



**16TH INTERNATIONAL  
HAEMOVIGILANCE SEMINAR**  
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# Ten years of Haemovigilance in Spain

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# The Haemovigilance system in Spain



At the national level is the result of the 17 Haemovigilance systems existing in the corresponding autonomous regions

# Working group on Haemovigilance

Consisting of 8 specialists in Blood Transfusion

Ministry of Health  
December, 1998

1. To design a system adapted to our political and administrative structure.
2. To elaborate the documents (Forms) necessary for the notification of adverse events.
3. To promote the development of Haemovigilance systems in the 17 autonomous regions (AR) that constitute our country.

- A Haemovigilance system based on the voluntary notification of adverse events was proposed.
- The Forms were accepted by all AR to be used in the regional systems.
- The necessary homogeneity in the notification was ensured.

# Agreement for a pilot Haemovigilance system in Spain (2003-2006)

Spanish Society of  
Blood Transfusion  
(SETS)

Spanish Association of  
Haematology and Haemotherapy  
(AEHH)

Ministry of Health

The implementation of a  
Haemovigilance system  
at the national level as  
an administrative matter



The implementation of a  
Haemovigilance system  
at the national level as a  
matter of medical interest

The Haemovigilance  
Unit was created in the  
Ministry of Health



- First report on Haemovigilance in Spain (6th EHN Seminar, Zürich, 2004)
- 12/17 Haemovigilance systems at the end of the pilot programme.



## Transposition in SPAIN

### **Directive 2002/98/EC (January, 2003)**

Setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components.



### **Real Decreto 1088/2005 (20 de septiembre)**

Requisitos técnicos y condiciones mínimas de la hemodonación y de los centros y servicios de transfusión

### **Directive 2005/61/EC (September, 2005)**

- Notification of serious adverse reactions and events
- Traceability requirements



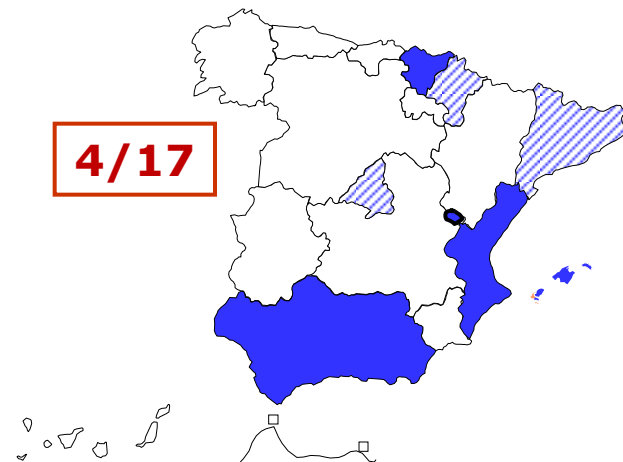
### **Orden SCO/322/2007 (17 de febrero)**

Requisitos de trazabilidad y de notificación de reacciones y efectos adversos de la sangre y de los componentes sanguíneos

The publication of the two directives boosted the development and consolidation of the Spanish Haemovigilance Network

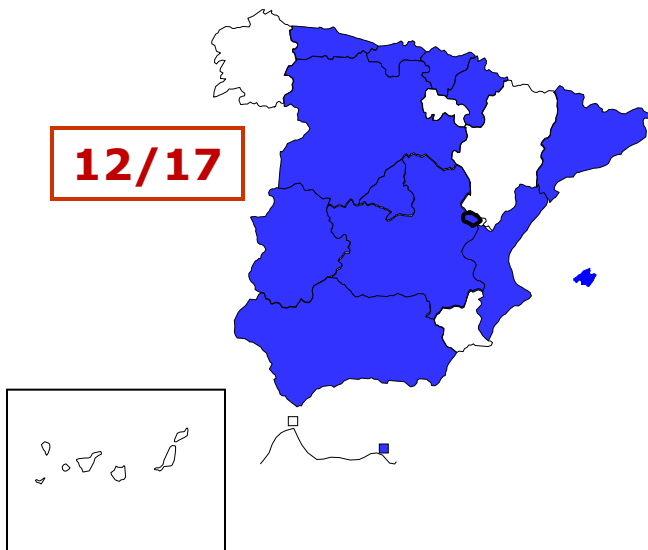
# Evolution of the Haemovigilance Network in Spain

**2003**



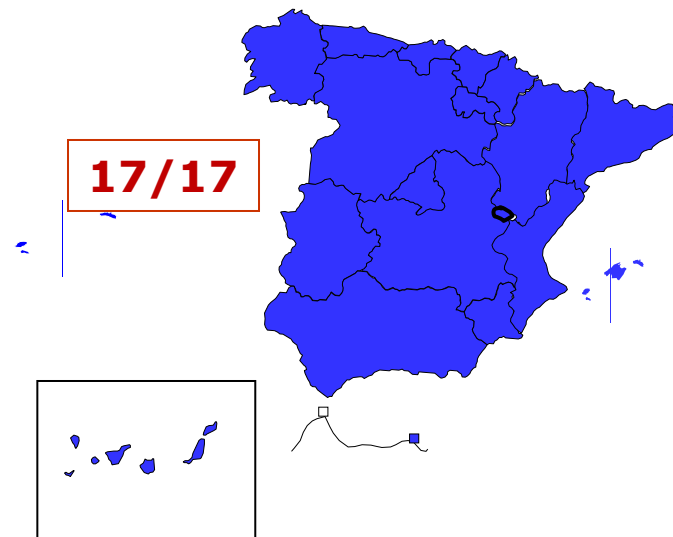
**2005**

**12/17**



**2009**

**17/17**



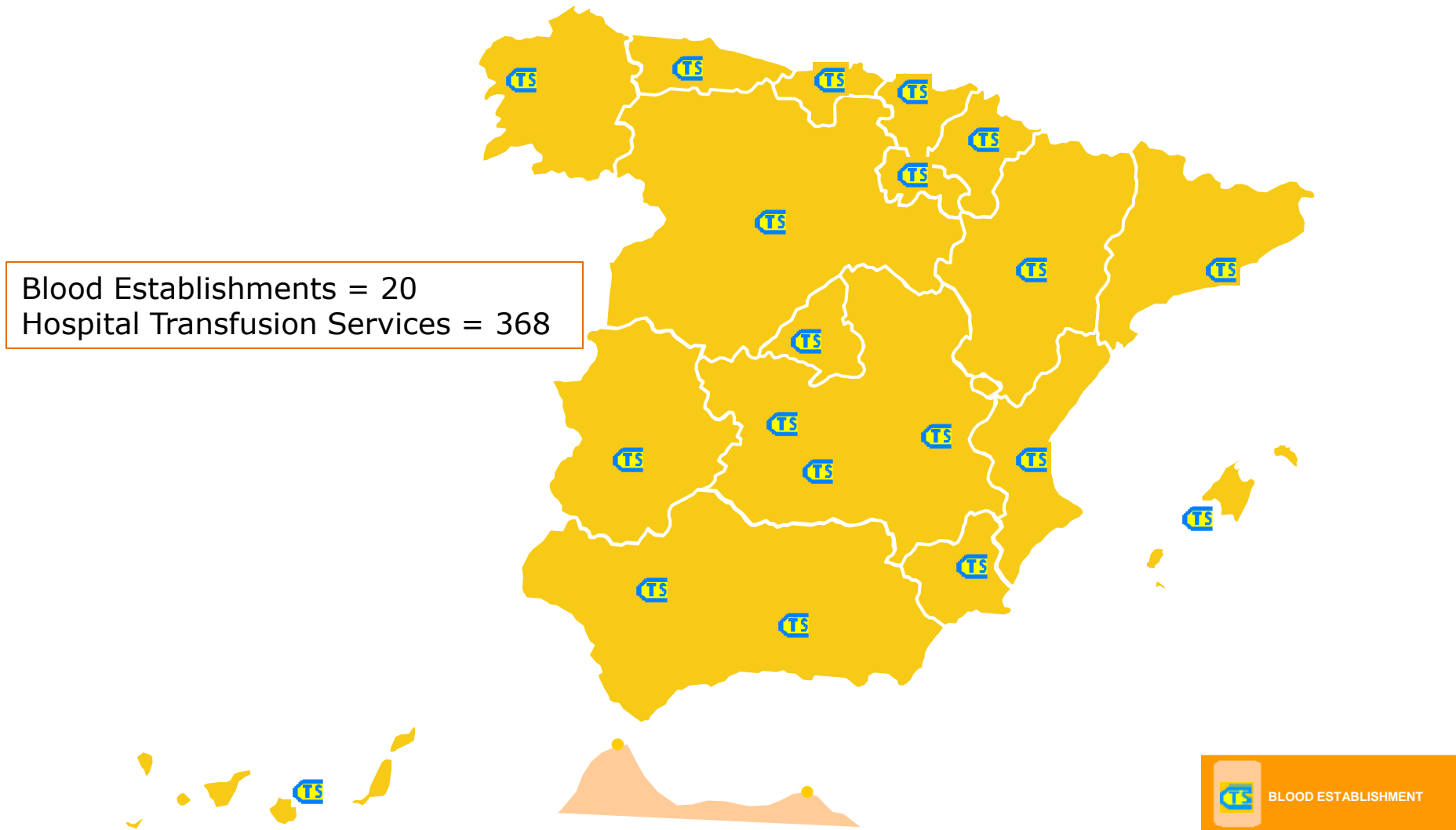
# Some data of the period 2007-2012

The scope  
of the  
Spanish  
Haemovigilance  
system  
at  
the  
national  
level

1. Recipients: adverse reactions and events (incidents and near misses).
2. Blood Donors.
3. SAR and SAE attributable to the quality and safety of blood components.



