

STARE

The International Haemovigilance Network Database

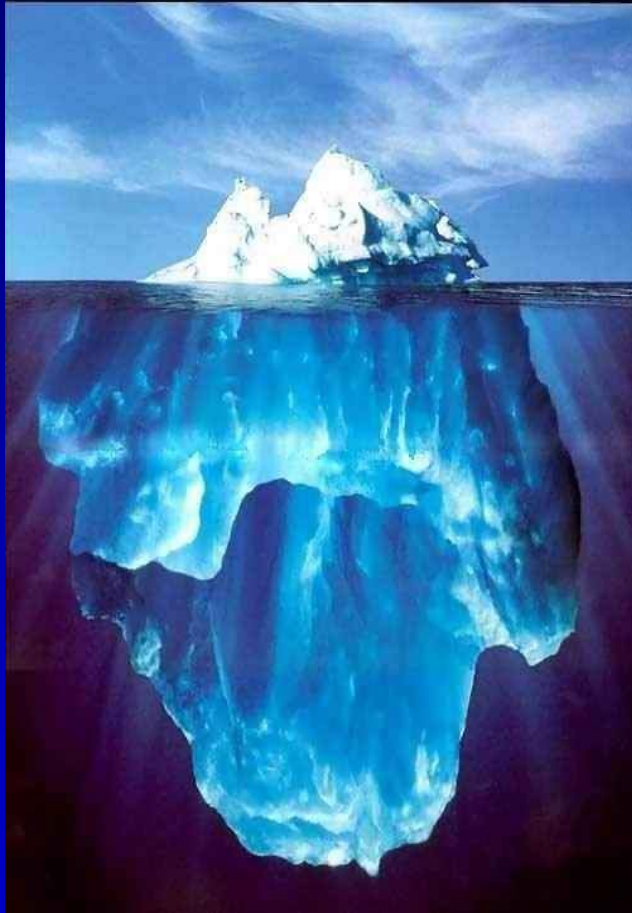
Second pilot phase



The Working Group

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**IHN promotes a holistic
haemovigilance approach**

The rationale of STARE
is to avoid restricting our observations to
only the tip of the ICEBERG

i.e. not only serious events
(like EU or Council of Europe)

Surveillance of Adverse Reactions/Events (STARE) associated with Blood Donation and Transfusion and of Medical Devices and Traceability

An Initiative for the Construction of an International Database

- **Frankfurt, Feb. 2008** EHN Mandate for the pilot project
- **Macao, June 2008** ISBT Working Group on Haemovigilance
decides to collaborate in a pilot study
- **Rome, Feb. 2009** EHN – presentation of results of 1st pilot

*Go-ahead given for a 2nd pilot to involve
a larger number of countries with different
haemovigilance systems using an improved
data collection tool*

Purpose of Database



Potential Uses

- Benchmarking for countries
- Risk assessment

Data analysis and dissemination

Main areas to be covered

- **Event rates per 100,000 overall and by product type**
- **Type of reaction and 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 will be marked in tables and diagrams by a code number allocated by the coordinators

The country's code will be known only to its representative

STARE Pilot Studies

- 2006
 - 10 countries
 - 1 region
 - Europe, Asia - Pacific,
North America
- 2007
 - 12 countries
 - 1 region
 - Europe, Asia - Pacific,
North America

- 2008
 - 15 countries
 - 1 region
 - Europe (69%),
Asia – Pacific, (18.5%)
North America (6.25%)
Africa (6.25%)

*We thank all participants for
their prompt and extensive
cooperation*

What data?

- **General information**
 - On the country's **haemovigilance** system and coverage
 - Reporting system of transfusion **medical devices/ reagents**
 - **Traceability**: % of issued blood component units with confirmed final disposition and **if this is based on data**
- **Denominators general for donors/ donations** and large categories of denominators data for products
- **Denominators specific for products**, for those who are able to provide this information
- **Adverse events in donors** with a definite, likely or possible relation to donation of whole blood or to aphaeresis
- **Errors – IBCT**
- **Adverse reactions in patients** that are possibly, probably or definitely associated with transfusion

Changes from the first pilot study

The spreadsheet has been amended slightly to improve validity of data

General simplification and clarification

Omission of some questions/ categories which we could not interpret:

- Near-miss events and uneventful transfusion errors
- Testing errors are excluded at present

Clarifications

- ABO incompatible transfusion

(all product type, irrespective of where the first error arose)

Sampling errors

(all events where the label on the tube is not the name of the patient whose blood is in the tube)

- Wrong label distinguishing blood service errors from errors in recipient name on the compatibility label

