HAEMOVIGILANCE
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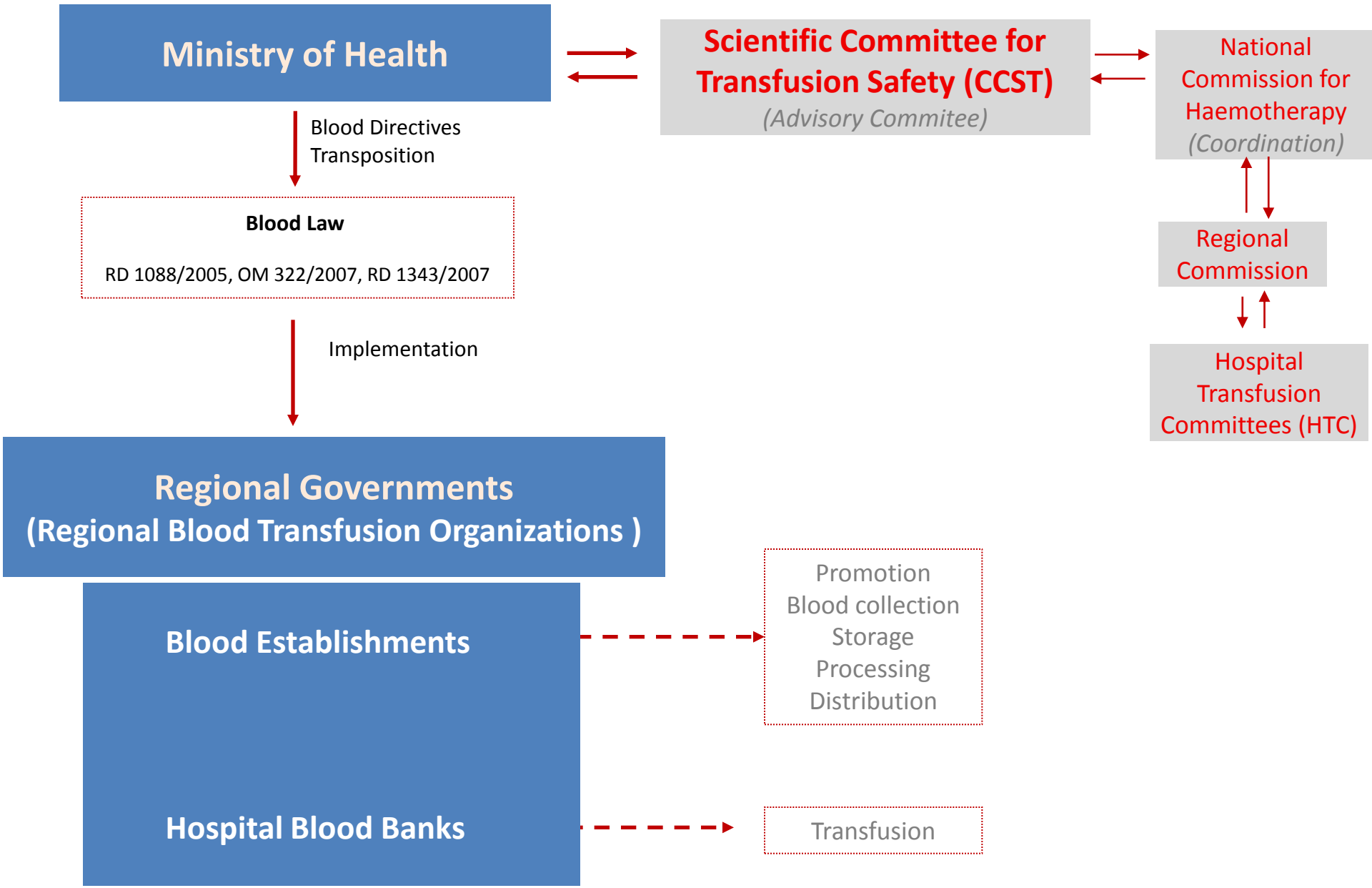
H A E M O V I G I L A N C E

The Spanish Haemovigilance System

Miguel Angel Vesga

IHS Barcelona, March 6th 2014

Blood and blood components main stakeholders in Spain



SPANISH BLOOD TRANSFUSION ORGANIZATION

BLOOD LAW 1088/2005

Competent Authority

Regional Governments
(Regional Blood Transfusion Organisation)

Regional Health Service

↓

Blood Establishment

↓

Hospital Blood Transfusion Units

SPANISH BLOOD TRANSFUSION ORGANIZATION

BLOOD LAW 1088/2005

Competent Authority

Ministry of Health

Spanish Blood Transfusion Advisory Board

Spanish Scientific Committee for Transfusion Safety

Haemovigilance Unit

msc.es/profesionales/saludPublica/medicinaTransfusional/home.htm

BLOOD LAW 1088/2005

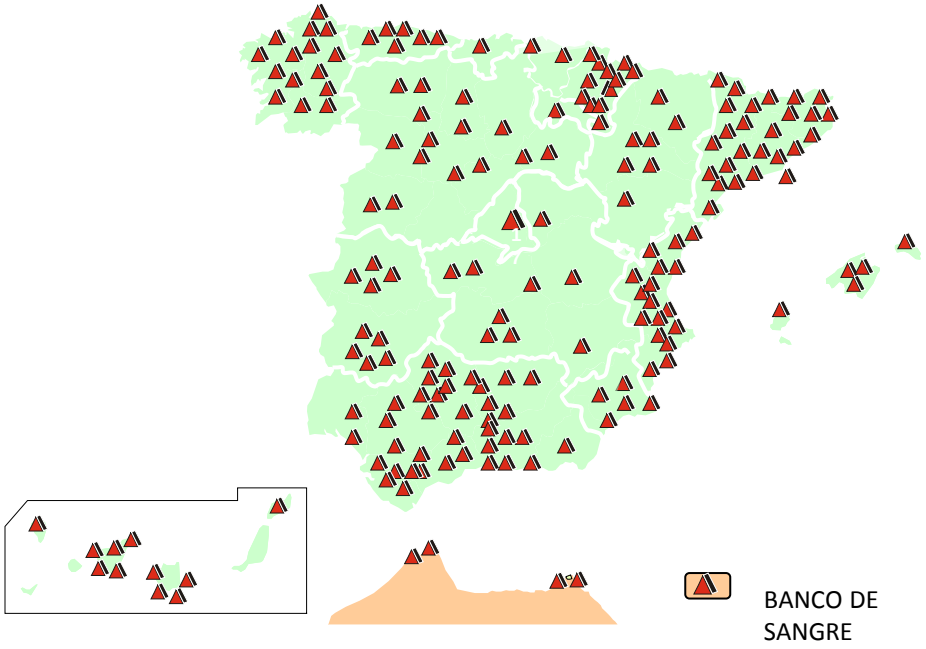
SPANISH BLOOD TRANSFUSION ORGANIZATION

BLOOD ESTABLISHMENT: Health establishment where each activity related to collection, qualification, processing, storage and distribution of blood and blood components is carried out no matter their final destination. The Director of a BE has to be a doctor specialist in Haematology and Blood Transfusion and a minimun experience of two years in a BE or Hospital Transfusion Unit is required.

HOSPITAL TRANSFUSION UNIT: Healthcare unit inside a Hospital Center BOND to a Blood Establishment , where, under the responsibility of a doctor specialist in Haematology and Blood Transfusion, blood componentes intended for transfusion are stored and hospital transfusion activities are organised and monitored.

