

**The International Haemovigilance Network Database for the
Surveillance of Adverse Reactions and Events in Donors and
Recipients of Blood Components (ISTARE)
From the pilot phase to a web-based database**



The Working Group

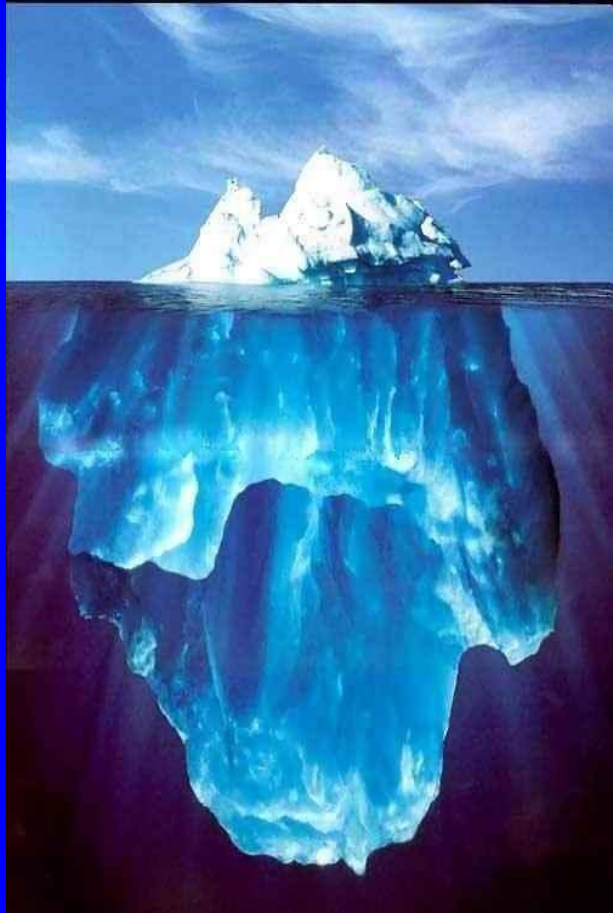
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P. Robillard, J. Wiersum

Background

Establishment of ISTARE: February 2008 by the EHN

Aim: The provision of an international tool for reporting and analyzing all adverse reactions (ARs) and events (AEs) associated with the donation and transfusion of blood components, irrespective of their severity



**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)

Purpose of the database

Information sharing

Surveillance,
monitoring

Analyzing data

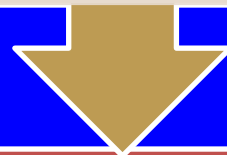


Potential uses

Benchmarking for
countries

Risk assessment

Education



Ultimate goal

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

**From the pilot phase
to a web-based database**

The chronicle

Frankfurt 2008	EHN	mandate for the pilot project
Macao 2008	ISBT	decides to collaborate
Rome 2009	EHN	presentation of results of 1st pilot
Dubrovnik 2010	IHN	results of 2nd pilot
Amsterdam 2011	IHN	results of 3rd pilot & start of fully functioning web-based system
Lisbon 2011	ISBT	development and finalization of the web based system
Montreal 2012	IHN	online ISTARE

The route to realization

After the successful completion of two pilot studies carried out in three rounds in 2006-2009, a permanent web-based international database was developed by the ISTARE Working Group and programmed by Steficon Ltd under contract to the IHN.

It was eventually uploaded to the IHN website in February 2012.

ISTARE is accessed through the IHN website: <http://www.ihn-org.com/haemovigilance-databases/istare-2>.

ISTARE Webpage on IHN Website

ISTARE : IHN - International Haemovigilance Network - Mozilla Firefox

Αρχείο Επεξεργασία Προβολή Ιστορικό Σελιδοδείκτες Εργαλεία Βοήθεια

IHN ISTARE : IHN - International Haemovigilanc...

www.ihn-org.com/haemovigilance-databases/istare-2/

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About ISTARE

Who can use ISTARE?

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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. Polltis (Greece) cpolltis@hol.gr skae@keelpno.gr

D. Rebiho (France) danielle.rebiho@efs.sante.fr

Latest News

IHN Haemovigilance Award

Nominations for 2012
Haemovigilance Award now
closed

[View more...](#)

IHS XIV Montreal 25th – 27th April 2012

Registration details and travel
fellowships

[View more...](#)

IHN Medal

Dr Jan Jorgenson

Submission of data

- Annual detailed haemovigilance data for 2010 were submitted **confidentially** online by countries using IHN/ISBT standard definitions
- **Detailed instructions for the use of ISTARÉ database** and further pages of information, including the roles of different categories of user, are provided online
- Submission of **re-evaluated data for 2006-2009**, previously provided for the pilot studies, was possible

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

Dissemination of data in anonymized form.

Each country's data marked in tables and diagrams by a code number allocated by the coordinators.

The country's code is known only to its representative.

What data?

- **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
- **Donor Complications:** events related to whole blood but also to apheresis donations
- **Errors-incorrect blood component transfused (IBCT):**
 - ✓ ABO incompatible transfusion
 - ✓ 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

Examples of screenshots

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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](#)

Donations*	
Collection type	Donations
Whole blood	614506
Aphaeresis	28646
Red cells	50
Platelets	23896
Plasma	2714
Multiple components	1986
Total	643152

 --> Are autologous donations included in the table? ☒ Yes ☐ No ☐ Unknown

 If yes include only the percentage of preoperative autologous donations: %

 --> For plasma please specify if this includes data on plasma going for fractionation. ☐ Yes ☒ No ☐ Unknown

 If yes enter the proportion going for fractionation: %

*Successful donations : units that met the specifications for processing

Blood components			
	Issued	Transfused	% Leuko-reduced
Whole blood	<input type="text"/>	<input type="text"/>	<input type="text"/>
RBC	442329	<input type="text"/>	<input type="text"/>
Platelet units for transfusion (adult dose)	133375	<input type="text"/>	<input type="text"/>
Plasma for transfusion (adult dose)	201909	<input type="text"/>	<input type="text"/>
Cryoprecipitate	<input type="text"/>	<input type="text"/>	<input type="text"/>
Granulocytes	<input type="text"/>	<input type="text"/>	<input type="text"/>
Others	<input type="text"/>	<input type="text"/>	<input type="text"/>
Total	777613	<input type="text"/>	

 Comments:



Logged in as **super**, [Logout](#)



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 ?									
Total number local symptoms ?	354	25	19	398	33	7		40	438
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 ?									
Total no. Vaso-Vagal Reactions ?	4235	837	31	5103					5103
Citrate reaction					129			129	129
Haemolysis									
Generalised allergic reaction	2			2					2
Air embolism									
Other	407	5	14	426					426
Total	4998	867	64	5929	162	7		169	6098

*Painful arm included tendon and nerve injury and irritation
VV R = vasovagal reaction



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International
Haemovigilance
Network

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

IBCT: Incorrect blood component transfused ?

