# Portuguese Blood System Organization

Instituto Português do Sangue
e da Transplantação, IP

Gracinda de Sousa

IPFA/PEI 23rd International Workshop on Surveillance and Screening of Blood Borne Pathogens

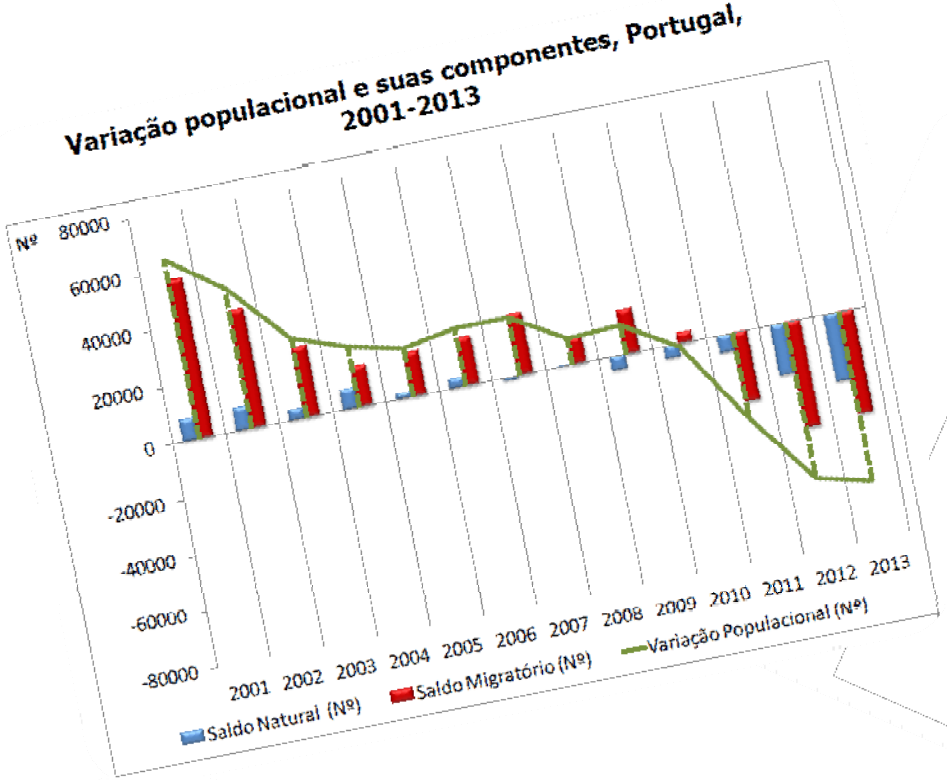
25-26th May 2016, Lisbon, Portugal

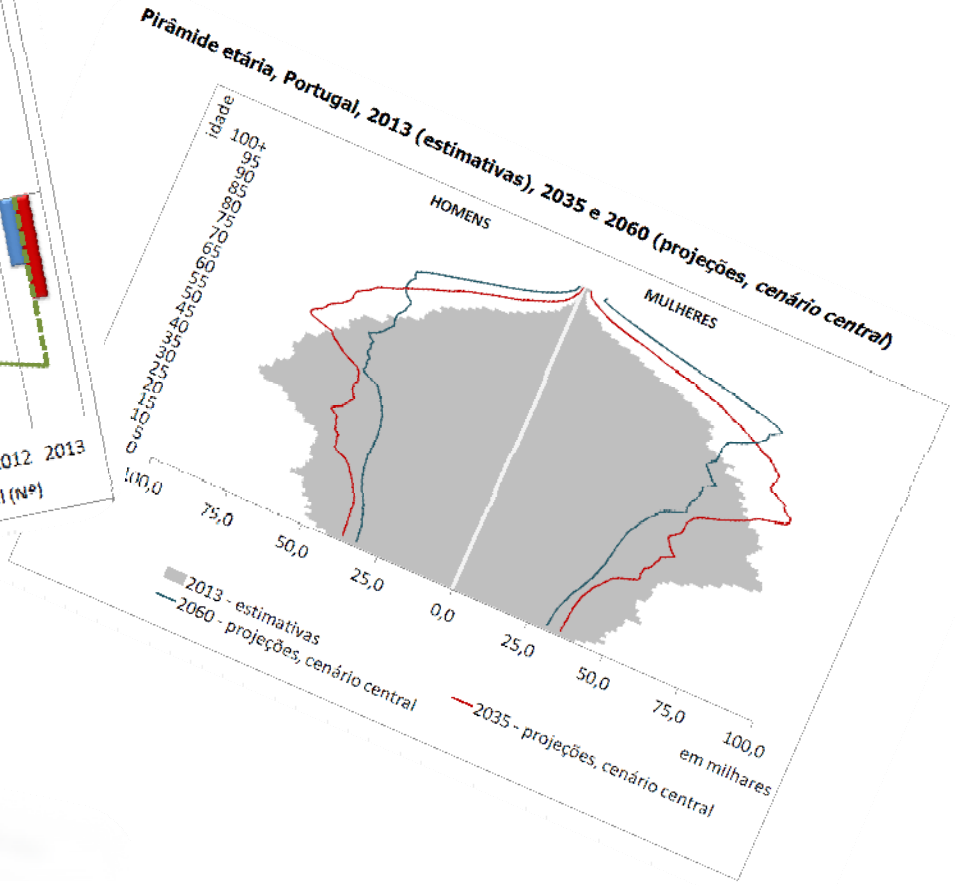
www.ipsangue.org

# Portuguese Blood System Organization
## summary/ topics

- Legal aspects
- Characterization of the System
- Portuguese Institute of Blood and Transplantation
- Donors Epi data
- Safety of blood

Portugal
92 000 Km²
10, 400 Million inhabitants

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destaque
informação à comunicação social