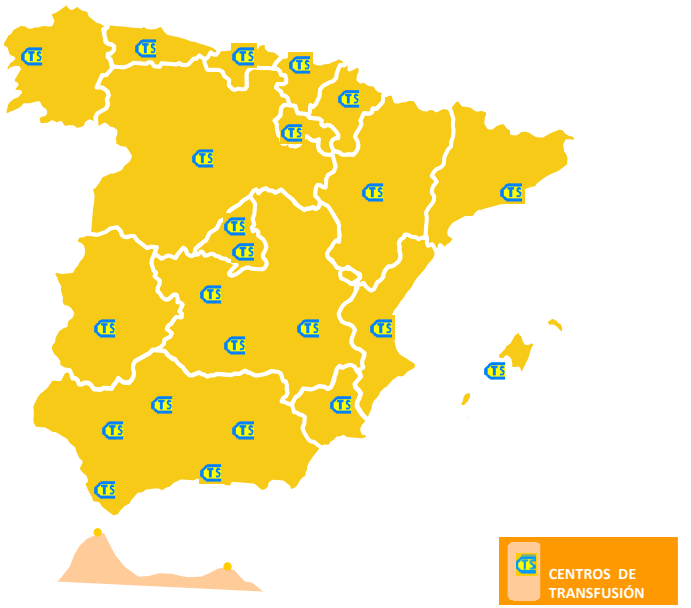
SPANISH TRANSFUSION NETWORK DEVELOPMENT

1983



Blood Donation Rate: 20/1000
Components Processing : 34%

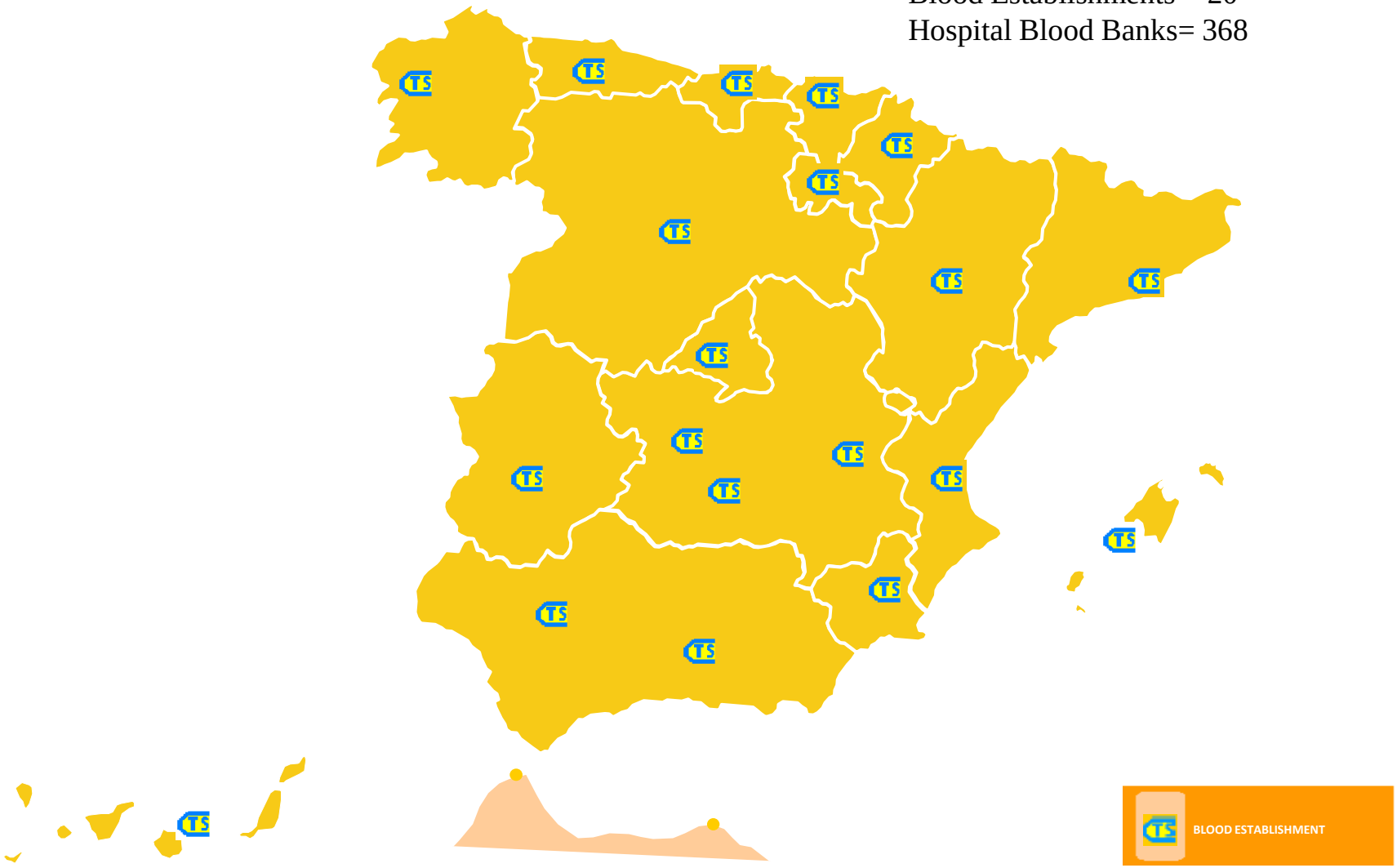
2012



Blood Establishments: 24
Blood Donation Rate: 38,2
Components Processing: >99%

SPANISH TRANSFUSION NETWORK
2014

Blood Establishments = 20
Hospital Blood Banks= 368



SPANISH NETWORK OF BLOOD ESTABLISHMENTS AND HOSPITAL BLOOD BANKS

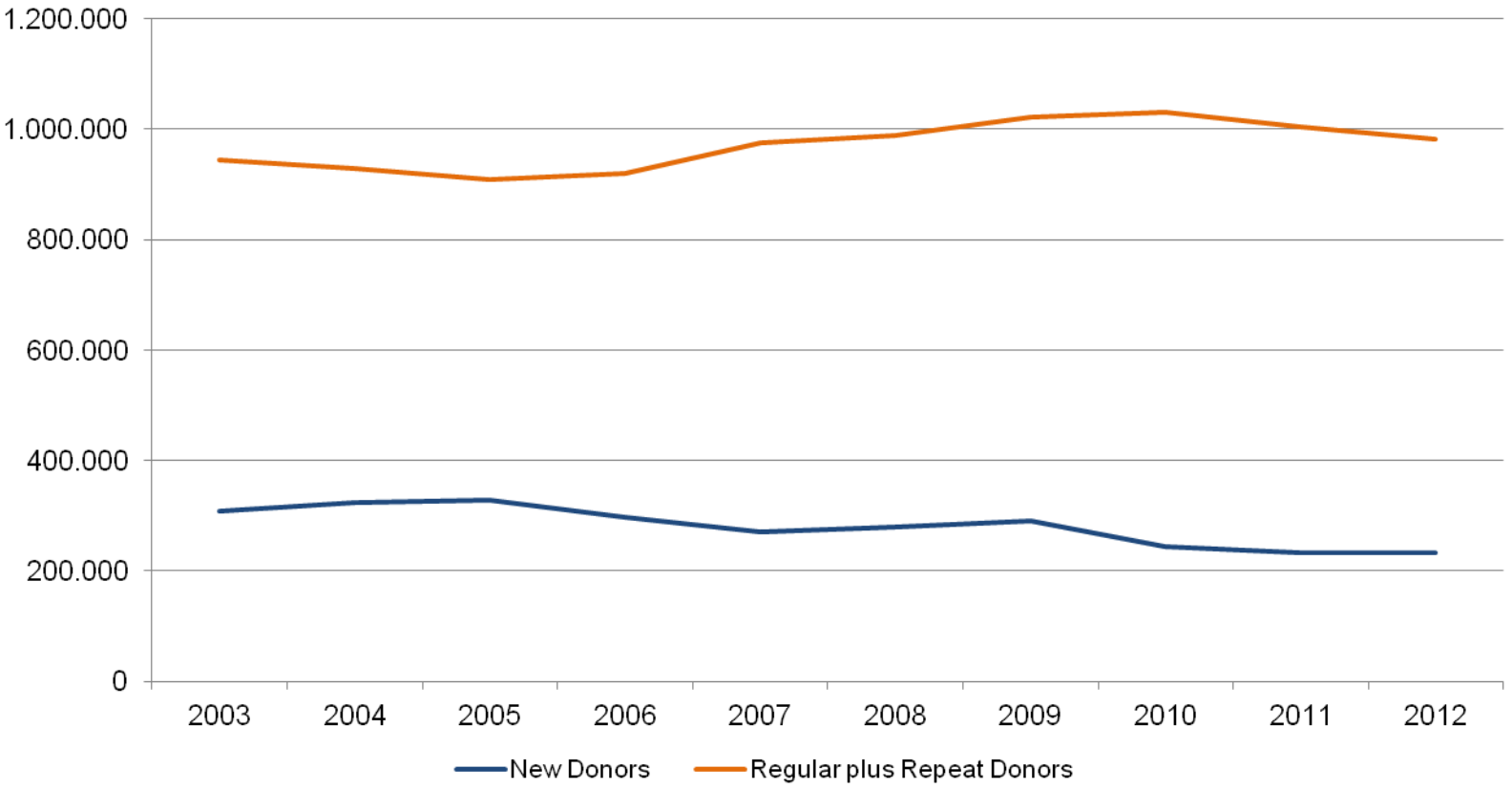
BLOOD LAW 1088/2005

- BE and HBB have to be licensed by the Competent Authority
- Binding Solidarity
- Common Objectives
- Reciprocity
- Public Service
- National Blood Care and Sufficiency

Blood Components Regional Movement 2012

- Red Cells: 15,000 Units (1% of production)
- Platelets: 400 Therapeutics doses (0, 2% of production)
- Plasma: 5.386 Units (2, 7% Transfused)

BLOOD DONORS

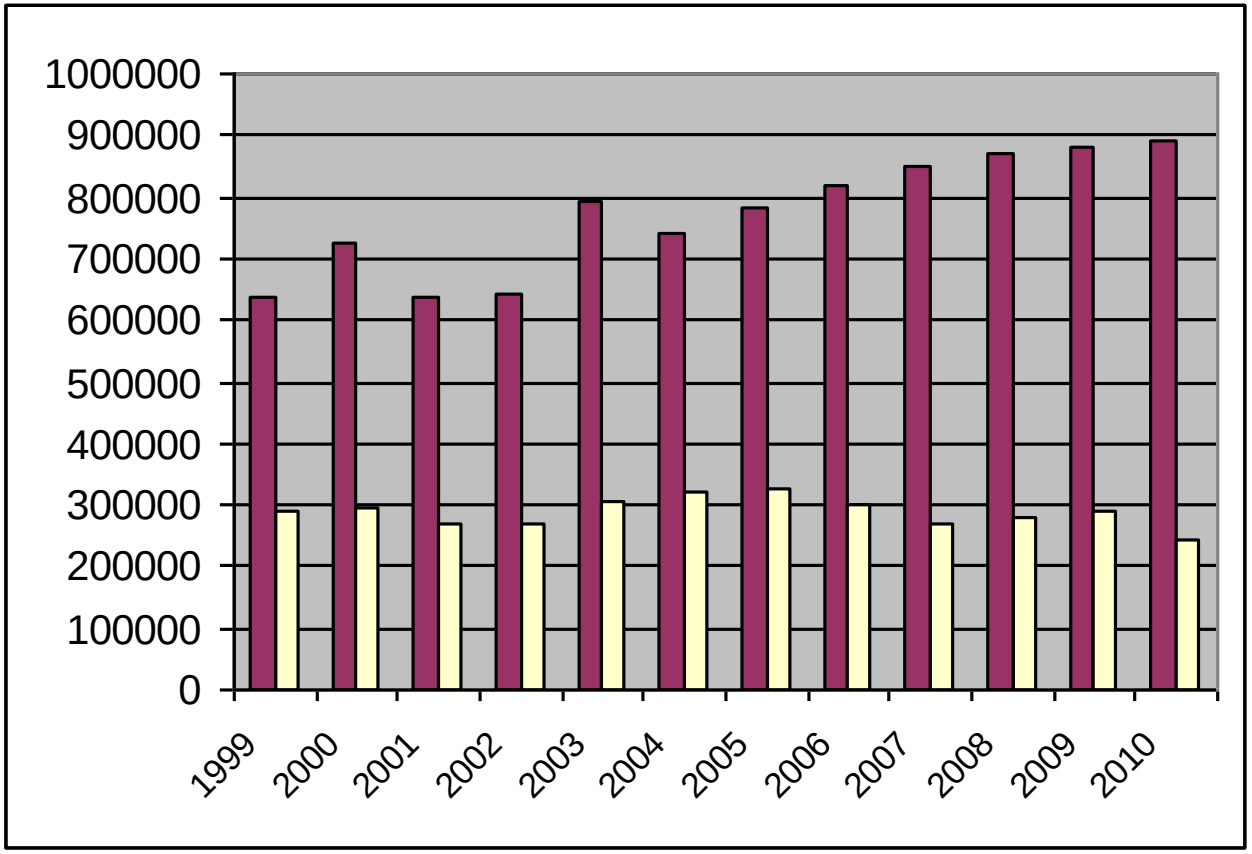


Source: Ministry of Health, Social Services and Equality

Sistema de Información del Sistema Nacional para la Seguridad Transfusional (SNST) Plan Nacional de Hemoterapia

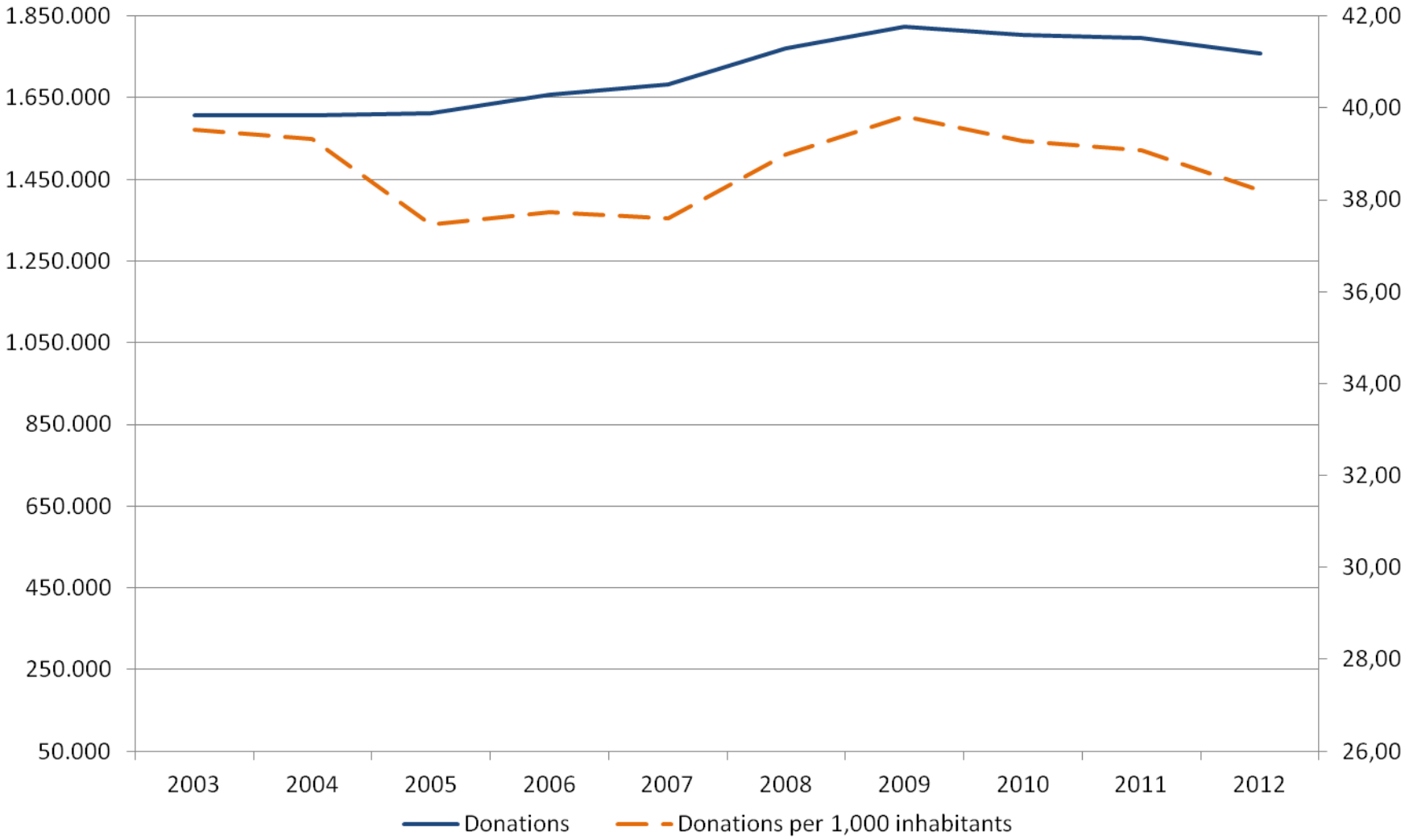
•REGULAR DONORS

•NEW DONORS



VNRBD (Blood Law)