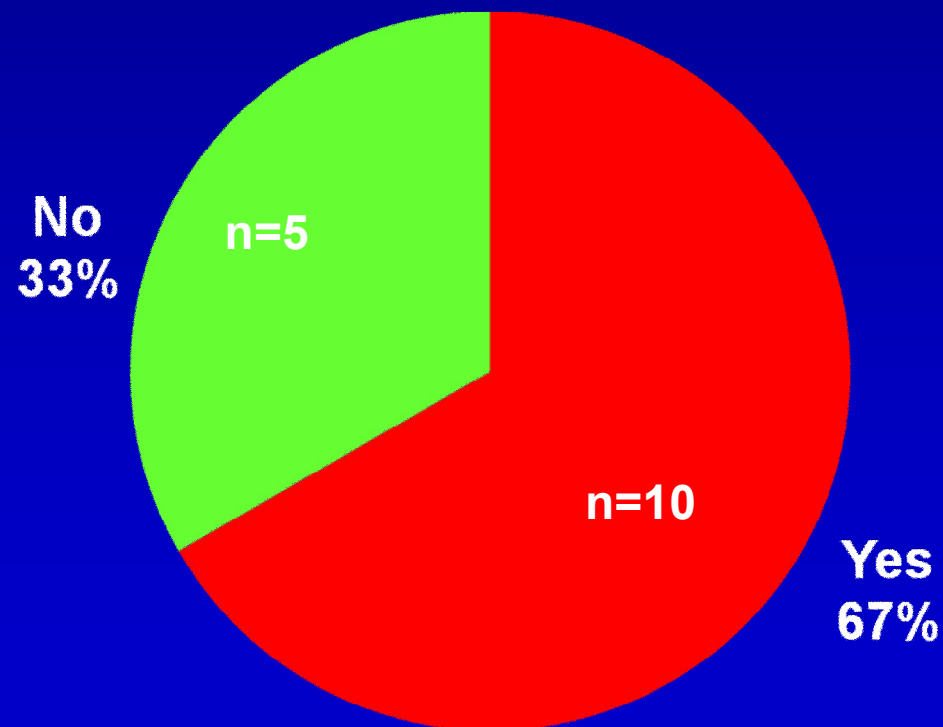
Results

General information, 2008

- **All participating countries have a national haemovigilance scheme**
- **In terms of total blood supply:**
 - **10/16 have 100% coverage and one >99%**
 - **2 more are around 90% coverage**
 - **3 are in the range 76-85%**

Medical devices and reagents, 2008

Is there a system for reporting on transfusion medical devices or reagent problems?



Traceability

1st Phase (n=9/13) in 2007

Coverage: most countries replied “100%”

We were not sure if this was genuinely the case, or if it just meant that in principle all blood was traceable

2nd Phase (n=12/16) in 2008

Issued blood component units with **confirmed final disposition**

n	%
5	100
2	99
1	98
4	<90

- *Based on return of bags/ of something else (forms) 5 (42%)*
- *Cited other data sources 5 (42%)*

Denominators general – Donations, 2008

Collection type	Donations
Whole blood	634.411
Apheresis	25.175
Red cells	1.540
Platelets	18.479
Plasma	3.143
Multiple components	2.013
Total	659.586

We asked if **autologous donations** were included. 6 countries said yes, but <1% of total.

We also asked if **plasma for fractionation** was included (and how much).

Denominators General, 2008

Blood components

Blood components			
	Issued	Transfused	% Leuko-reduced
Whole blood	4.067		
RBC	192.746	193.516	9.9%
Platelet units for transfusion (adult dose)	31.788	30.417	
Plasma for transfusion (adult dose)	57.330	55.416	
Cryoprecipitate	3.889		
Granulocytes	856		
Others	0		
Total	290.676	279.349	

15/16 (94%) countries reported the blood components **issued**
 8/16 (50%) reported the number **transfused**

Denominators specific, 2008

Product	Issued	Transfused
Whole blood	186	
RBC	622.829	
Plasma- Aphaeresis	3.102	0
Standard	2.232	
Pathogen inactivated	870	
Plasma- WBD	28.866	0
Standard		
Pathogen inactivated	28.866	
SD plasma units for transfusion		
Cryoprecipitate supernatant		
Cryoprecipitate		
Platelets WBD	118.874	0
PRP*	115.162	
PRP/5	23.032	0
BC	3.712	
Pathogen inactivated		
Platelets- Aphaeresis	17.059	0
Standard	17.059	
Pathogen inactivated		
Granulocytes		
Others		
Total	790.916	0
Number of patients transfused (if known)		

