



**ISTARE**



# **The IHN Database for the Surveillance of Adverse Reactions and Events in Donors and Recipients of Blood Components 2006-2011**

## **The Working Group**

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# ISTARE

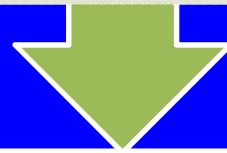
- IHN established ISTARE 5 years ago
- to implement a holistic approach to collecting data on **ALL** adverse reactions (AR) and adverse events (AE) associated with donation and transfusion of blood components, **regardless of severity**

## Purpose of the database

Information sharing

Surveillance,  
monitoring

Analyzing data

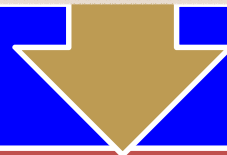


## Potential uses

Benchmarking for  
countries

Risk assessment

Education



## Ultimate goal

Contributing to international scientific efforts to prevent and correct errors in transfusion

- ISTARE has gained approval and trust among countries that possess or are developing haemovigilance systems, and
- apply IHN/IBST standards
- Now a fully functional web-based database, developed by ISTARE Working Group
- Programmed by Steficon Ltd under IHN contract
- Access through IHN website (see Abstract for address)

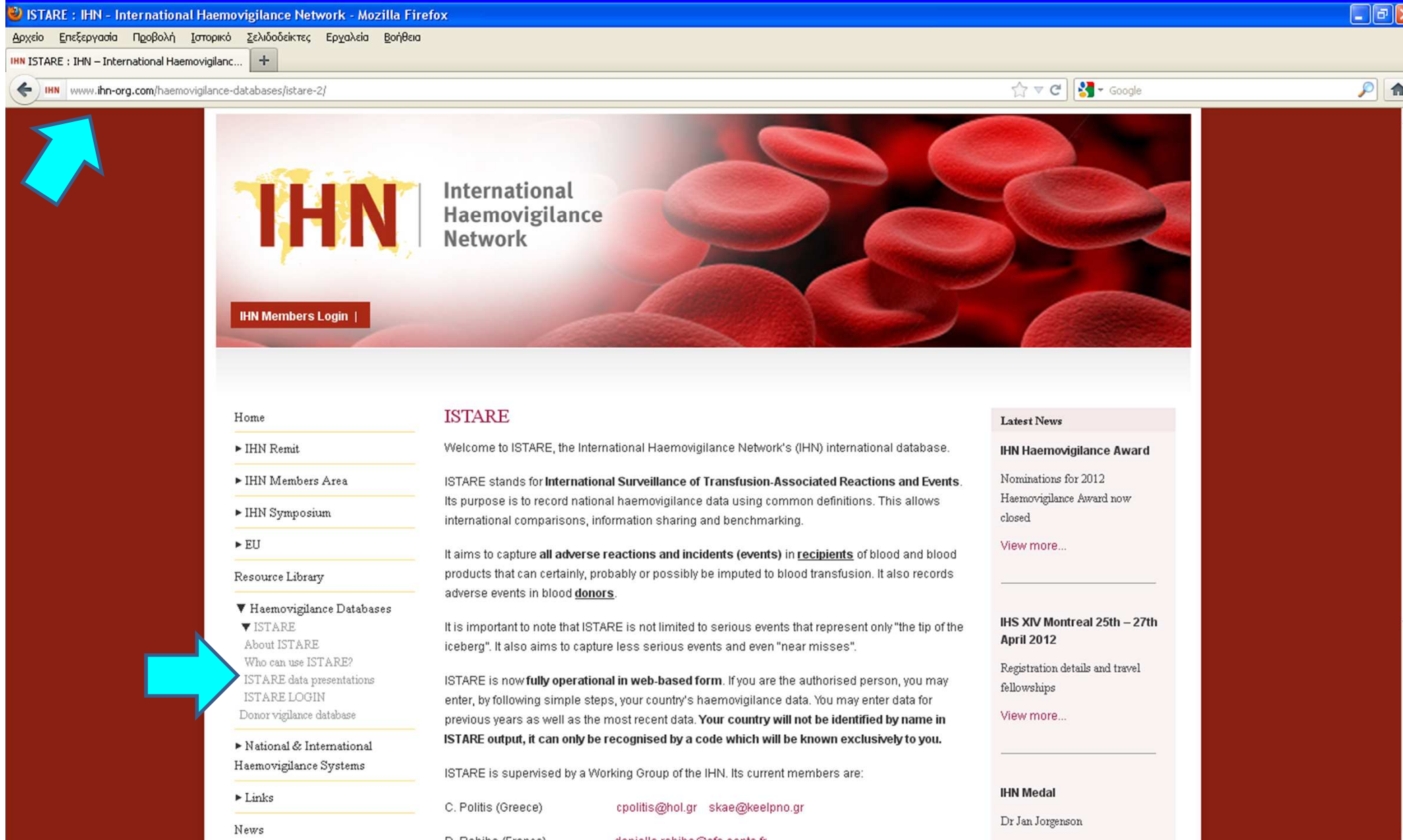
# ISTARE Webpage on IHN Website

ISTARE : IHN - International Haemovigilance Network - Mozilla Firefox

Αρχείο Επεξεργασία Προβολή Ιστορικό Σελιδοδείκτες Εργαλεία Βοήθεια

IHN ISTARE : IHN - International Haemovigilanc... +

← IHN www.ihn-org.com/haemovigilance-databases/istare-2/ ☆ Google



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  - [Who can use ISTARE?](#)
  - [ISTARE data presentations](#)
  - [ISTARE LOGIN](#)
  - [Donor vigilance database](#)
- ▶ [National & International Haemovigilance Systems](#)
- ▶ [Links](#)

### News

## ISTARE

Welcome to ISTARE, the International Haemovigilance Network's (IHN) international database.

ISTARE stands for **International Surveillance of Transfusion-Associated Reactions and Events**. Its purpose is to record national haemovigilance data using common definitions. This allows international comparisons, information sharing and benchmarking.

It aims to capture **all adverse reactions and incidents (events)** in recipients of blood and blood products that can certainly, probably or possibly be imputed to blood transfusion. It also records adverse events in blood donors.

It is important to note that ISTARE is not limited to serious events that represent only "the tip of the iceberg". It also aims to capture less serious events and even "near misses".

ISTARE is now **fully operational in web-based form**. If you are the authorised person, you may enter, by following simple steps, your country's haemovigilance data. You may enter data for previous years as well as the most recent data. **Your country will not be identified by name in ISTARE output, it can only be recognised by a code which will be known exclusively to you.**

ISTARE is supervised by a Working Group of the IHN. Its current members are:

C. Politis (Greece)	<a href="mailto:cpolitis@hol.gr">cpolitis@hol.gr</a>	<a href="mailto:skae@keelpno.gr">skae@keelpno.gr</a>
D. Rebibo (France)	<a href="mailto:danielle.rebibo@efs.sante.fr">danielle.rebibo@efs.sante.fr</a>	

### Latest News

#### IHN Haemovigilance Award

Nominations for 2012 Haemovigilance Award now closed

[View more...](#)

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#### IHS XIV Montreal 25th – 27th April 2012

Registration details and travel fellowships

[View more...](#)

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#### IHN Medal

Dr Jan Jorgenson

## Submission of data

- Annual aggregate haemovigilance data are submitted confidentially online using **IHN/ISBT standard definitions**
- Data are for countries: exceptionally for regions
- Detailed instructions and definitions are provided online

# Data analysis and dissemination

ISTARE automatically provides rates and ratios of ARs for analysis of national data and produces charts comparing international data for one or more years.

## Main areas covered

- Event rates, overall and by product type
- Type of reaction, by severity and imputability
- Distributions of types of event
- Averages for global regions
- Monitoring trends

*Data are disseminated only in **anonymized** form.*

*Each country is marked in tables and diagrams by a code number.*

## What data (1)?

- **General information:** structure and coverage of the haemovigilance system
- **General denominators:** data on numbers of donors/donations and main categories of blood products
- **Specific denominators:** denominator data for specific types of blood components issued and transfused



# What data (2)?

- **Donor Complications:** events related to whole blood and also to apheresis donations
- **Errors-incorrect blood component transfused (IBCT):**  
ABO incompatible - Sampling errors - Wrong label
- **Adverse transfusion reactions**
  - ✓ By blood **component**
  - ✓ By **imputability**: “possibly”, “probably” and “definitely”
  - ✓ By **severity**: non-severe, severe, life-threatening and fatal


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General Information   Denominators General   Denominators Specific   **Donor Complications**   Errors-IBCT   Adverse Reactions By Component   Adverse Reactions By Severity   Adverse Reactions By Imputability   Rates-Ratio General   Rates-Ratio Specific

Specify if adverse events related to autologous donations are included in the tables: ☐ Yes ☒ No ☐ Unknown

☒ Whole Blood and Aphaeresis Donations ☐ All Donations

Category	Number of cases-Whole blood				Number of cases-Aphaeresis				Total
	Mild ?	Moderate ?	Severe ?	Subtotal	Mild ?	Moderate ?	Severe ?	Subtotal	
Haematoma ?	340	24	10	374	33	7		40	414
Arterial puncture ?	10		8	18					18
Delayed bleeding ?									
Painful arm* ?	4	1	1	6					6
Localised infection									
Thrombophlebitis ?									
<b>Total number local symptoms ?</b>	<b>354</b>	<b>25</b>	<b>19</b>	<b>398</b>	<b>33</b>	<b>7</b>		<b>40</b>	<b>438</b>
VV R Immediate type ?	4005	795	29	4829					4829
VV R Immediate, accident ?	19		2	21					21
VV R Delayed type ?	211	42		253					253
VV R Delayed, accident ?									
<b>Total no. Vaso-Vagal Reactions ?</b>	<b>4235</b>	<b>837</b>	<b>31</b>	<b>5103</b>					<b>5103</b>
Citrate reaction					129			129	129
Haemolysis									
Generalised allergic reaction	2			2					2
Air embolism									
Other	407	5	14	426					426
<b>Total</b>	<b>4998</b>	<b>867</b>	<b>64</b>	<b>5929</b>	<b>162</b>	<b>7</b>		<b>169</b>	<b>6098</b>