Site of primary error	Transfused with reaction	Transfused without reaction	Component not transfused (near misses)
Blood unit			
Wrong donor group label	1		3
Wrong recipient identification on unit		2	
Patient sample			
Wrong name on tube (including wrong patient collected) ?	4		1
Transfusion			
ABO incompatible transfusion ?	5		
Wrong patient but ABO compatible			
Wrong product type (ex.: plasma vs platelets)			

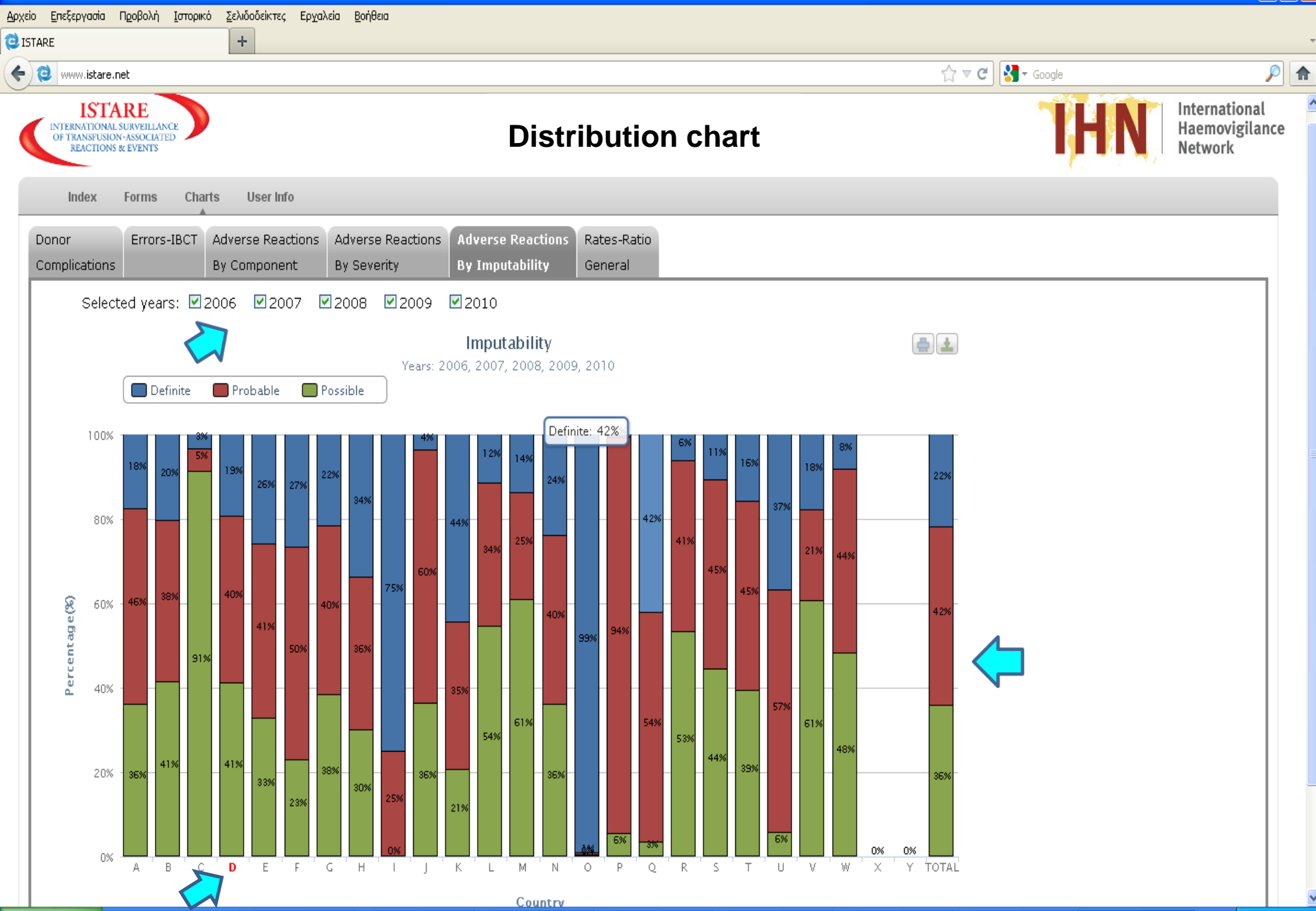
Comments:

ISTARE charts for national use

(annual/cumulative data)

ISTARE provides two main categories of charts that facilitate benchmarking

- **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





Rates & Ratio charts



Index Forms Charts User Info

Donor Complications Errors-IBCT Adverse Reactions By Component Adverse Reactions By Severity Adverse Reactions By Imputability Rates-Ratio General

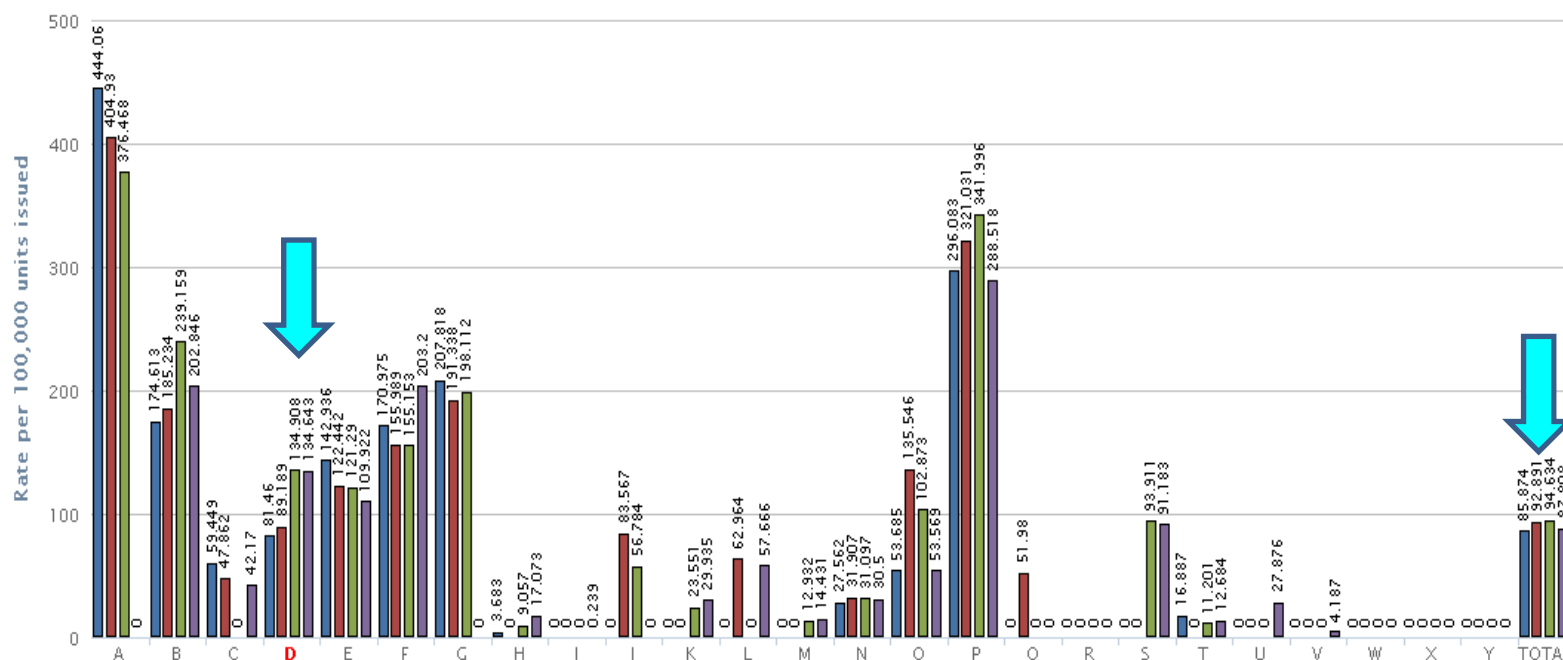
Selected years: ☐ 2006 ☒ 2007 ☒ 2008 ☒ 2009 ☒ 2010