**14/16 (87.5%) countries
provided this information**

**Only 2 (12.5%) supplied the
number of patients
transfused**

Donor adverse events, 2008

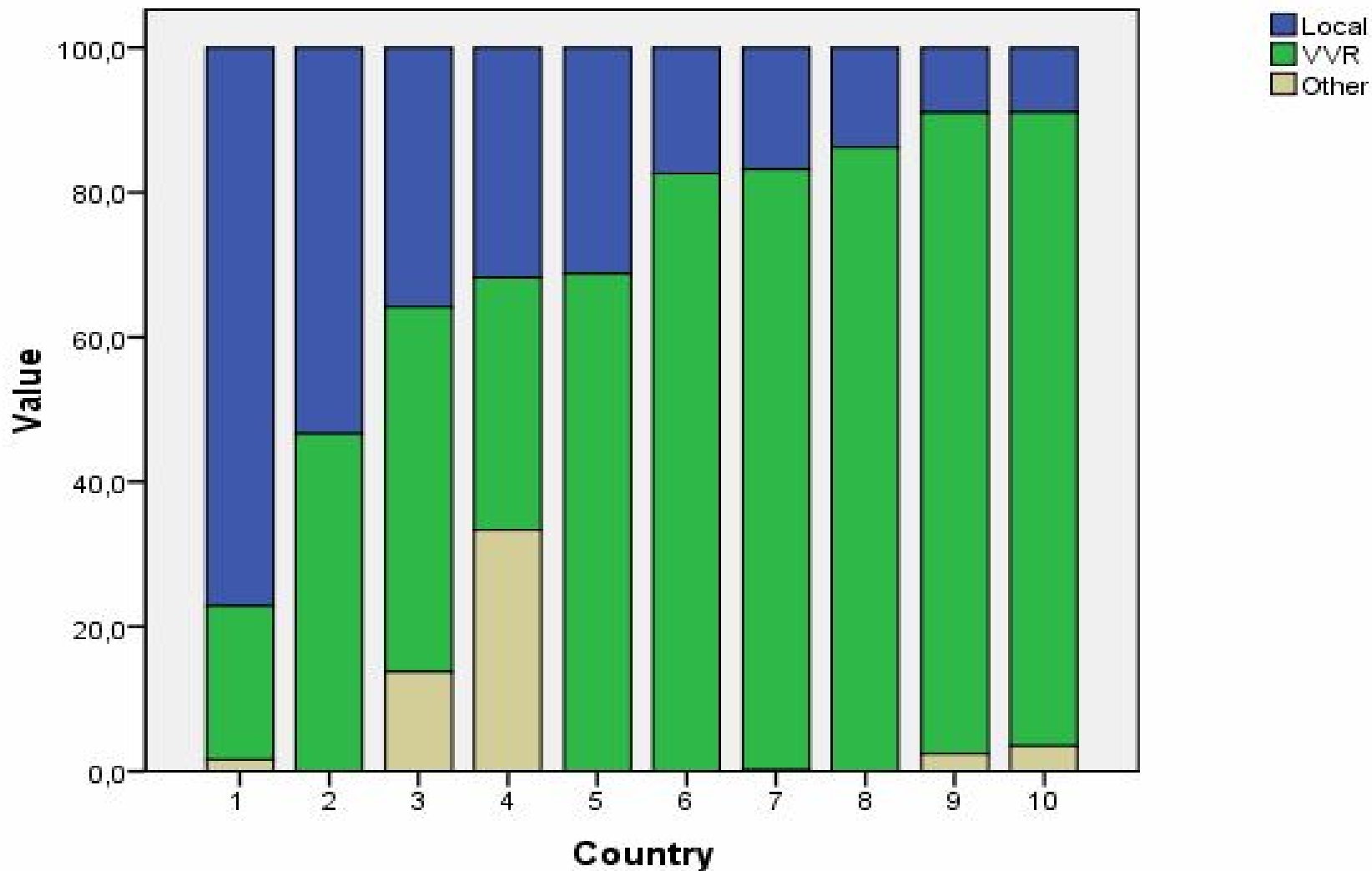
Category	Number of cases- Whole blood			
	Mild	Moderate	Severe	Total
Haematoma	320	9	12	341
Arterial puncture	2			2
Delayed bleeding				0
Painful arm*	188	16	1	205
Localised infection				0
Thrombophlebitis				0
Total number local sympt.	510	25	13	548
VV R Immediate type	2.060	402	2	2.464
VV R Immediate , accident				0
VV R Delayed type	180	66		246
VV R Delayed, accident				0
Total number VVR	2.240	468	2	2.710
Citrate reaction				0
Haemolysis				0
Generalised allergic reaction	1			1
Air embolism				0
Other	1	2		3
Total	2.752	495	15	3.262