\*Painful arm included tendon and nerve injury and irritation

VV R = vasovagal reaction

# Charts available within ISTARE for national use

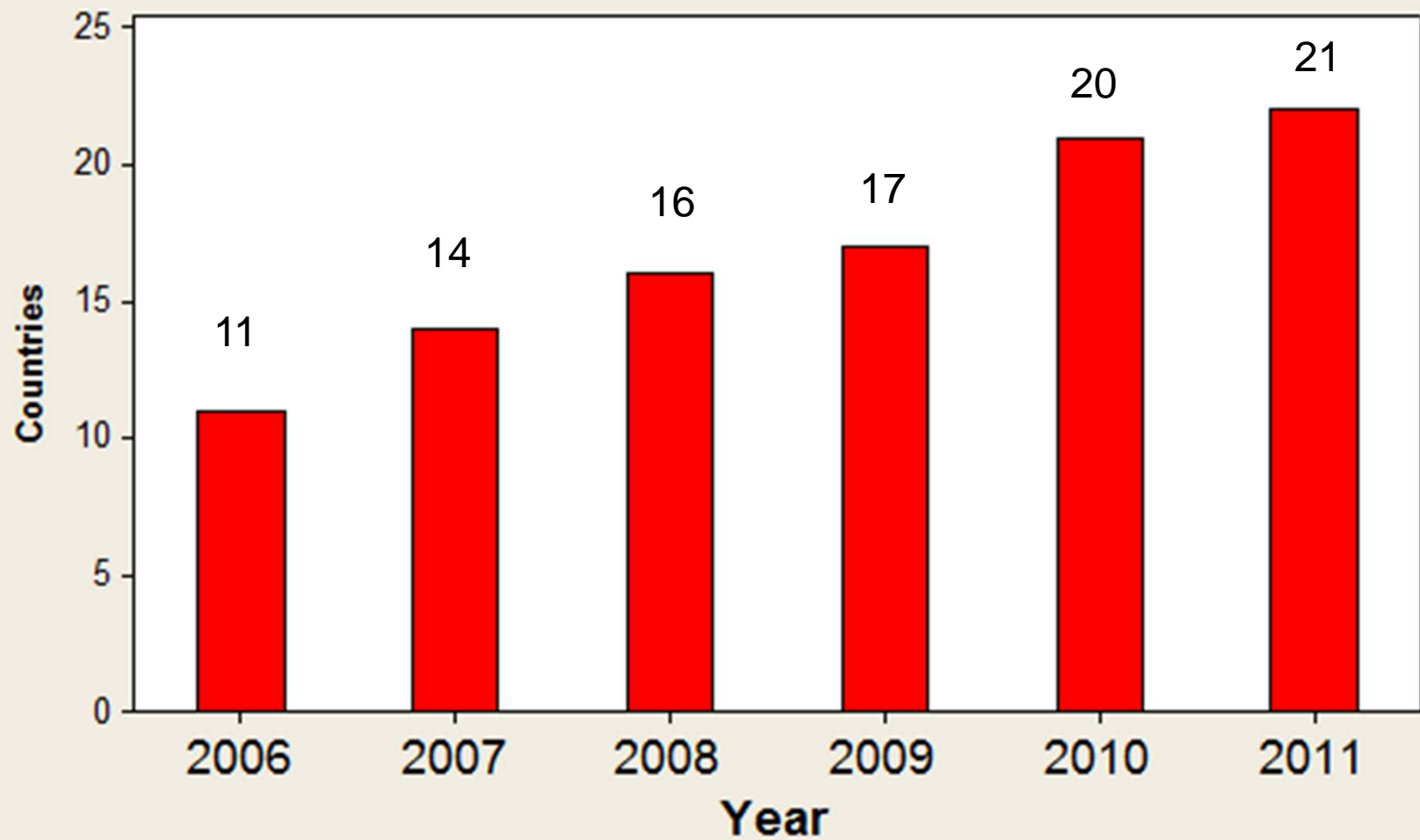
- **Distribution chart**
  - Donor complications
  - Errors - incorrect blood component transfused (IBCT)
  - Adverse reaction by imputability
- **Rates and ratios charts**
  - Adverse transfusion reactions by blood component
  - Adverse transfusion reactions by severity
  - Incidence of all ARs

**Examples will be shown later.**

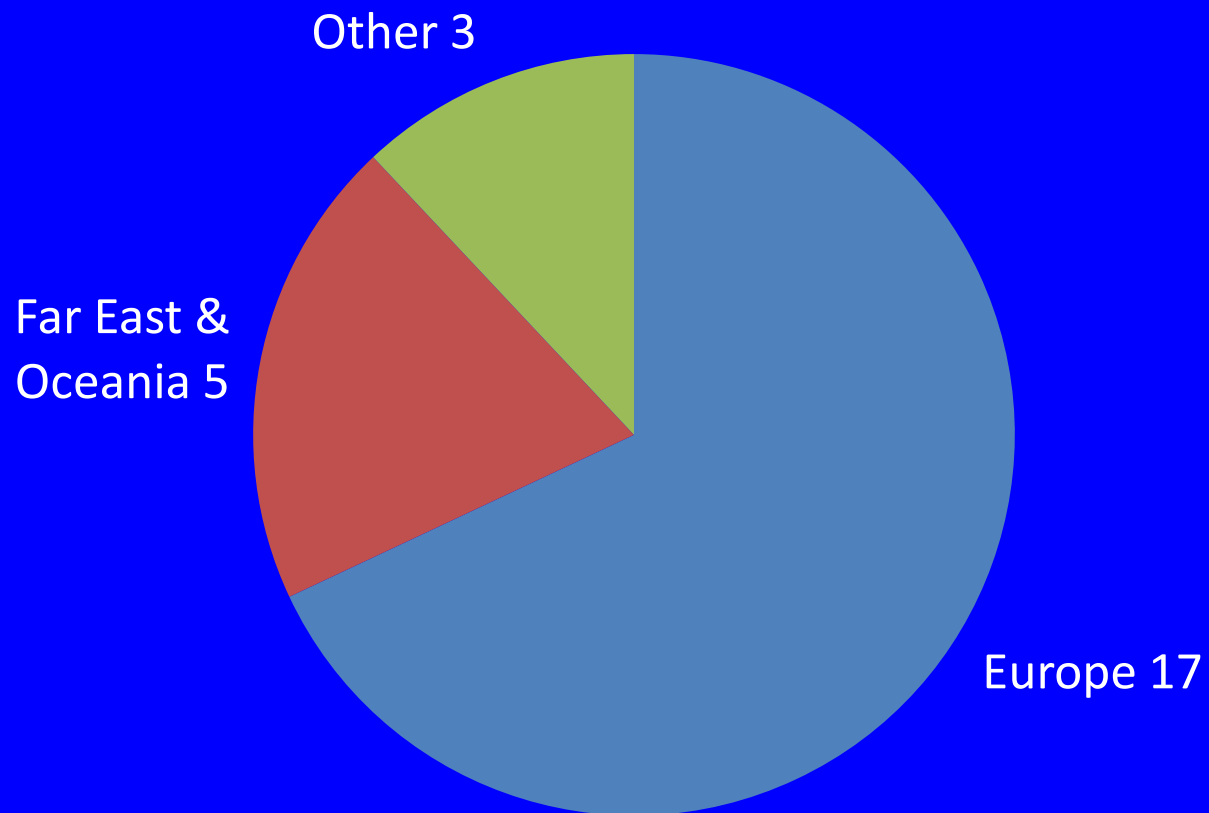
# **Results**

## **2006-2011**

## Participation in ISTARE



25 countries from 5 continents have participated in ISTARE, with 102 reports

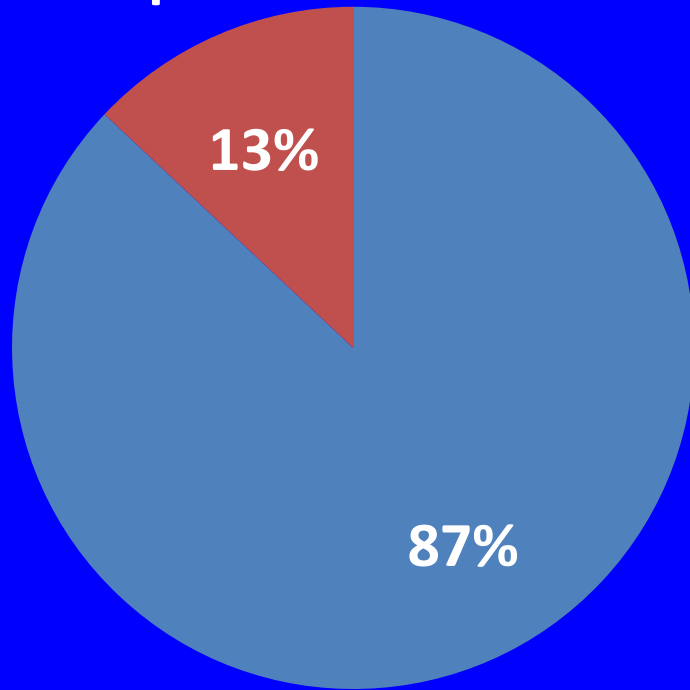


# Years of participation by each country

6 years	7 countries
At least 5 yrs	10
At least 4 yrs	16
At least 3 yrs	19
At least 2 yrs	24
Total participants	25 countries