# SPANISH TRANSFUSION NETWORK 2014



87% of the transfusional activity is concentrated in state hospitals



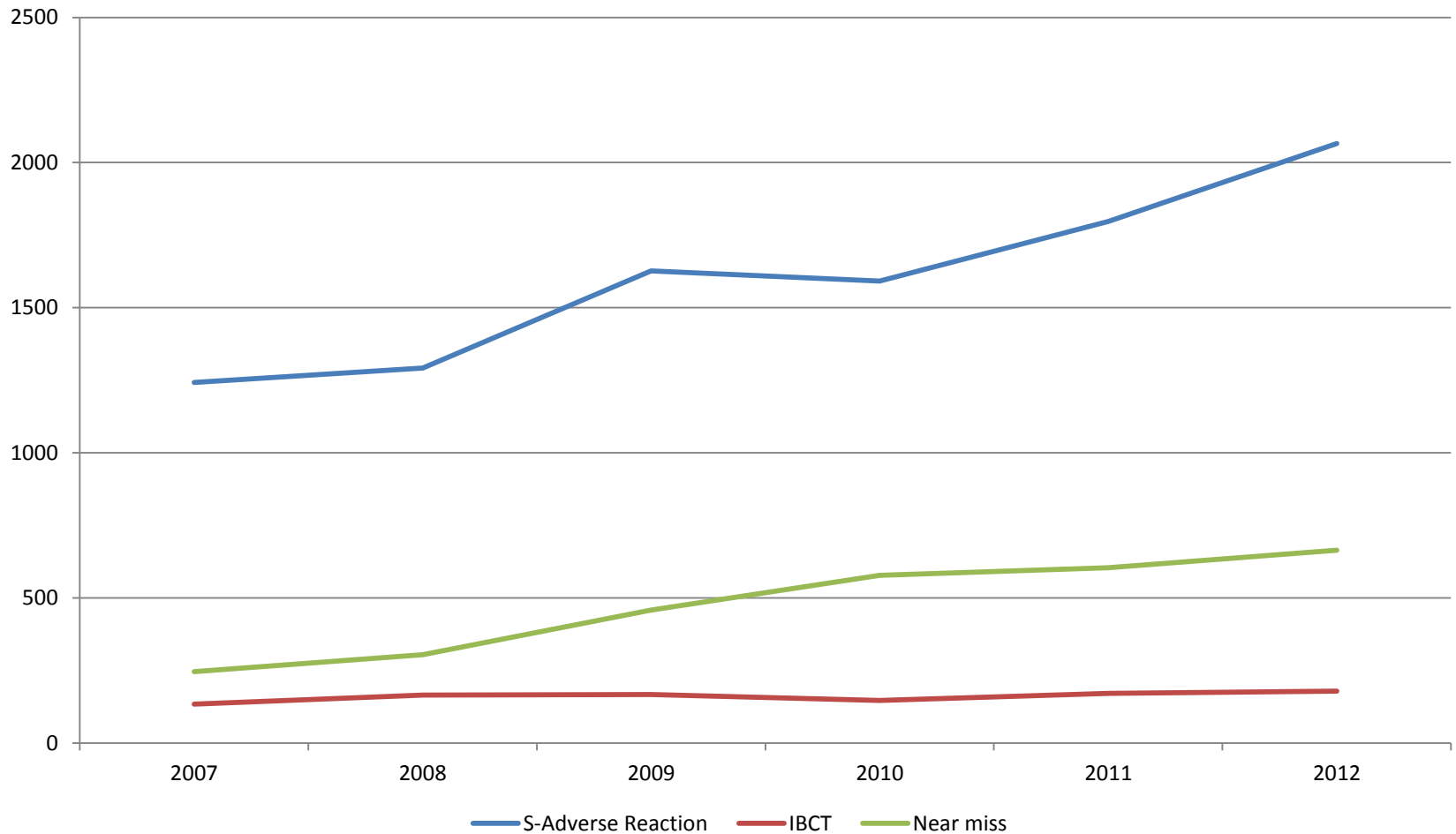
## Number of blood components transfused and number of reports /10.000 units (2007-2012)

YEAR	N. Transfused Units*	Reports	Reports** / 10.000 units
2007	1.864.554	1705	9,1
2008	2.000.131	1848	9,2
2009	2.015.408	2436	12,1
2010	2.003.327	2486	12,4
2011	1.968.769	2713	13,8
2012	1.922.065	2909	<b>15,5</b>