This part of the table is for *whole blood*

Further columns record similar data for *apheresis*

2008

% distribution of donor AEs



Data from 10/16
(62,5%) countries

Corresponding to
10.8 million
donations

Errors – IBCT, 2008

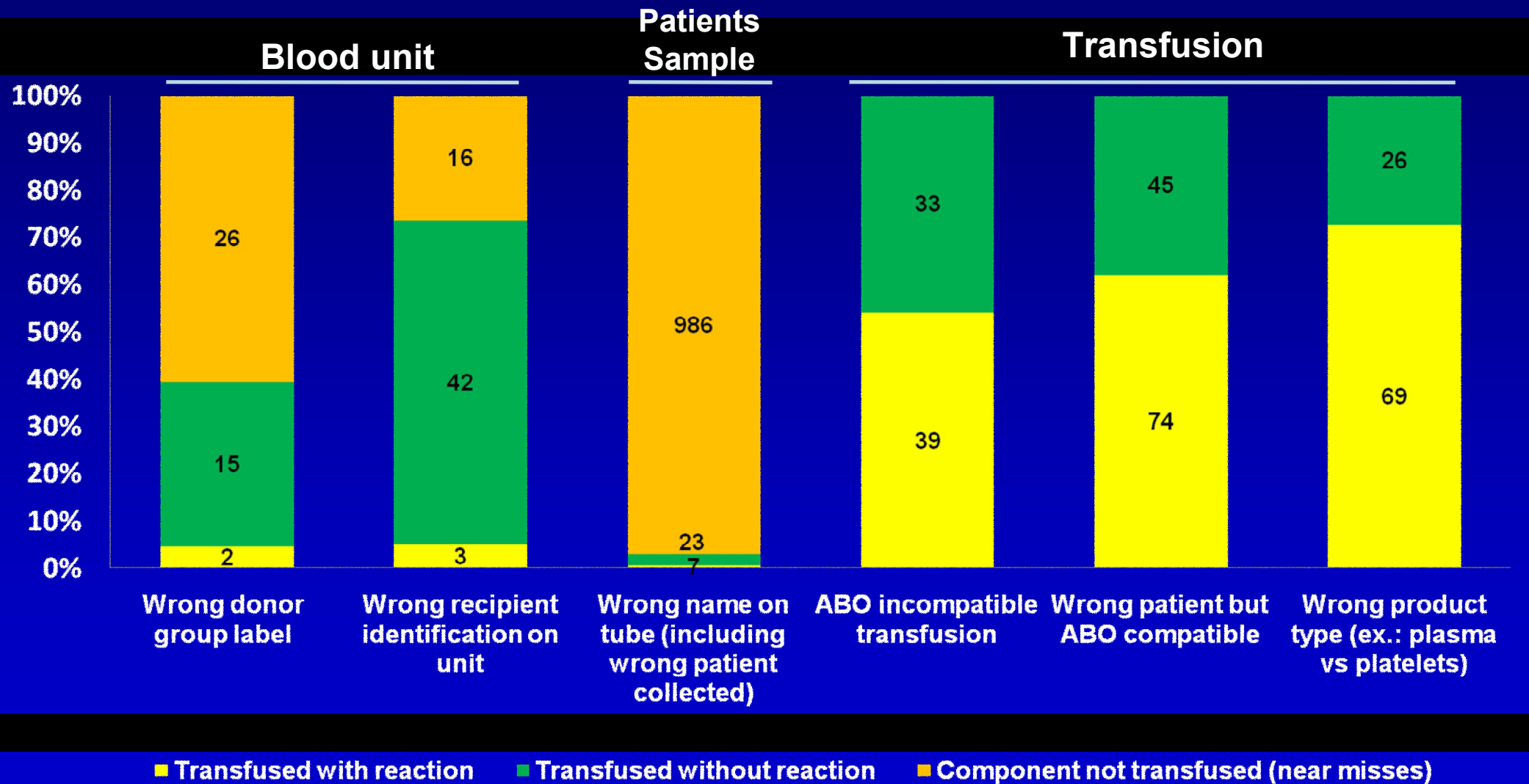
Site of primary error (transfused with reaction, without reaction and component not transfused – near miss)

Blood unit	Wrong donors group label, Wrong recipient identification on unit
Patient sample	Wrong name on tube (including wrong patient collected)
Transfusion	ABO incompatible transfusion Wrong patient but ABO incompatible Wrong product type

14/16 (88%) countries provided information.

Although the spreadsheet was much clearer than in the 1st pilot study, the fact that several responders **have added written comments** suggests that further improvement is desirable.

