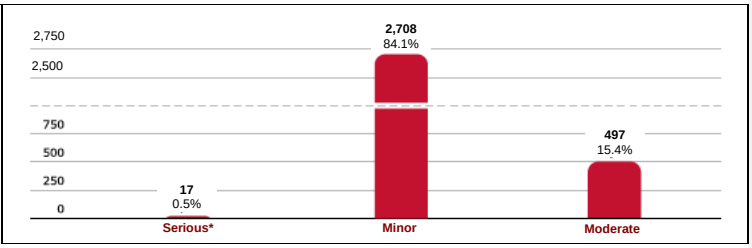
2.1 Seriousness of the adverse reactions to blood donation

84.1% of the reactions were minor; 15.4% were moderate and 0.5% were classified as serious. The serious reactions were losses of consciousness, which in 7 donors caused bruising, but these were all healed without leaving any type of scarring (Figure 22).

Figure 22
Seriousness of the adverse reactions to blood donations

Notifications sent: **3,252**
Included: **3,222**

Loss of consciousness* with minor injuries in 7 cases.



2.2 Seroconversions in donors

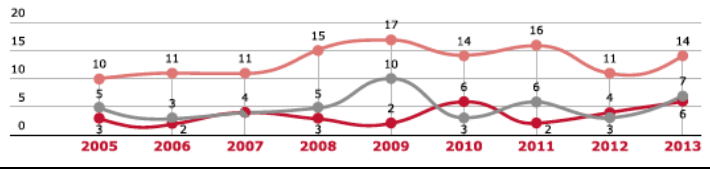
In 2012, 27 seroconversions were detected: 14 for HIV, 7 for HBV and 6 for HCV (Table 25). In none of the cases was it found that the infection was caused by a previous donation. In 2012, 58 cases of seroconversions for syphilis and 1 for HTLV-I were also detected. Finally, none of the regular donors were found to be carriers of HTLV-II or Chagas disease.

Table 25
Seroconversions in donors

Seroconversion to syphilis: **58**
HTLV identified in regular donors: **1** HTLV-I | **0** HTLV-II
Chagas disease identified in regular donors: **0**

	2005	2006	2007	2008	2009	2010	2011	2012	2013
HIV	10	11	11	15	17	14	16	11	14
HBV	5	3	4	5	10	3	6	3	7
HCV	3	2	4	3	2	6	2	4	6
Total	**18**	**16**	**19**	**23**	**29**	**23**	**24**	**18**	**27**

Development of seroconversions in donors. Period 2005-2013



3
ADVERSE EFFECTS RELATED TO THE QUALITY AND SAFETY OF BLOOD COMPONENTS

The adverse effects collected in this report have been classified according to the framework included in the annex of Directive 2005/61/EC. In this framework, all the transfusion phases are considered, from the extraction of the blood, passing through processing and storage and up to the distribution of the blood components. Furthermore, the possible adverse effects are considered in the sections on defective products, equipment failures and human errors.

Table 26 shows the distribution of the 152 adverse effects registered, all of which are near-misses and as such were detected before the transfusion could be carried out. Following the trend set by the European Commission, the errors in distributing components that did not comply with the stipulated quality and safety criteria should be highlighted. In this case, the component crossed all the barriers before distribution, and as such, the adverse effect could be considered more serious. Within this group, the distribution of 3 bags with the incorrect phenotype for the antigens S (n=2) and Fyb (n=1) should be mentioned. However, it should be remembered that these errors were detected in time, before the transfusion could be carried out.

Table 26
Adverse effects related to the quality and safety of the blood components

Total**: 152**

Category	Num. total: 152	Specification and/or type		
		Product Defect	Equipment failure	Human error
Whole blood extraction	101		9 IT system	5 Incomplete/incorrect registry 41 Non-matching file/bag/vials 5 Inappropriately selected donors* 41 Post-donation declared risk*
Extraction by aphaeresis				
Processing	34			34 Incorrect labelling
Distribution	3			3 Units with the wrong phenotype: 2 S, 1 Fyb
Material	14		3 Leaking connector in the aphaeresis equipment (Terumo BCT) 3 Extraction bag with tubing broken (Terumo) 2 Extraction bag with bevel needle bent (Terumo) 1 Extraction bag without needle protection cap (Terumo) 1 Extraction bag with connection to mother and satellite bag (Terumo) 2 Transfusion equipment without filter (Bexen) 1 Defective transfusion equipment (Bexen) 1 Bend in connection tube COBE Spectra equipment	

All of these errors were detected before the transfusion and did not cause any problem for the patients "Near-misses".