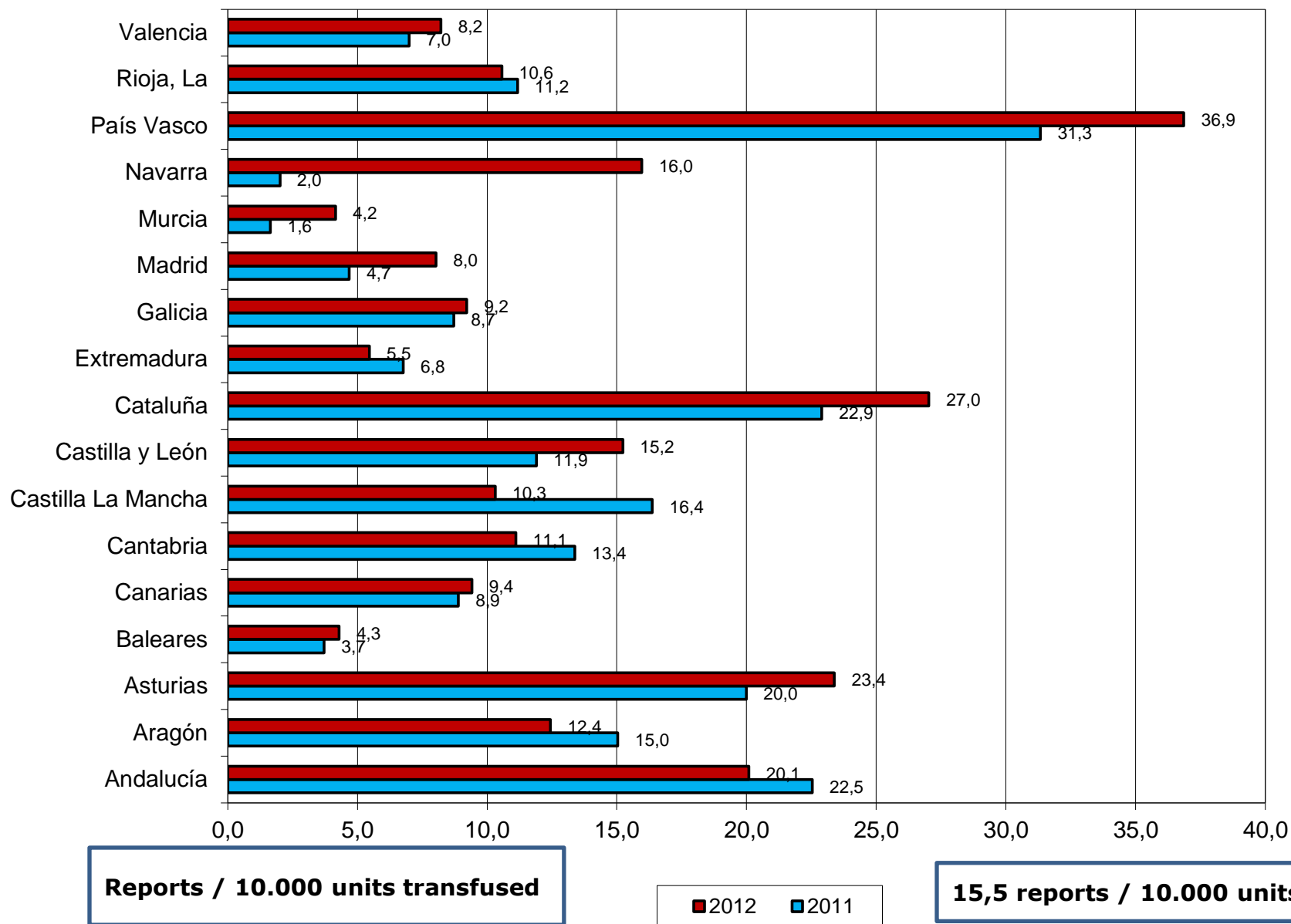
\*Therapeutic dosis of platelets

\*\*Reactions, errors and near misses

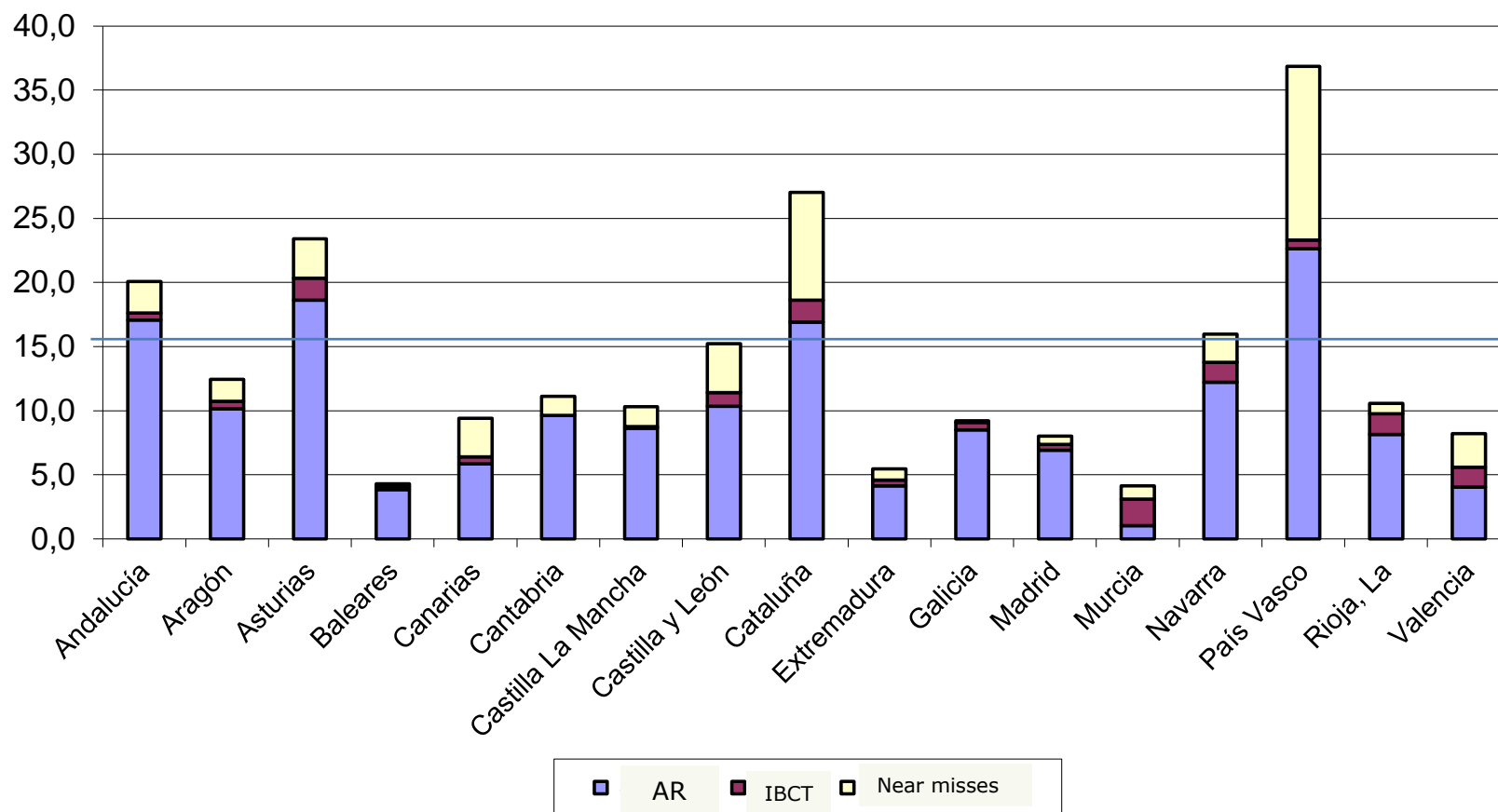
# Trend of the number of adverse events reported: reactions, IBCT and near miss events (2007-2012)



# Haemovigilance Report in 2012



# Haemovigilance Report in 2012

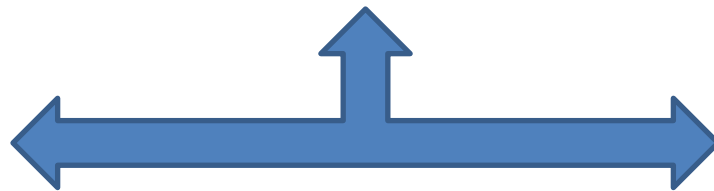


**Reports of reactions, IBCT and near misses / 10.000 units transfused**

# Level of participation

- 100% of Blood Transfusion Establishments
- 90% of Hospital Blood Transfusion Services

Actively participate in the Haemovigilance Programme



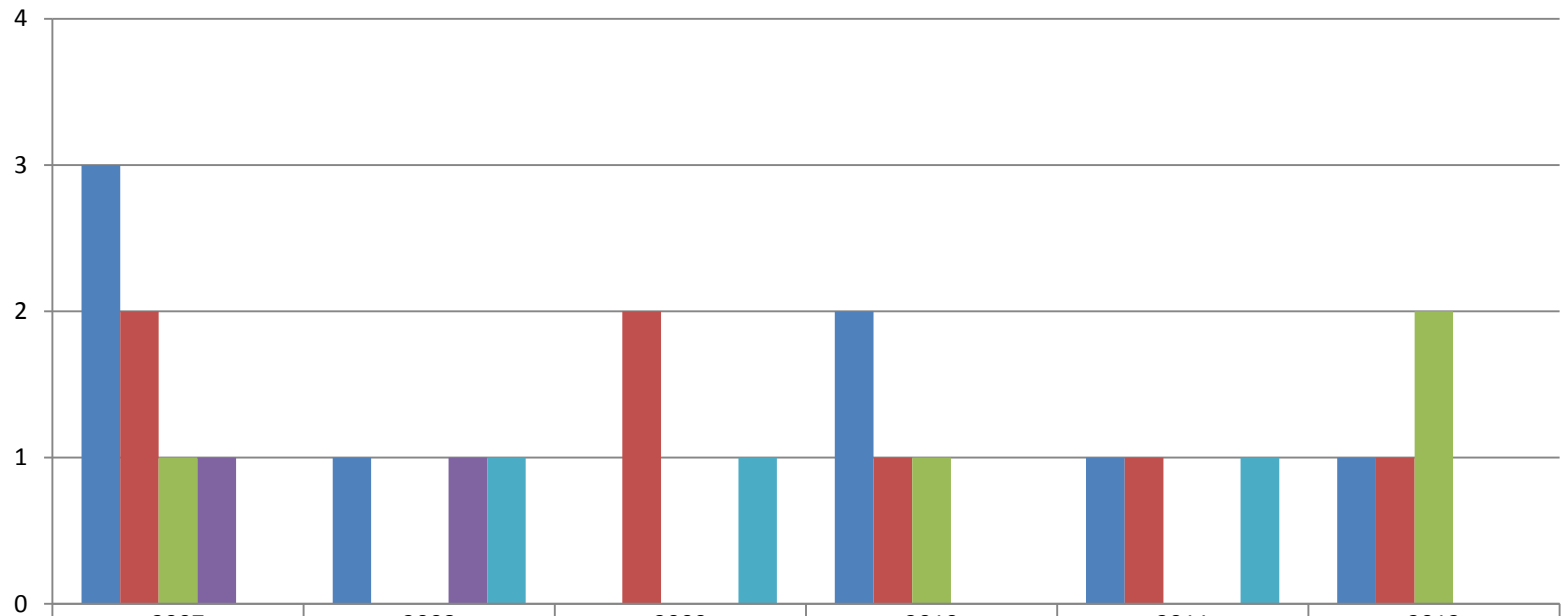
- 82% of the units are transfused in HTS which are regular reporters

What were the risks of blood transfusion in Spain according to the data provided by the Haemovigilance system during the period 2007-2012?