Errors – IBCT, 2008, Site of primary error



Adverse events Europe, 2008

Directive 2005/61/EC

D1 Serious adverse events*, which may affect quality and safety of blood component due to a deviation in :	Total number	Product defect	Equipment failure	Human error	Other
Whole blood collection	0				
Aphaeresis collections	0				
Testing	0				
Processing	277		276	1	
Storage	0				
Distribution	0				
Materials	0				
Others	0				
*Definition of EU					

We do not envisage the above information will be part of the international database

Adverse reactions by component, 2008

		Platelets WBD				
		RBC	PRP	BC	Pathogen inactivated	Total
AHTR		11				0
DHTR		9				0
DSTR		2				0
Allergic reaction		216	45	2		47
Febrile Nonhemolytic Transfusion Reaction (FNHTR)		286	18			18
Circulatory overload (TACO)		11	4			4
Transfusion related acute lung injury (TRALI)		3	1			1
Transfusion associated dyspnea (TAD)		25	1			1
Transfusion transmitted viral infection	HBV	2				0
	HCV					0
	HIV					0
	Other					0
Transfusion transmitted parasitic infection	Malaria					0
	Other					0
Transfusion transmitted bacterial		1	1			1
Hypotensive reaction						0
Transfusion associated Graft versus host disease (TA-GVHD)						0
Post transfusion purpura						0
Hyperkalemia						0
Hypocalcaemia						0
Other transfusion reaction		15	2			2
Unclassifiable complication of transfusion (UCT)		2				0
Total		583	72	2	0	74

More columns follow:

- Platelets-apheresis,
- Plasma-WBD,
- Plasma aphaeresis
- etc.

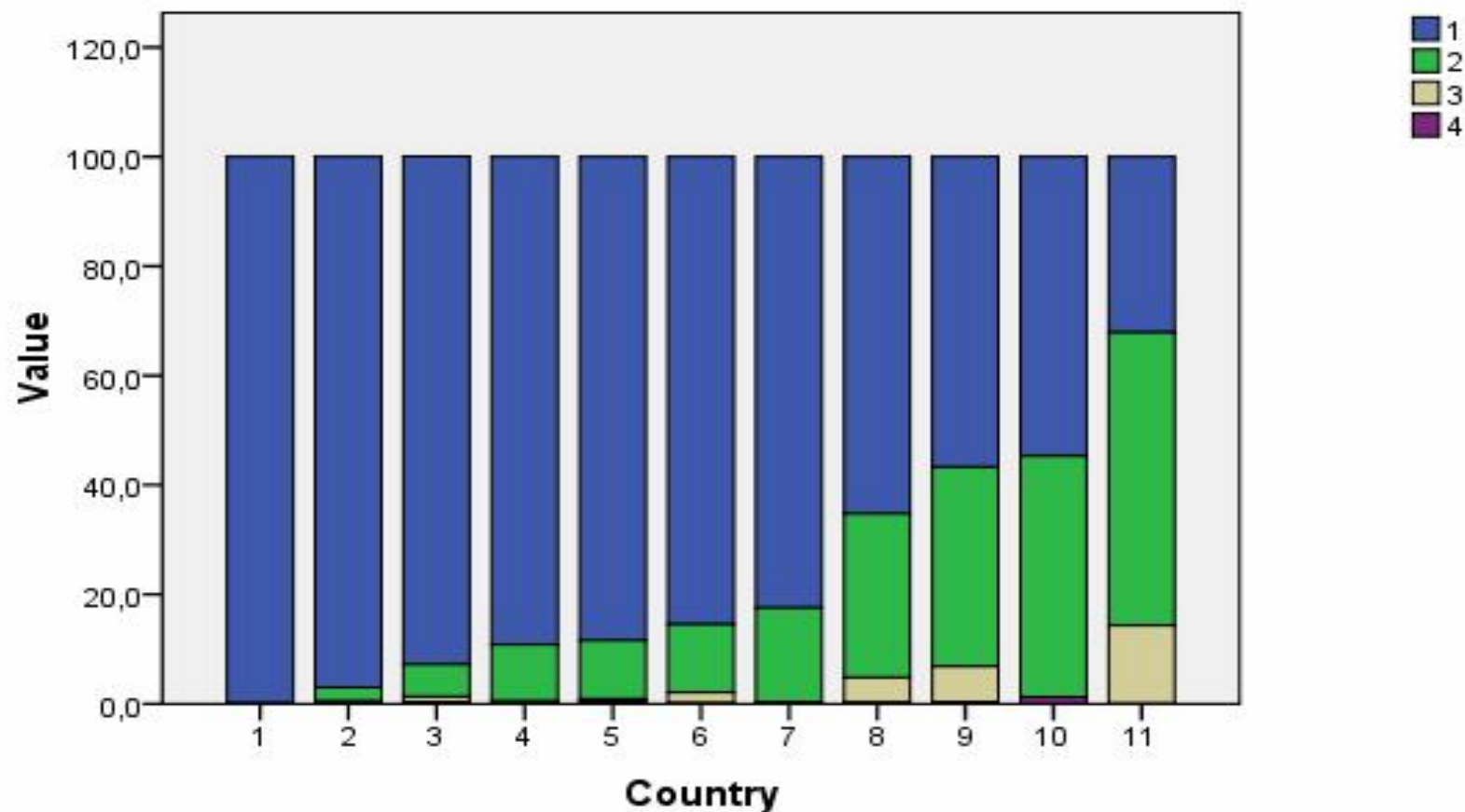
Then all by *severity* and again by *imputability*.