Incidence of all adverse reactions by country

Years: 2007, 2008, 2009, 2010



2007 2008 2009 2010



Results

2006-2010

ISTARE database

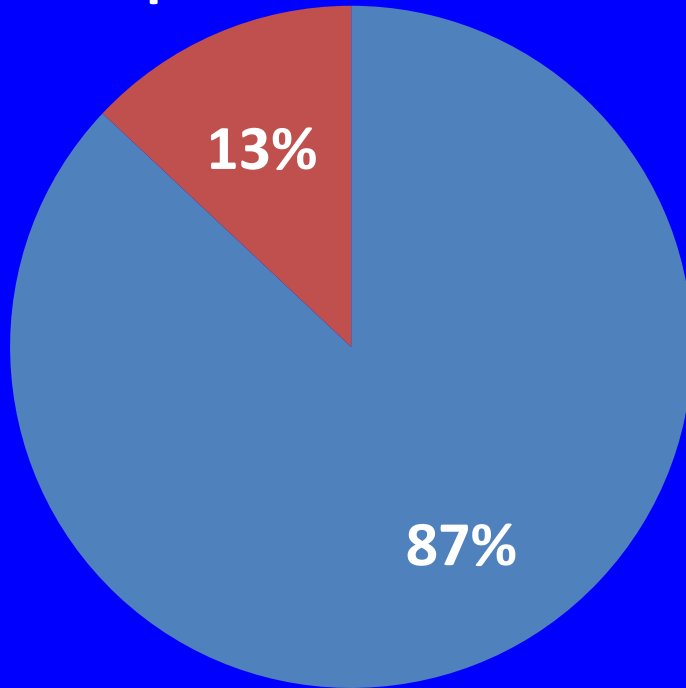
- Data have been collected in 4 rounds
- 2006 & 2007, 2008, 2009, 2010
- 25 countries have participated in at least one round
- 16 countries have participated at least 3 times
- 11 countries have participated 4 times
- Total reports 77

Participation in ISTARE

	Year	Total	Europe	Asia/Pacific	North America	Africa
1 st phase	2006	11	6/11	3/11	1/11	1/11
	2007	13	9/13	3/13	1/13	
2 nd phase	2008	16	11/16	3/16	1/16	1/16
	2009	17	11/16	4/16	1/16	1/16
Online ISTARE	2010	20	14/20	5/20	1/20	
Total reports		77	51	18	5	3
Total countries		25	17	5	2	1