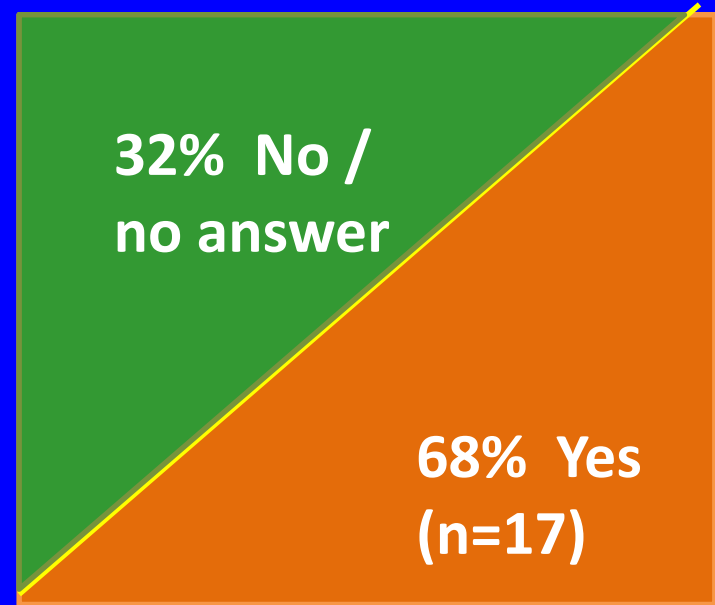
# Haemovigilance coverage

Incomplete HV data



Complete HV

Vigilance for  
materials/reagents





## Volume of data, 2006-2011

### Data

Units issued	111,533,743
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Units transfused (in 10 countries)	30,782,487
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Total ARs	83,123
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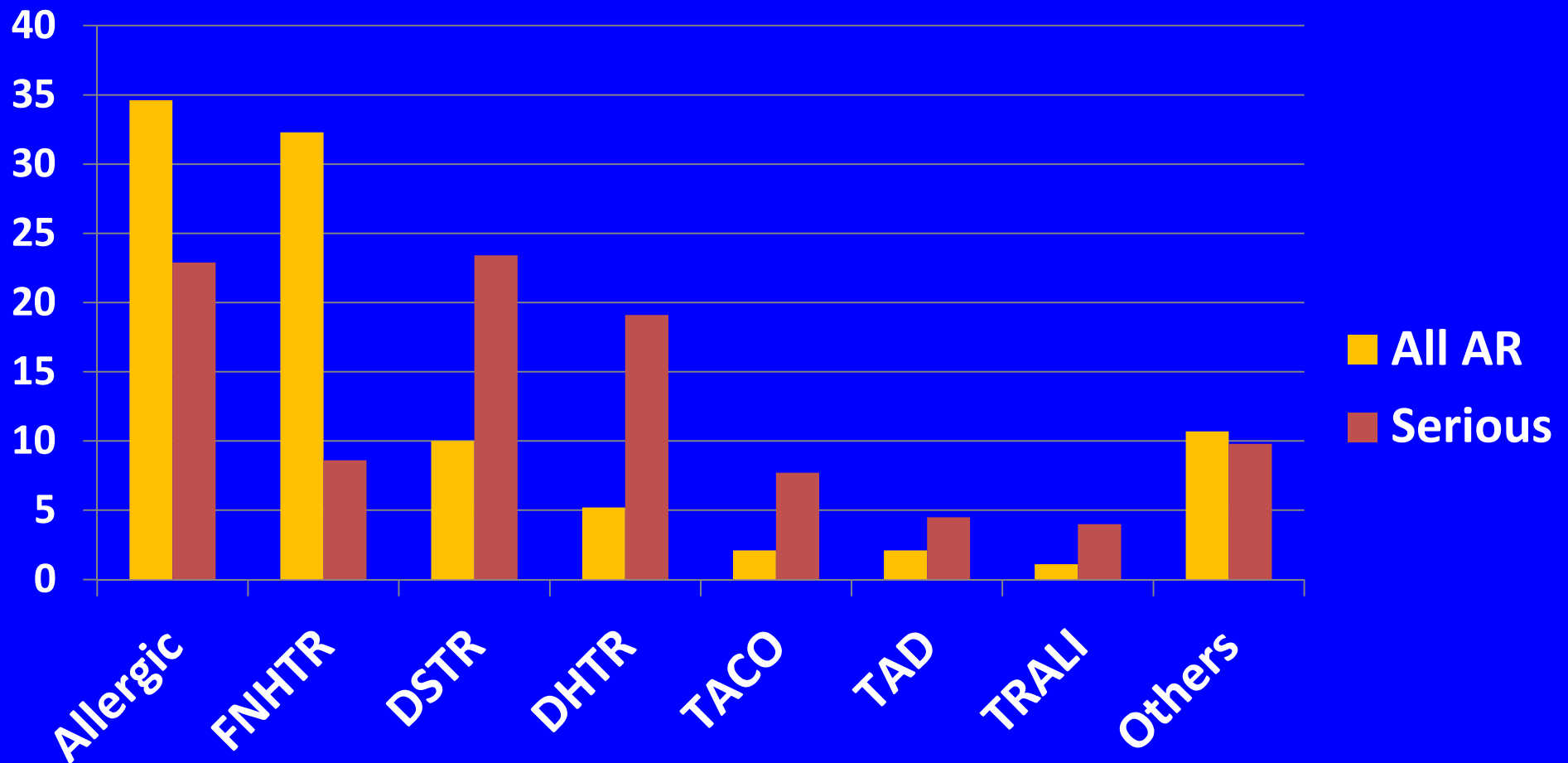
<i>Incidence per 100,000 units issued</i>	<i>74.5</i>
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Deaths	283
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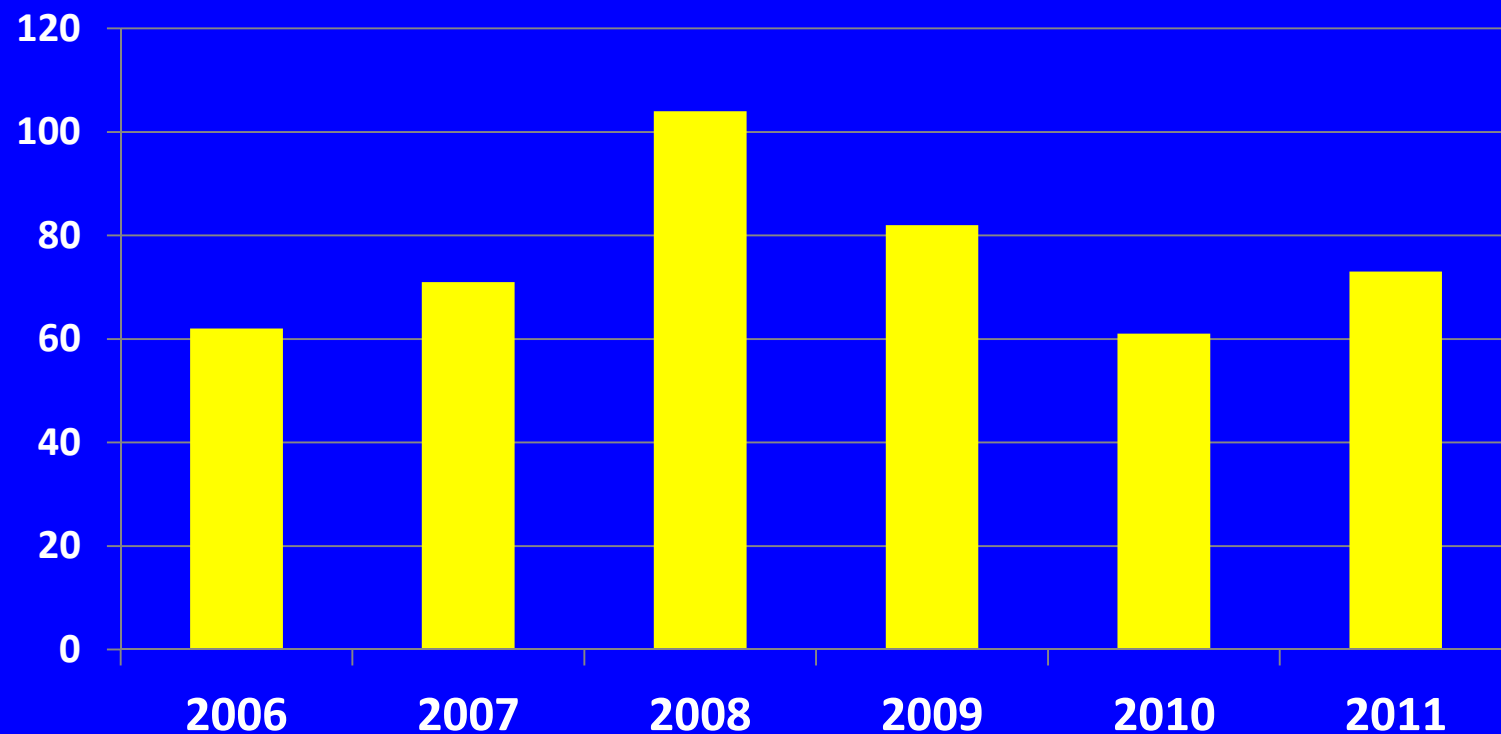
<i>Incidence per 100,000 units issued</i>	<i>0.25</i>
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Total donor complications	364,384
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# % breakdown of AR, 2006-2011