INSTITUTO NACIONAL DE ESTATÍSTICA
STATISTICS PORTUGAL

10 de julho de 2014

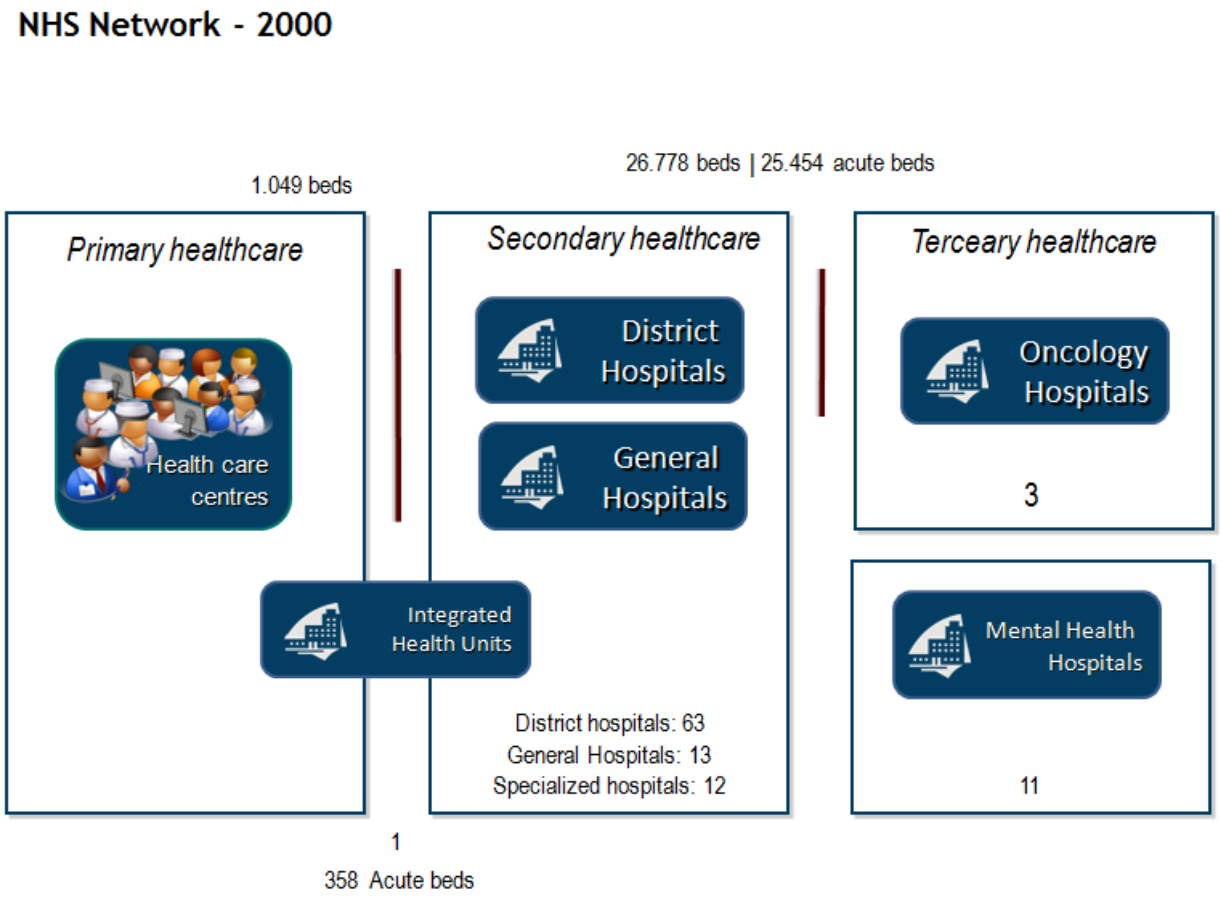
Dia Mundial da População
11 julho de 2014

IP ST
Instituto Português do Sangue e da Transplantação IP

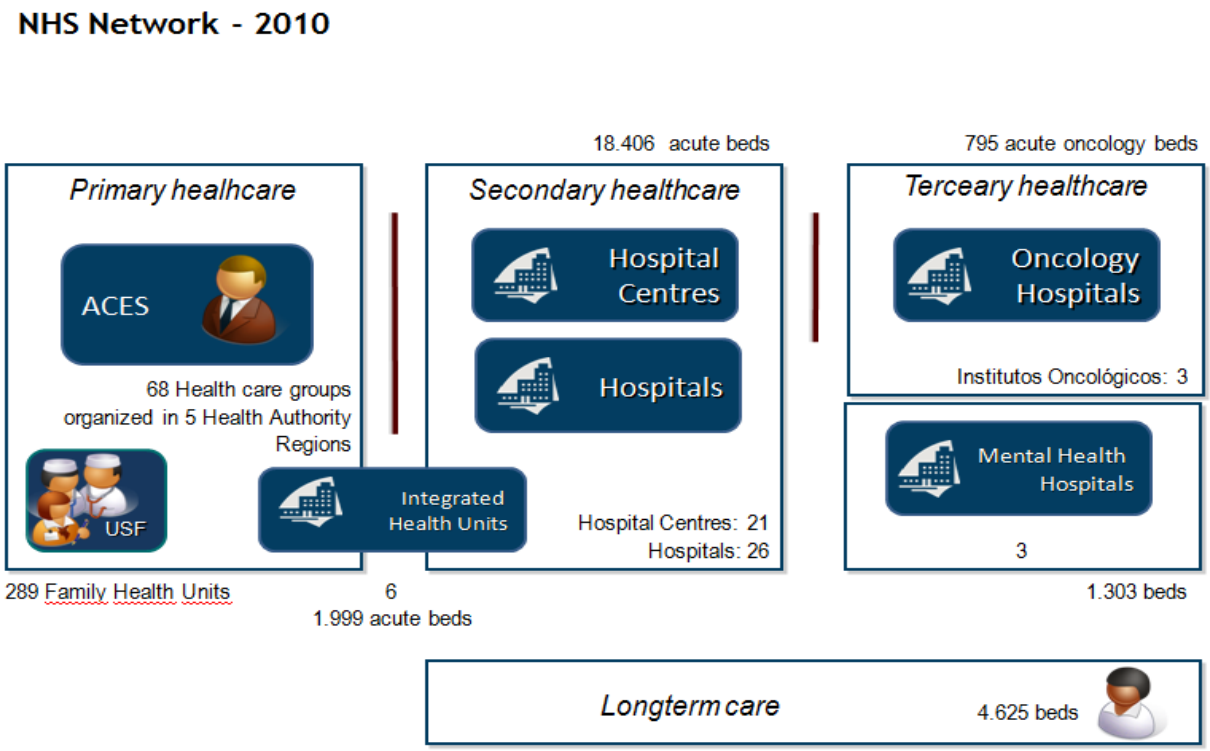
# PREMAC (Plano de Redução e Melhoria da Administração Central) Central Administration Reduction Plan and Improvement

- July 2011
- Aimed at ataining permanent reduction of expenditure and implementation of more efficient models for the functioning of the central administration
- New Organic Laws
- Mergers
- Reduction of services
- Reduction of management personnel

# National Health Service Network before
## (ACSS/Central Administration of the Health System)



# National Health Service Network (ACSS/Central Administration of the Health System)



# Legislation – Blood organization

Dec-Law **1958** – National Blood Institute (INS)

**1981** – Medical specialization in Transfusion Medicine (6yrs C) (Imunohemoterapia)

Law 25/1989; Dec-Law 294/**1990** – Portuguese Blood Institute (IPS)

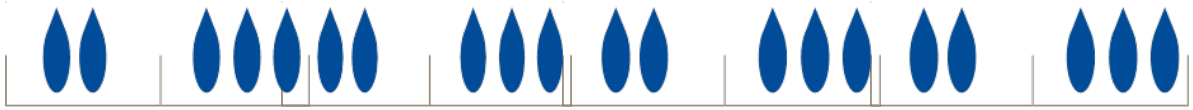
- Dec-Law 267/ **2007** – Transposition of the Diretives of the European Parliament and of the Council "setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components" (2002/98/EC; 2004/33/EC; 2005/61/EC and 2005/62/EC)

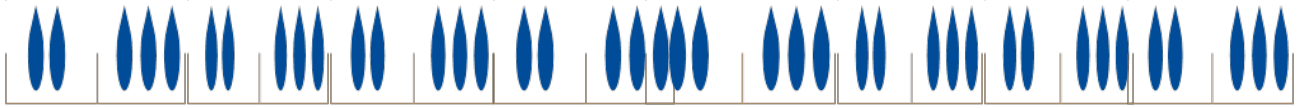
Dec-Law 39/**2012** – Portuguese Institute of Blood and Transplantation (IPST IP) Organic Law