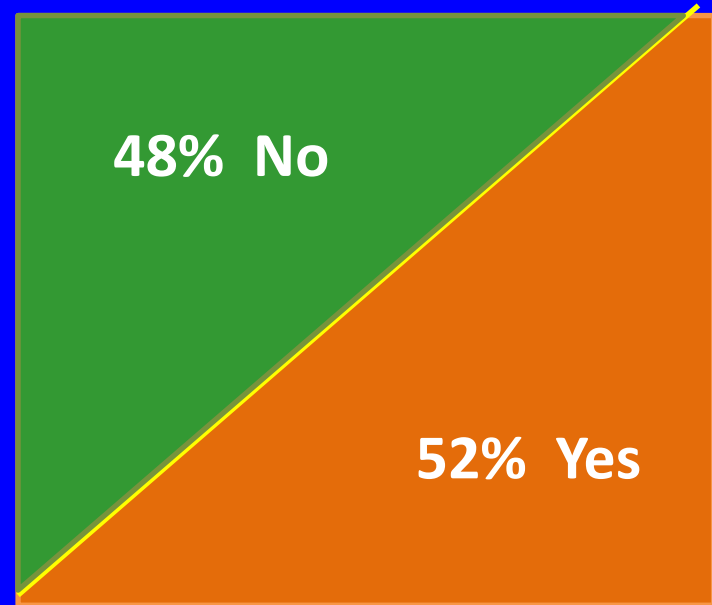
Haemovigilance coverage

Incomplete HV data



Complete HV

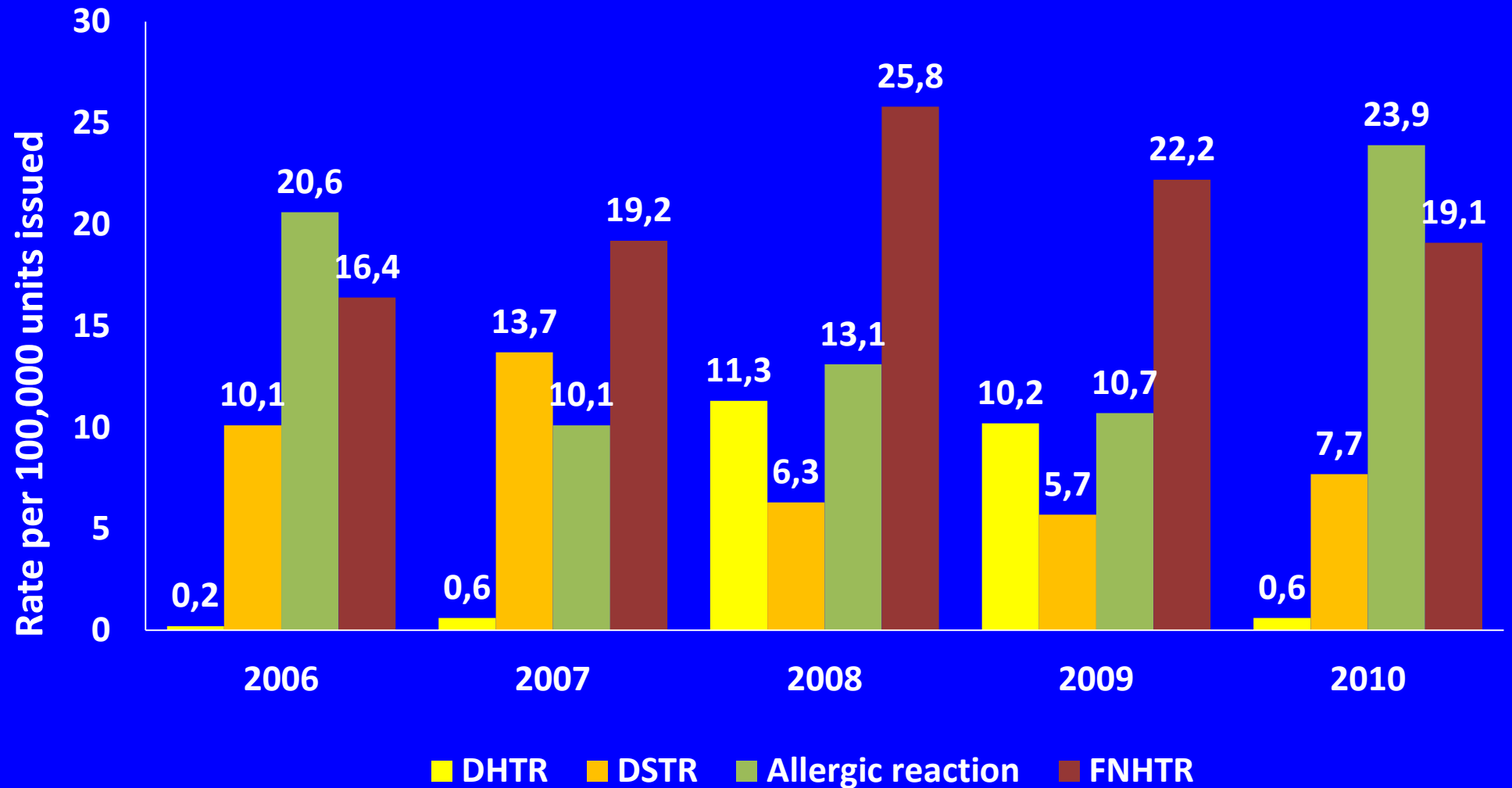
Vigilance for
materials/reagents



Volume of data, 2006-2010

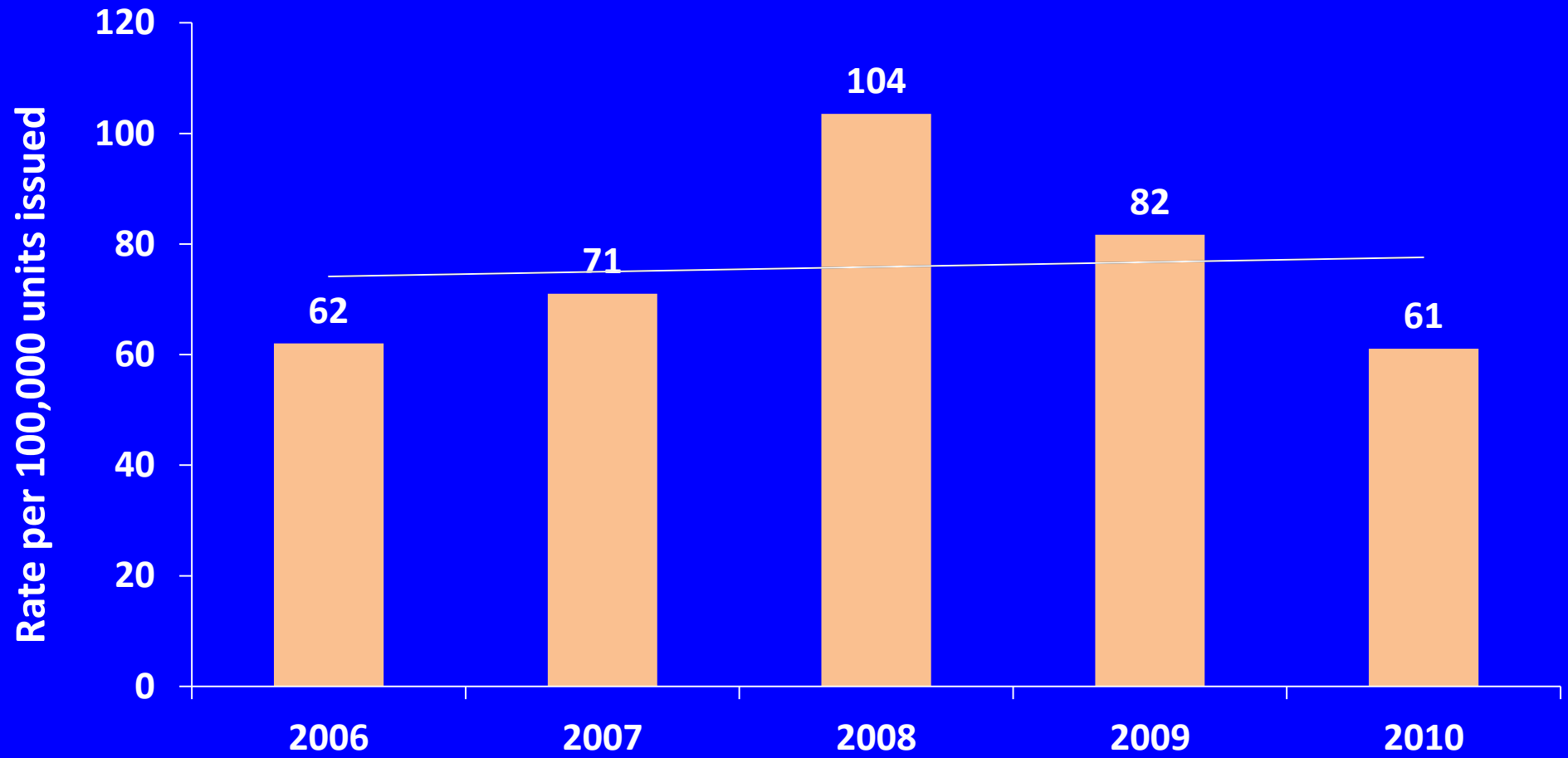
Data	n
Units issued	84,120,836
Units transfused	19,980,404
Total ARs	62,262
<i>Incidence per 100,000 units issued</i>	<i>74</i>
Deaths	233
<i>Incidence per 100,000 units issued</i>	<i>0.28</i>
Total donor complications	242,889