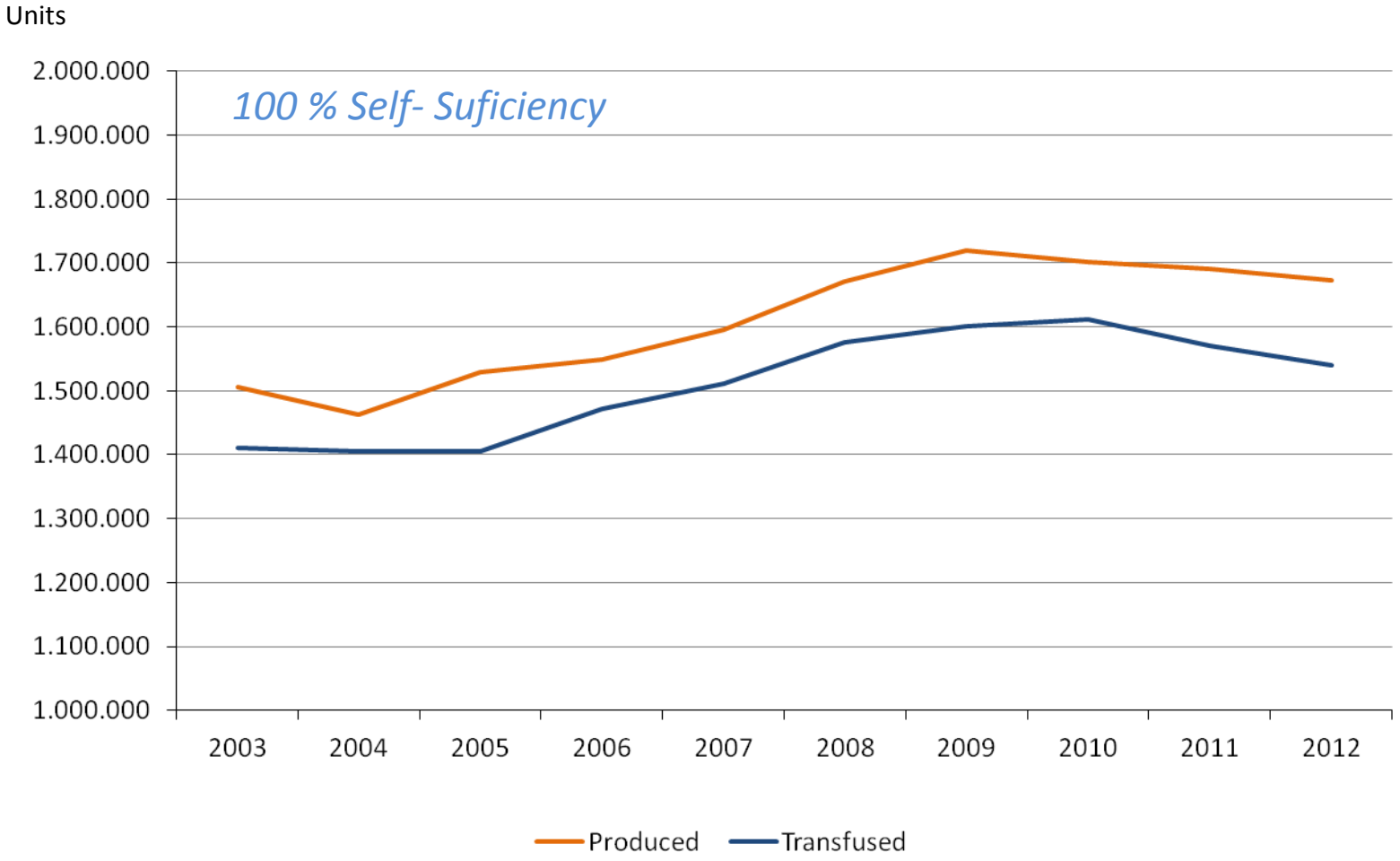
DONATIONS



Source: Ministry of Health Social Services and Equality

Sistema de Información del Sistema Nacional para la Seguridad Transfusional (SNST) Plan Nacional de Hemoterapia

RED CELLS: PRODUCTION AND TRANSFUSION

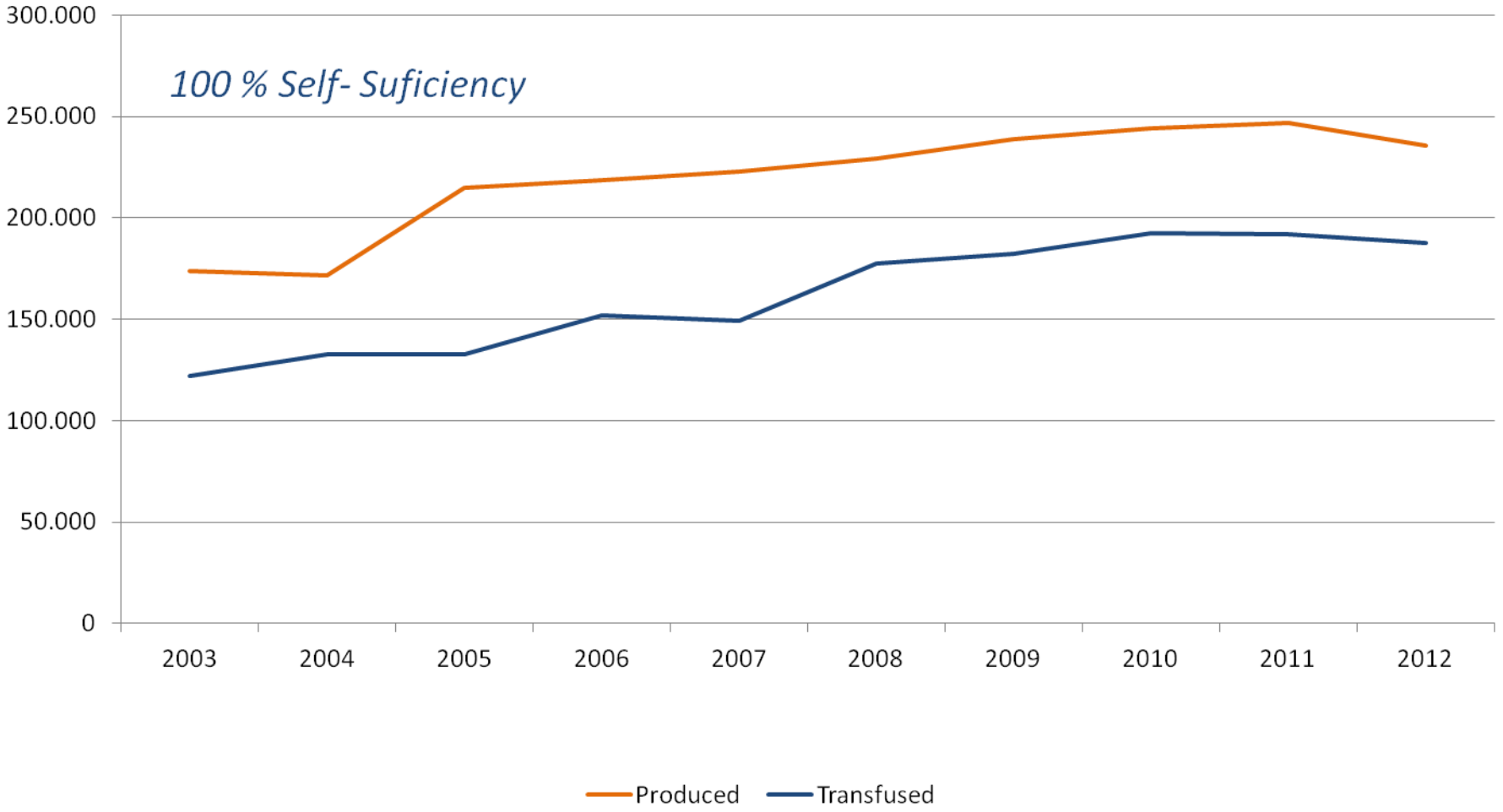


Source: Ministry of Health, Social Services and Equality

Sistema de Información del Sistema Nacional para la Seguridad Transfusional (SNST) Plan Nacional de Hemoterapia

PLATELETS: PRODUCTION AND TRANSFUSION

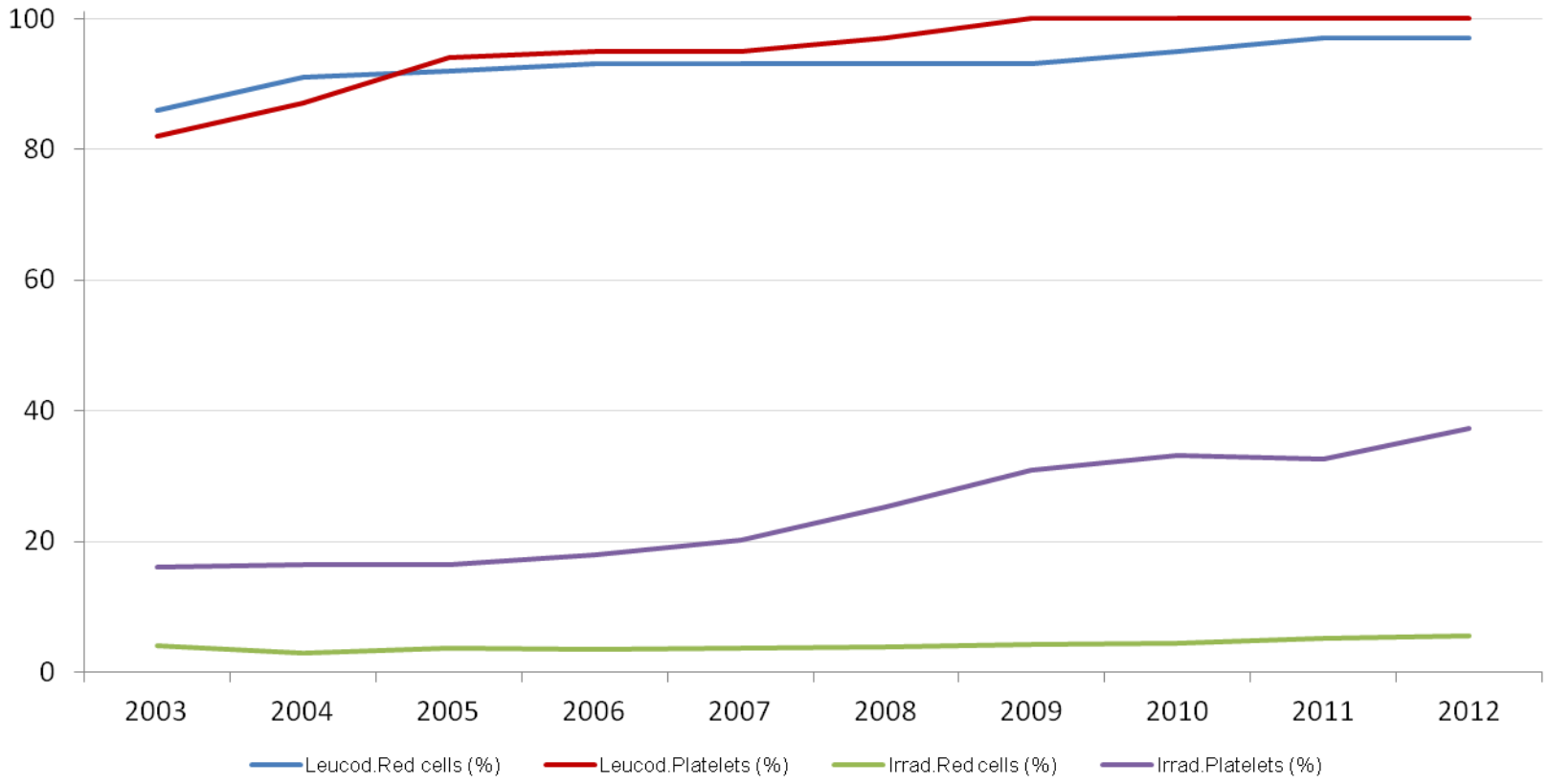
Therapeutic doses



Source: Ministry of Health Social Services and Equality

Sistema de Información del Sistema Nacional para la Seguridad Transfusional (SNST) Plan Nacional de Hemoterapia