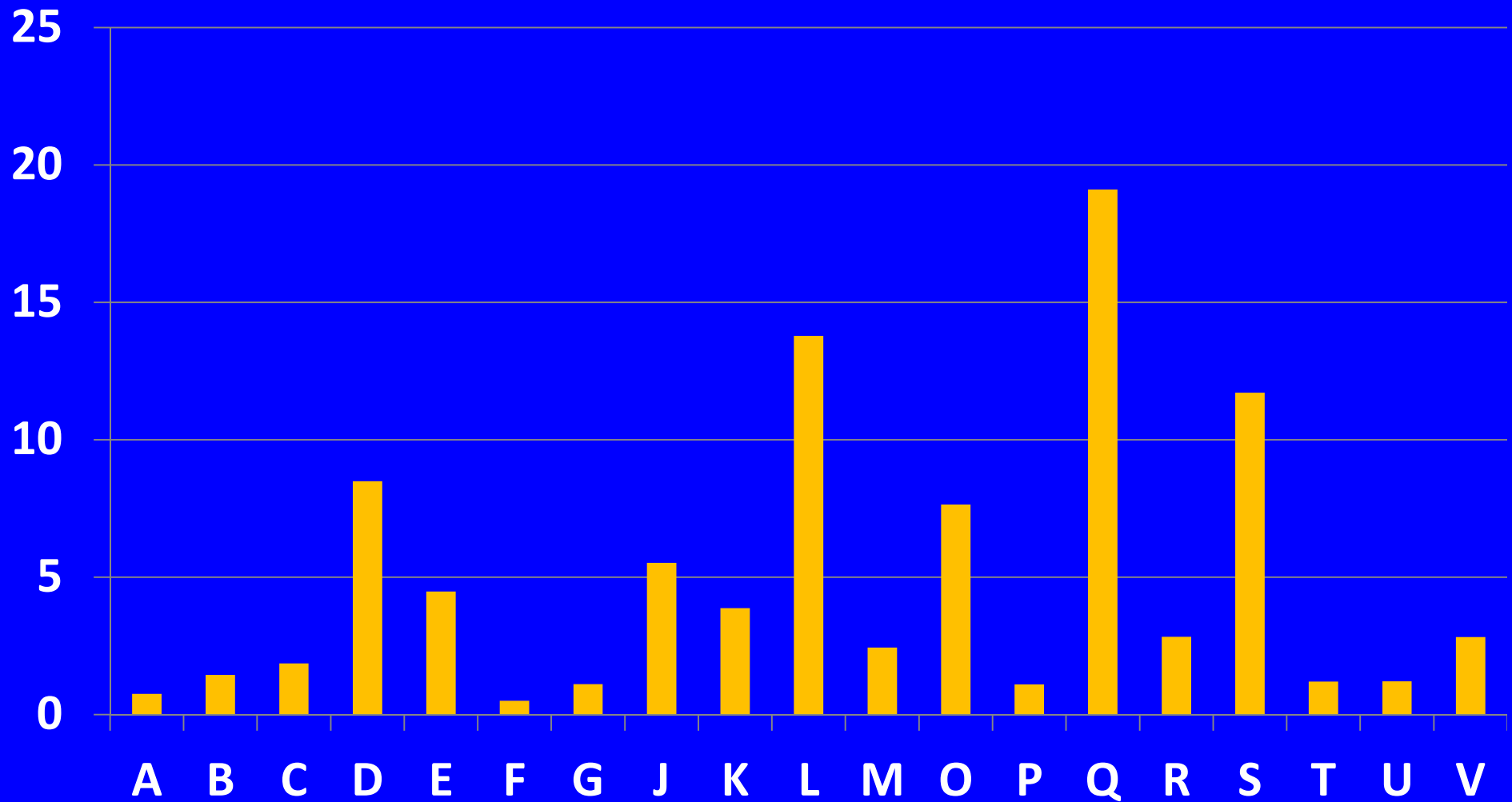


# AR incidence per 100,000 units issued



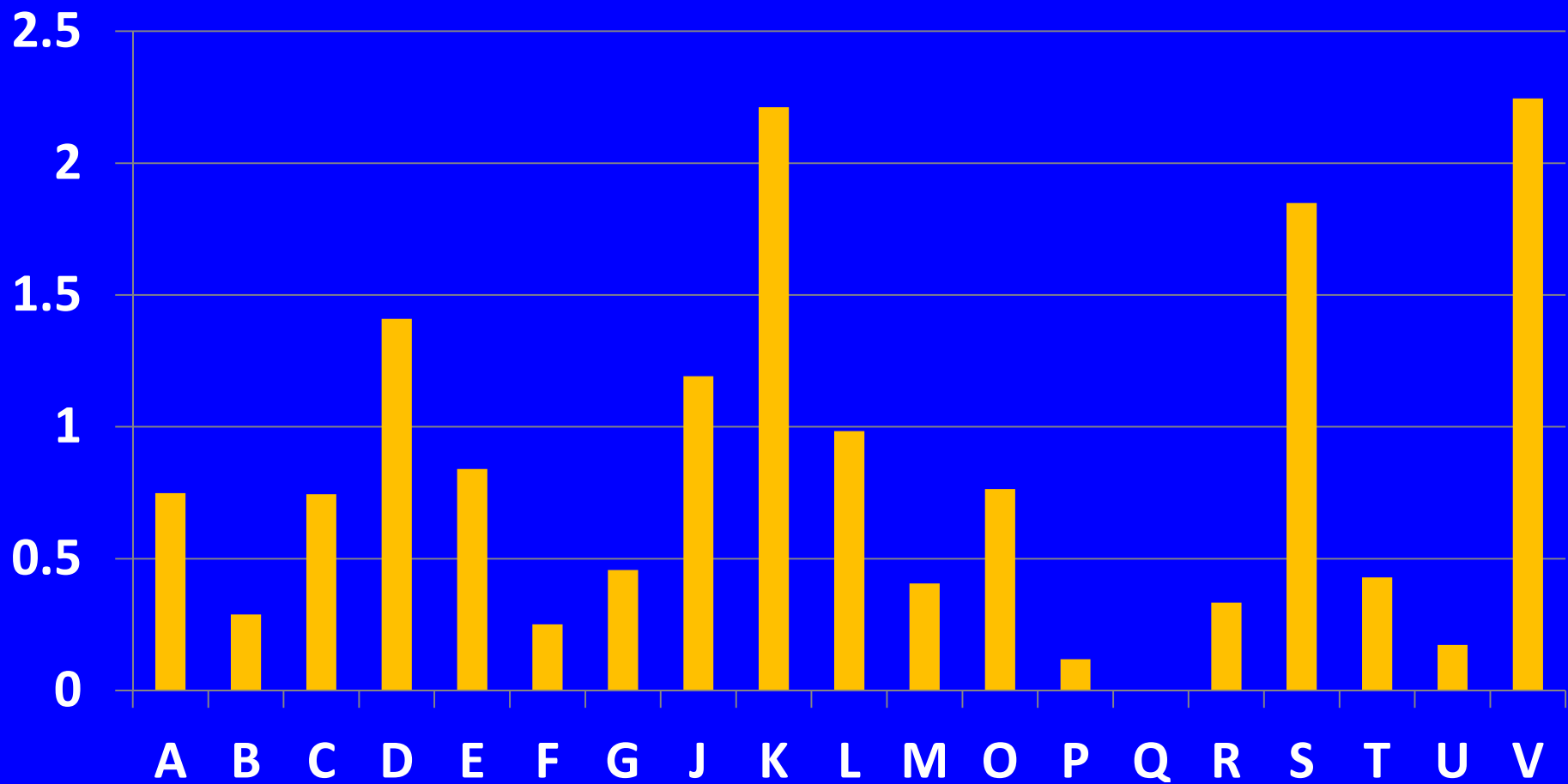
# Incidence of TACO by country, 2011

(per 100,000 units issued)

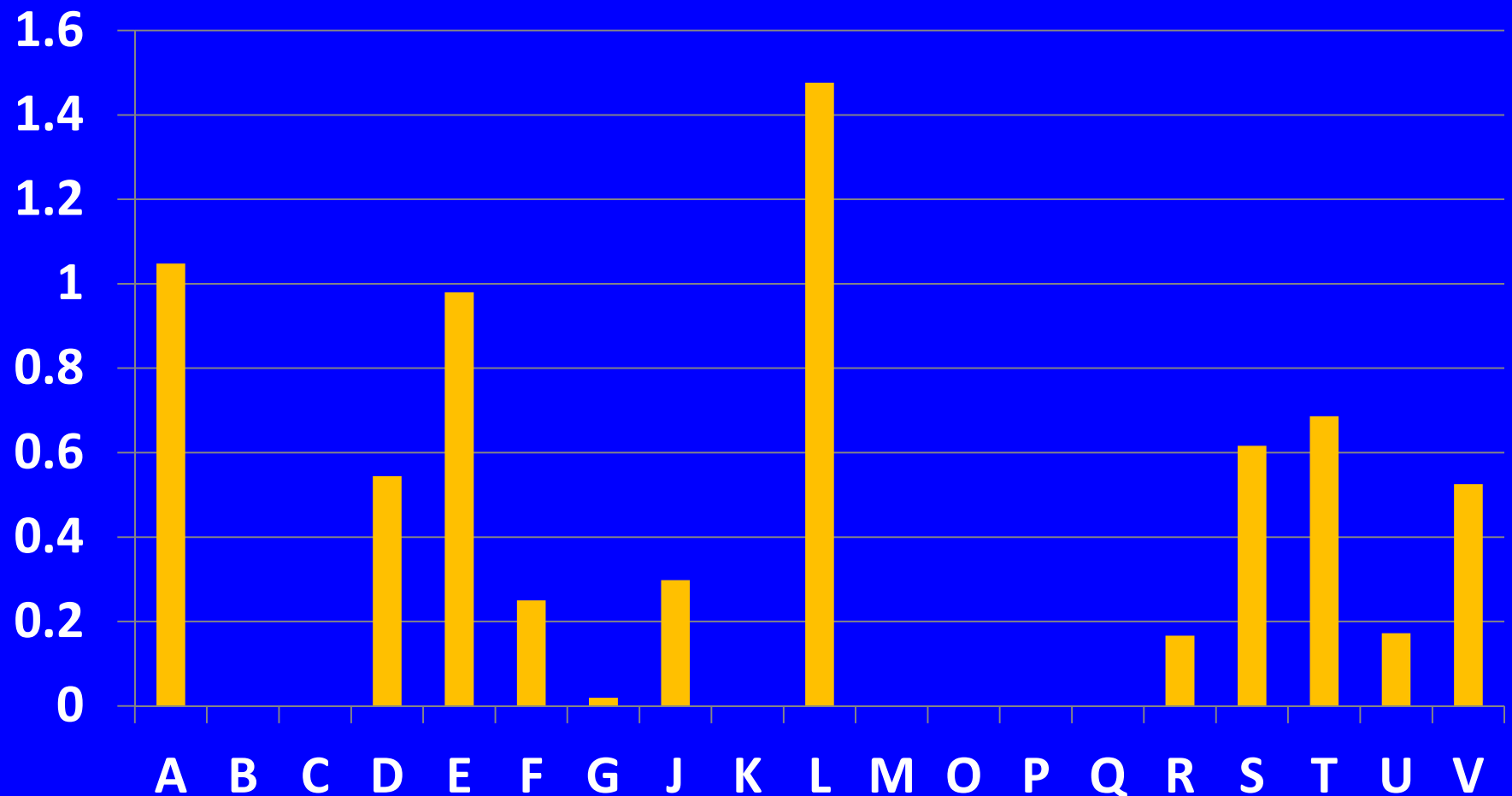


# Incidence of TRALI by country, 2011

(per 100,000 units issued)