Most frequent ARs, 2006-2010



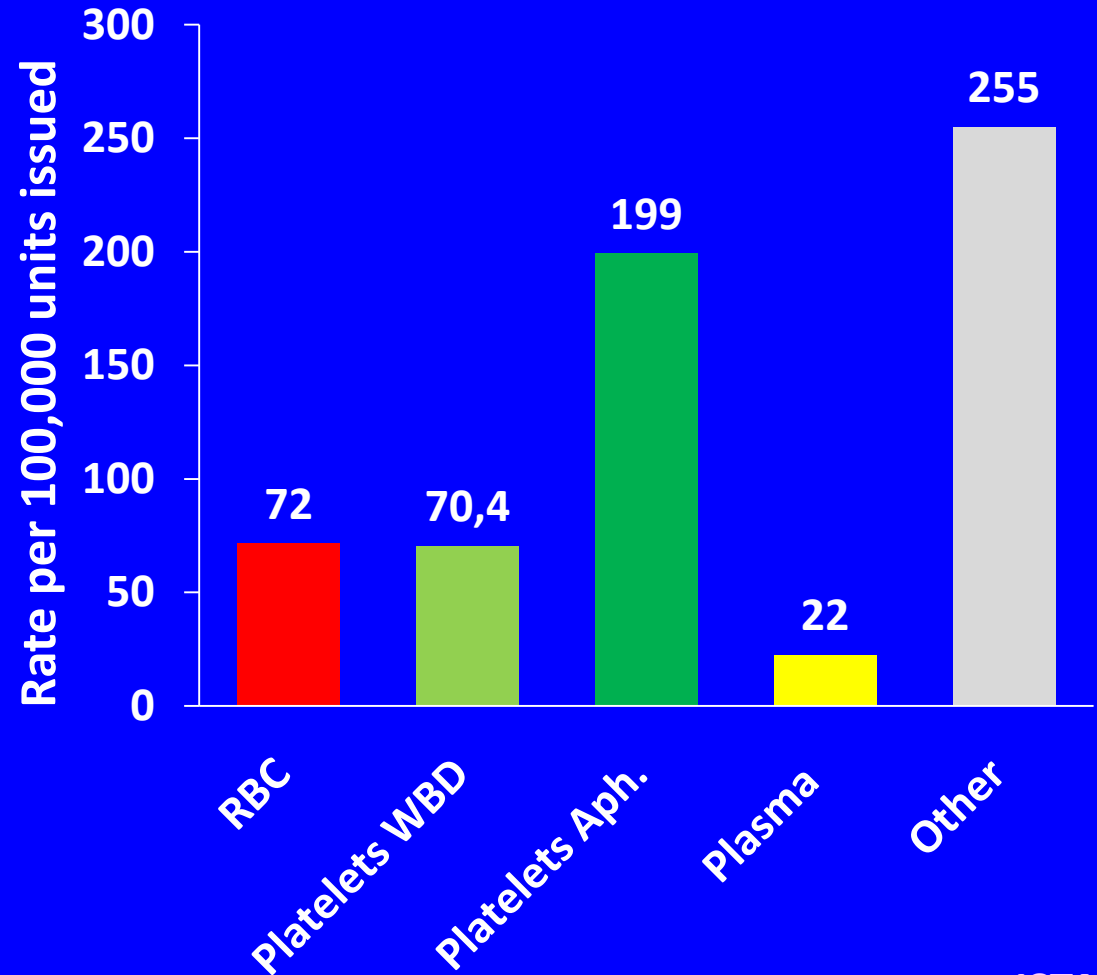
Reporting ARs by imputability

2006-2010



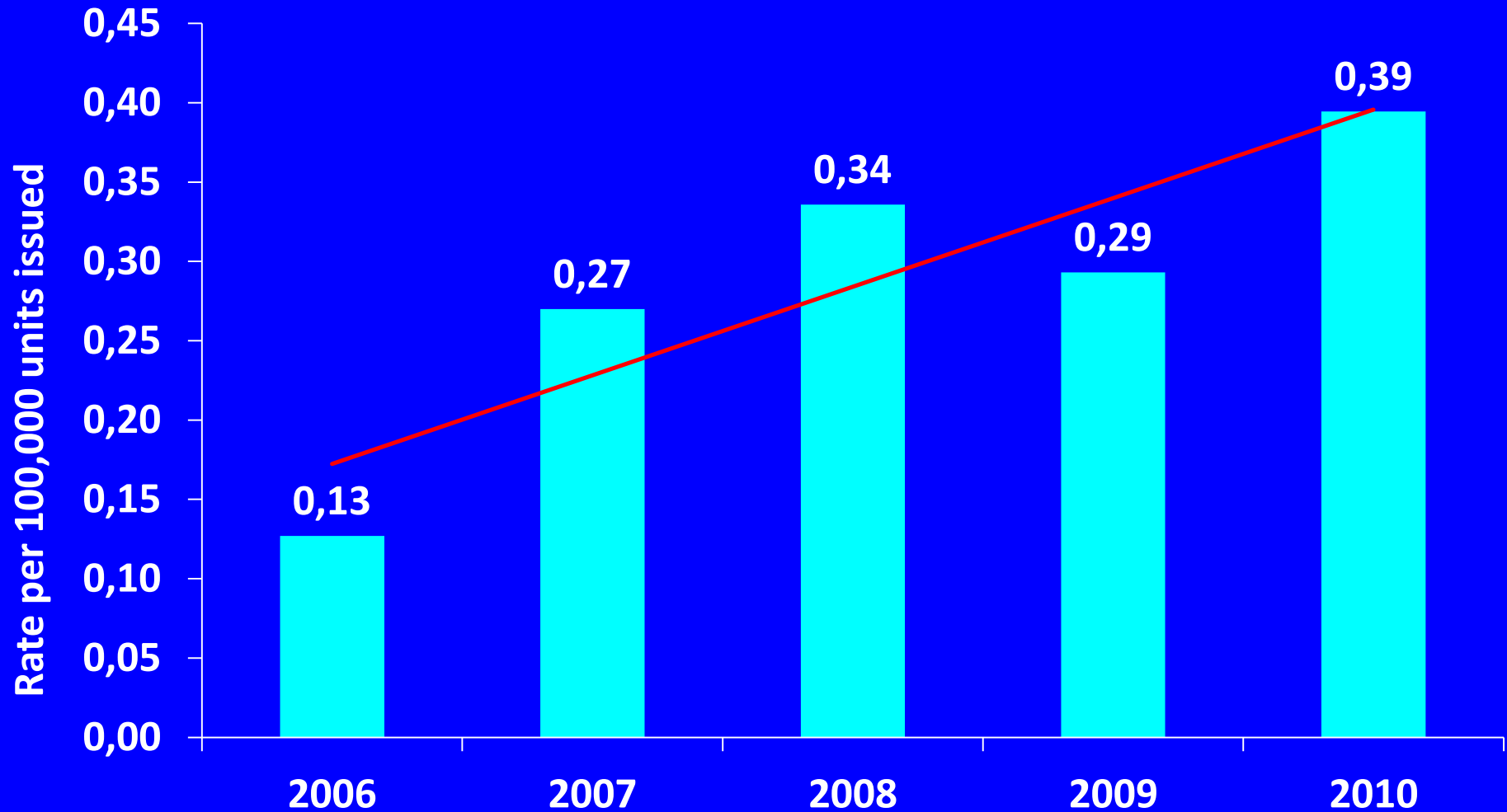
ARs by blood component, 2006-2010

Blood component	Incidence per 100,000
RBC	72
Platelets WBD	70
Platelets Aphaeresis	199
Plasma	22
Other	255