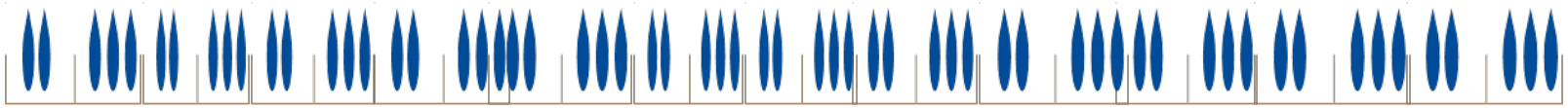
**Merger:**

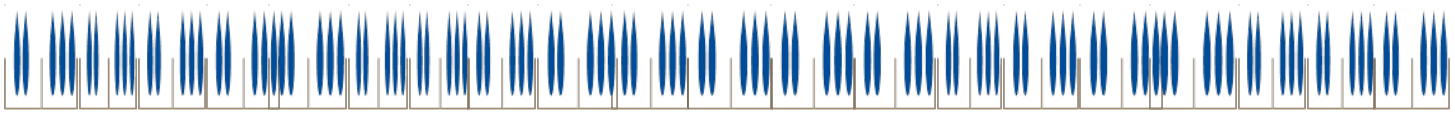
- IPS (3 Regional Blood Centres) with
- 3 Histocompatibility Centres
- ASST former Competent Authority (part of regulatory functions in transplantation)

The donor award program includes a National Blood Card after the first donation, certificates and medals (copper, silver and gold) after 10, 20, 40, 60 and 100 donations.