# Mortality associated with transfusion ( $I \geq 2$ ) 2007-2012

N= 24



	2007	2008	2009	2010	2011	2012
HTR(ABO)	3	1	0	2	1	1
TRALI	2	0	2	1	1	1
TACO	1	0	0	1	0	2
TTBI	1	1	0	0	0	0
HTR (no-ABO)	0	1	1	0	1	0

8  
7  
4  
2  
3

# The risks of Blood Transfusion in Spain

- Haemolytic transfusion reactions (HTR) due to ABO incompatibility

- Incorrect blood component transfused (IBCT)

**IDENTIFICATION  
ERRORS**

- Transfusion-related acute lung injury (TRALI)

- Transfusion-associated circulatory overload (TACO)

Blood components  
are very safe

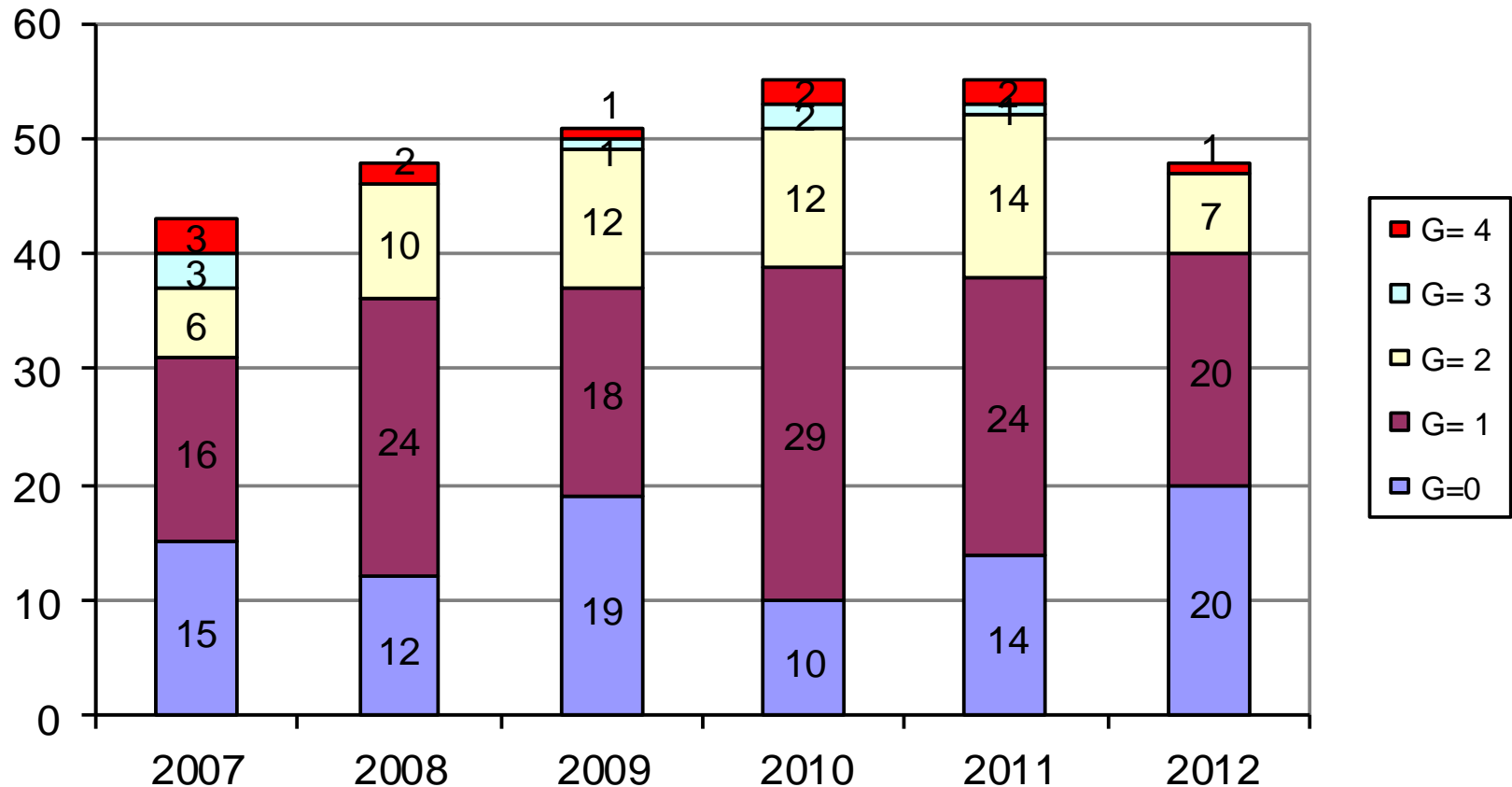
**BUT**

Blood transfusion in the hospital setting  
has still not achieved the same level  
of safety



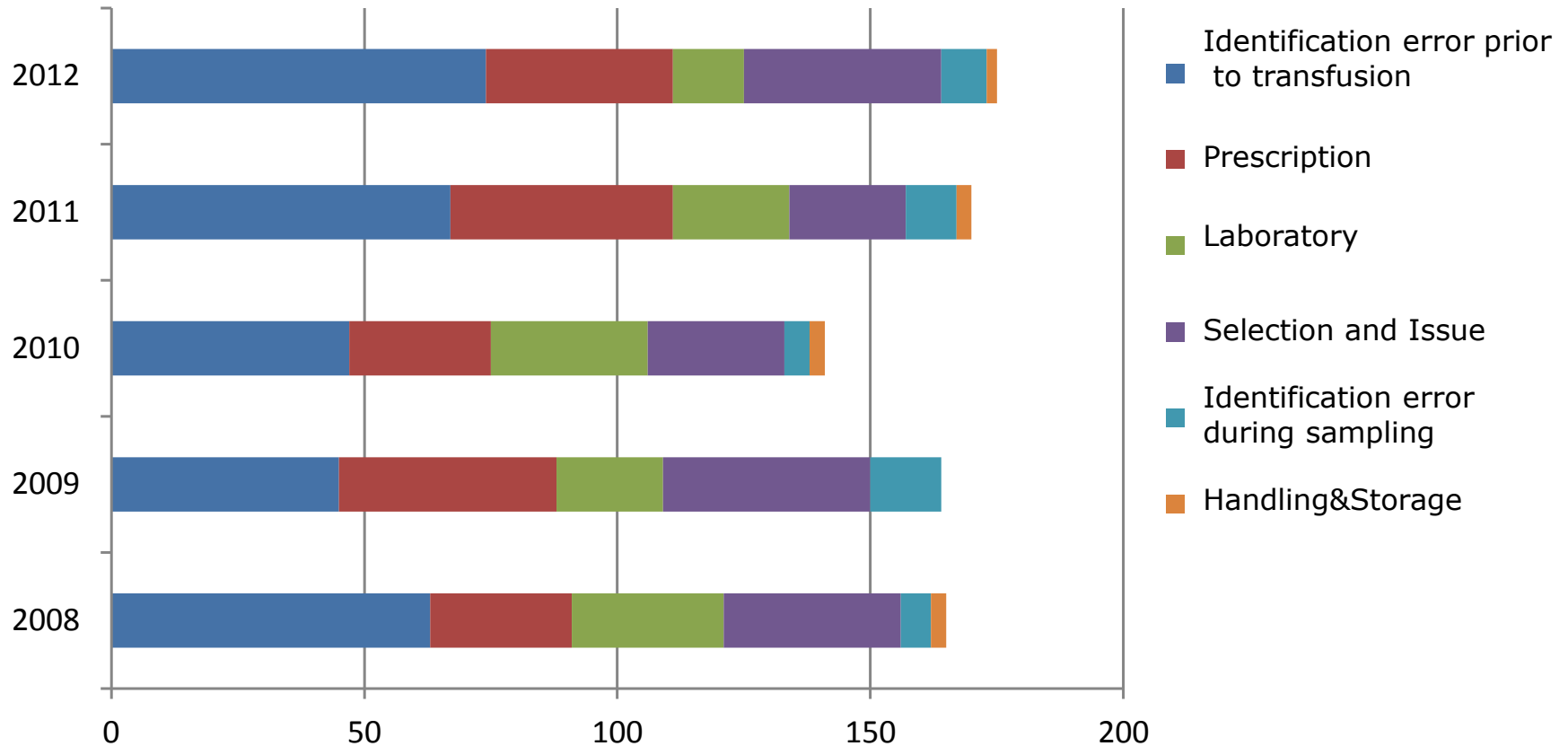
# Haemolytic Transfusion Reactions (N= 350)