The units were not processed.*

4
CONCLUSIONS

In 2013, there was another **significant increase to the number of notifications (n=1,064) and the rate of notifications per 1,000 components transfused** (3.54‰). This increase is due to the higher number of notifications of incidents and, specifically, of near-misses coming from a small number of centres that have searched for this type of errors with a lot of interest. This explains why the percentage error notifications (incidents and near-misses) (54.3%) is higher than the percentage of adverse reaction (45.7%) for the first time.

Febrile reactions and allergic reactions continue to account for the majority of the immune reactions (97.5% of the total figure). In none of the serious allergic reactions studied (47%) was an IgA deficit detected, nor was the presence of anti-IgA antibodies. In 11 of the 17 serious reactions, platelet mixtures were the blood component involved, without finding any cause that could justify this observation up until now. We must wait to confirm whether the platelets play a greater role in this type of serious reaction.

Once more, the **acute haemolytic reactions** notified (n=4) were due to errors in administering ABO incompatible blood components with serious clinical expressions in two cases.

A low presence of **TRALI** (0.5% of the immune reactions) was maintained, which we believe is associated with the effectiveness of the measure to exclusively transfuse plasma from male donors.

In the **cardiovascular complications** group, the percentage of cases of **cardiogenic pulmonary oedema** caused by volume overload (51.8%) stands out once again and is much higher compared to the previous year (33.3%). One patient died in hospital as a consequence of this complication with the maximum degree of imputability (I=3, certain).

One case of **bacterial contamination** by *Yersinia enterocolitica* was diagnosed, found in a unit of red blood cells.

The overall analysis of the transfusion reactions shows that nearly 90% of them were minor, and around 9% were considered serious, including two cases of hospitalised death due to a TRALI (I=1, possible) and cardiogenic pulmonary oedema because of circulatory overload (I=3, certain), respectively.

Among the **errors in administering components**, errors in administering at the patient's bedside stand out (60 out of a total of 95) and 6 of these were due to the incorrect identification of the patient at the moment of carrying out the transfusion, resulting in 6 erroneous transfusions correspondingly. In 4 patients this caused haemolytic reactions due to ABO group incompatibility. The transfusion services were responsible for 5 erroneous transfusions due to incorrectly delivering the blood component, as they did not carry out the digital output in real time. All of these could have been detected at the moment of transfusion, but again failure to comply with the procedure for the safe administering of blood prevented this from happening.

Unsuitable and unnecessary transfusions (n=8) were due to incorrect prescriptions in which the transfusion instructions were based on incorrect haemoglobin or platelet amounts (n=5) or indicating an unsuitable degree of urgency (n=3).

Transfusions of components that did not meet the necessary requirements (n=15) were due to incorrect prescriptions (n=8), the transfusion service delivering components that did not comply with the desired requirements (n=6), or the erroneous extraction of samples to carry out compatibility tests (n=1).

Unsafe transfusions (n=59) were mainly due to the transfusion of red blood cells that lasted unnecessarily for more than 4 hours (n=15), or on the contrary, transfusions that were carried out at a higher speed than required according to the physical characteristics and/or pathology of the patient (n=22).

Regarding the degree of seriousness, 95.8% of the incidents had no clinical expression, but 2.1% did (2 ABO incompatible haemolytic reactions) and in another 2.1% the patients' life was put at risk (2 ABO incompatible haemolytic reactions).

Overall, we can say that the trend of all types of incidents is continuing to rise, except for the extraction incidents, which have remained stable.

In the **near-misses** group (n=483) those due to incorrect identification of the request and/or the sample at the moment of extraction continue to stand out (n=284), followed by incorrect prescriptions (n=122), those that took place within the transfusion service itself (n=46), those related to the preservation and/or handling of the blood components (n=22) and finally, those detected at the patients' bedside (n=9). It should be

pointed out that the majority of these errors were detected by the transfusion service, which prevented the transfusion from being carried out. The transfusion service errors were also detected by the service itself through the various measures and strategies it employs that are reflected in their working procedures.

In comparing the **rates of the principal adverse effects to transfusion** from different countries such as France or the United Kingdom we can see a much higher rate of error in administering blood components in Catalonia (1/3,200), clearly higher than that of the United Kingdom (1/11,000) or France (1/20,000). The rest of the rates related to transfusion reactions are very similar, despite some small differences. The excellent level of notification in Catalonia allows us to understand this situation and at the same time, it shows us that one of the main challenges we are facing now is reducing these errors to a minimum.