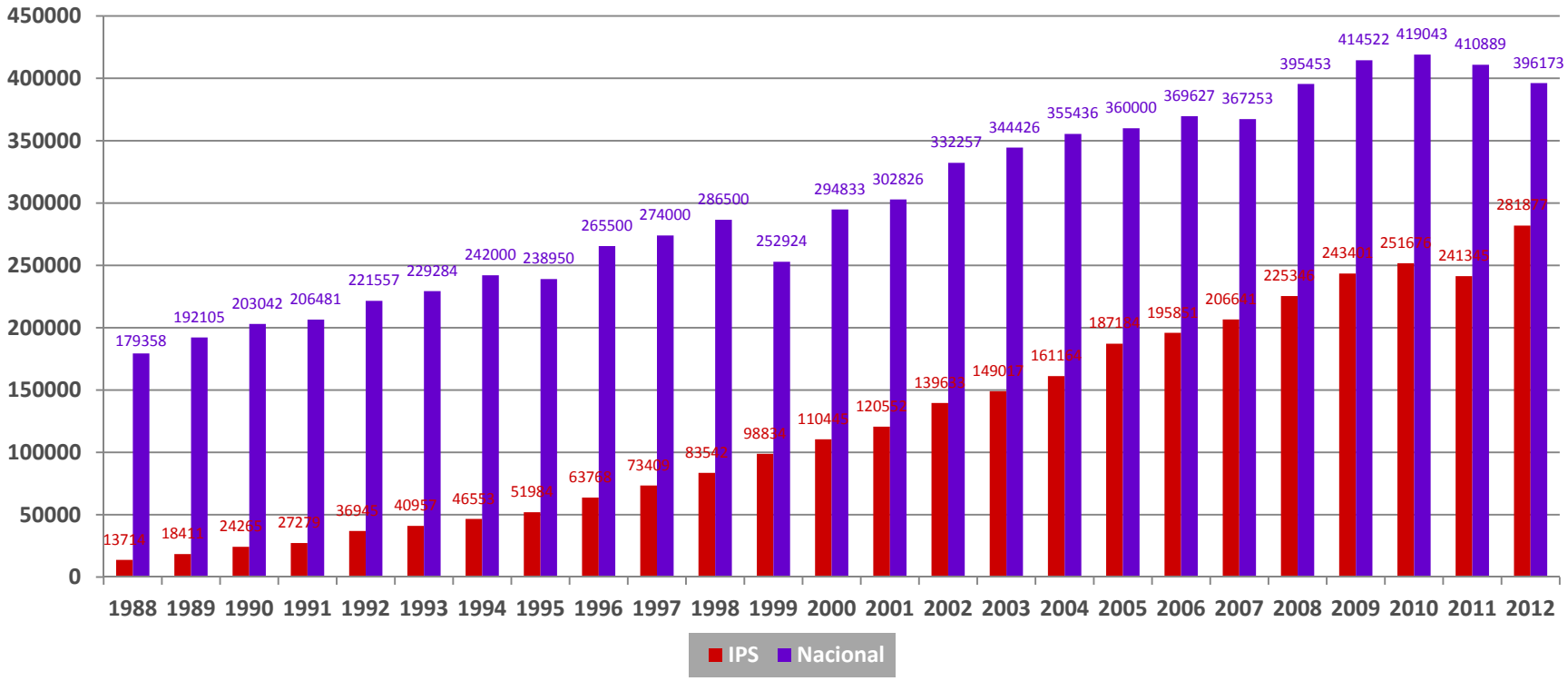




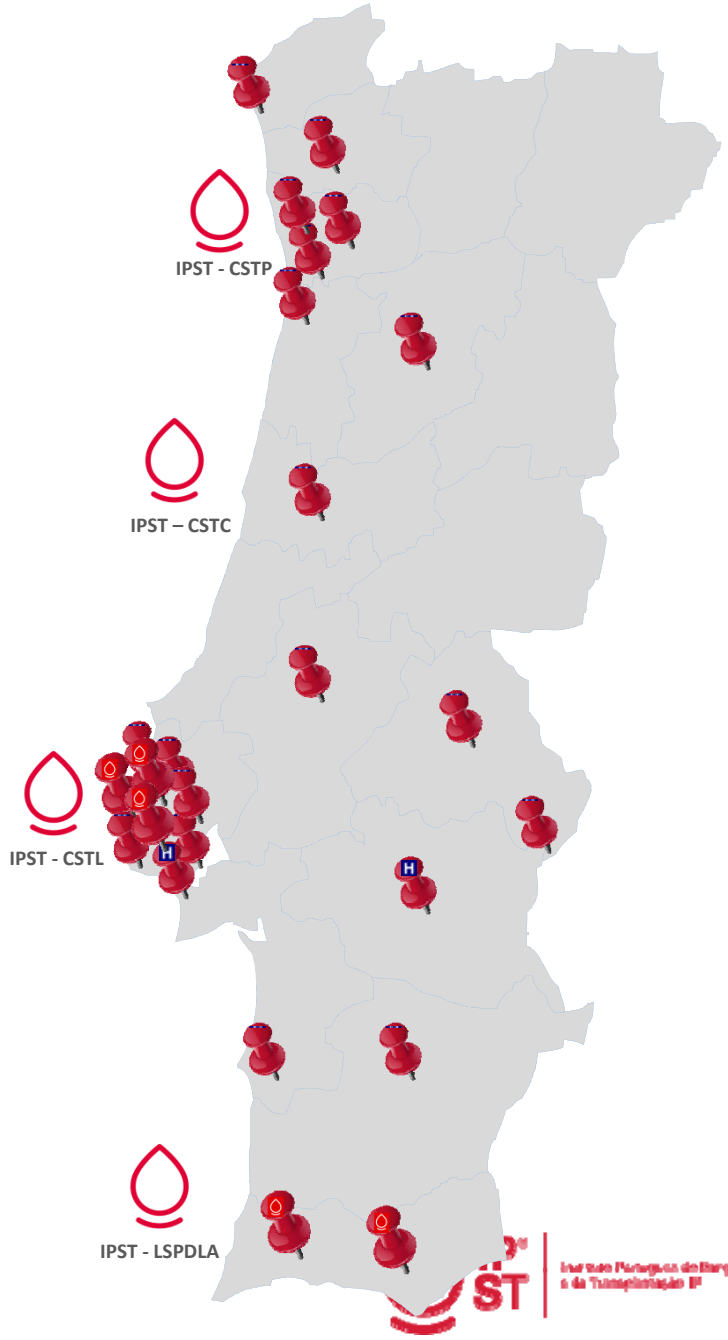




# Blood Collection



# Portuguese Blood System
## (Blood Establishments)



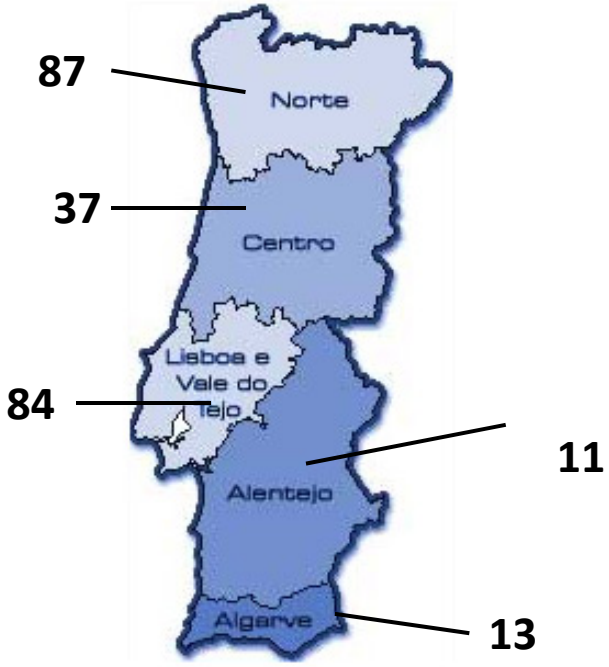

Hospital BE

Hospital BE with blood collection only (Partnership with PBTI / IPST)

# Blood Establishments and Transfusion Medicine Services

RAM 3

RAA 3




| Type of activity (2014) | | | | | | |
|---|---|---|---|---|---|---|
| | Collect | Processing | Testing | Distribution | Disponibiliz | Transfus. |
| YES | 32 | 24 | 26 | 73 | 95 | 231 |
| NO | 206 | 214 | 212 | 165 | 143 | 7 |

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## Blood Establishment
(Serviço de Sangue)

Health structures responsible for the collection and testing of human blood and/or blood components and their processing, storage and distribution intended for transfusion

## Transfusion Medicine Service (Serviço de Medicina Transfusional)

Hospital units that store, distribute and provide blood and blood components, perform compatibility tests for hospital use, among other hospital based transfusion activities

# Portuguese Institute of Blood and Transplantation - IPST IP

- 60% country Blood Collection (+processing, testing, distribution)
- PR/ Intercept treated Platelets (since 2010)
- Portuguese PR/ Intercept  treated Plasma (since 2014)
- Portuguese SD Plasma (since 2014)

- Portuguese Hemovigilance System

- Unrelated Bone Marrow Donors Registry (CEDACE)
- Public Cord Blood Bank
- Multiorganic Tissue Bank (import+export authorization)
- National Coordination of Organ Transplantation
- Transplantation donor/ receptor pairs (Histocompatibility)

# Portuguese Plasma Fracionation (SPMS)

## Shared Services of the Health Ministry

- Public supply contract of human plasma derived medicinal products resulting from fraccionation of portuguese human plasma
- Competitive dialogue:  procedure in which any economic operator may request to participate and whereby the contracting authority conducts a dialogue with the candidates admitted to that procedure, with the aim of developing one or more suitable alternatives capable of meeting requirements on the basis of which, the candidates chosen are invited to tender
- August 2015 – Beginning of the procedure
- January /February 2016 – criteria for qualitative selection
- April  2016 – official list of approved economic operators
- November/December 2016 – Conclusion of procedure:  public supply contract with the best tenderer

# Blood Donation Screening tests

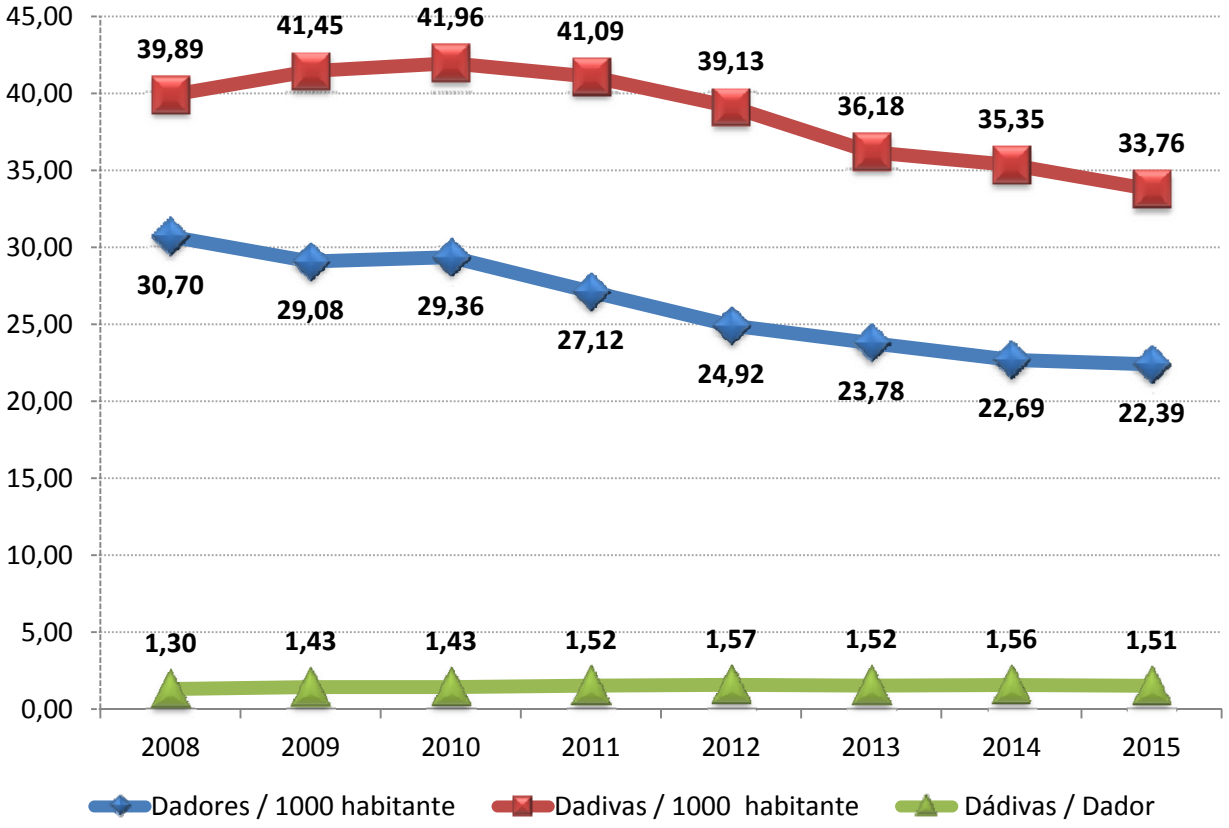
- HBs Ag
- Anti-HBc Ab
- Anti-HBs if Anti-HBc Ab Positive
- Anti-HCV Ab
- Trep Pallidum Ab
- $HIV_{1/2}$ Ab
- NAT HIV/HCV/HBV