Adverse reactions, 2008

- 11/14 (79%) countries provided all information
- 2 countries supplied no information on AR
- Of the remainder:
 - 1/14 lacked the breakdown by **component**
 - 2/14 lacked the breakdown by **severity**
 - 1/14 lacked the breakdown by **imputability**, but some others seemed to be using only one of the categories

% distribution of AR by severity

1 non severe, 2 severe, 3 life-threat., 4 death



All ARs 12,439

Grades	%
Non severe	79
Severe	24
Life –threat .	2.7
Death	0.3

Adverse Transfusion Reactions, 2008

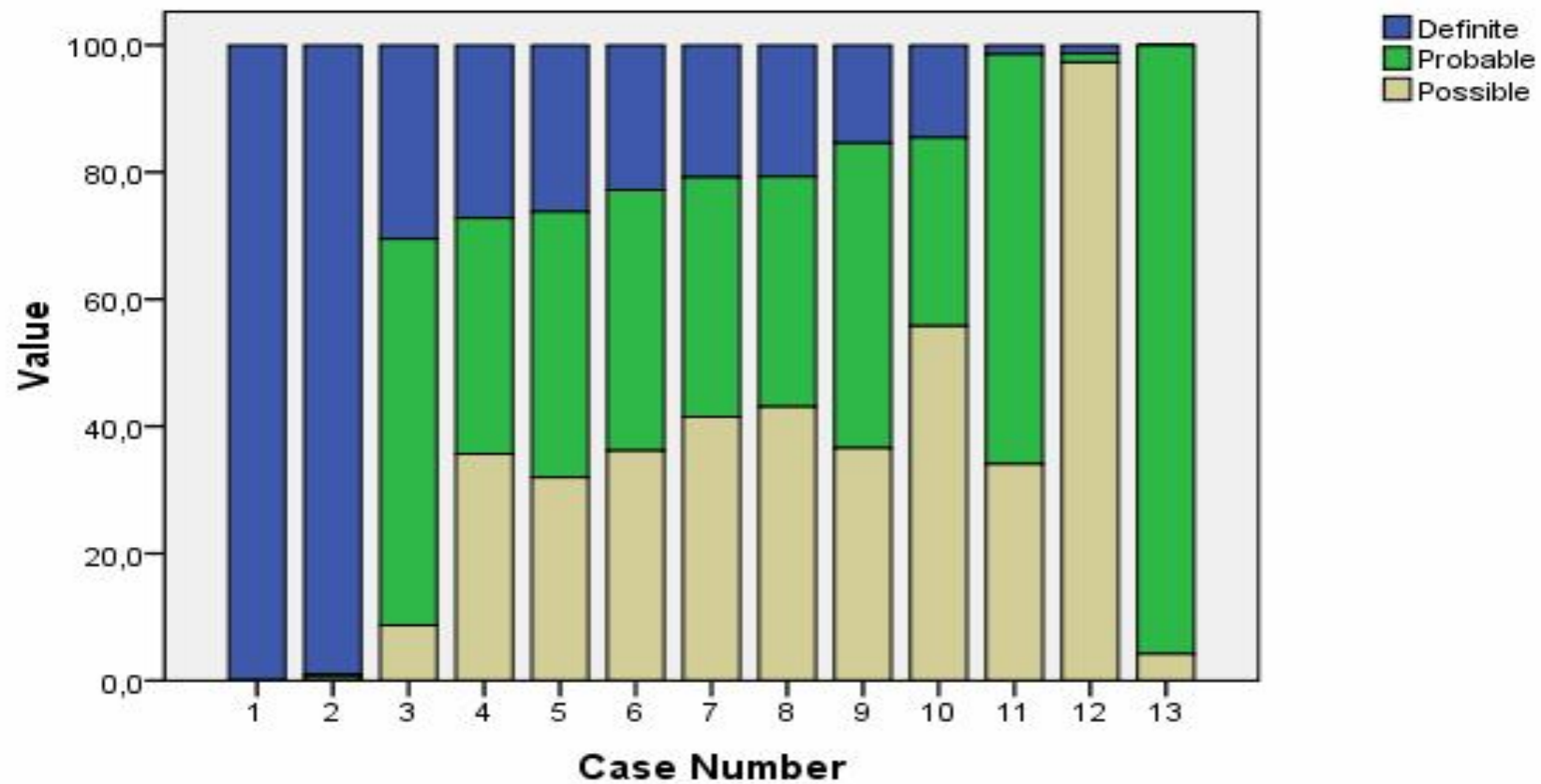
Total deaths

Type	n	%
TRALI	12	26.1
TACO	8	17.4
TAD	3	6.5
Allergic	3	6.5
AHTR	3	6.5
Bacterial	2	4.3
Other	9*	19.6
UCT	6	13.0

** Including 1 FNHTR and 1 hypotensive*

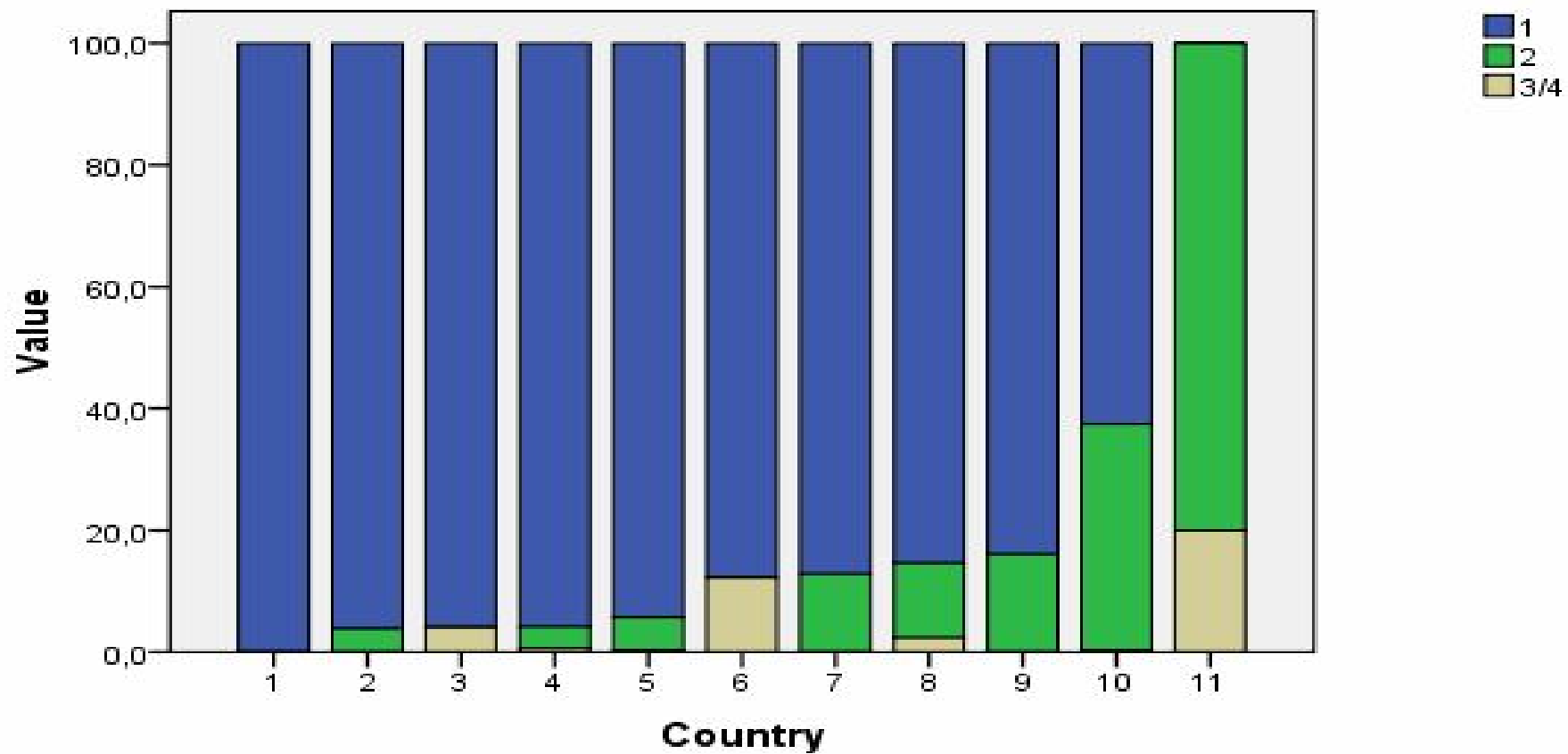
% distribution of AR by imputability

(Definite, Probable, Possible)