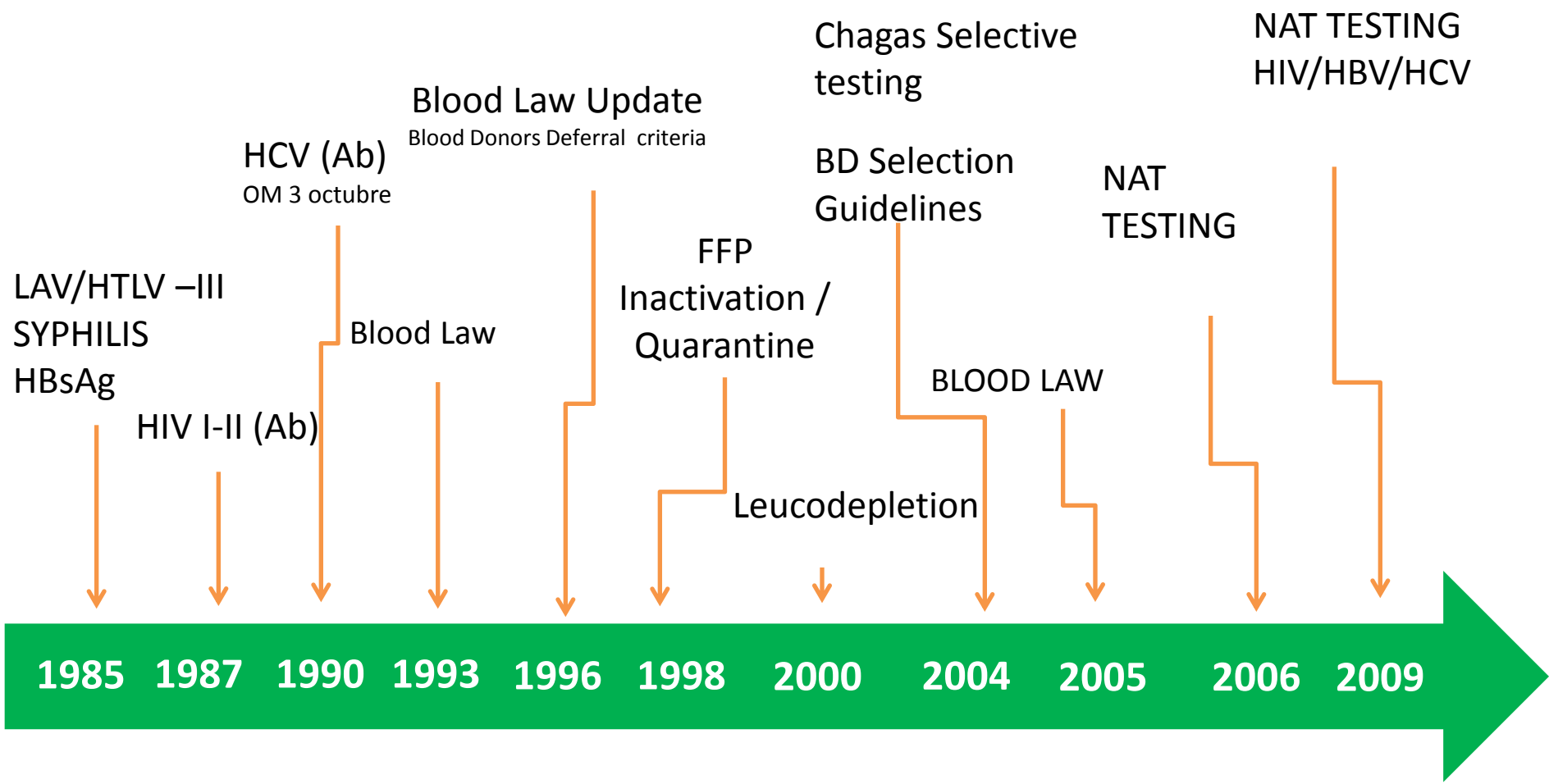
LEUCODEPLETION / IRRADIATION



Source: Ministry of Health Social Services and Equality

Sistema de Información del Sistema Nacional para la Seguridad Transfusional (SNST) *Plan Nacional de Hemoterapia*

BLOOD SAFETY MEASURES (CCST)



▪ BACKGROUND

1998. Ministry of Health. Haemovigilance Group

- Evaluation of different European Haemovigilance Systems
- Questionnaires designed and adopted by the whole country

2003-2006. First Spanish Haemovigilance project

- Ministry of Health
- Spanish Society of Blood Transfusion (SETS)
- Spanish Society of Haematology and Haemotherapy (AEHH)

2007. Ministry of Health: Unit of Haemovigilance

- Blood Law

HAEMOVIGILANCE (Chapter VIII. RD 1088/2005, September 16th setting the technical requirements for Blood Donation, Blood Establishments and Hospital Transfusion services

Haemovigilance System: "The Competent Health Authorities will implement a Haemovigilance System including, at least, an organized set of vigilance procedures concerning those severe effects adverse reactions on blood donors and recipients, and the epidemiology monitorization of blood donors"

Traceability

Adverse reactions and effects notification

BLOOD LAW

Orden Ministerial SCO/322/2007, February 9th, as regards traceability requirements and notifications of serious adverse reactions and events

SCOPE:

Blood Establishments and Hospital Transfusion Services Spanish Network

- **Blood Law**

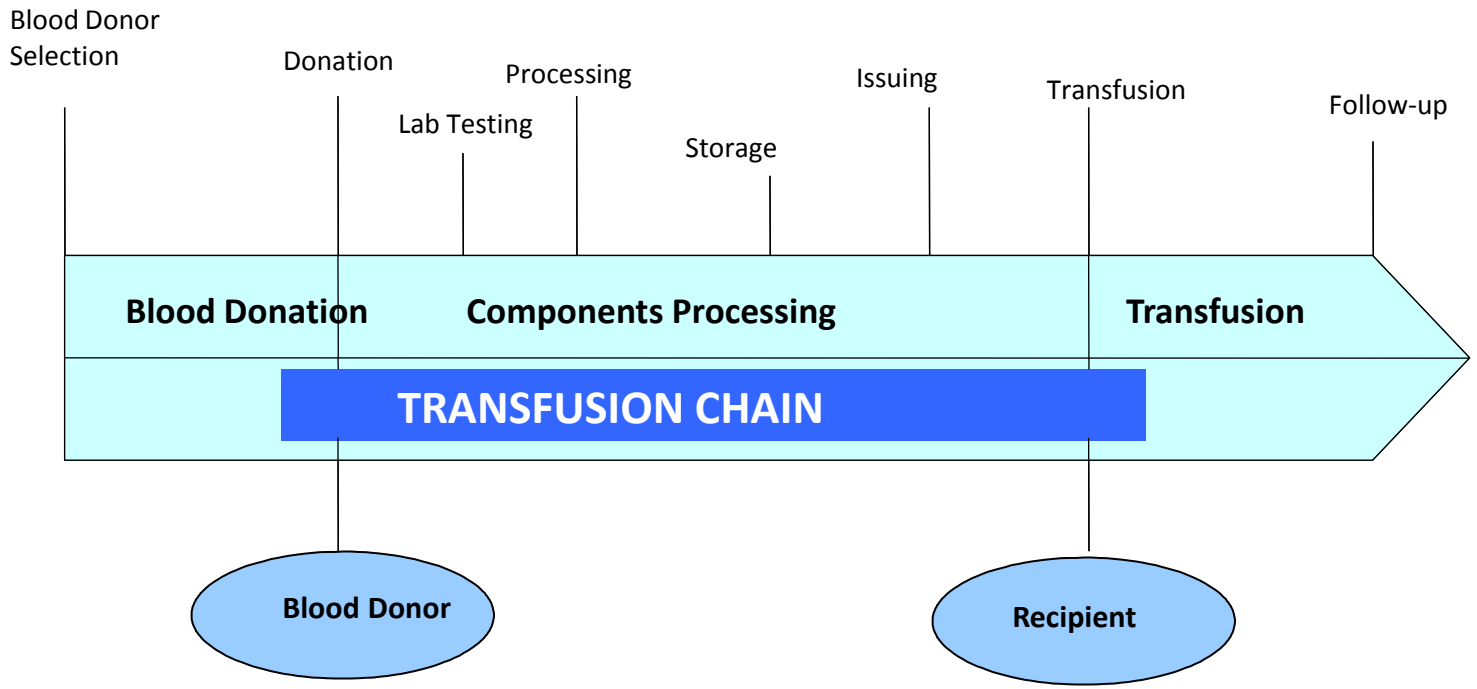
(OM SCO/322/2007)

Haemovigilance: Set of surveillance organized procedures relating to serious, unexpected adverse reactions and events that can appear at any point of the transfusion chain, from the blood donation to the clinical monitorization of blood recipients, aimed to prevent or resolve its appearance or recurrence.

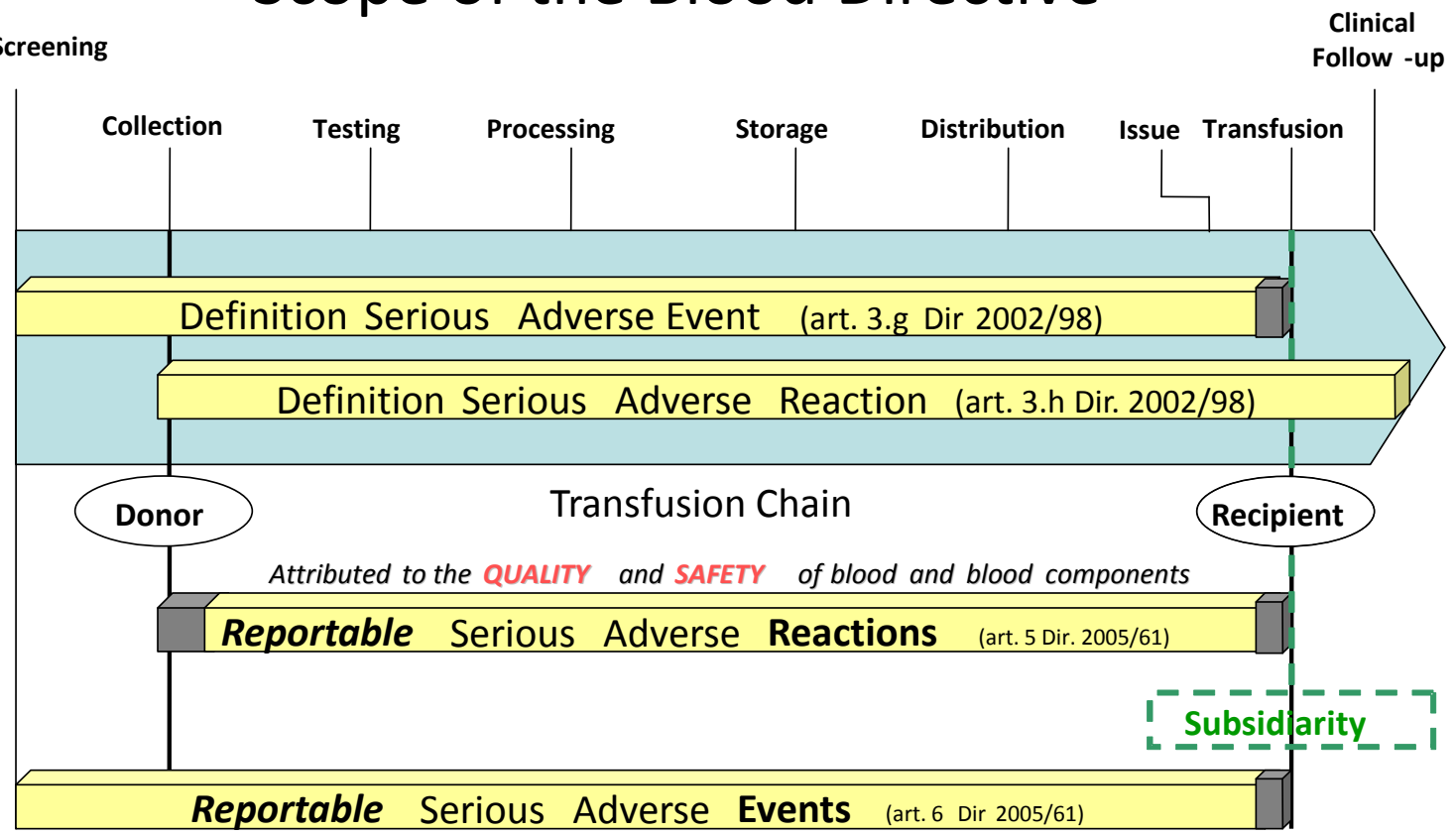
Serious adverse reactions: Unintended response in donor or in patient associated with the collection or transfusion of blood or blood components that is fatal, life-threatening, disabling, icapacitating, or which results in, or prolongs, hospitalisation or morbidity.

Serious adverse events: Any untoward occurrence associated with the collection, testing, processing, storage and distribution of blood and blood components that might lead to death or life-threatening, disabling or incapactating conditions for patients or which results in, or prolongs, hospitalisation or morbidity

SCOPE OF HAEMOVIGILANCE



Serious adverse reactions & events
Scope of the Blood Directive



Subsidiarty Agreement (Art. 152Treaty of Amsterdam):

The clinical use of Blood and Blood Components is a responsability of Member States., as those adverse events and reactions not related to the quality and safety of blood that occur in clinical facilities

- **BLOOD LAW**

(OM SCO/322/2007)

TRACEABILITY: Ability to trace each individual unit or blood component derived thereof from the donor to its final destination, whether this is a recipient, a manufacturer of medicinalproducts or disposal, and vice versa

Requirements for Blood Establishments and Hospital Transfusion Services*:*

- Confirmation procedures of the final destination of each component issued.
- Registry System of each blood component received and its final destination.
- Identification code: Link between blood donation and components produced.
- Traceability records kept for no less than 30 years.