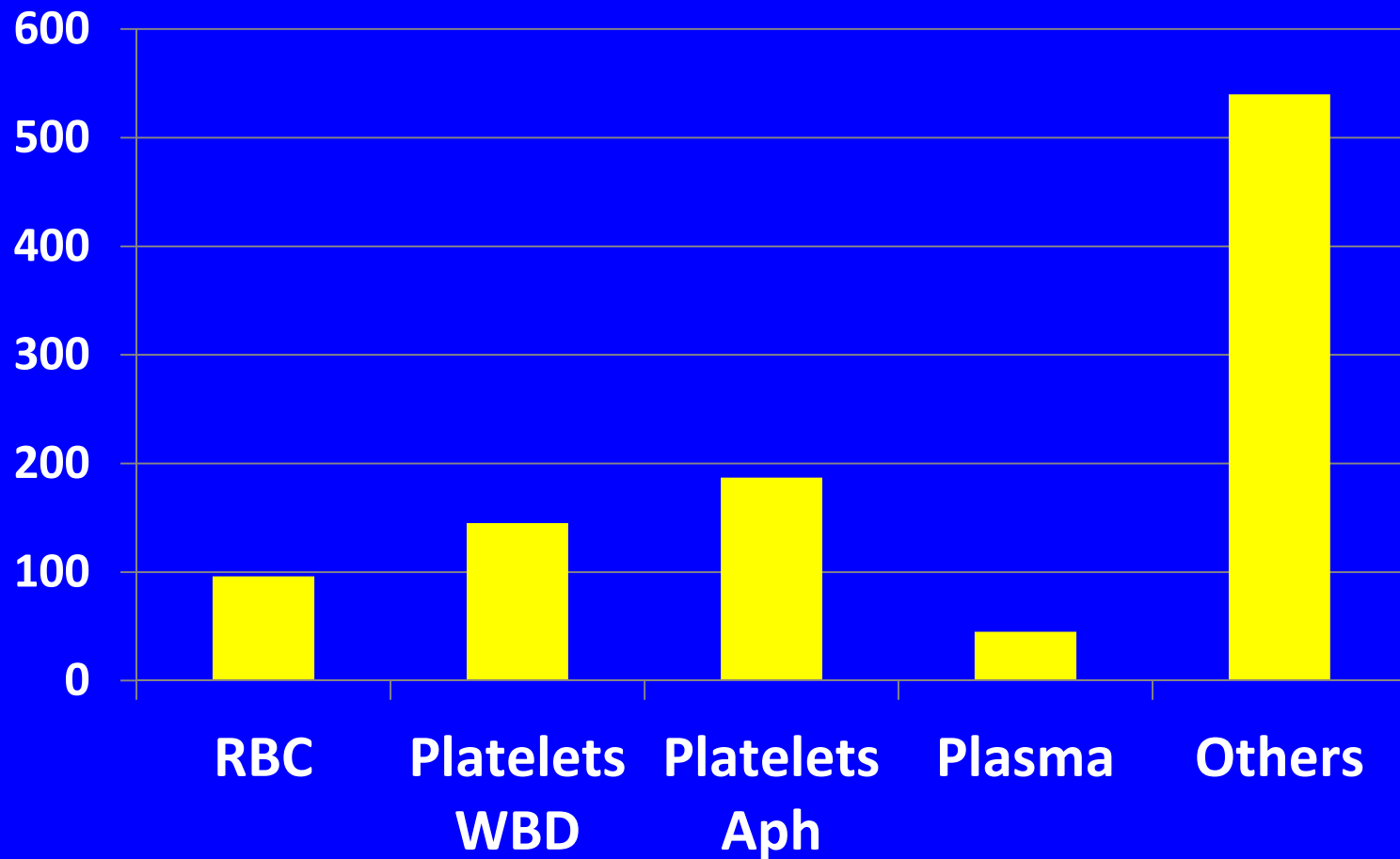


# Incidence of bacterial infection by country, 2011 (per 100,000 units issued)

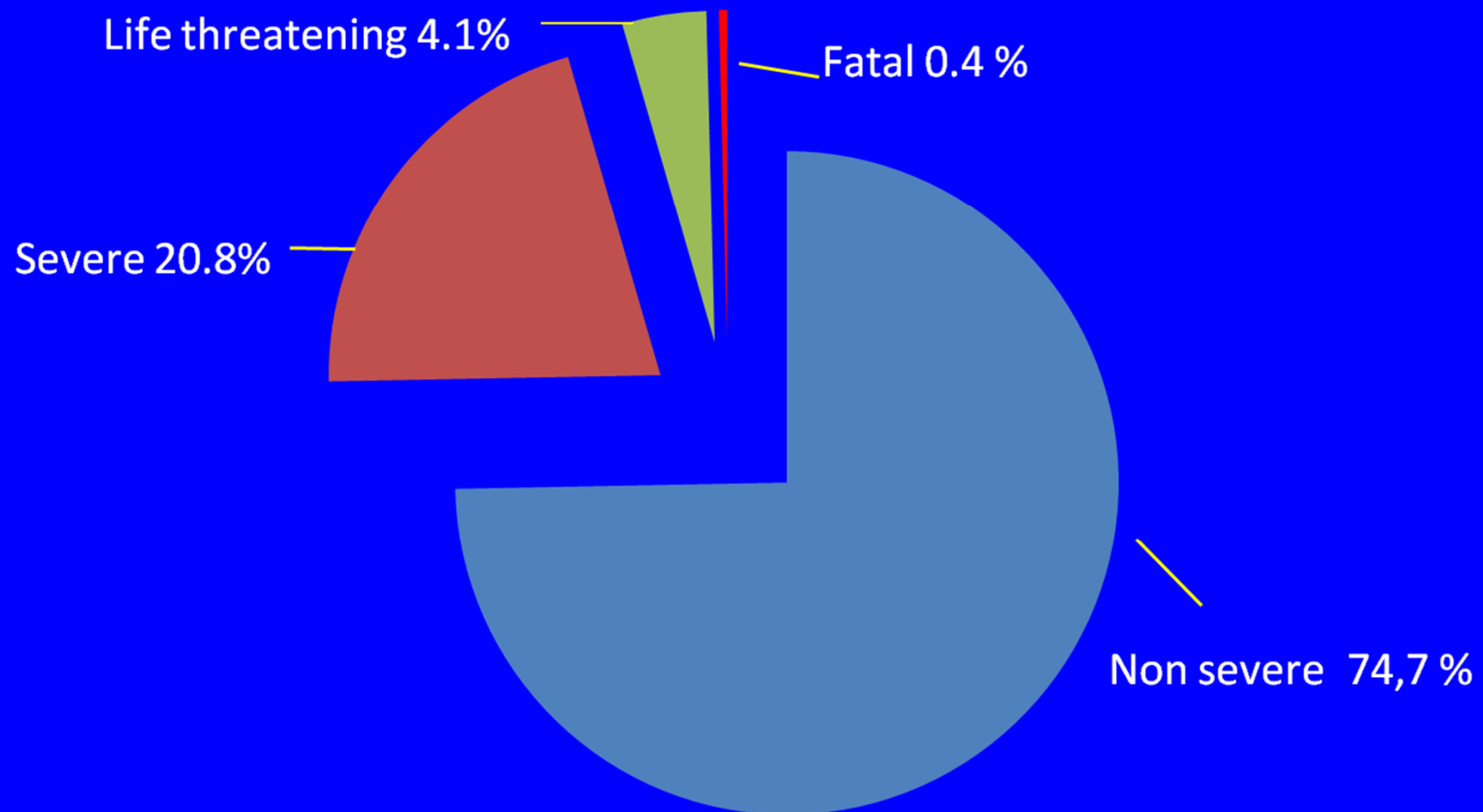


# AR by blood component, 2006-2011

rate per 100,000



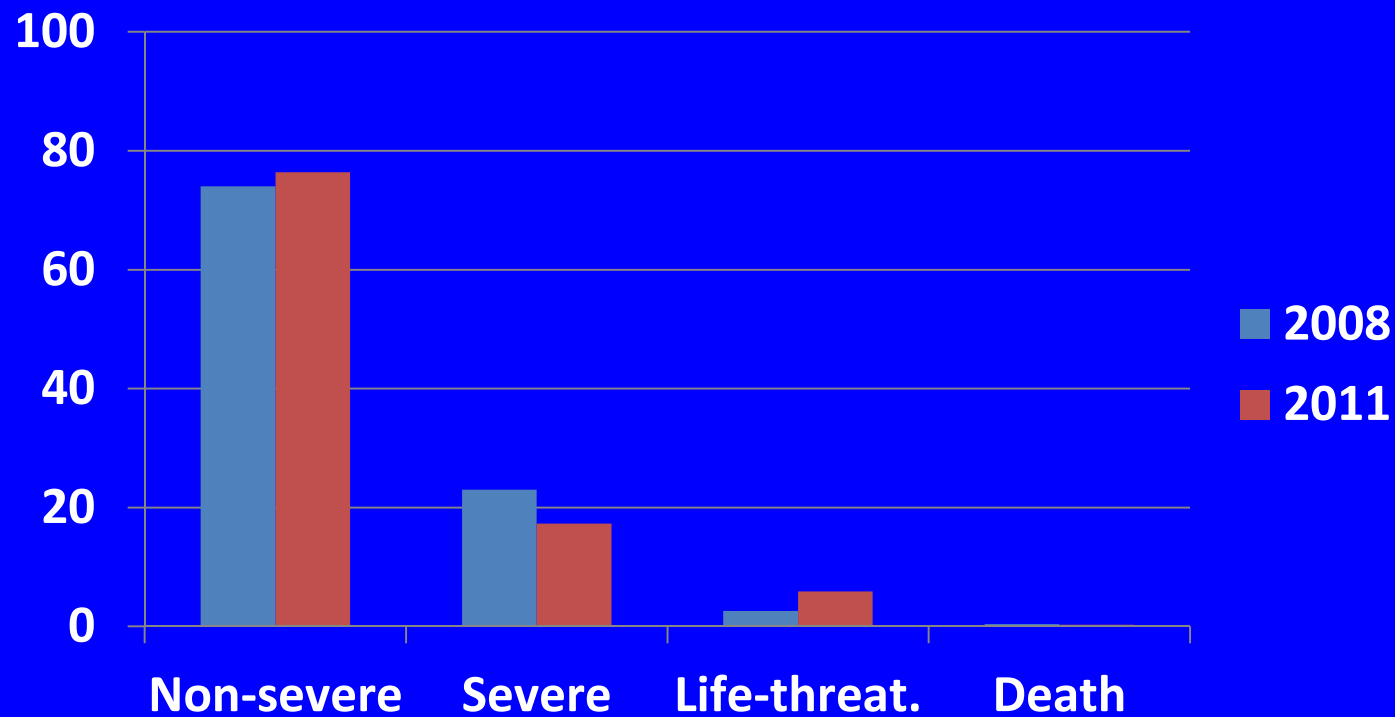
# Total ARs by severity n=83,123





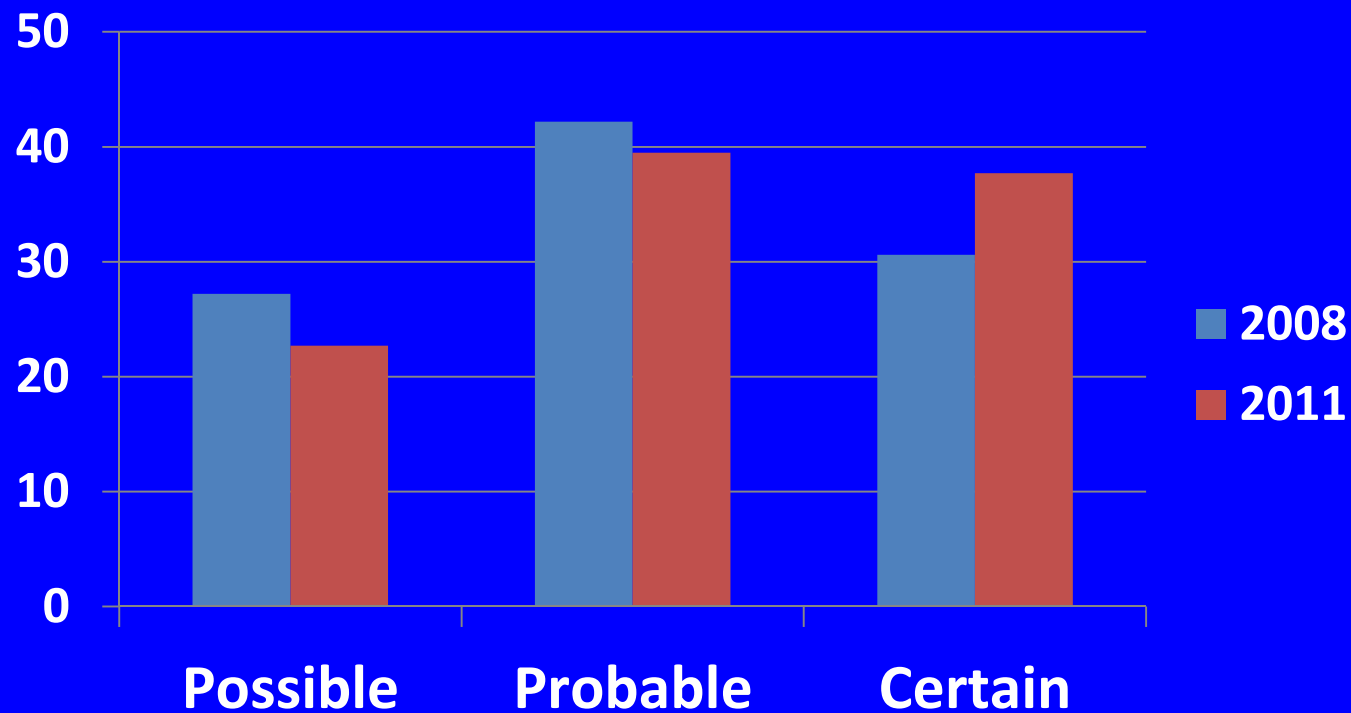
# AR by severity (%)