- Anti-HTLV I/II*
- Plasmodium Ab*
- Trypanosoma cruzi Ab*
- WNV NAT*
- DENV NAT* *(Madeira Island)*

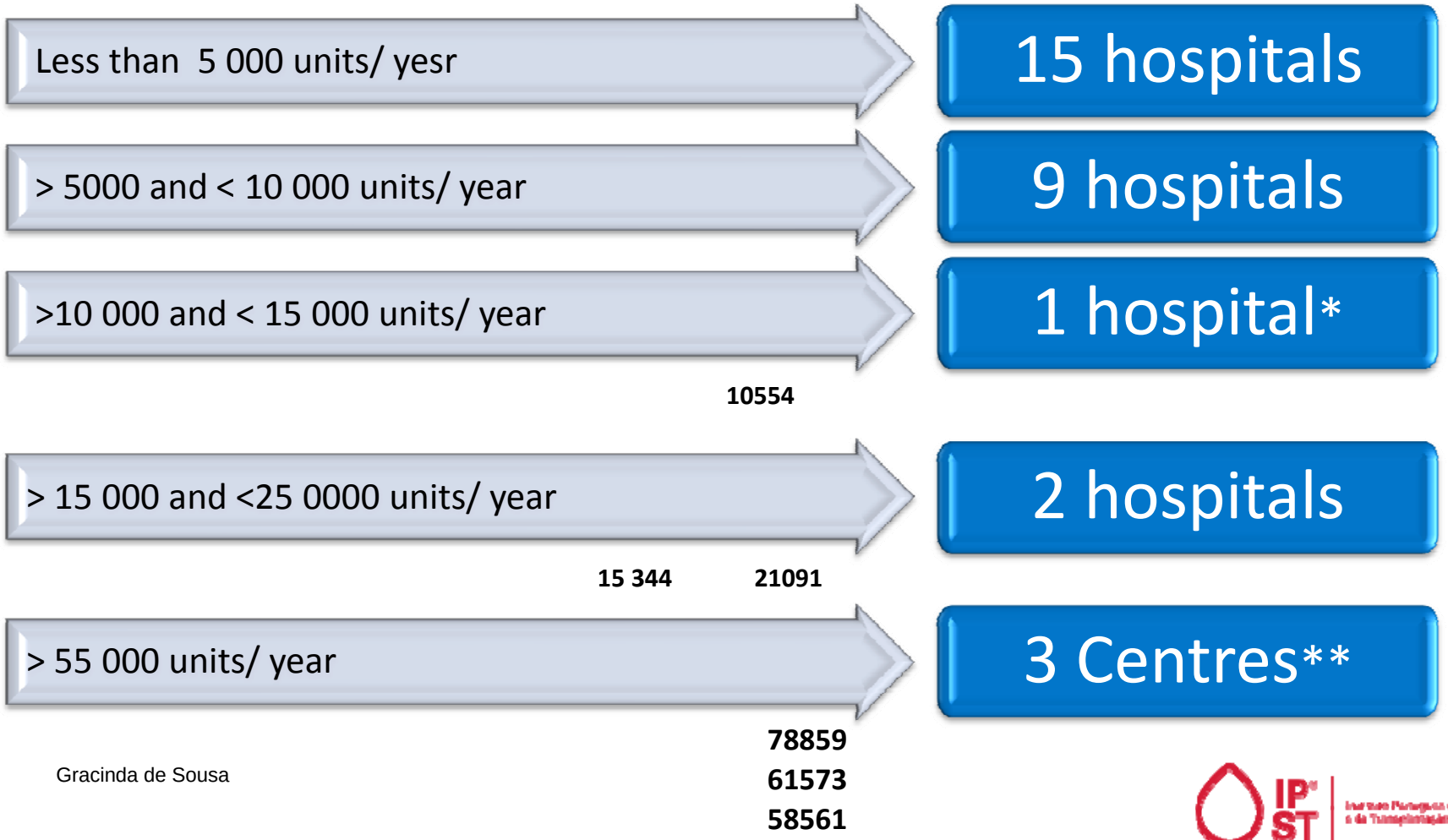
…

# Blood System Characterization

## Donors, Donations, Donation Indexes: 2008 - 2015



# BE/ Services with Blood Collection (2014)



# Hepatitis B Virus I

| | 2012 | 2013 | 2014 | 2015 |
|---|---|---|---|---|
| Total **HBV+ donors** | 55 | 55 | 40 | 37 |
| Total **1st time donors HBV+** | 48 | 49 | 34 | 32 |
| Total **regular donors HBV+** | 7 | 6 | 6 | 5 |
| Total nr donors with donations | 249 168 | 237 826 | 226 882 | 223 924 |
| Total 1st time donors | 44 877 | 38 558 | 36 172 | 37 593 |
| Total regular donors | 204 291 | 199 268 | 190 710 | 186 331 |

| | 2012 | 2013 | 2014 | 2015 |
|---|---|---|---|---|
| **Prevalence per 100 000** | 22,07 | 23,13 | 18,07 | 16,52 |
| **Incidence per 100 000** | 3,43 | 3,01 | 3,15 | 2,68 |
| **Residual Risk 100 000** | 0,20 | 0,17 | 0,18 | 0,15 |

# Hepatitis B Virus II

| | 2012 | 2013 | 2014 | 2015* |
|---|---|---|---|---|
| Anti HBc positive with Anti HBs negative Total | 380 | 387 | 530 | 664 |
| Anti HBc positive with AntiHBs negative 1st time | 91 | 123 | 132 | 185 |
| Anti HBc positive with Anti HBs negative regular | 289 | 264 | 398 | 479 |
| Anti HBc positive with Anti HBs positive Total | 6765 | 6692 | 6965 | 3223 |
| Anti HBc positive with Anti HBs positive 1st time | 707 | 586 | 595 | 442 |
| Anti HBc positive with Anti HBs positive regular | 6058 | 6106 | 6370 | 2781 |
| Anti HBc positive (with or without Anti HBs) with HBs Ag negative and NAT positive Total | **4** | **8** | **10** | **2** |
| Anti HBc positive (with or without Anti HBs) with HBs Ag negative and NAT positive 1st time | 0 | 3 | 2 | 1 |
| Anti HBc positive (with or without Anti HBs) with HBs Ag negative and NAT positive regular | 4 | 5 | 8 | 1 |