- **BLOOD LAW**

(OM SCO/322/2007)

NOTIFICATION OF SERIOUS ADVERSE REACTIONS (RAs)

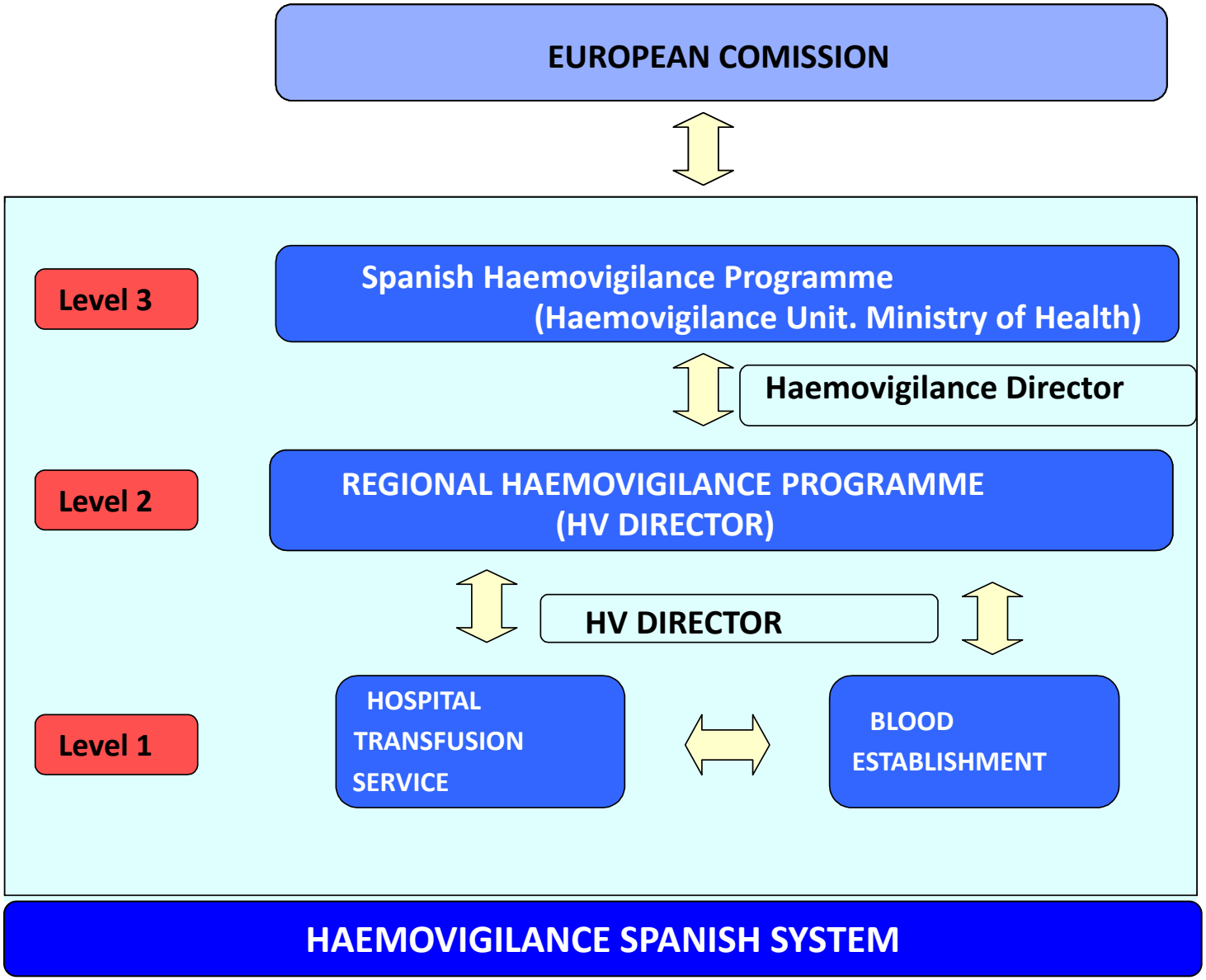
Hospital Transfusion Services: Inmediate notification to BE about any serious reaction in recipients related to quality and safety of blood or blood components.

Transfusion Committee: Analysis and assesment of any adverse reactions related to blood transfusion.

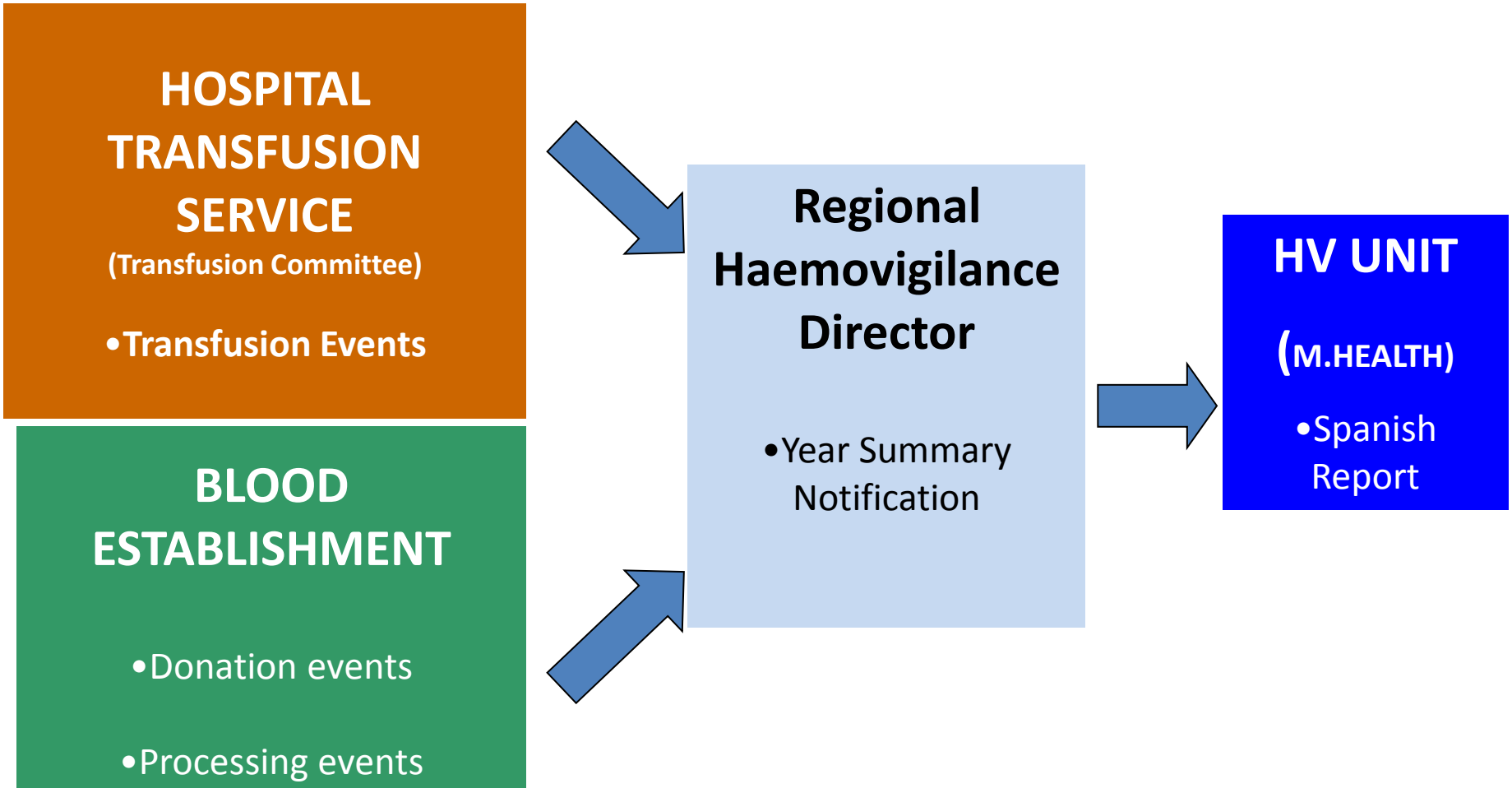
Reporting Establishments Requirements:

- Notify the Competent Authority those adverse reactions related to quality and safety of blood and blood components
- Any case of infectious disease transmission through blood or blood components
- Actions taken on other components involved and issued
- Assesment of serious ARs according to seriousness and imputability levels established
- Present year report of ARs

▪ HAEMOVGILANCE SPANISH SYSTEM



- **Notification process**



TRANSFUSION RELATED EVENTS

NOTIFICATION: Types of Incidents

TYPES
Transfusion Adverse Reactions (ARs): Unexpected response in a patient associated with the transfusion of blood or blood components.
Blood Component Administration Error (EAC): When a blood component not fulfilling the correct requirements, or directed to other recipient is transfused to a patient.
Events without an effect: Any error that if not detected would have been able to cause an incident at any point of the transfusion process

TRANSFUSION RELATED ADVERSE REACTIONS

NOTIFICATION: Events clasification

SERIOUSNESS	
0	No clinical signs / symptoms
1	No life-threatening signs. Complete resolution
2	Inmediate life-threatening signs
3	Long term morbidity
4	Death of patient
NC	Seriousness related symptoms not available

TRANSFUSION RELATED ADVERSE REACTIONS

NOTIFICATION: Events clasification

IMPUTABILITY: LIKELIHOOD THAT A SERIOUS ADVERSE REACTION IN A RECIPIENT CAN BE ATTRIBUTED TO THE BLOOD OR BLOOD COMPONENT TRANSFUSED.		
0	**Excluded**	When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to alternative causes
	Unlikely	When the evidence is clearly in favor of attributing the adverse reaction to causes other than the blood or blood components.
1	**Possible**	When the evidence is indeterminate for attributing adverse reaction either to the blood or blood component or to alternative causes
2	**Probable**	When the evidence is clear ly in favour of attributing the adverse reaction to the blood or blood component
3	**Certain**	When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to the blood or blood component.
NC	**Not available**	Data concerning imputability are not available
NE	**Not assessable**	When there is insufficient data for imputability assessment

- **Adverse reactions and events related to the quality and safety of blood (Directive 2005/61/CE)**

Notification of Adverse Reactions

- Serious adverse confirmed reactions during the previous year
- Imputability level 2 or 3.
- Adverse Reactions on Blood Donors: Only in the case they have an impact on the quality and safety of blood components.
- Definitions of the different types of adverse reactions established by ISBT are recommended.

- **Adverse reactions and events related to the quality and safety of blood (Directiva 2005/61/CE)**

Notification of Adverse Reactions

Type of serious adverse reaction:

— ABO Hemolytic reaction

— Non ABO Hemolytic Reaction

— Non immune hemolytic reaction

— Bacterial infection transmitted by transfusion
— Anaphilaxia / Severe allergic reaction

— TRALI

— Viral infection transmitted by transfusion

— Parasitic infection transmitted by transfusion

— Postransfusion Purpura

— GVHD

— Other serious reactions

- **Adverse reactions and events related to the quality and safety of blood (Directiva 2005/61/CE)**

Notification of adverse events

- Involvement of Blood Establishments

		Desglose (Especificaciones)			
Efecto adverso grave, que afecta a la calidad y la seguridad del componente sanguíneo, debido a un problema en:	NÚMERO TOTAL	Producto defectuoso	Fallo de los equipos	Error humano	Otro
Extracción de sangre total					
Extracción por aféresis					
Verificación de las donaciones					
Procesamiento					
Almacenamiento					
Distribución					
Materiales					
Otros					
TOTAL					

Efecto adverso grave: cualquier hecho desfavorable vinculado a la extracción, verificación, tratamiento, almacenamiento y distribución de sangre y componentes, **que pueda conducir a la muerte del paciente o a estados que puedan hacer peligrar su vida, a minusvalías o incapacidades, o dé lugar a hospitalización o enfermedad o, en su caso las prolongue**

- **Adverse reactions and events related to the quality and safety of blood (Directiva 2005/61/CE)**

Notification of adverse events

- **Defective Blood Component:** Blood or blood component that do not fulfill the demanded quality and safety requirements, or it is contaminated in spite of have been tested for infectious diseases, or these testing or processing have not been correctly carried out , or because a window period