$I \geq 2 = 300$  /  $S$  and  $I \geq 2 = 79$  (26%)



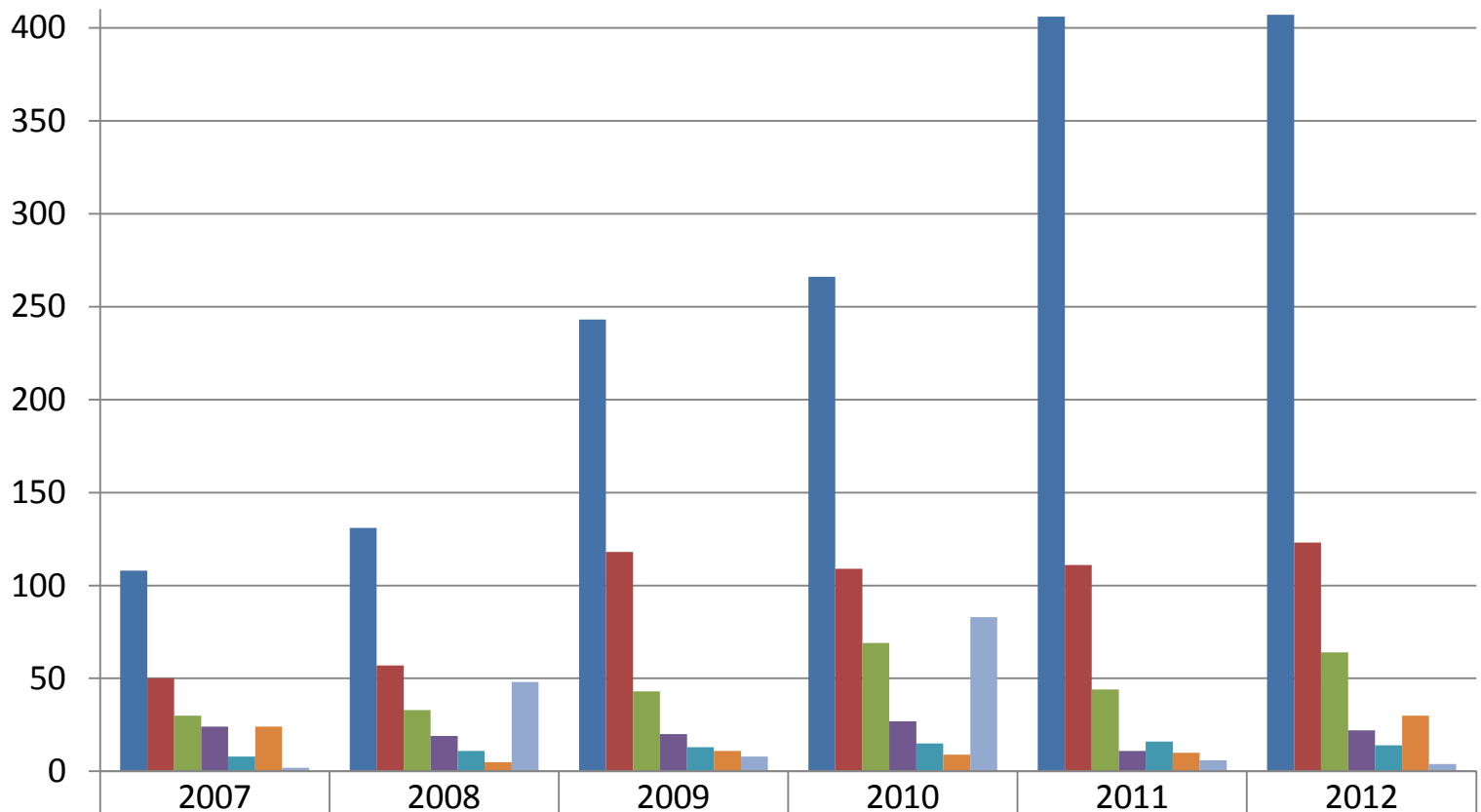
- 79 cases with Severity and Immutability  $\geq 2$
- 8 deaths due to errors in patient identification: positive patient identification and/or matching wristband identification to the blood compatibility label were omitted.

# Incorrect blood component transfused (IBCT) (2007-2012)



Errors in patient identification prior to transfusion are still the major reason for incorrect blood component transfused

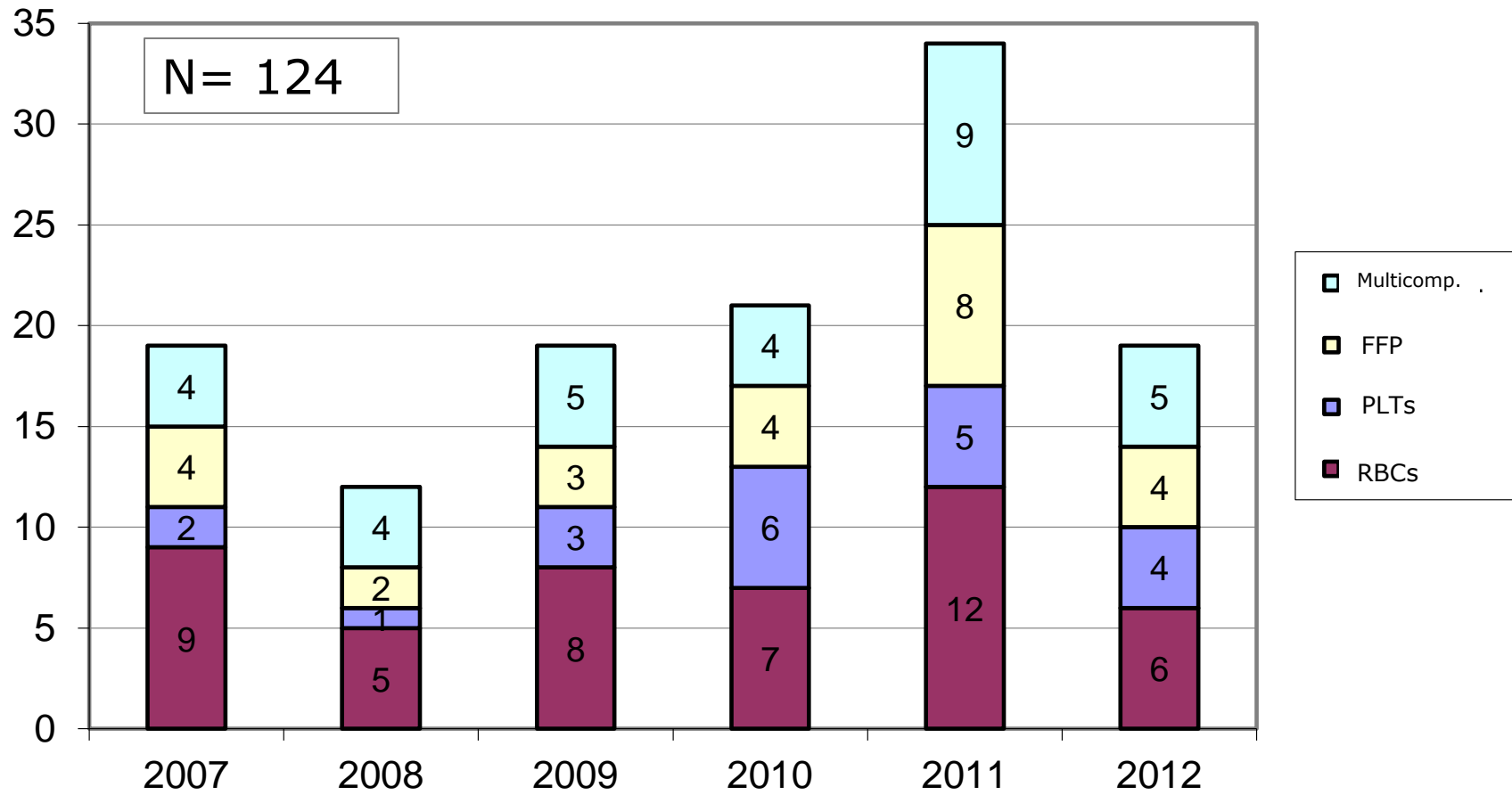
# NEAR MISS EVENTS (2007 - 2012)



Sampling	108	131	243	266	406	407
Prescription	50	57	118	109	111	123
Laboratory	30	33	43	69	44	64
Selection	24	19	20	27	11	22
Administration	8	11	13	15	16	14
Handling & Storage	24	5	11	9	10	30
Others	2	48	8	83	6	4