## 2011 versus 2008

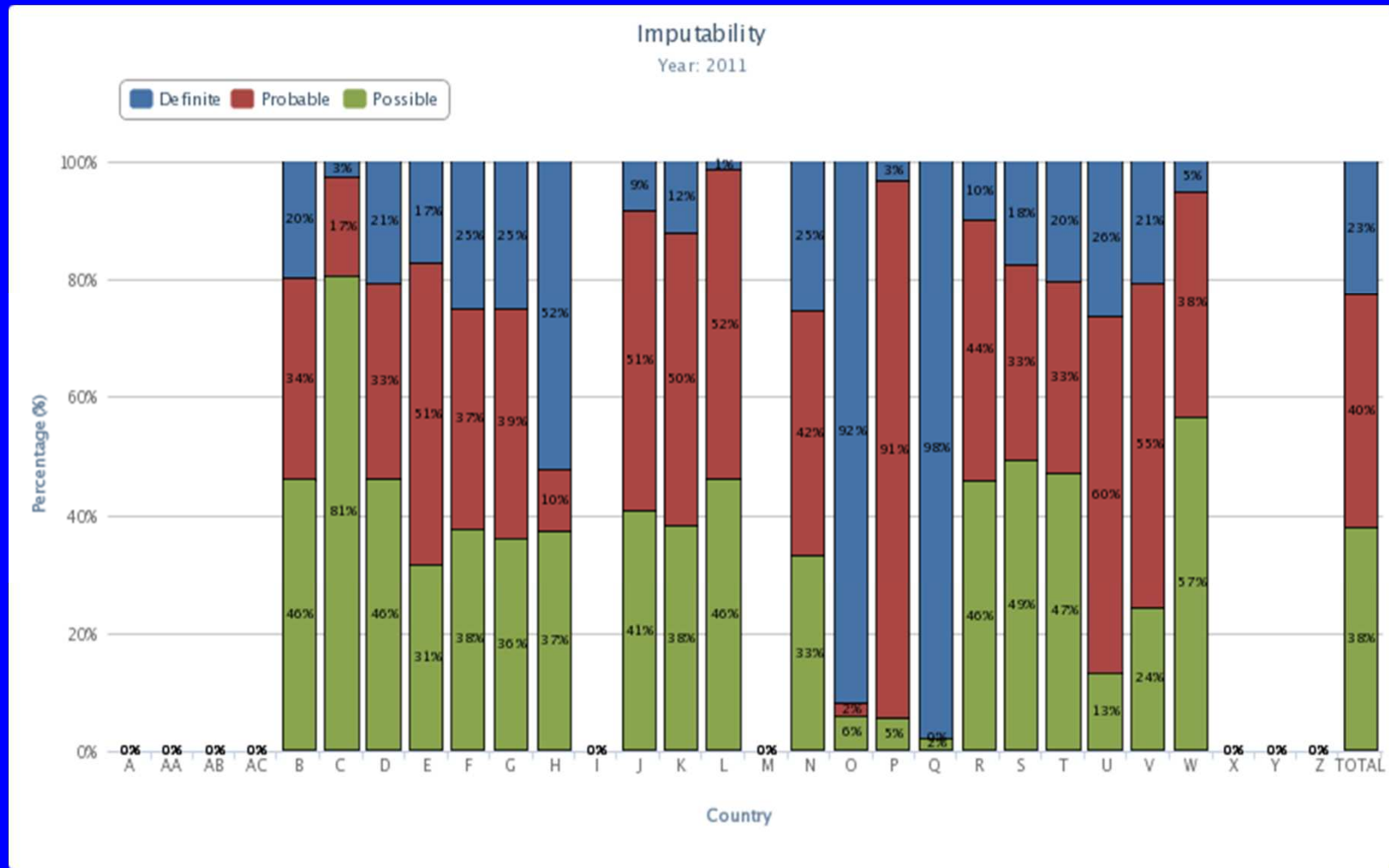


# AR by imputability (%)

## 2011 versus 2008

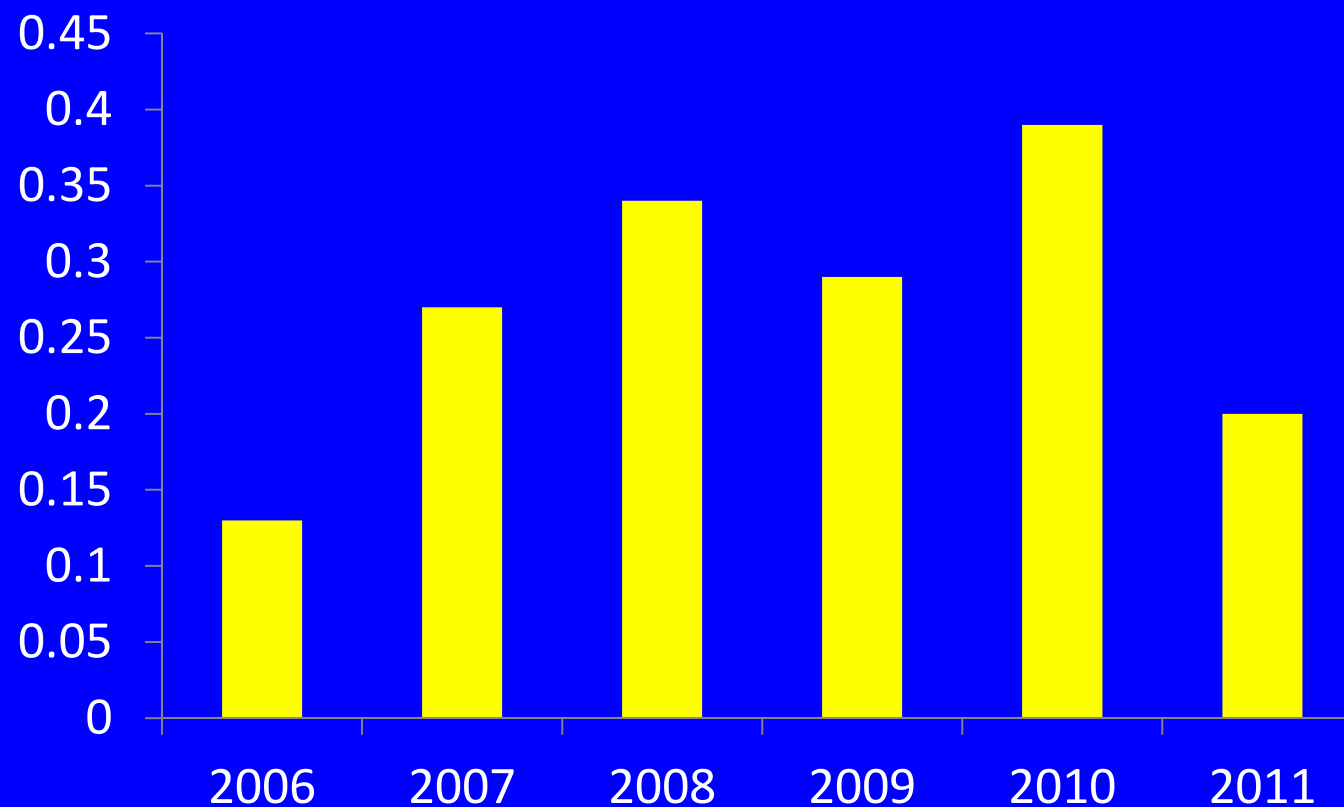


# AR by imputability, by country, 2011

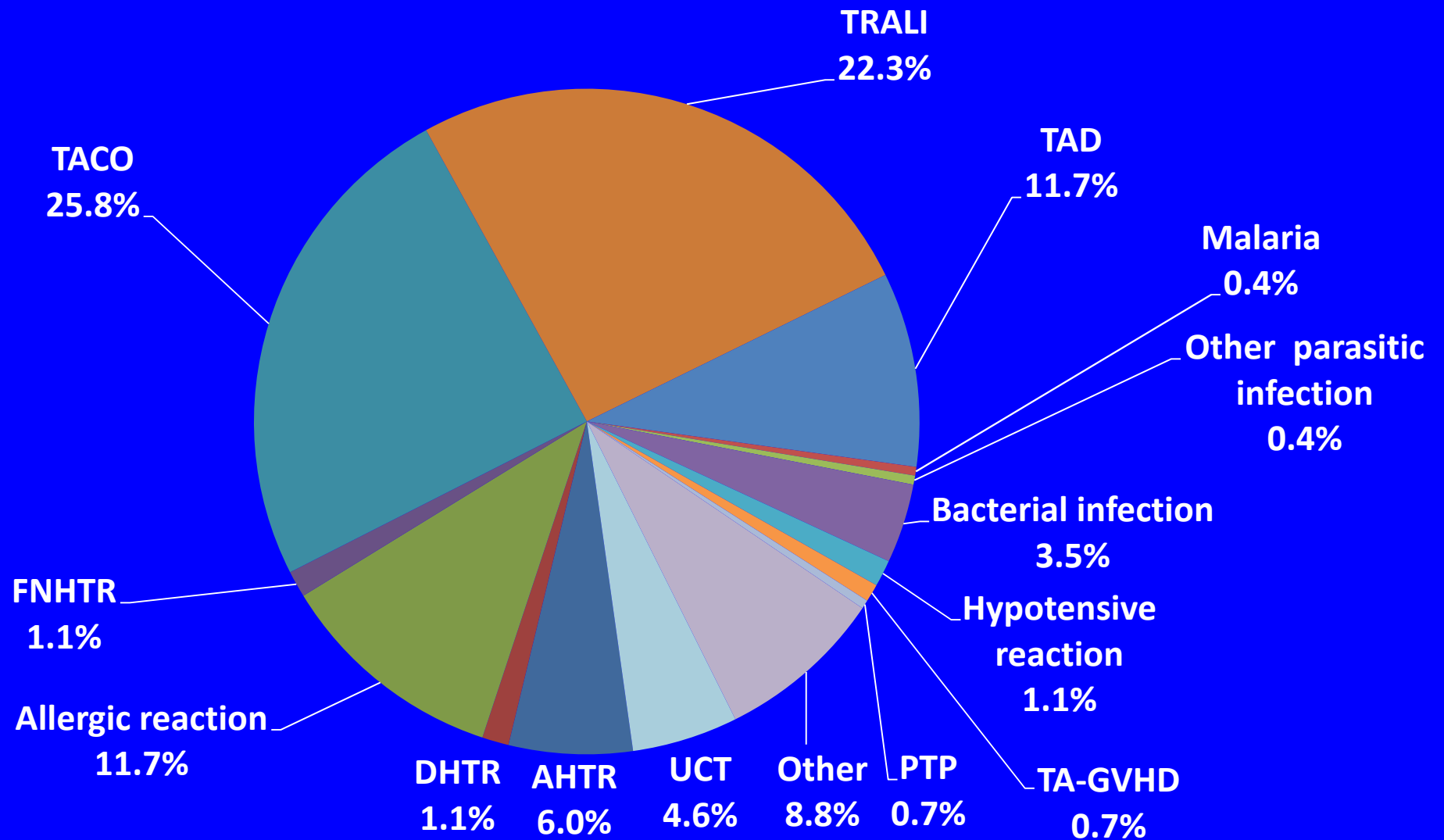


# Deaths per 100,000 in 2006-2011

(n=283)

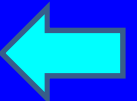


# Distribution of causes of death 2006-2011

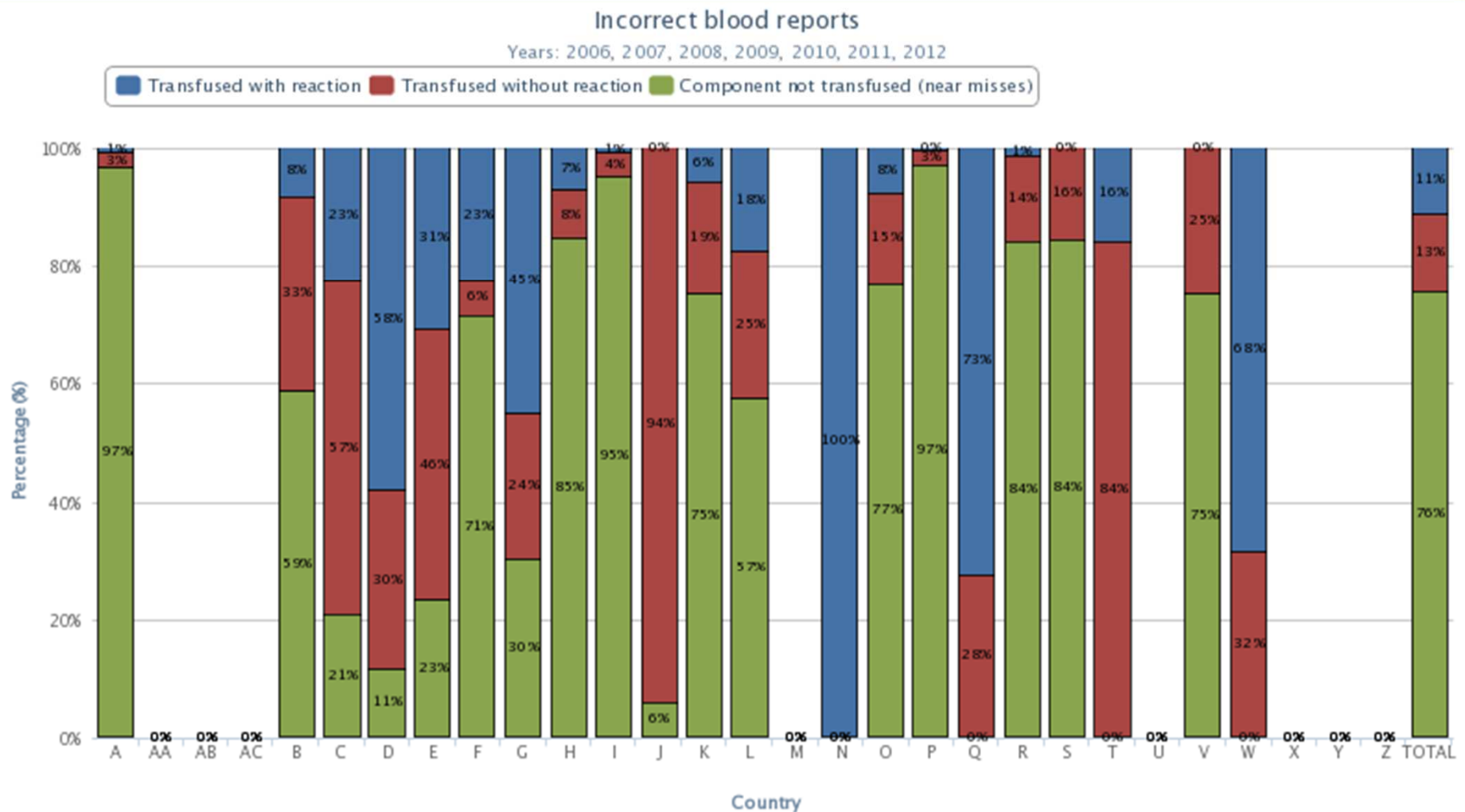


# Errors-IBCT, 2006-2011

Site of primary error	Transfused with reaction	Transfused without reaction	Component not transfused (near misses)	Total
<b>Blood unit</b>				
Wrong donor group label	12	22	33	67
Wrong recipient identification on unit	13	115	91	157
<b>Patient sample</b>				
Wrong name on tube (including wrong patient collected)	250	73	4,884	5,207
<b>Transfusion</b>				
ABO incompatible transfusion	251	163		414
Wrong patient but ABO compatible	136	382		518
Wrong product type (e.g.plasma for platelets)	90	111		201