# Hepatitis C Virus

| | 2012 | 2013 | 2014 | 2015 |
|---|---|---|---|---|
| Total **HCV+ donors** | 32 | 37 | 22 | 21 |
| Total **1st time donors HCV+** | 29 | 27 | 21 | 19 |
| Total **regular donors HCV+** | 3 | 10 | 1 | 2 |
| Total nr donors with donations | 249 168 | 237 826 | 226 882 | 223 924 |
| Total 1st time donors | 44 877 | 38 558 | 36 172 | 37 593 |
| Total regular donors | 204 291 | 199 268 | 190 710 | 186 331 |

| | 2012 | 2013 | 2014 | 2015 |
|---|---|---|---|---|
| **Prevalence per 100 000** | 12,84 | 15,56 | 9,70 | 9,38 |
| **Incidence per 100 000** | 1,47 | 5,02 | 0,52 | 1,07 |
| **Residual Risk 100 000** | 0,06 | 0,21 | 0,02 | 0,06 |

# HIV

| | 2012 | 2013 | 2014 | 2015 |
|---|---|---|---|---|
| Total **HIV+ donors** | 33 | 39 | 26 | 28 |
| Total **1st time donors HIV+** | 18 | 16 | 7 | 5 |
| Total **regular donors HIV+** | 15 | 23 | 19 | 23 |
| Total nr donors with donation | 249 168 | 237 826 | 226 882 | 223 924 |
| Total 1st time donors | 44 877 | 38 558 | 36 172 | 37 593 |
| Total regular donors | 204 291 | 199 268 | 190 710 | 186 331 |

| | 2012 | 2013 | 2014 | 2015 |
|---|---|---|---|---|
| **Prevalence per 100 000** | 13,24 | 16,40 | 11,46 | 12,50 |
| **Incidence per 100 000** | 7,34 | 11,54 | 9,96 | 12,34 |
| **Residual Risk 100 000** | 0,12 | 0,19 | 0,16 | 0,71 |

# Viruses, type of donor and identified risk 2014

| | HTLV | VHB | VHC | VIH | Total |
|---|---|---|---|---|---|
| **Heterossexual Contact** | | **2** | | **5** | **7** |
| 1st time Donor | | 2 | | 2 | 4 |
| Seroconversion | | | | 3 | 3 |
| **MSM** | | | | **9** | **9** |
| 1st time Donor | | | | 2 | 2 |
| Seroconversion | | | | **7** | **7** |
| **Not identified** | | **24** | **14** | **9** | **47** |
| 1st time Donor | | 20 | 14 | 2 | 36 |
| Seroconversion | | 4 | | 7 | 11 |
| **Origin endemic zone** | **1** | **5** | | | **6** |
| 1st time Donor | 1 | 5 | | | 6 |
| **Other** | | **7** | | **2** | **9** |
| 1st time Donor | | 5 | | 1 | 6 |
| Seroconversion | | 2 | | 1 | 3 |
| **IVD** | | | **1** | | **1** |
| 1st time Donor | | | 1 | | 1 |
| **Without data** | | **3** | **7** | **1** | **11** |
| 1st time Donor | | 3 | 6 | | 9 |
| Seroconversion | | | 1 | 1 | 2 |
| **Total** | **1** | **41** | **22** | **26** | **90** |

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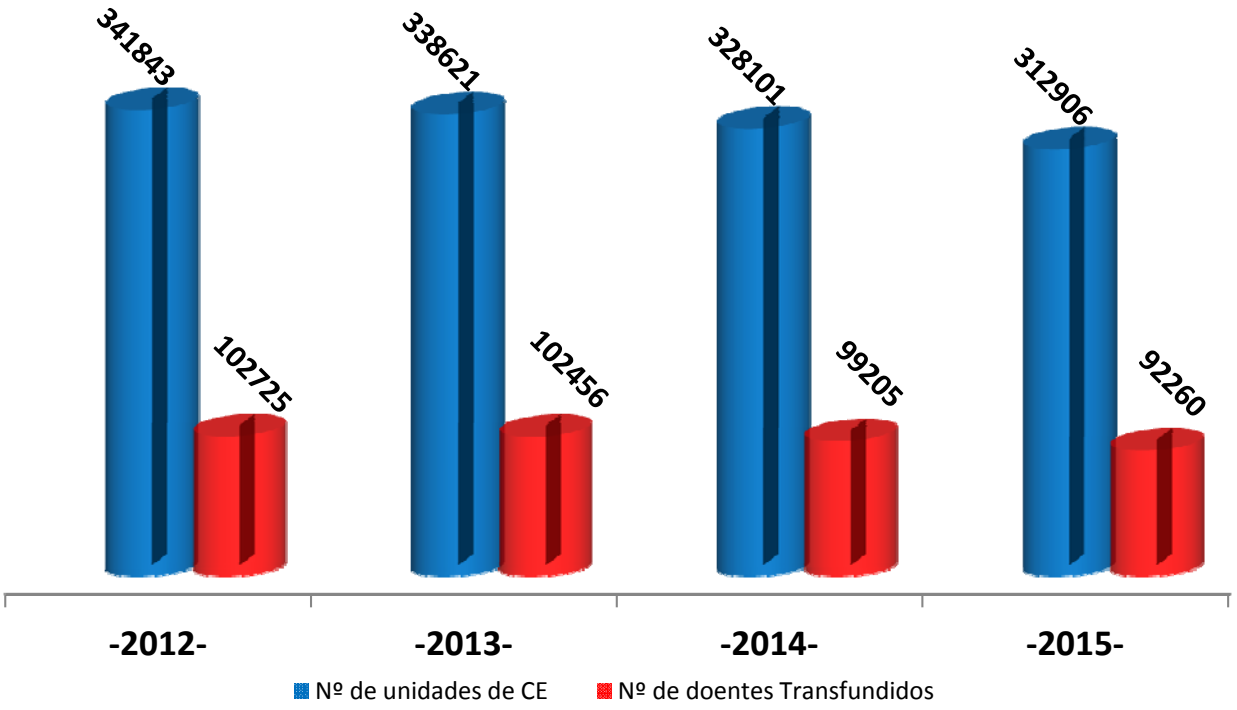
# Blood System Characterization 2012-2015

## Nr of Transfused RCC units and Nr of Transfused Patients




| | 2012 | 2013 | 2014 | 2015 |
|---|---|---|---|---|
| Nr RCC Units/ patient | 3,33 | 3,31 | 3,31 | 3,39 |
| Nr of RCC Units transfused/ 1000 hab | 34,2 | 33,9 | 32,8 | 31,29 |

# Transfused Red Cell units and Transfused Platelet units - Trends

| | 2012 | | 2014 | 2015 | 2016 |
|---|---|---|---|---|---|
| Nr of RC units | 341 843 | 338 621 | 328 101 | 322 46,3 | 315 575,3 |
| | | -0,94% | -3,11% | -1,72% | -2,13% |
| Nr of Patients | 102 725 | 102 456 | 99 205 | 97 942 | 96 182 |
| | | -0,26% | -3,17% | -1,27% | -1,80% |

| | 2012 | 2013 | 2014 | 2015 | 2016 |
|---|---|---|---|---|---|
| Nr of Platelet units * | 29 573 | 36 679 | 37 487 | 42 493,67 | 46 450,67 |
| | | +24,03% | +2,20% | +13,36% | +9,31% |
| Nr of Patients | 9740 | 10 834 | 10 457 | 11 060,67 | 11 419,17 |
| | | +11,23% | -3,48% | +5,77% | +3,24% |