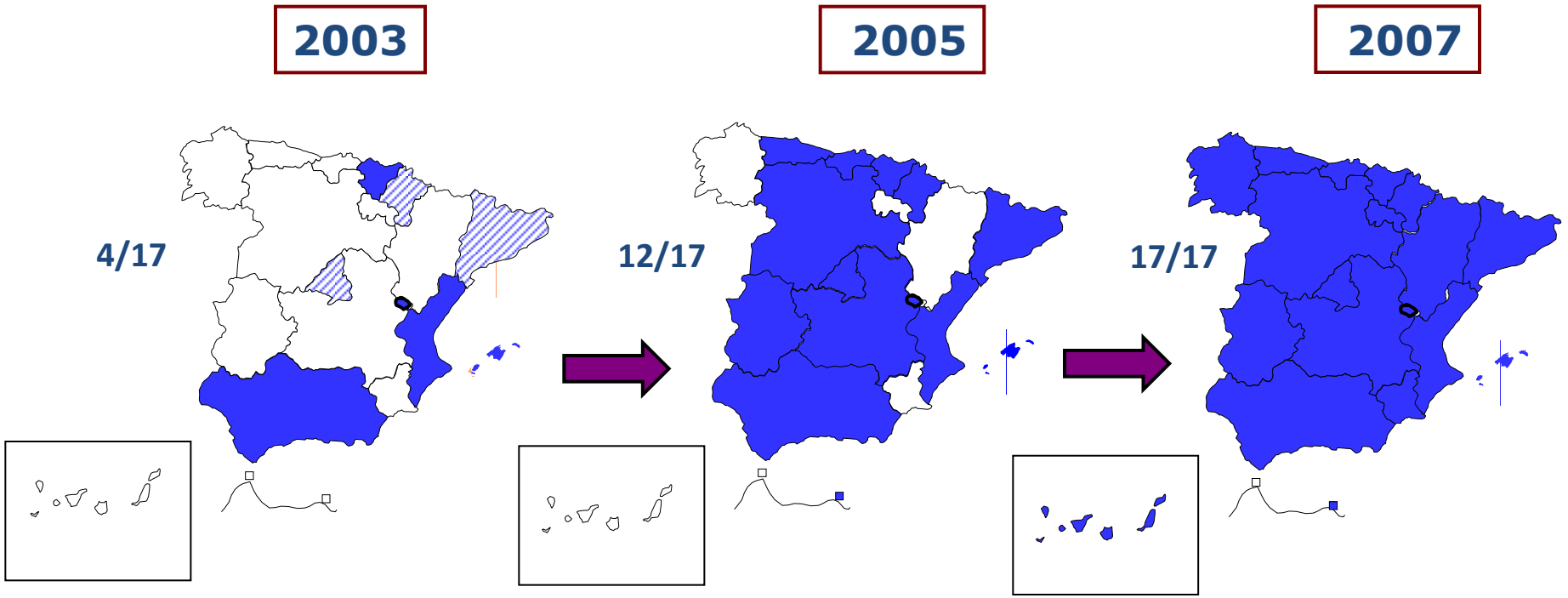
- **Equipment failure:** Any material or equipment employed (blood bags, lab products, blood fiters, IT systems……)

- **Human error:** Inapropriate or undesirable decision or behaviour that might reduce the quality, safety or efficacy of the process (Blood Donor selection…….)

- **Other:** Any serious adverse event difficult to classify

HAEMOVIGILANCE SPANISH NETWORK

(REGIONAL EVOLUTION)



Blood Events and Reactions Report Forms

Form 1. Transfusion Reaction initial report

Form 2. Blood Transfusion related event

Form 3. Blood donation event.

Form 4. Blood Components processing event

Form 5. Blood Component Transfusion error.

Form 6. Acute and delayed hemolytic transfusion reaction

Form 7. Allergic / Anaphylactic Reaction

Form 8. Bacterial Contamination

Form 9. TRALI / TACO

Form 10. Postransfusion Purpura

Form 11. GVHD

Form 12. Blood related viral infection

Form 13. Severe hypotensive and fever reaction

Form 14. Iron Overload

Form 15: Blood related Parasitic infection

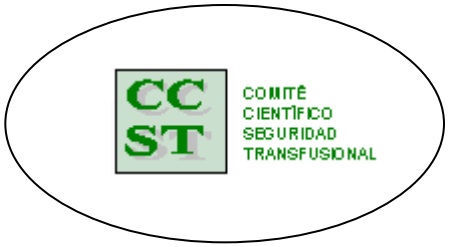
Form 16. Events without effect

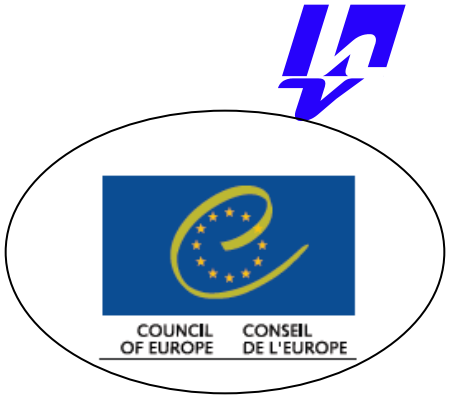
Guía de procedimiento PEHV. Junio 2004

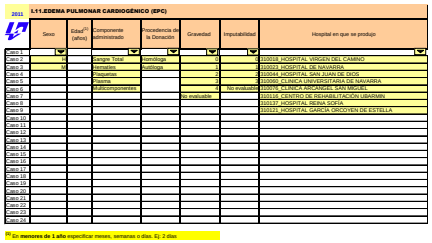
YEAR REPORT SUMMARY

2011	I.11.EDEMA PULMONAR CARDIOGÉNICO (EPC)						
	Sexo	Edad[(1)] (años)	Componente administrado	Procedencia de la Donación	Gravedad	Imputabilidad	Hospital en que se produjo
Caso 1							
Caso 2	H		Sangre Total	Homóloga	0	0	310018_HOSPITAL VIRGEN DEL CAMINO
Caso 3	M		Hematíes	Autóloga	1	1	310023_HOSPITAL DE NAVARRA
Caso 4			Plaquetas		2	2	310044_HOSPITAL SAN JUAN DE DIOS
Caso 5			Plasma		3	3	310060_CLINICA UNIVERSITARIA DE NAVARRA
Caso 6			Multicomponentes		4	No evaluable	310076_CLÍNICA ARCANGEL SAN MIGUEL
Caso 7					No evaluable		310116_CENTRO DE REHABILITACIÓN UBARMIN
Caso 8							310137_HOSPITAL REINA SOFÍA
Caso 9							310121_HOSPITAL GARCÍA ORCOYEN DE ESTELLA
Caso 10							
Caso 11							
Caso 12							
Caso 13							
Caso 14							
Caso 15							
Caso 16							
Caso 17							
Caso 18							
Caso 19							
Caso 20							
Caso 21							
Caso 22							
Caso 23							
Caso 24							

[(1)] En **menores de 1 año** especificar meses, semanas o días. Ej: 2 días






I.11.EDEMA PULMONAR CARDIOGENICO (EPC)

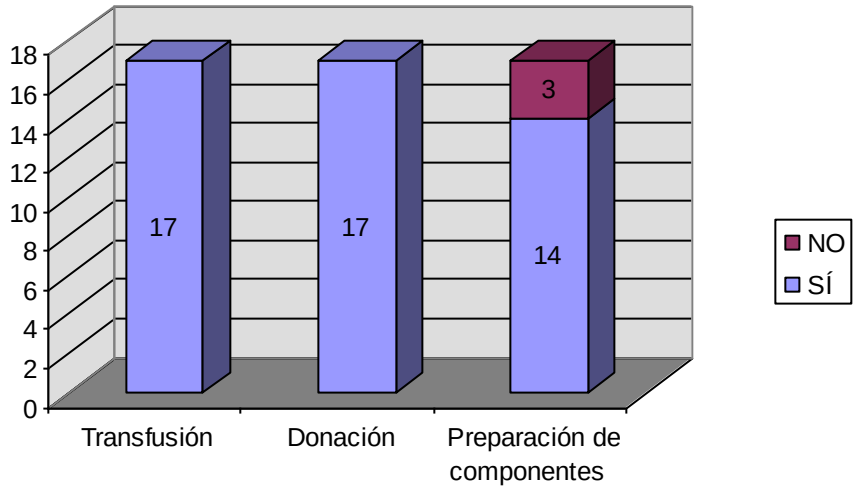
	Sexo	Edad[1] (años)	Componente administrado	Procedencia de la Donación	Gravedad	Imputabilidad	Hospital en que se produjo
Caso 1							
Caso 2	H		Sangre Total	Alogénica	0		3100018_HOSPITAL VIRGEN DEL CAMINO
Caso 3	M		Hematíes	Autóloga	1		3100019_HOSPITAL DE NAVARRA
Caso 4			Plaquetas		2		3100044_HOSPITAL SAN JUAN DE DIOS
Caso 5			Plasma		3		3100060_CLINICA UNIVERSITARIA DE NAVARRA
Caso 6			Multicomponentes		4	No evaluable	3100076_CLINICA ARCANGEL SAN MIGUEL
Caso 7					No evaluable		3100100_CENTRO DE REHABILITACION LIBARMIN
Caso 8							3100137_HOSPITAL REINA SOFIA
Caso 9							3100151_HOSPITAL GARCIA ORCOYEN DE ESTELLA
Caso 10							
Caso 11							
Caso 12							
Caso 13							
Caso 14							
Caso 15							
Caso 16							
Caso 17							
Caso 18							
Caso 19							
Caso 20							
Caso 21							
Caso 22							
Caso 23							
Caso 24							

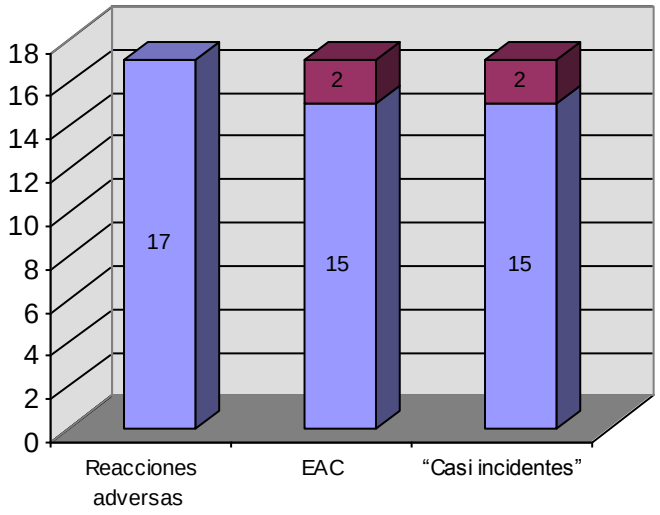
[1] En **menores de 1 año** especificar meses, semanas o días. Ej: 2 días

HAEMOVIGILANCE YEAR REPORTS

Haemovigilance Network : Regional Level

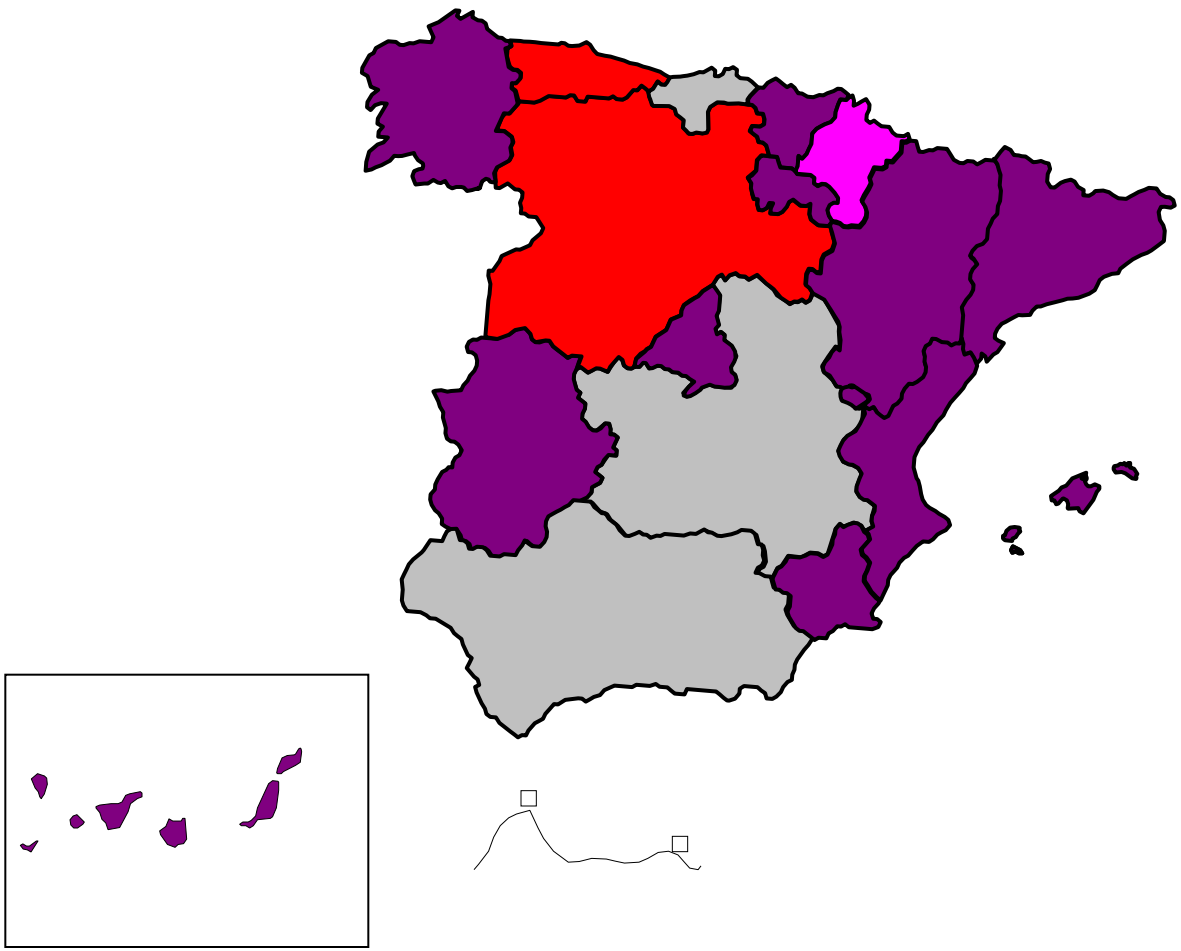
Regional Incidents registered





Haemovigilance Network: Regional Level

Head of Haemovigilance Management Programme



Healt Authorities (1)