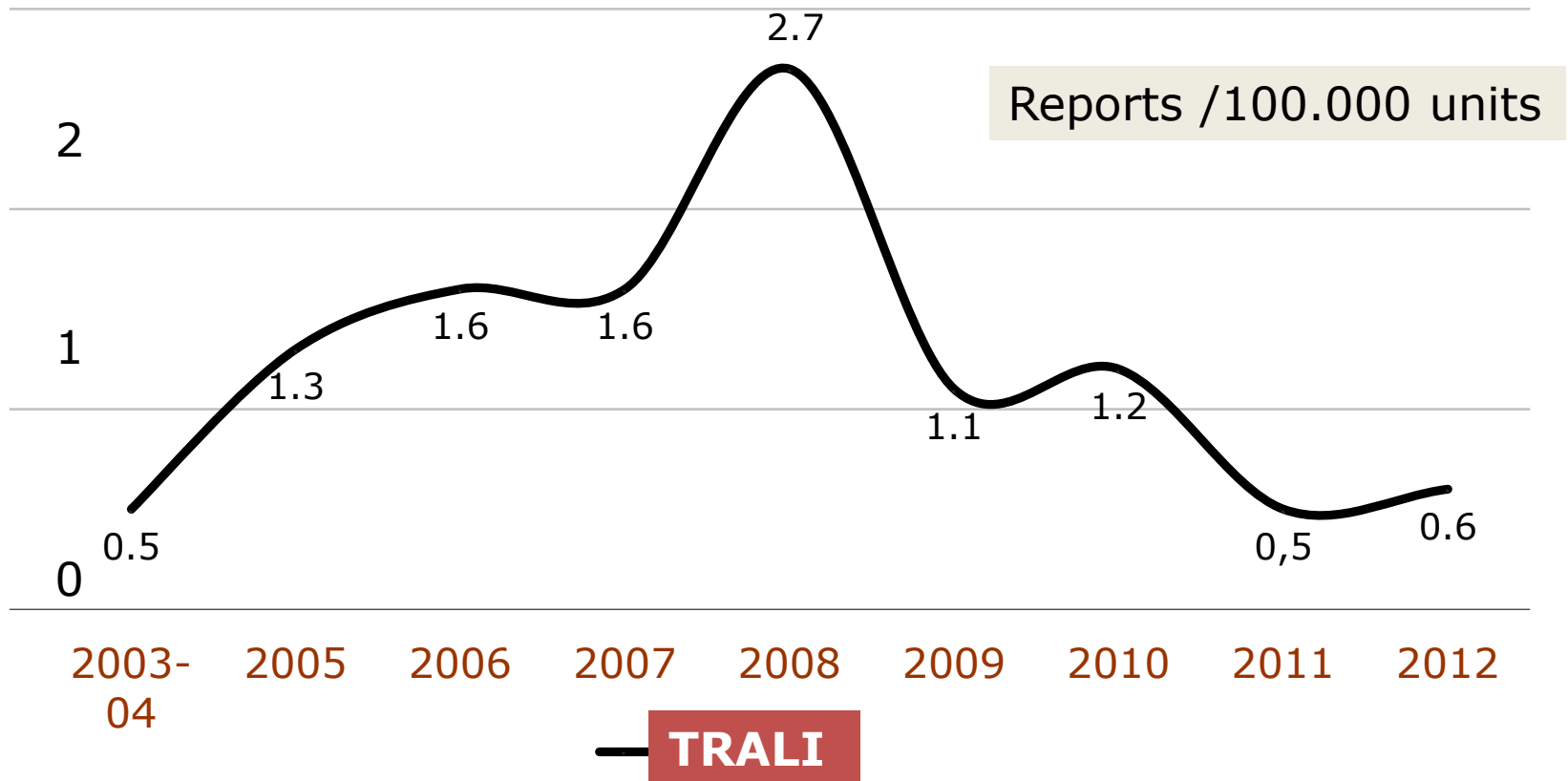
# TRALI (N= 218)

Severity and Imputability  $\geq 2$  (N= 124, 57%)



- 7 deaths due to components containing plasma or multicomponents

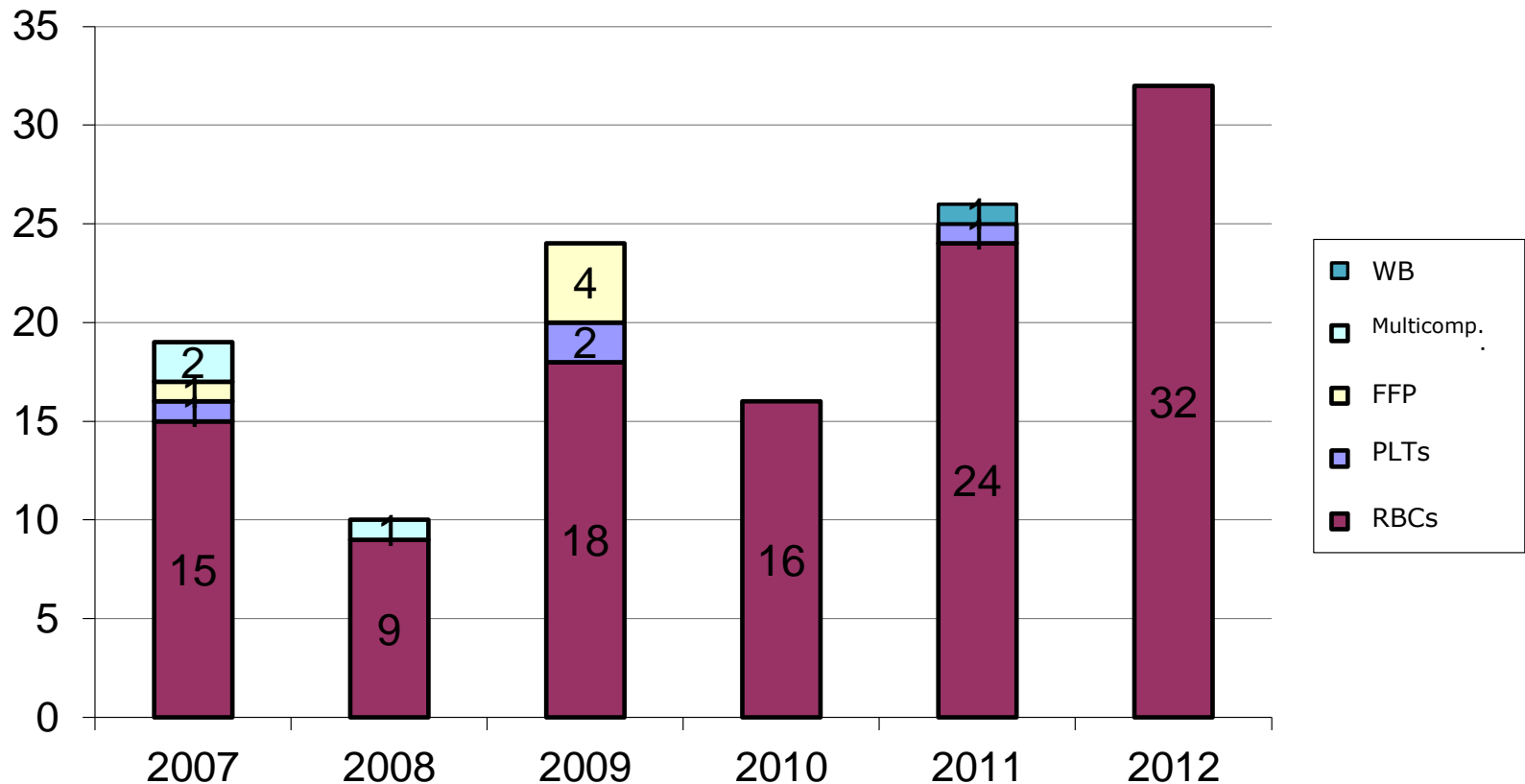
# The use of plasma exclusively from male donors



10 anys d'Hemovigilància a Catalunya

# TACO (N= 278)

Severity and Imputability  $\geq 2$  (N= 127, 46%)



- 90% produced by red blood cells
- 4 deaths: 1 in 2007, 1 in 2010 and 2 in 2012.

# Common clinical characteristics of the patients who suffered from TACO

## (2010 Report: 17 cases)

- Most patients were elderly with a mean age of 77 years, median 83 (34-100) years.
- All of them had predisposing factors: cardiac insufficiency or kidney insufficiency, hypoalbuminemia, etc.
- In all cases the rate and volume of transfusion did not meet the clinical requirements of these patients.
- In most cases (>90%) the doctor had not provided specific instructions for blood administration.