11% of all the errors (incidents and near-misses) were committed in the transfusion service and 89% were from outside of the service and mainly related to incorrect prescriptions, unsuitable extractions of samples and the incorrect preservation and/or handling of the components at the moment of transfusion.

The staff involved in the transfusion process from outside of the transfusion service (prescribing doctors, nursing staff, extractors) need to be aware of the HV reports and participate in improvement measures to achieve safer transfusions. A haemovigilance nurse could be decisive in achieving this objective.

Regarding **donation complications** the rate of notification was 12.57‰. This rate reflects the effort made by the professionals who are in contact with the blood donors to record all the complications that they observed, from the most minor to the most serious, as was requested with the aim of having a more complete and representative report on what the complications involved in blood donation are. The majority were vasovagal reactions (86.9%), followed by cases of extravasation (9.8%) (hematomas in 93% of all cases), pain (3.2%), and a small amount of other complications (0.1%).

Regarding the vasovagal reactions, the notifications corresponding to the aforementioned delayed reactions (21.8% of all the vasovagal reactions) that took place outside of the donation area should be highlighted, as this implies that there was an added degree of seriousness. However, it should be pointed out that, on the whole, 84.1% of the reactions notified were minor, 15.4% were moderate and only 0.5% were considered serious. This final group includes 7 cases of loss of consciousness causing the donor to take a fall and the appearance of bruising, which was eventually healed without leaving any kind of scarring.

Of the **adverse effects related to the quality and safety of the blood components** (n=152), it is only necessary to highlight 3 distribution errors related to erroneous phenotypes. However, all these errors and the others were detected in time, before the transfusion could be carried out, which means they can be classified as near-misses.

5
FINAL RECOMMENDATIONS

The final recommendations given below correspond almost entirely to those of the previous years. The data analysed and the results found mean that it is advisable to keep the same recommendations in force, and that there should not be any significant changes, especially for those regarding the training and recruitment of staff responsible for the transfusion of blood and blood components.

1. The prescribing doctors and the professionals who are responsible for administering blood and blood components (mainly nursing staff) need to be aware of the haemovigilance report. The general sessions in the hospitals could be an excellent stage to submit the report and encourage a debate between the various parties involved in the transfusion process.

2. The professionals responsible for administering blood and blood components, nurses, need to receive the necessary and sufficient information and training to make it possible to safely administer blood.

3. The inclusion of a checklist as part of the procedure for safely administering blood could help to minimise the numerous identification errors that lead to erroneous transfusions (Annex 1).

4. The role of a haemovigilance nurse could be the key to solving the majority of these problems and to make blood transfusion in hospitals as safe as the components that we transfuse nowadays.

5. The process for administering blood should be subject to a regular audit and the responsible professionals should renew their qualifications in order to carry out this function.

ANNEX
PROPOSED CHECKLIST FROM THE HAEMOVIGILANCE COMMITTEE OF CATALONIA

Pre-transfusion verification list

List of steps that should be taken to carry out the correct and safe transfusion practice at the patient's bedside.

With the team responsible for the patient	CHECKED
1 Medical order available: component, quantity, duration and specifications*	
When with the recipient	**CHECKED**
2 Active identification of the patient if conscious**	
3 Verify name and surnames on the bag and bracelet	
4 Verify the security number on the bag and bracelet***	
5 Inform patient, consent given	
6 Verify constants	
7 Use protective measures (gloves) to make the approach or clean hands	
8 Inspect expiry date and integrity of the bag, colour and presence of any coagulate.	
9 Check compatibility of the ABO group of the bag and the recipient.	
10 Verify that the venous access is correct and functioning	
11 Connect equipment to the bag with a 170 m filter and prime the line	
12 Initiate perfusion at a low speed	
13 Accelerate after 10 minutes according to medical instructions	
14 Ask patient to inform of any symptoms	
15 If anything is not correct, the blood must be immediately returned	

* Specifications: fractionated, irradiated, with premedication...
** Identity bracelet, medical records number, family, staff responsible for the patient.
*** If applicable.

Acknowledgments

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Banc de Sang i Teixits
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Pilar Ortiz, Roger Palau, Conxita Pastoret, Lluís Puig, Elisabeth Reyes, Silvia Sauleda, Manel Tarifa

For all the employees who send the notifications.