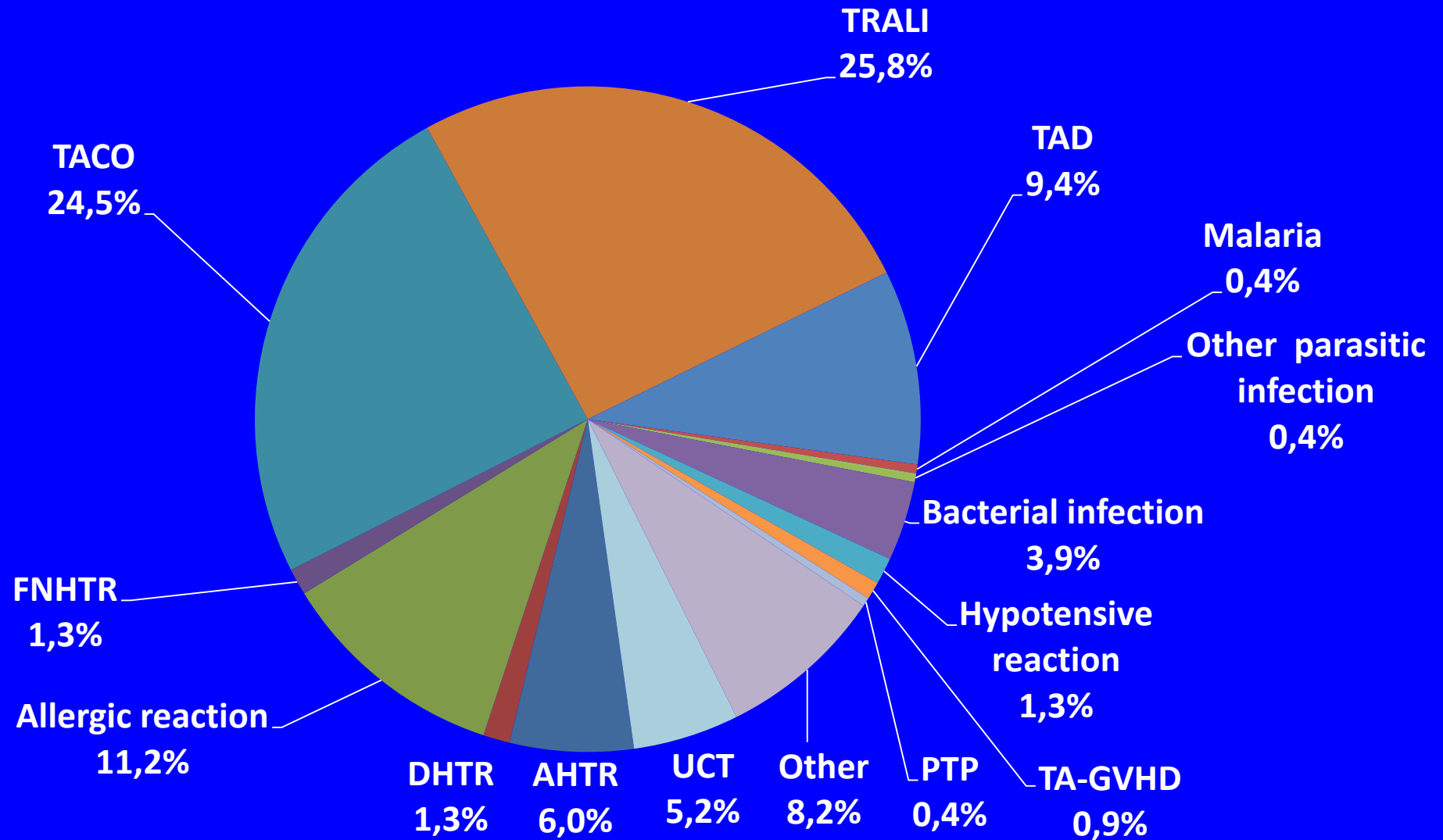


Deaths, 2006-2010

(n=233)



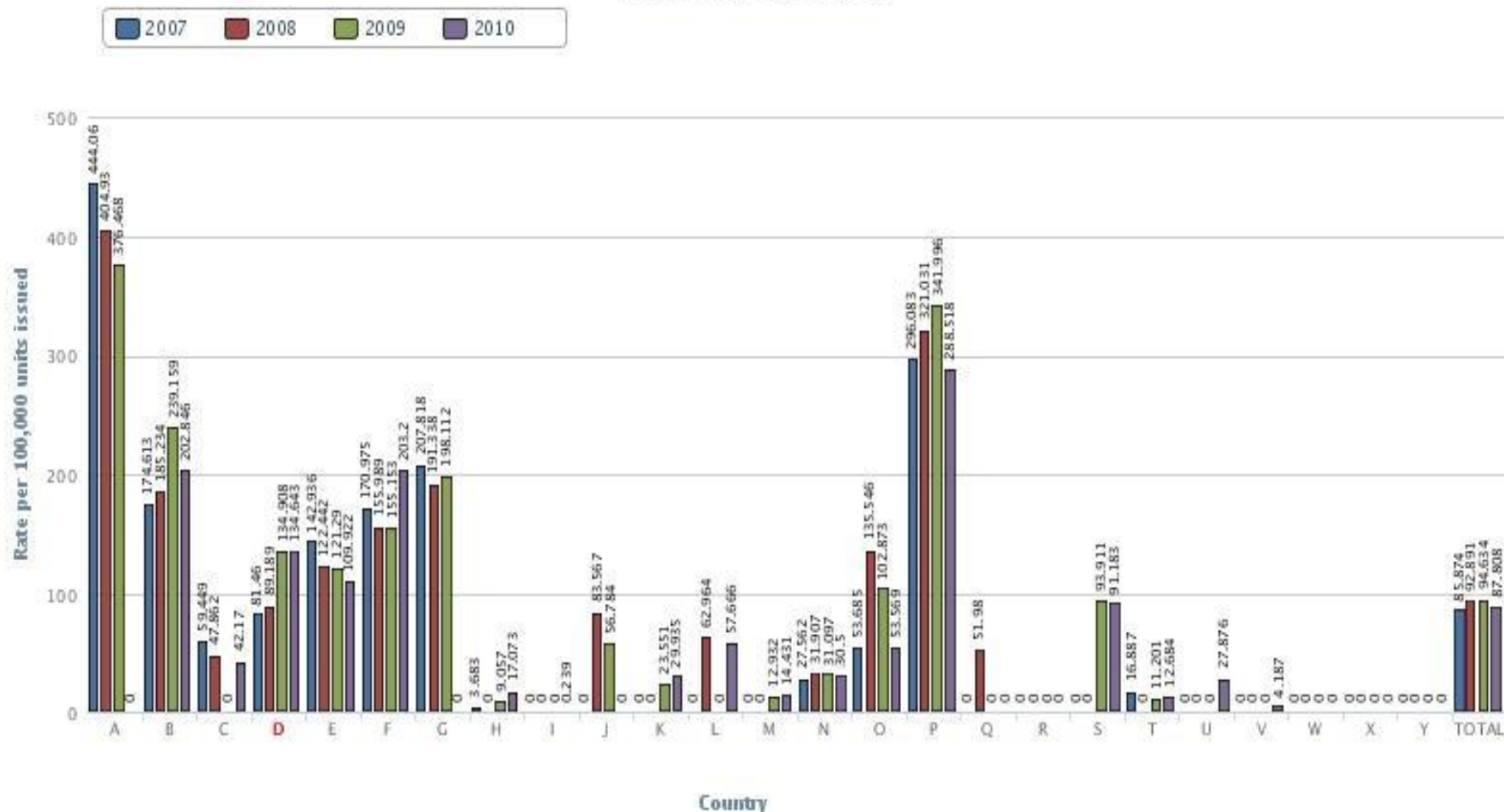
Distribution of causes of death 2006-2010