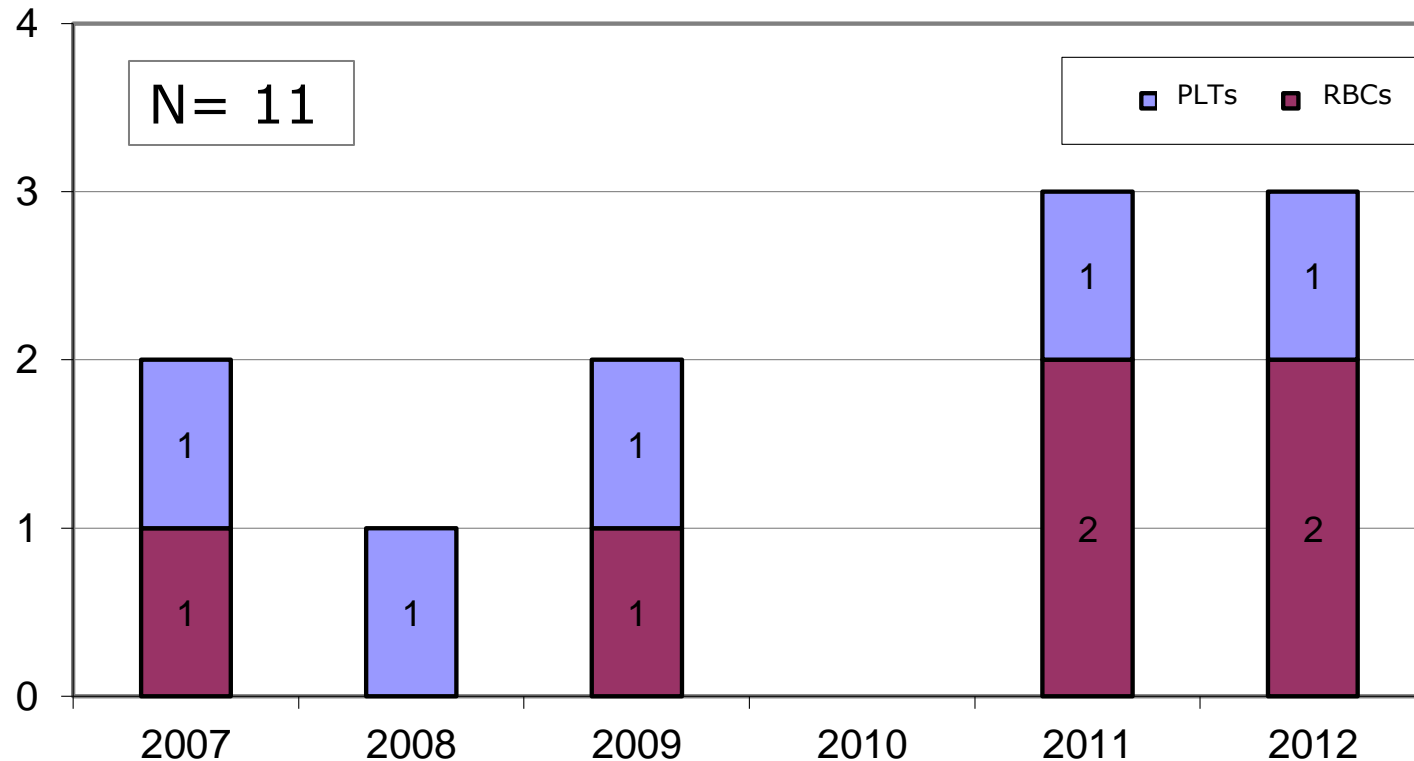
### Measures proposed

- Doctors must be aware of this preventable complication and the **maximum diffusion of the HV report** is essential.
- Doctors must elaborate **precise medical instructions** about rate and volume of transfusion, and must prescribe associated medication (diuretics...) when necessary.
- **Fractioned red cell units** must be elaborated by BE and should be prescribed for these patients.

4.4% of fractioned red cells in 2013

# Transfusion-Transmitted Bacterial Infection (N= 82)

## Severity and Imputability $\geq 2$ (N= 11, 13%)



- 5 cases transmitted by red blood cells and 6 cases transmitted by platelets
- 2 deaths induced by Platelets (*Streptococcus agalactiae*, *Serratia marcescens*),
- The deviation pouch using during blood drawing from a blood donor was implemented in 2007

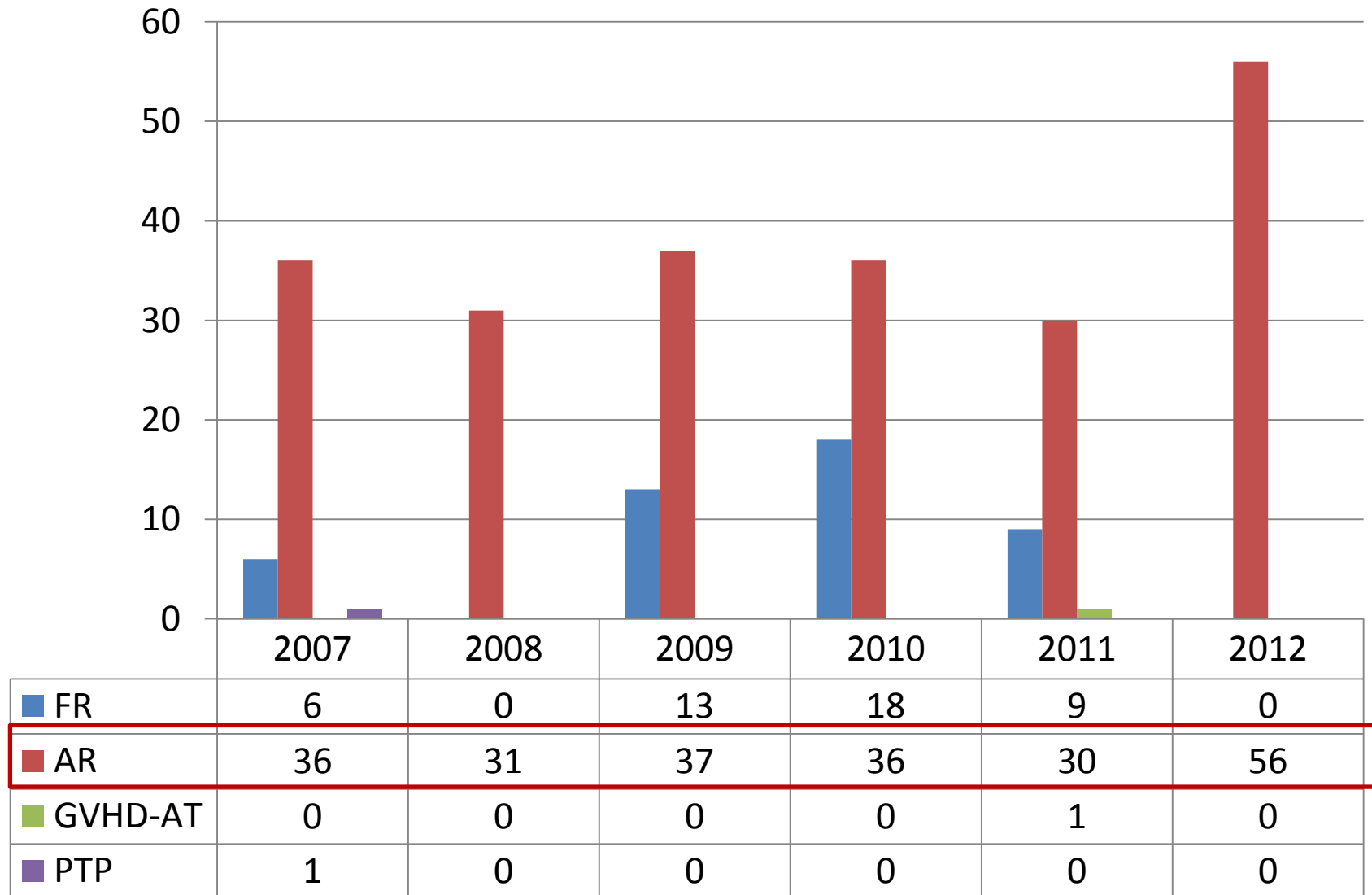


# Other Transfusion-Transmitted infections

- No Viral-TTI were reported during the period studied.
  
- A Parasitic-TTI was reported in 2007.
  - It was a case of Chagas transmission due to a failure in the identification procedure of the donors at risk.
  - Chagas screening in donors at risk was implemented in 2005
    - Donors born or resident in endemic areas
    - Or whose mother was born in endemic areas.