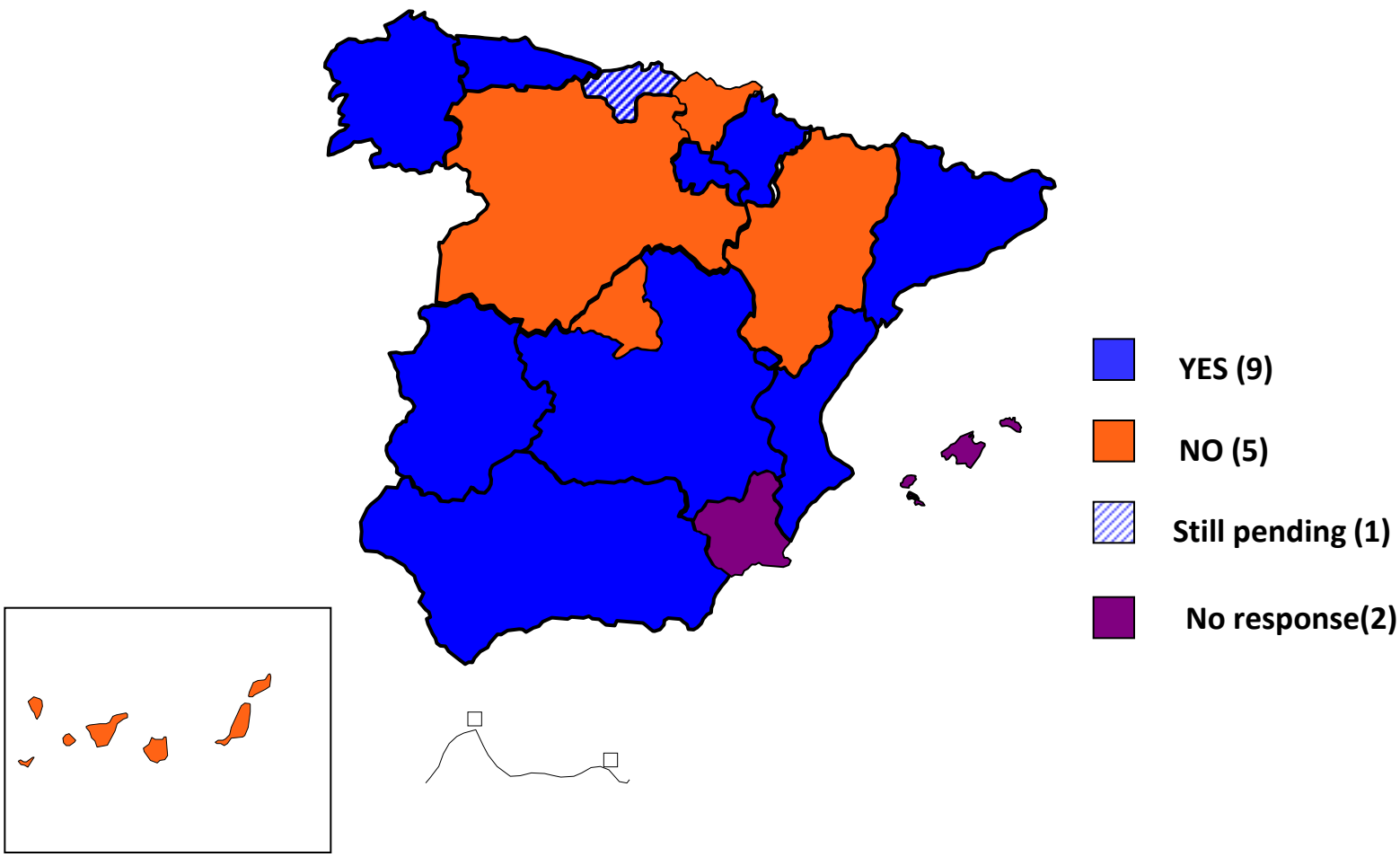
Blood Establishment (11)

Hospital Transfusion Service (2)

Mixed (3)