Incidence of all adverse reactions 2007-2010

Incidence of all adverse reactions by country

Years: 2007, 2008, 2009, 2010



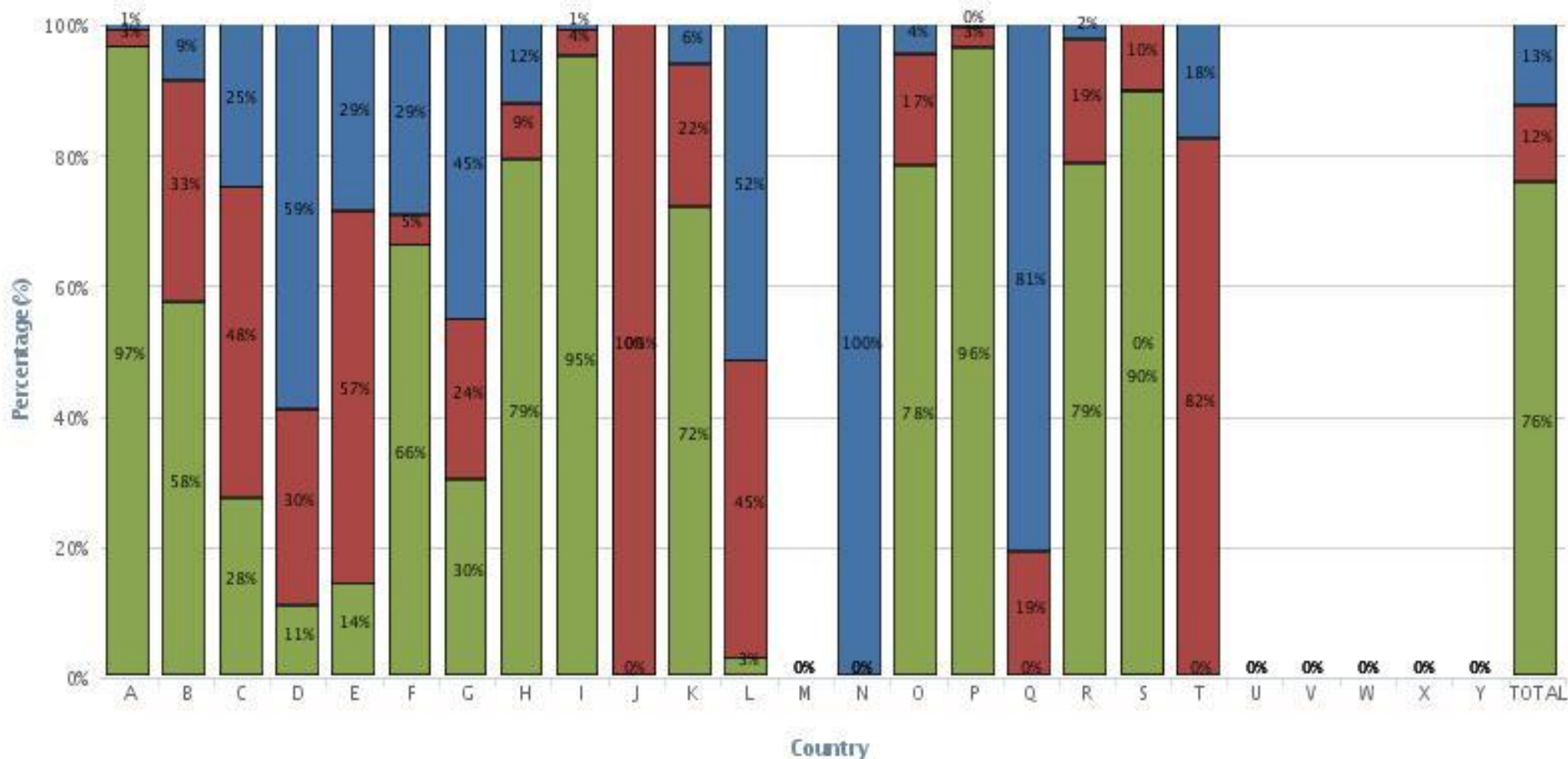
Errors-IBCT, 2006-2010

Site of primary error	Transfused with reaction	Transfused without reaction	Component not transfused (near misses)	Total
Blood unit				
Wrong donor group label	11	17	20	48
Wrong recipient identification on unit	12	83	62	157
Patient sample				
Wrong name on tube (including wrong patient collected)	240	55	3,920	4,215
Transfusion				
ABO incompatible transfusion	197	122		319
Wrong patient but ABO compatible	120	257		377
Wrong product type (e.g.plasma for platelets)	82	87		169

Incorrect blood reports

Years: 2006, 2007, 2008, 2009, 2010

Transfused with reaction Transfused without reaction Component not transfused (near misses)



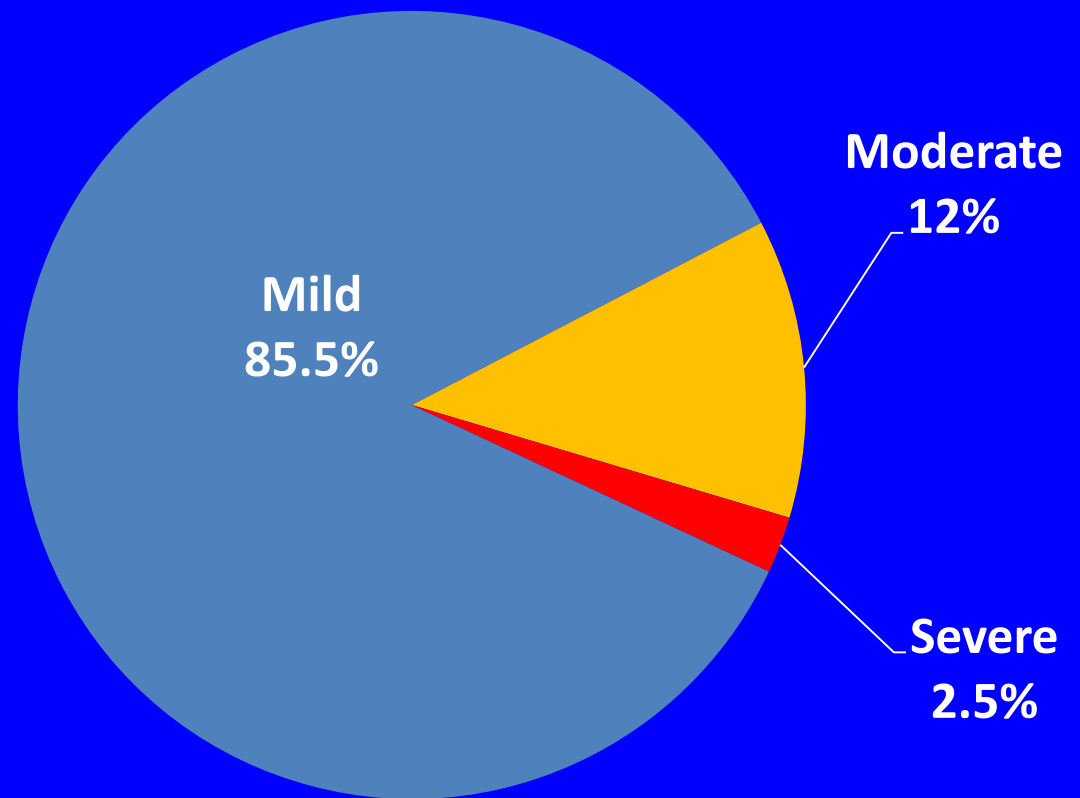
Donor Complications

Donor complications, 2006-2010 (n=242,889)