# Other Adverse Reactions (S and I $\geq 2$ )



# Rates of the main adverse reactions and events

	SPAIN 2007-2012	SPAIN 2012
IBCT	1/12.000	<b>1/11.000</b>
HTR	1/150.000	1/240.000
TRALI	1/95.000	1/100.000
TACO	1/93.000	<b>1/60.000</b>
Bacterial-TTI	1/1.000.000	1/640.000
Viral-TTI	0	0
Parasitic-TTI	1/11.000.000	0
Deaths probably or definitely attributed to transfusion	1/500.000	1/500.000
<b>Total blood components transfused</b>	<b>11.809.531</b>	<b>1.922.065</b>



A lush green forest scene with a railway track curving through the undergrowth. Tall trees with vibrant green foliage surround the track, which is partially covered by ferns and other forest plants. The lighting is bright, suggesting a sunny day, with sunlight filtering through the leaves.

**WHERE  
DO  
WE GO  
FROM  
HERE?**

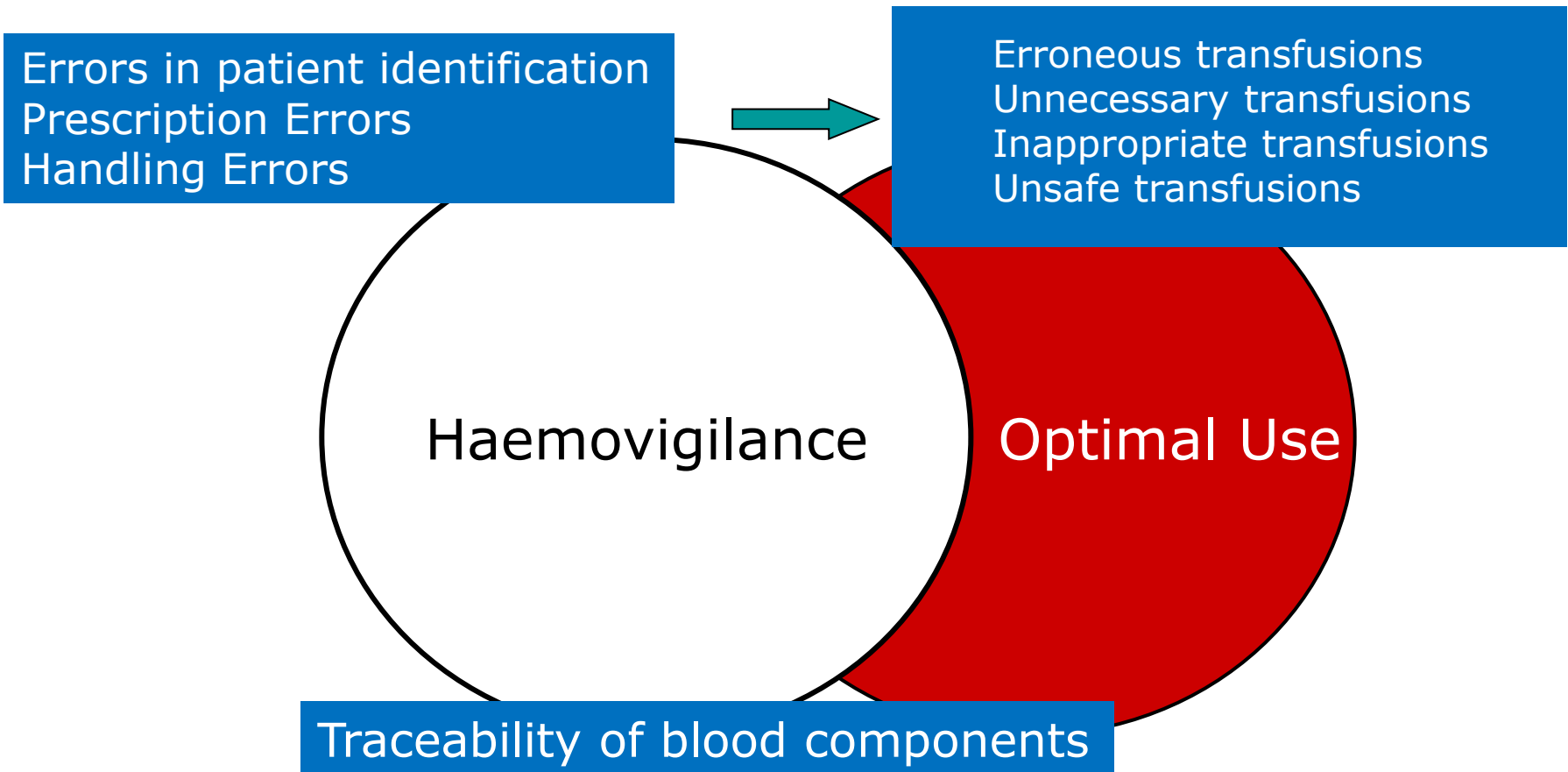


# To improve the quality and safety of transfusion practice

- To educate and train the staff involved in blood transfusion.
- To expand and to consolidate the role of the Transfusion nurse.
- To increase the role of new technologies: bar-coding, radiofrequency...
- To extend the use of the check-list for a safe transfusion administration and for a safe sample collection.



# Optimal blood use and patient blood management



# Optimal blood use and patient blood management

- We should broaden the scope of our Haemovigilance system in order to give **the best advice on the treatment with blood components** or blood alternatives.
- We should generate **data on the benefit of transfusion** in different clinical situations in order to be able to make risk-benefit calculations.
- We have to implement or to expand **a set of indicators on optimal blood use** easily provided by most hospital information systems.
- **Audit methods** should be more adapted to ensure and analyse critical parameters for optimal blood use such as compliance with guidelines.

The Unit of Haemovigilance is working in a selection of good indicators to measure the optimal use of blood components to be included in the annual Haemovigilance report



# TRANSFUSION PRACTICE

## The epidemiology of blood component transfusion in Catalonia, Northeastern Spain

Transfusion 2011

*M. Alba Bosch, Enric Contreras, Pedro Madoz, Pilar Ortiz, Arturo Pereira, and M. Mar Pujol on behalf of the Catalan Blood Transfusion Epidemiology Study Group*

## Spanish Consensus Statement on alternatives to allogeneic blood transfusion: the 2013 update of the "Seville Document"

Blood Transf 2013

Santiago R. Leal-Noval<sup>1</sup>, Manuel Muñoz<sup>2</sup>, Marisol Asuero<sup>3</sup>, Enric Contreras<sup>3</sup>, José A. García-Erce<sup>3</sup>, Juan V. Llauz<sup>3</sup>, Victoria Moral<sup>3</sup>, José A. Páramo<sup>3</sup>, Manuel Quintana<sup>3</sup>, for the Spanish Expert Panel on Alternatives to Allogeneic Blood Transfusion<sup>4</sup>

## The NEW ENGLAND JOURNAL of MEDICINE

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## Transfusion Strategies for Acute Upper Gastrointestinal Bleeding

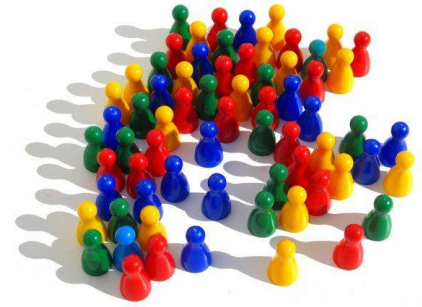
NEJM 2013

Càndid Villanueva, M.D., Alan Colomo, M.D., Alba Bosch, M.D., Mar Concepción, M.D., Virginia Hernandez-Gea, M.D., Carles Aracil, M.D., Isabel Graupera, M.D., María Poca, M.D., Cristina Alvarez-Urturi, M.D., Jordi Gordillo, M.D., Carlos Guarner-Argente, M.D., Miquel Santaló, M.D., Eduardo Muñoz, M.D., and Carlos Guarner, M.D.

ABSTRACT



# Conclusions



- **Haemovigilance** is today in Spain a tool that **is fully integrated** into the activities carried out by the BTC and HTS.
- **The risks of blood transfusion** do not differ from the risks detected in other Haemovigilance systems.
  - **Acute Haemolytic Reactions** caused by major ABO incompatibility **due to errors** in patient identification prior to transfusion continue to be the most important cause of morbidity and mortality associated with transfusion.
  - **TACO** has emerged as an important cause of morbidity and mortality associated with transfusion...and it is a preventable complication.
- It is high time to move **from Haemovigilance to optimal blood use** and patient blood management.
- The Unit of Haemovigilance will give impetus to the two tasks and the 17 regional Haemovigilance systems will be invited to support this new initiative.

Thank you very much  
for your attention!



Working together to improve the quality and safety of transfusion practice