***Pools and Apheresis***
***Trend calculation (yellow)***

# Transfused Red Cell units and Transfused Platelet units (Pool and Apheresis)

| | 2012 | 2013 | 2014 | 2015 |
|---|---|---|---|---|
| Nr of RC units | 341 843 | 338 621 | 328 101 | 312 906 |
| | | -0,94% | -3,11% | -4,86% |
| Nr of Patients | 102 725 | 102 456 | 99 205 | 92 260 |
| | | -0,26% | -3,17% | -7,53% |

| | 2012 | 2013 | 2014 | 2015 |
|---|---|---|---|---|
| Nr of Platelet units* | 29 573 | 36 679 | 37 487 | 37 159 |
| | | +24,03% | +2,20% | -0,88% |
| Nr of Patients | 9740 | 10 834 | 10 457 | 10 609 |
| | | +11,23% | -3,48% | +1,43% |

***Pools and Apheresis***

# Transfused Plasma Units (Q e SD), Patients and units/ patient

| | 2012 | 2013 | 2014 |
|---|---|---|---|
| Fresh Frozen Plasma | 6 578 | 9 627 | 7 913 |
| Nr of Patients | 1 951 | 2 845 | 1 893 |
| **Nr of Units/Patient** | 3,37 | 3,38 | 4,18 |
| | | | |
| Plasma SD (Solvent Detergent Treated) - industrial | 63 433 | 67 446 | 63 863 |
| Nr of Patients | 10 848 | 11 610 | 9 859 |
| **Nr of Units/Patient** | 5,85 | 5,81 | 6,48 |

# BLOOD DONATION AND TRANSFUSIONS

EUROBAROMETER

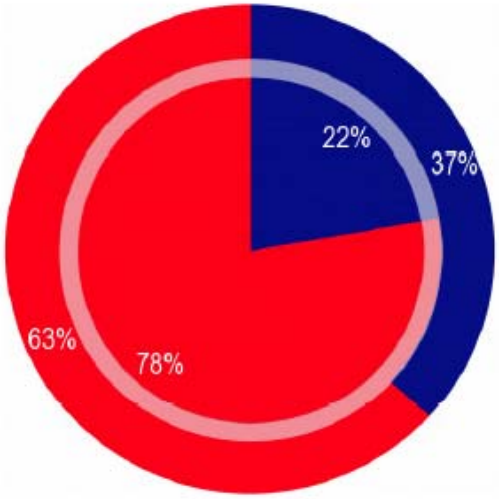
EU27 — Number of interviews: 26.788 — Fieldwork: 02/10-19/10/2009

PT — Number of interviews: 1.031 — Fieldwork: 02/10-18/10/2009

Methodology: face-to-face

European Commission

## QE6. Have you given blood before?

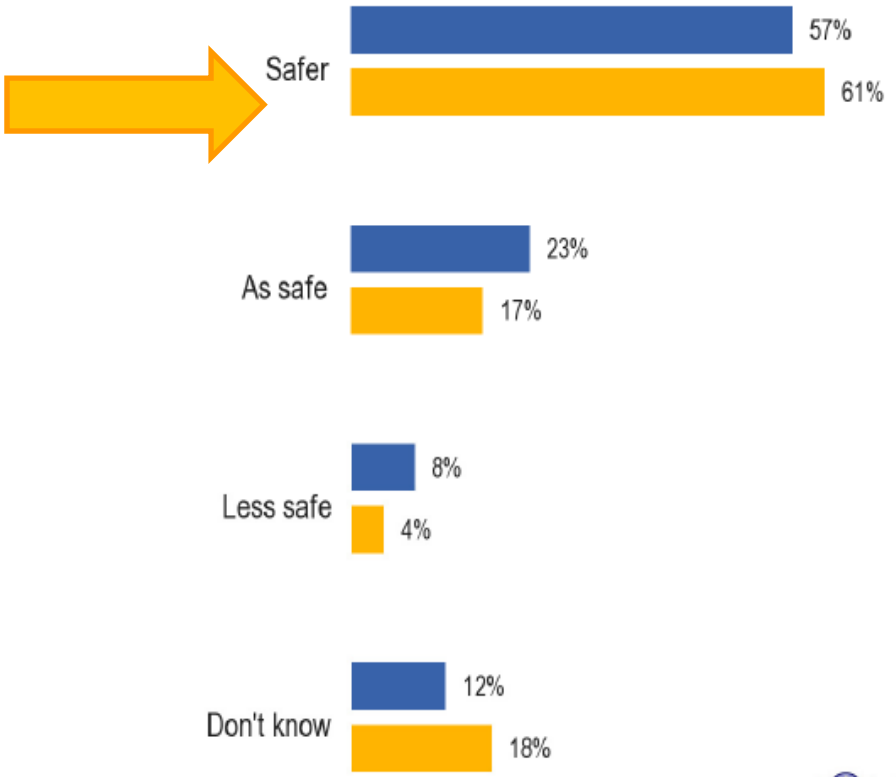



EU27 Outer pie PT Inner pie

| | EU27 | | PT |
|---|---|---|---|
| | EB72.3 | EB72.3-EB58.2 | EB72.3 |
| Yes | 37% | + 7 | 22% |
| No | 63% | - 6 | 78% |
| Don't know | 0% | - 1 | 0% |

Evolution 10/2009 (EU27) - 11/2002 (EU15)

## QE7. Do you think that blood transfusions are safer, as safe or less safe than they were around 10 years ago?



# Donor Adverse Reaction
# Recipient Adverse Reaction (RAR) 2015

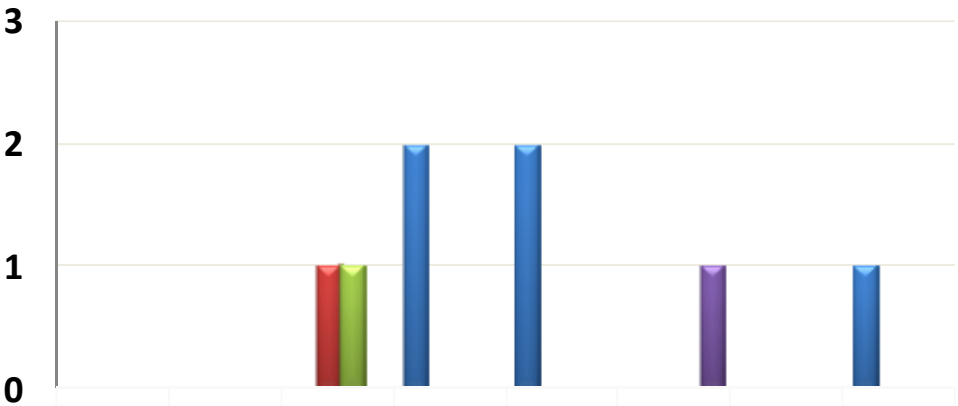
- DAR 3,35/ 1 000 donations
- DAR 5,0/ 1 000 Donor