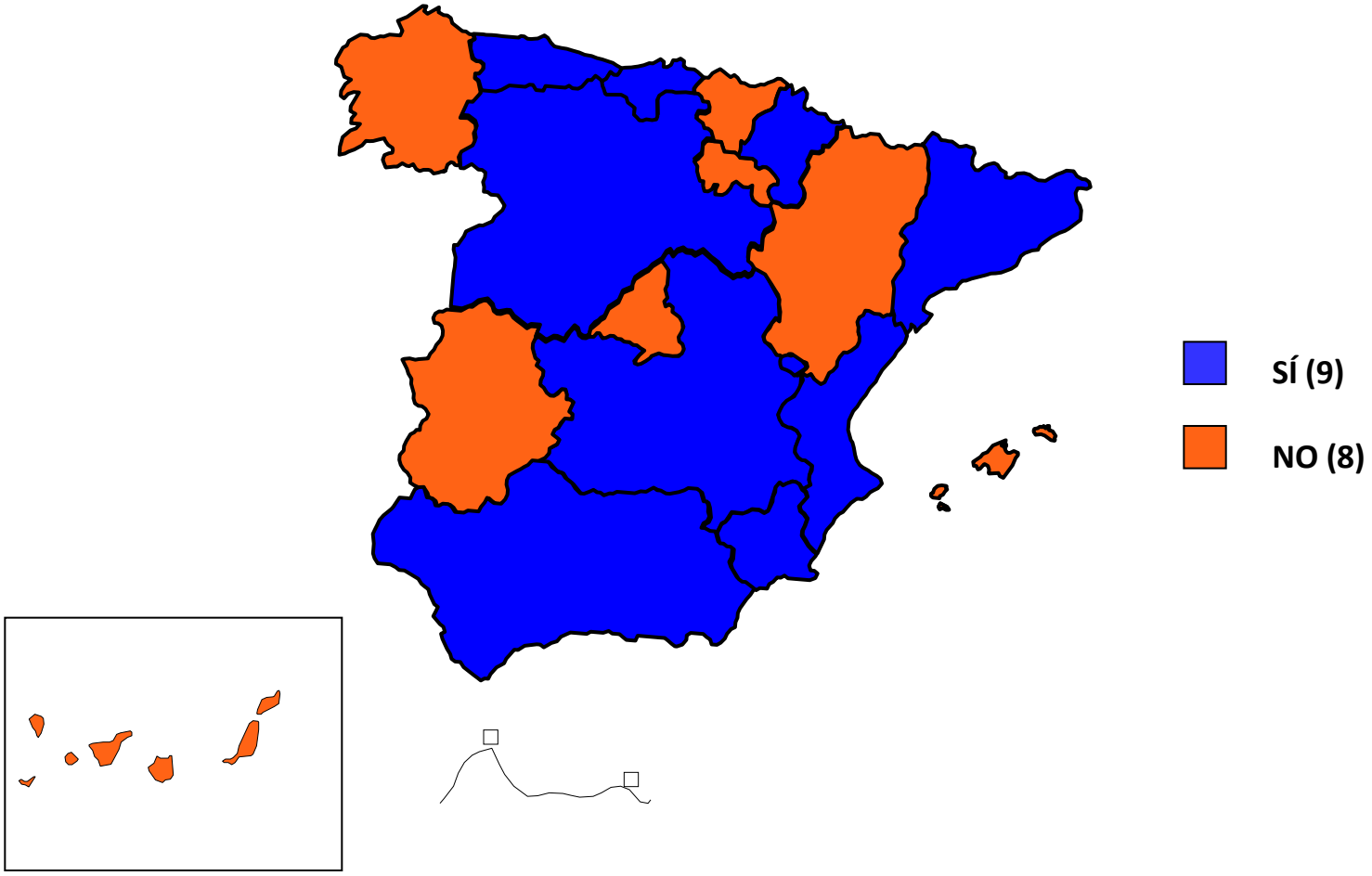
Haemovigilance Network : Regional Level

Regional Law



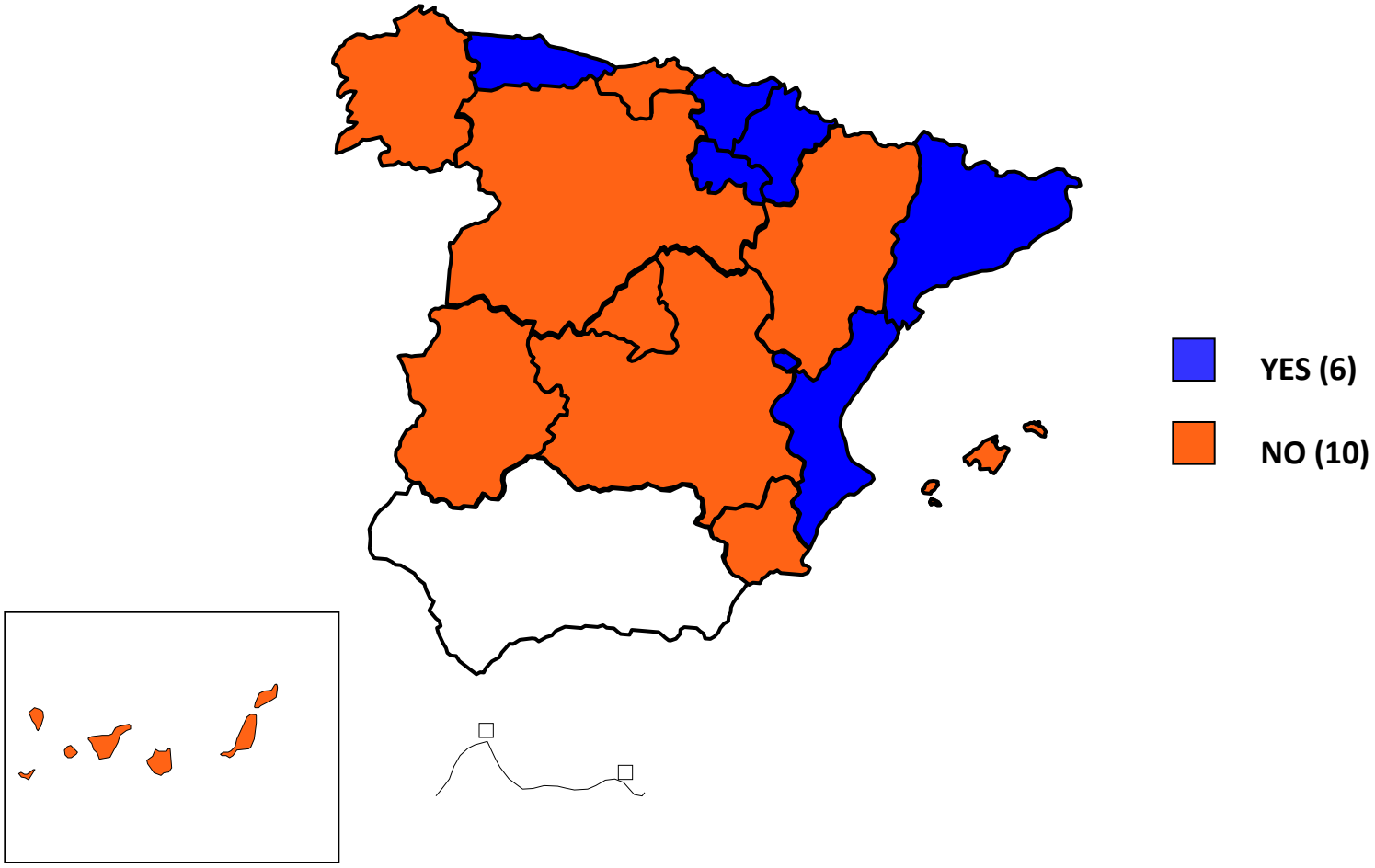
Haemovigilance Network : Regional Level

Haemovigilance Committee



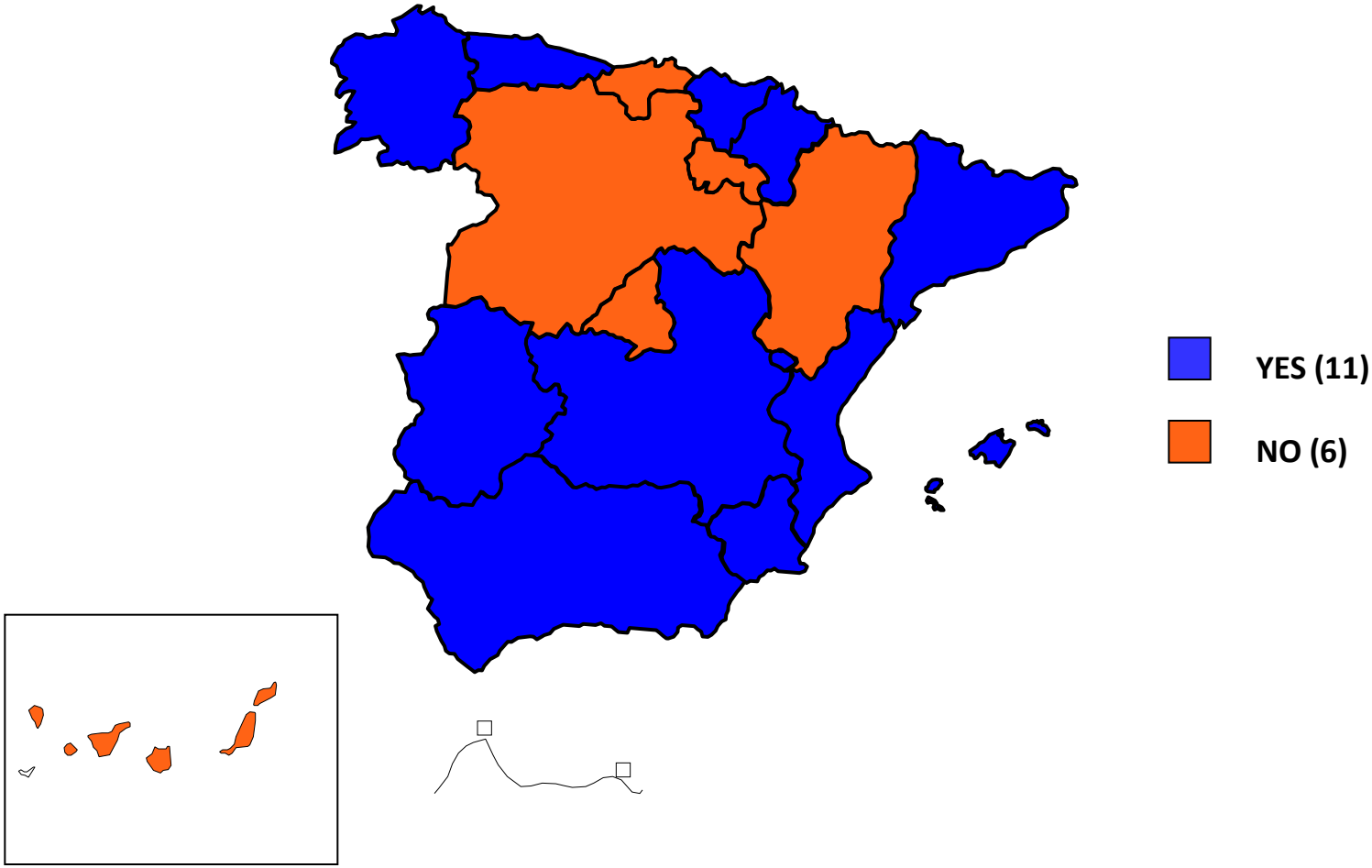
Haemovigilance Network : Regional Level

Inspections (By Competent Authority) on Haemovigilance procedures



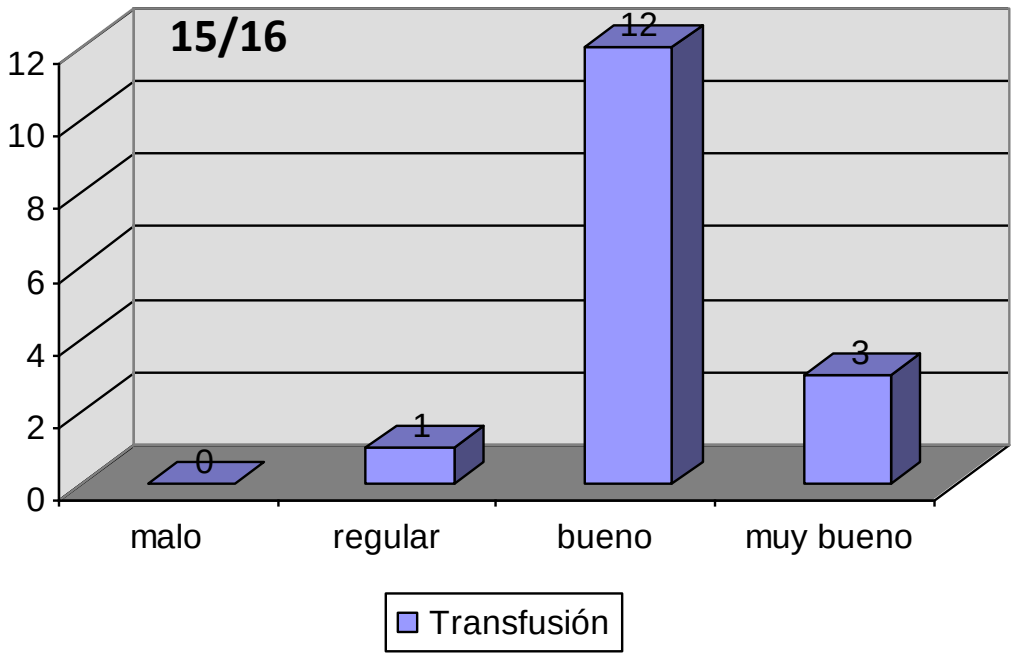
Haemovigilance Network : Regional Level

Regional Haemovigilance Training / Information activities



Procedure / Format Assesment
Transfusion related events

2008	I.4. REACCIÓN HEMOLÍTICA*							
	Componente administrado	Procedencia de la Donación	Inmune (Estudio)		No Inmune (citar causa)	Gravedad	Imputabilidad	Hospital en que se produjo
			Tipo	Ac Implicado				
Caso 1								
Caso 2								

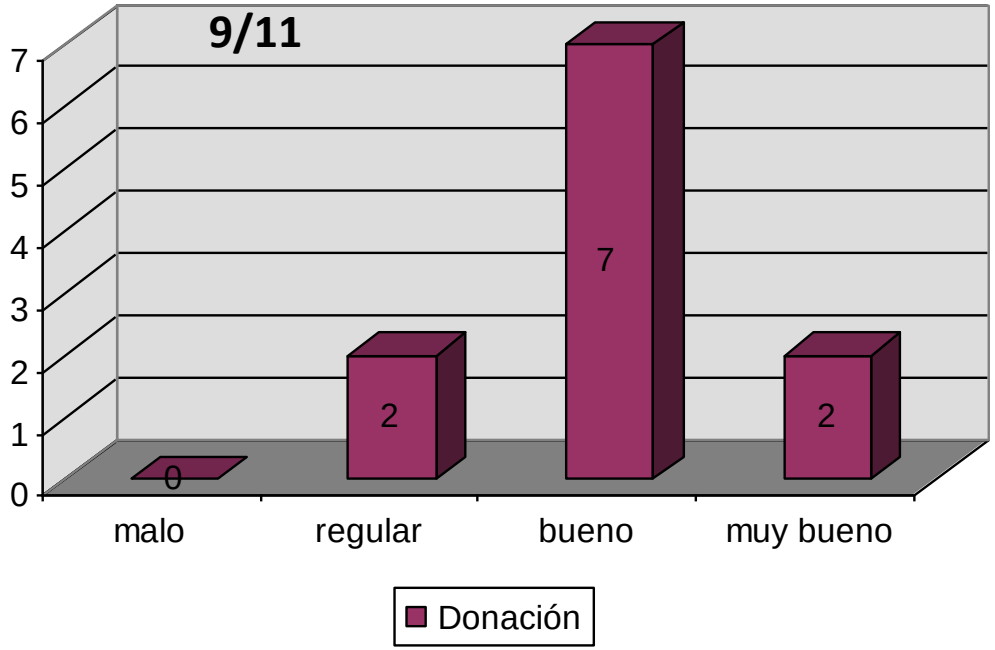


Suggestions for improvement

- Common Information system
- More fields for events definition

Procedure / Format Assesment
Blood Donation related events

2008	INCIDENTES RELACIONADOS CON LA DONACIÓN DE SANGRE										
	COMPLICACIONES										
	A. Caracterizadas principalmente por síntomas locales				B. Caracterizadas principalmente por síntomas generales		Otras	Características del donante	Características de la donación	Gravedad	Imputabilidad
	Extravasación	Dolor	Otros síntomas	Otras complicaciones (texto libre)	Reacción vasovagal	Otras complicaciones (texto libre)					
Caso 1											
Caso 2											

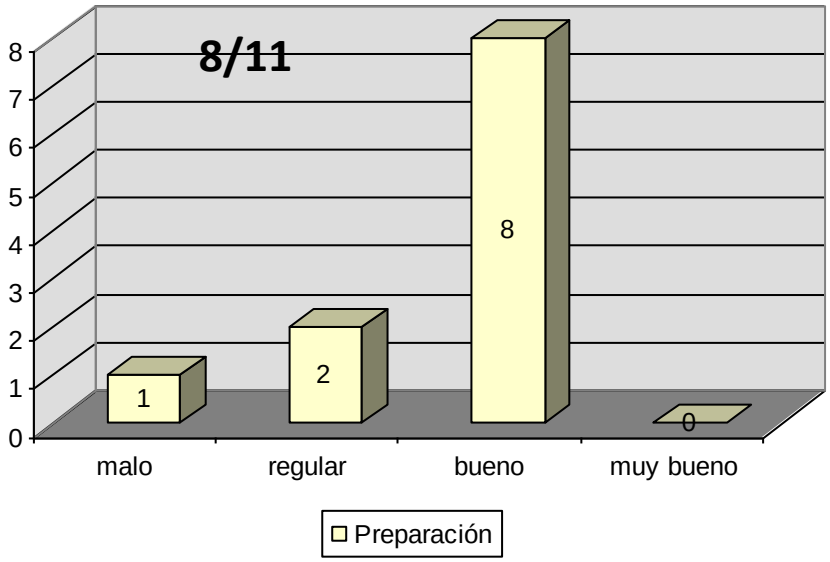


Suggestions for improvement

- Registration of global data
- Improvement of filling instructions
- Some items are not easily understood
- Correspondance to the questionnaire in place
- More room for events definition and explanation

Procedure / Format Assesment
Blood Components Processing related events

2008	INCIDENTES ADVERSOS GRAVES RELACIONADOS CON LA PREPARACIÓN DE COMPONENTES			
	Efecto adverso grave, que puede afectar a la calidad y la seguridad del componente sanguíneo, debido a un problema en:	Desglose	Descripción del incidente	Comentarios
Incidente 1				
Incidente 2				



Suggestions for improvement

- Registration of global data
- Better definition of events to be registered and declared
- Declare only those reactions and events related to the quality and safety of blood components

Conclusions

- After a few pilot projects regionally or nationally tested since 2000, the current Haemovigilance System was eventually implemented in 2007, once the European Directive was transposed into the Spanish Legislation.

- The system is based on a broad network of Reporting Establishments notifying events and reactions occurring in Blood Etablishments and Hospital Transfusion Services, and a Central Office located at the Ministry of Health in charge of annual reports and the dissemination of all the relevant information and quick alerts to the different Spanish and European Organizations.

Conclusions

- **The Regional Haemovigilance Coordinator has become one of the key elements to guarantee the success of the whole system**

- **The consistency of the system has been repeateadly confirmed in spite of the different regional procedures, and quite a few points of improvement have been suggested.**

- **In 2014 the notification general procedures will be changed. A new simple direct electronic notification from the reporting establishments to the central office is expected to be available in the next few months to improve the availability and rapidity of updated information to all the involved organizations.**