Analysis by type

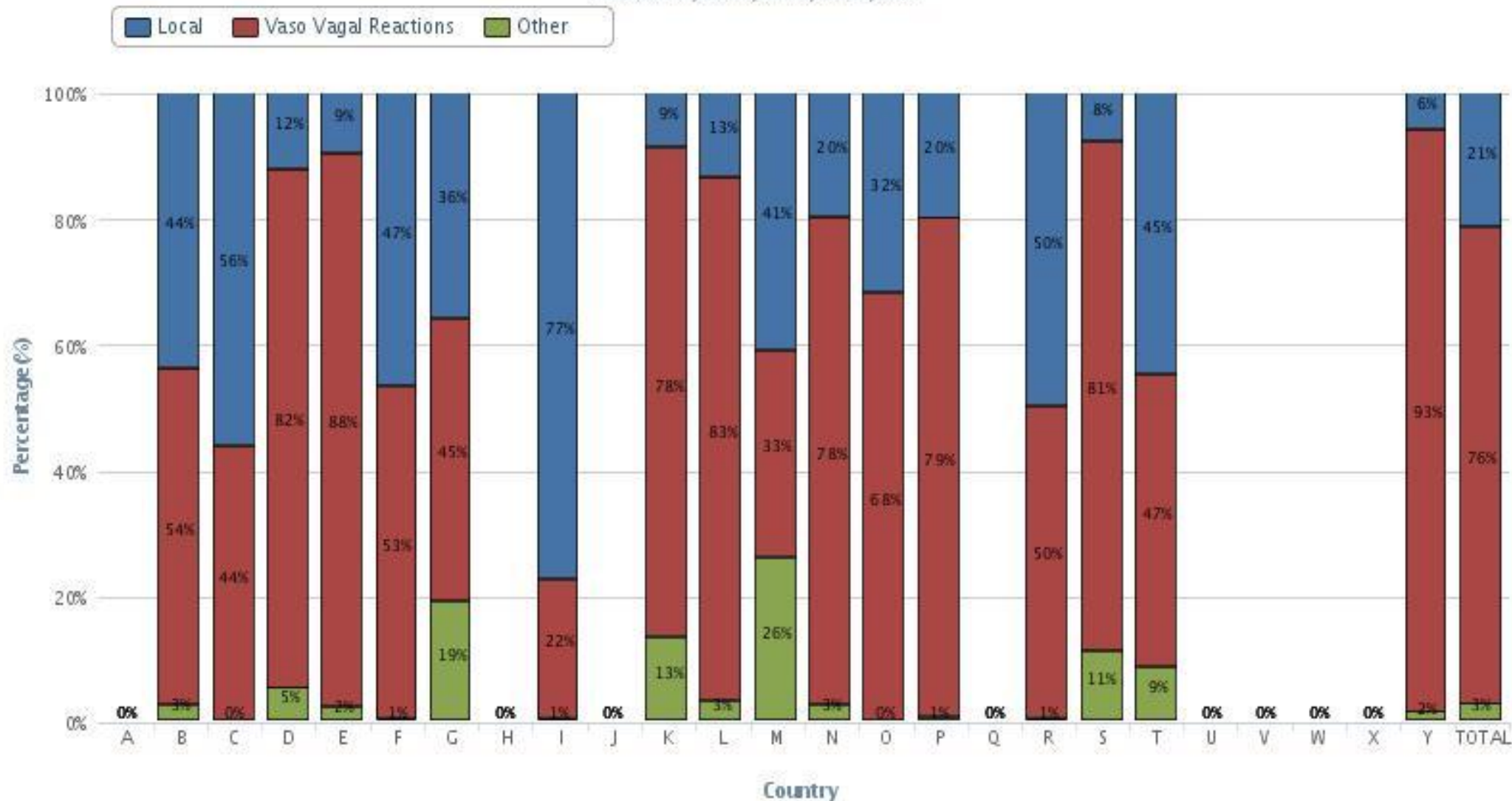
Donor complications	%
VV Reactions	75.9
Local	20.3
Citrate	1.2
Other	2.6
Total	100.0

Analysis by severity

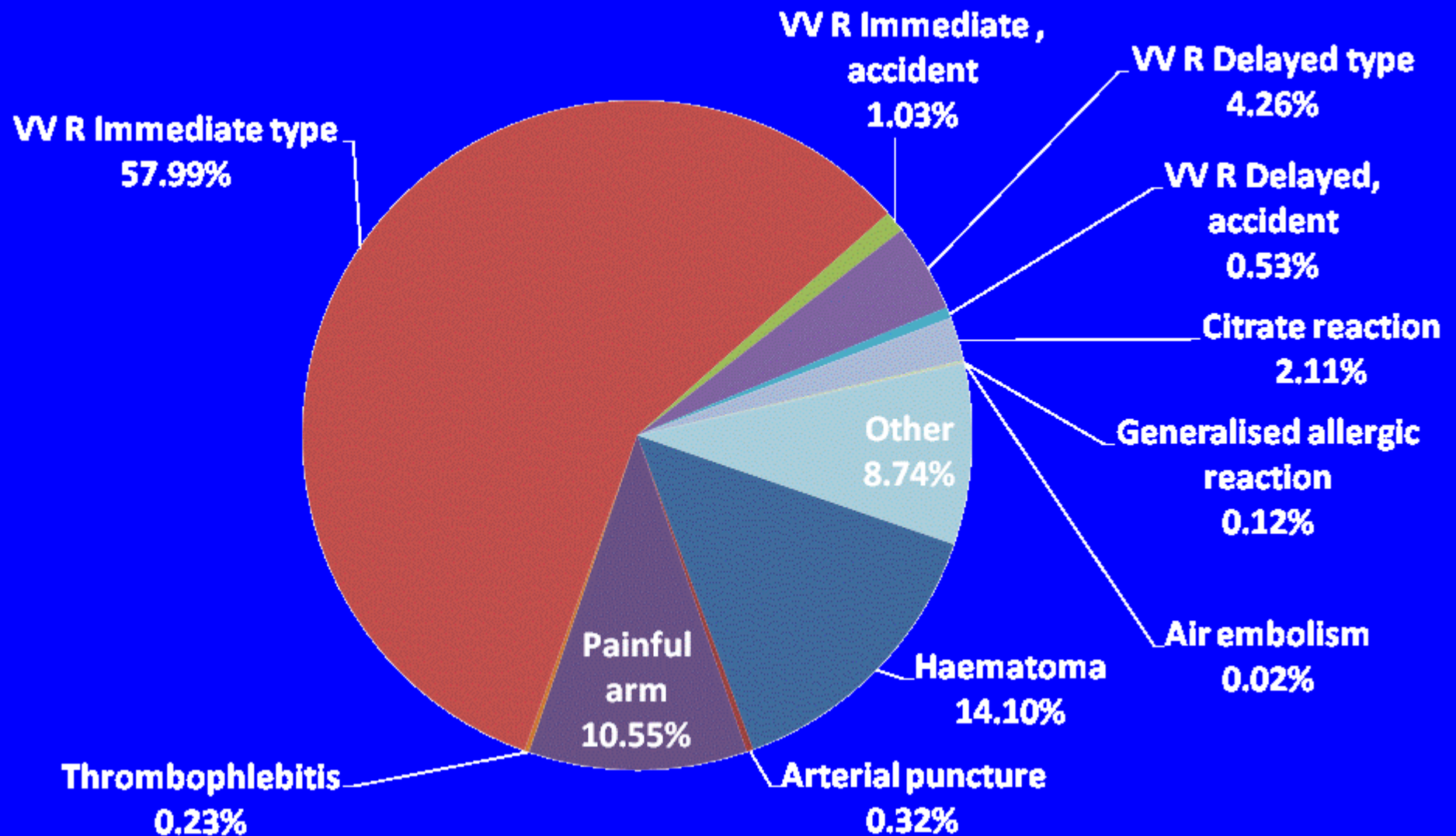


Donor Complications

Years: 2006, 2007, 2008, 2009, 2010



Severe donor complications, 2006-2010



Conclusions



- The pilot studies demonstrated the feasibility and value of the IHN database which is now operational
- A 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
- ISTARE web-based system initiates new prospects for the future of haemovigilance



Next steps

- New participants to submit previous years' data (2006-2009) (if available)
- Final submission of users' haemovigilance data (2010)
- Receiving feedback from ISTARE users
- Adding more information in IHN website about ISTARE (publications, articles, presentation, FAQs etc)
- Investigate possible extension of ISTARE application
 - Adding new graphs
 - Adding new tables or categories
- Need for more in-depth analysis of ISTARE data
 - Continuous update of ISTARE in order to meet forthcoming haemovigilance challenges

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

Compliments to

**Jan Jorgensen
Rene de Vries
IHN Secretariat
IHN President
SKAE staff
Steficon SA**