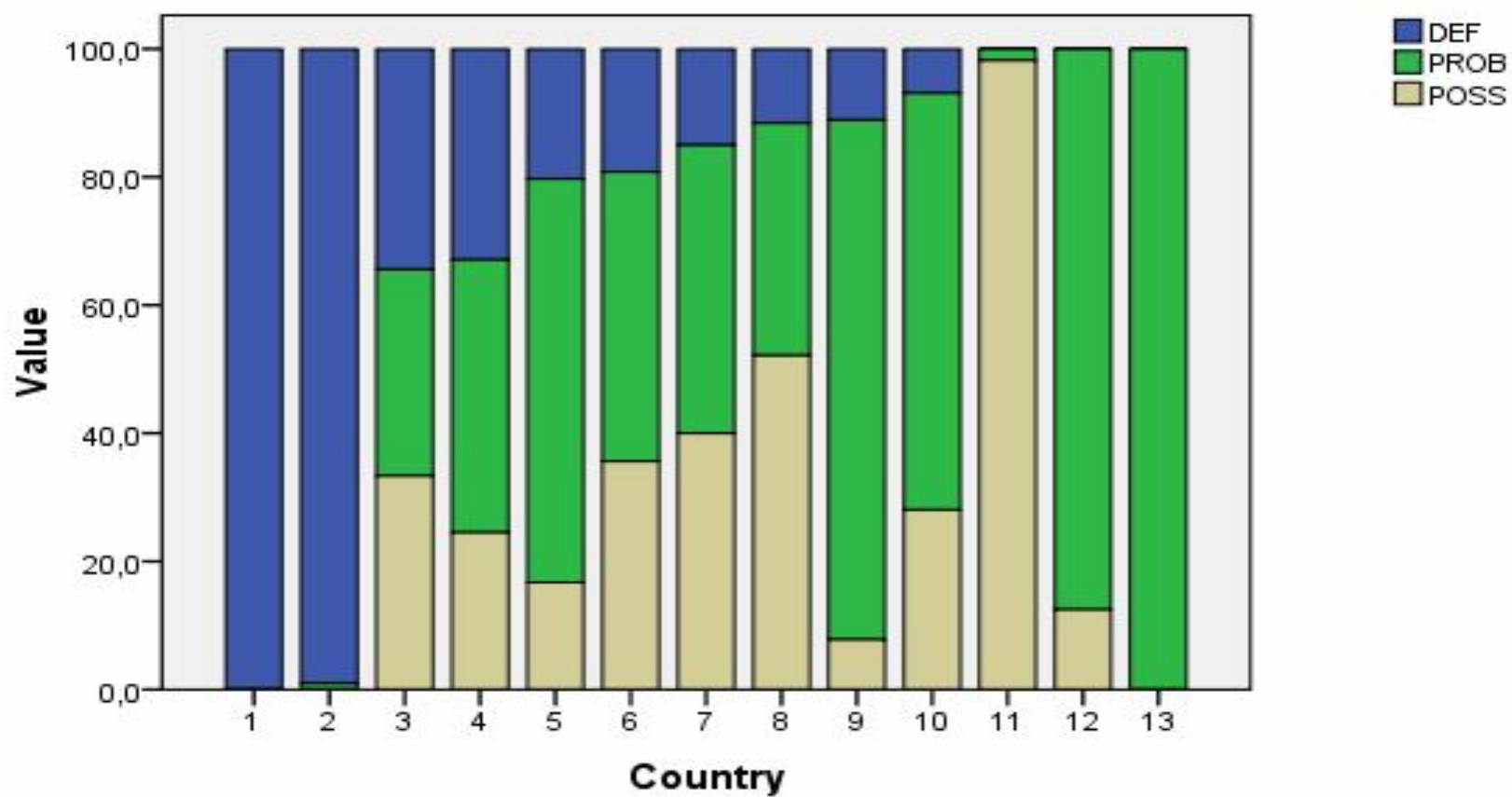
Allergic reactions by severity, by country

1 non severe, 2 severe, 3/4 life-threat./fatal



Allergic reactions by imputability, by country

Definite - Probable - Possible





Conclusions

- Experience of two pilot studies demonstrates the **feasibility** and **value** of IHN database
- Compliance with international definitions is not optimal. Standardized definitions for errors and near misses are needed
- STARE will contribute to improving this situation



Conclusions

- Surveillance of all ARs/AEs instead of only serious ones, allows better assessment of trends
- STARE adds value to regulatory surveillance
 - analysed scientifically
 - covering all aspects of transfusion not only quality of products
 - more detailed breakdown of data allowing better examination of differences between countries
- **STARE has a future!**