- RAR 12,9/ 10 000 Red Cell transfused
- RAR 43,9/ 10 000 Patient transfused

# Transfusion Associated Risk in Portugal
## (/10 000 transfused blood components)

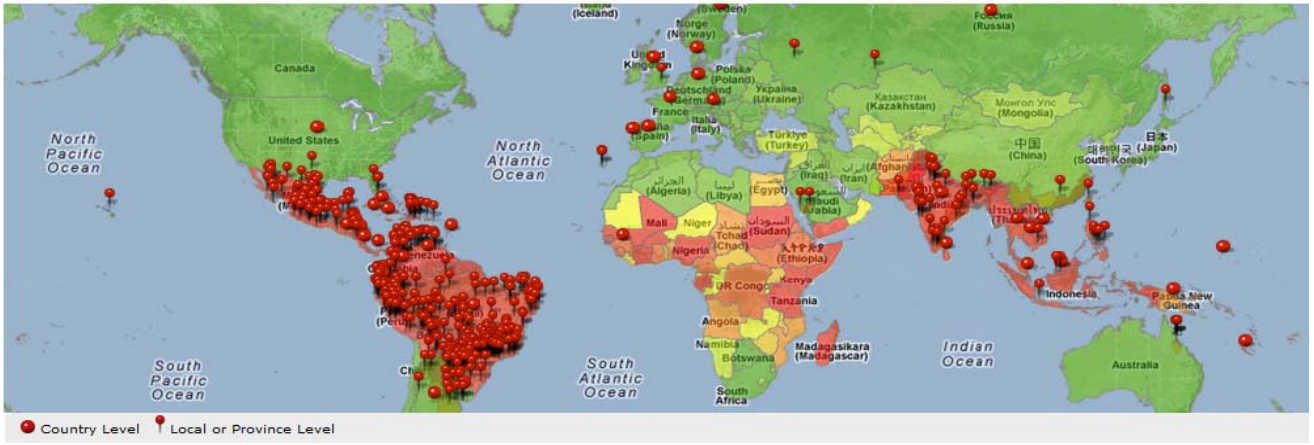
| | 2008-2012 | 2013 | 2014 | 2015 |
|---|---|---|---|---|
| Errors | 0,8 | 0,6 | 1,1 | 1,41 |
| Hemolitic Reactions due to AB0 incompatibility | 0,3 | 0,1 | 0,1 | 0,26 |
| Transfusion respiratory complications | 1,1 | 1,4 | 1,2 | 1,02 |
| TACO | 0.4 | 0,7 | 0,6 | 0,54 |
| TRALI | 0,05 | 0,07 | - | 0,03 |
| Death attributable to transfusion | 0,03 | 0,02 | - | 0,03 |

# Mortality associated to transfusion
## (2008 -2015)




| | 2008 | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 |
|---|---|---|---|---|---|---|---|---|
| Hemólise por incomp ABO | 0 | 0 | 0 | 2 | 2 | 0 | 0 | 1 |
| TACO | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 |
| Anafilaxia | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 |
| Outro | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 |

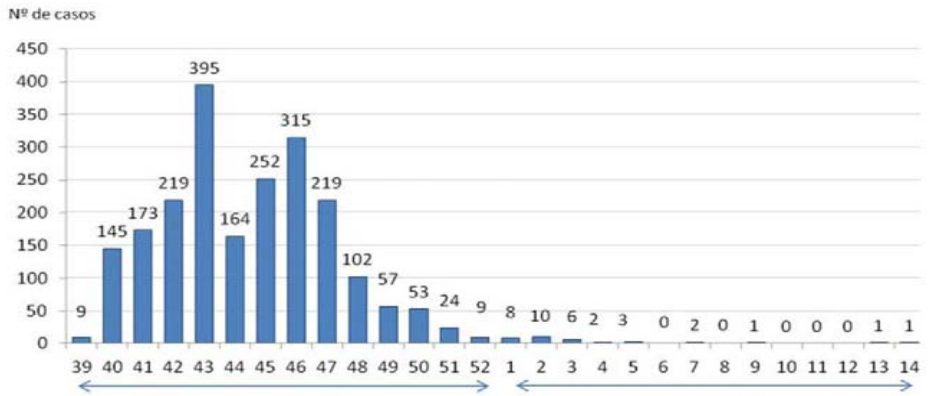
# Dengue Outbreak in Madeira Island




- On October 3rd, 2012, two cases of confirmed Dengue infection were reported by Autonomous Region of Madeira in patients residing in Madeira Island
- Both patients had no recent travel history abroad.
- The presence of *aedes aegypti* in the island was known since 2005

First known occurrence of authochtonous Dengue Fever.

# National Alert 2012 – Dengue Outbreak (Madeira Island)




Number of Dengue cases by week, 2012-2013

- From 3rd October 2012 to **3rd March 2013** (under control)
  - 2182 cases had been reported in Madeira island.
    - 0,83% of Madeira island population
    - 2,0% of Funchal population
  - 82 cases among travelers returning from Madeira
- There were no registered deaths
- RT – PCR screening test **2,26**/ 100 positive blood donations in asymptomatic donors: **DENV -1 virus**.
- The case number and incidence rate decreased to residual values since January 2013 and there were no laboratory-confirmed dengue cases since the 4th February.

Imported cases reported 2012-2013

| Countries | N of cases |
|---|---|
| Portugal mainland | 11 |
| UK | 23 |
| Germany | 19 |
| France | 3 |
| Sweden | 6 |
| Finland | 7 |
| Denmark | 2 |
| Austria | 2 |
| Norway | 2 |
| Croatia | 1 |
| Slovenia | 1 |
| Spain | 1 |
| Switzerland | 1 |
| Belgium | 1 |
| Total | 82 |

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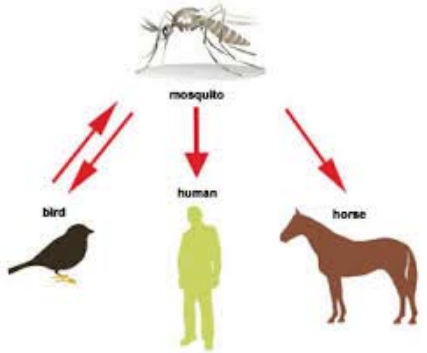
# National Alert 2014 – Legionella Outbreak

7th November to 15th December 2014

- 375 cases of Legionella Pneumophila pneumonia
  - 78% patients residing in Vila Franca de Xira, 11% in Loures and 11% in other parishes
  - All cases with epidemiologic conection with Vila Franca de Xira
  - 12 deaths (3,2%)

  Alerts at 11, 13, 28 de November and 22 December
- Zero cases of transmission through transfusion (Port Hemovigilance System)

# National Alert 2015- WNV




- From 30th August to 30th October 2015
  - 1 confirmed case of West Nile Virus infection in Algarve
  - In the afected area: Blood collection canceled, until WNV ID NAT screening was used to test each donation
  - Outside of the afected area: Temporary deferral for 28 days of blood donors, having at least stayed one night in the affected region, or alternatively, blood donors acceptance if WNV ID NAT screening available and used
  - Zero positive results:
    - 4274 blood units (2429 of which collected in Algarve)

# Reflections and conclusions

- Voluntary non remunerated Donors based Blood collection
- Self suficiency in Blood components  (reduction in blood collection and RC and Platelet usage)+ Blood Supply Management + Patient Blood Management
- Mixed BE system (IPST+ HH)
- Strategic Planning of Blood Establishments (based in cost efectiveness evaluation)

- Report of all SARE parameters
- Transfusion Risk stable in BE and in TMServices

- Challenges to the next decades (reduction of population; reduction of young and increasing of older inhabitants)

# Thank you for your atention!