# Incorrect blood reports, by country, 2006-2011 (% distribution)



## **Donor Complications**

**These data are provided by 17 countries**

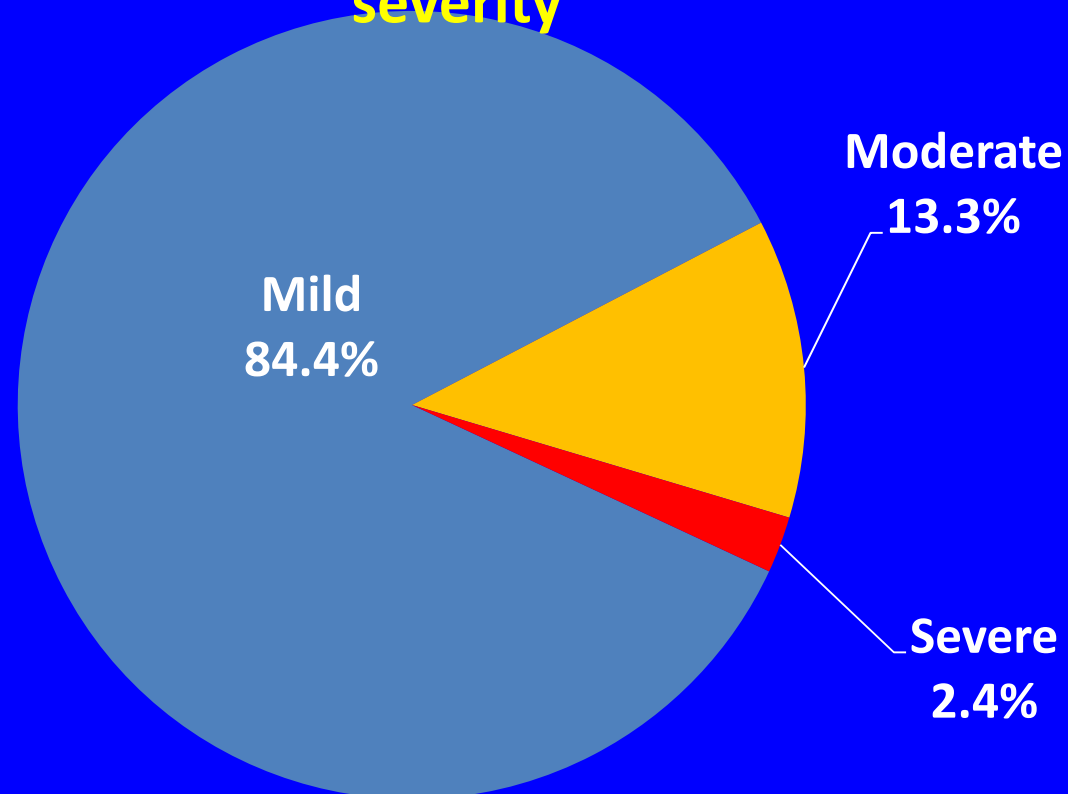


# Donor complications, 2006-2011 (n=364,384)

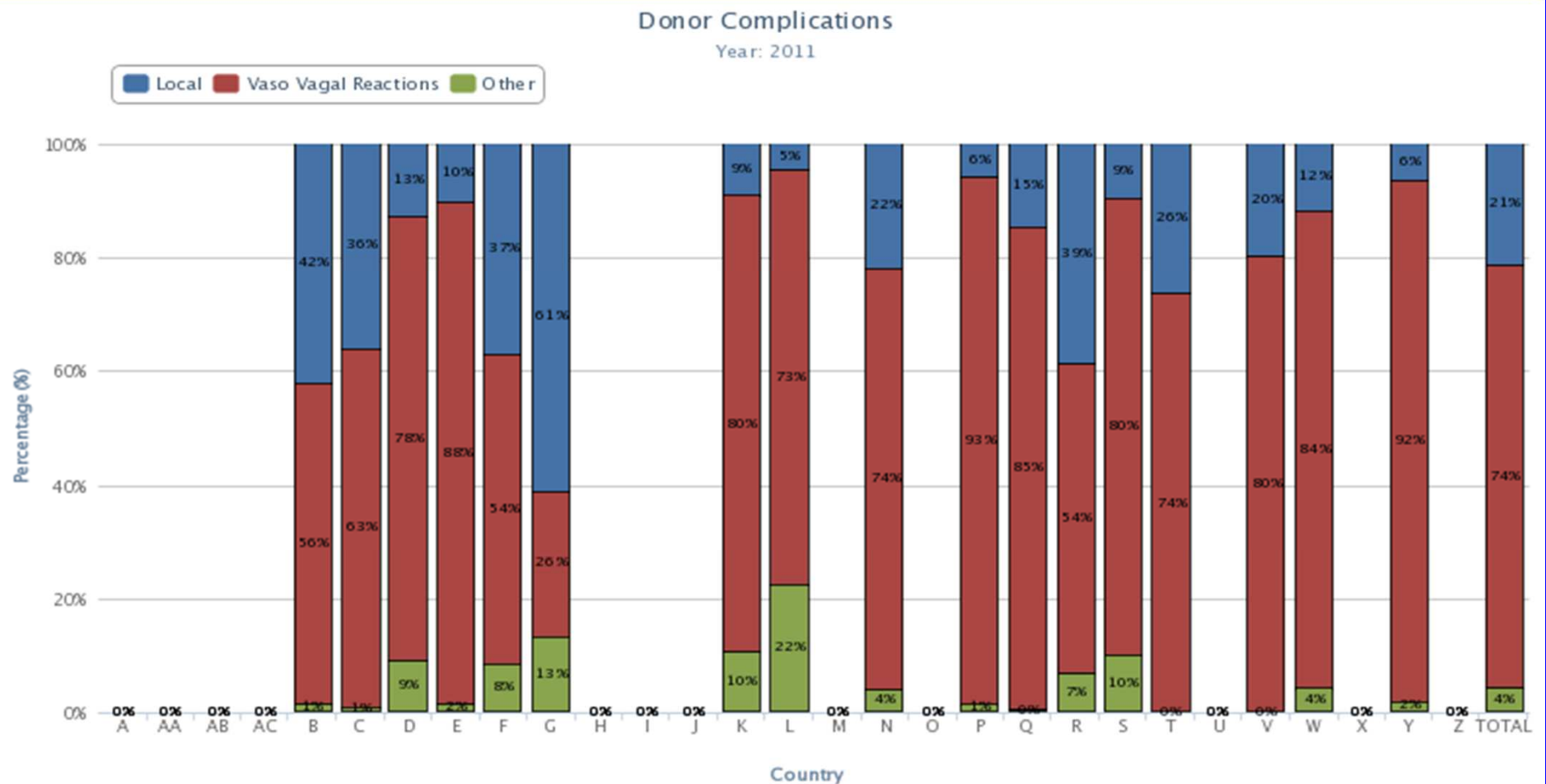
## Analysis by type

<u>Donor complications</u>	<u>%</u>
VV Reactions	75.8
Local	20.3
Citrate	1.3
Other	2.6
Total	100.0

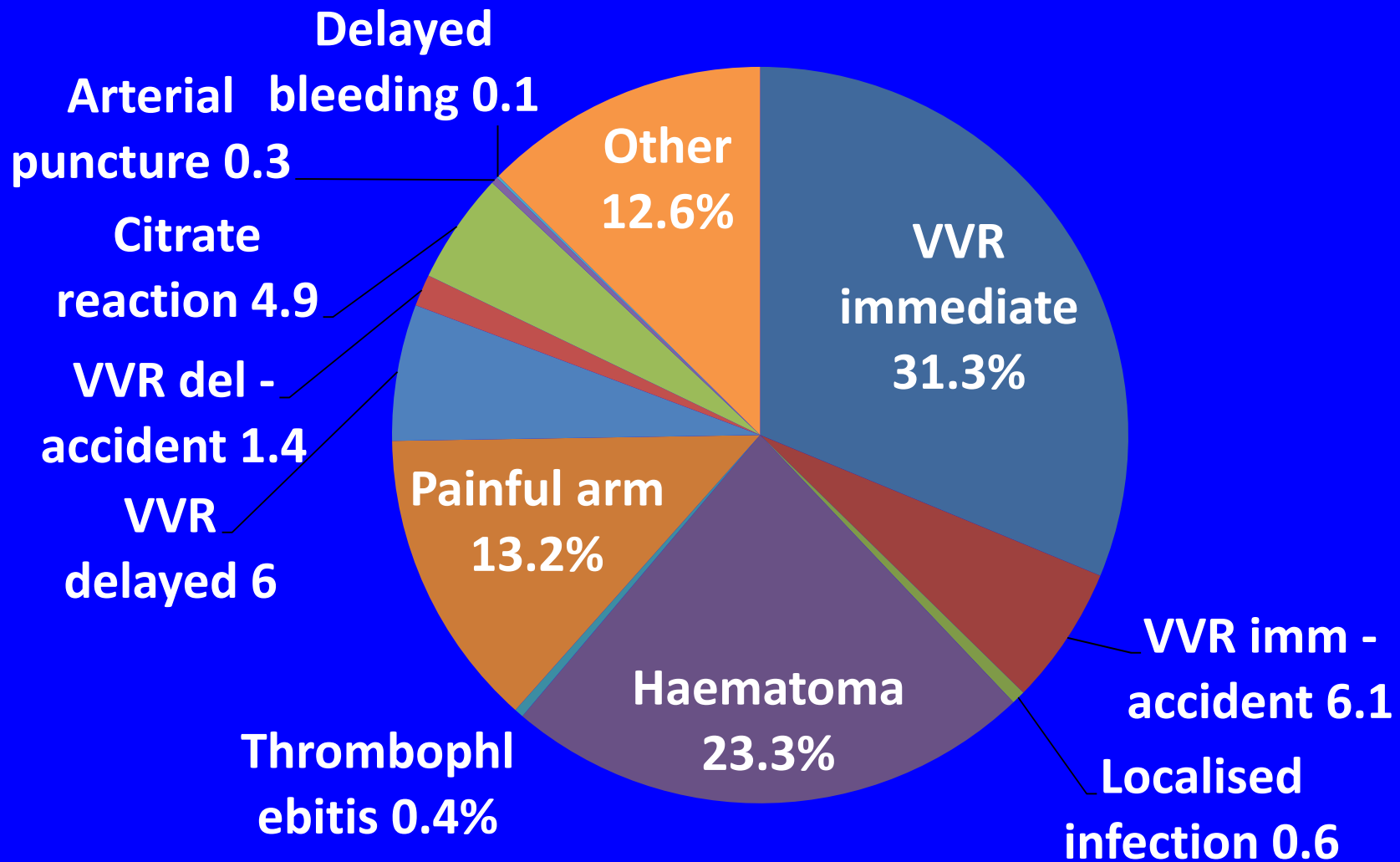
## Analysis by severity



# Donor complications by country, 2011



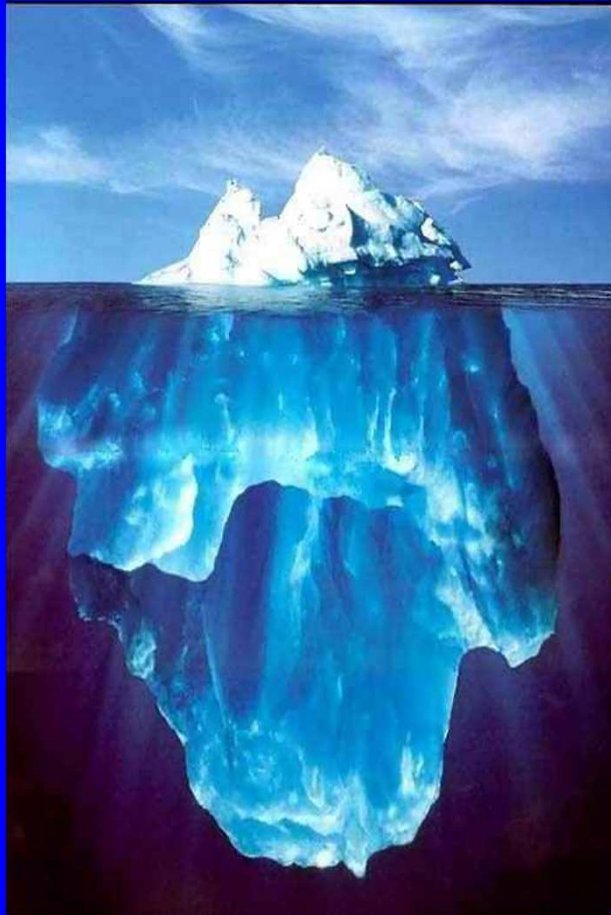
# Severe donor complications, 2011



# Conclusions



- The permanent web-based system enables the collection and analysis of annual data from any country that gathers detailed haemovigilance data
- It differs from EU and Council of Europe data collection systems in its **holistic approach**, aiming at the surveillance of **all** ARs and AEs, not just serious ones.
- Amongst other things, ISTARE will permit better assessment of trends
- Enhanced calculations capabilities are also planned
- **The ISTARE web-based system initiates new prospects for the future of haemovigilance**



**IHN promotes a holistic  
haemovigilance approach**

**The rationale of ISTARE**  
is to avoid restricting our  
observations to only the tip of the  
iceberg

i.e. not only serious events  
(unlike EU and Council of Europe)

- **Next steps**

- Technical maintenance and hosting
- Improvements and further development. Examples of possible developments:
  - Help facility
  - Improve reporting, according to user requests
  - Improve export of data
  - More charts
  - Transfusion – related iron overload
  - Self calculated totals

***Special thanks to all correspondents  
who provided comprehensive  
haemovigilance data  
for their countries or regions***

**And to**

**Jean-Claude Faber**

**Rene de Vries**

**Jan Jorgensen**

**IHN Secretariat**

**SKAE staff**

**Michael Sarantinos & Steficon SA**