

STARE

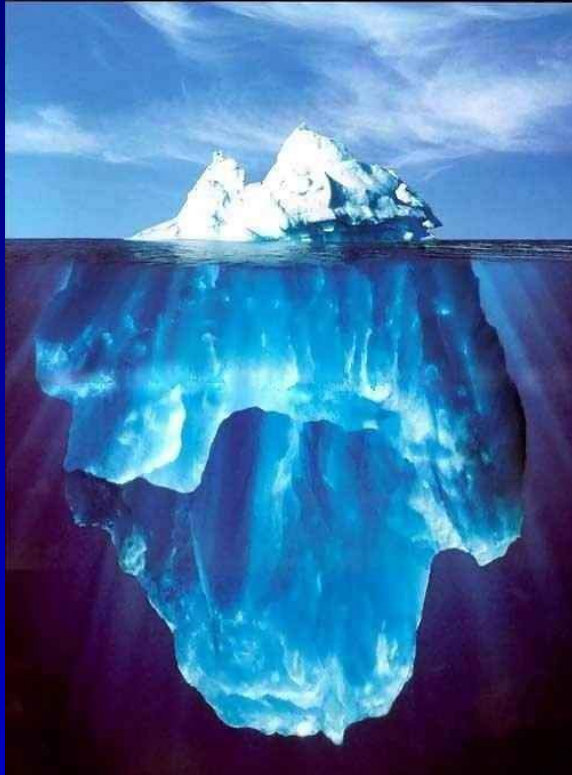
The European Haemovigilance Network Database Establishment and First Results



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**EHN promotes a holistic
haemovigilance approach**

The rationale of STARE

**To build on the concept of avoiding
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 establishment
- Amsterdam, Apr. 2008: 1st meeting of the working group to prepare a protocol
- Macao, June 2008: ISBT working group on HV decides to collaborate in a pilot study

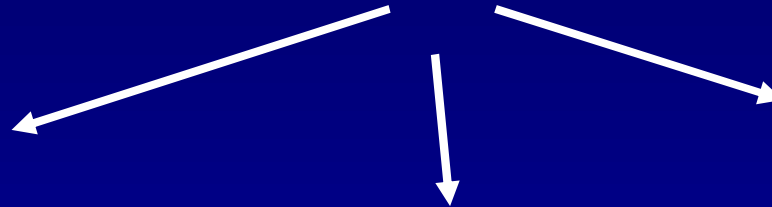
Nov. 2008, Starting the pilot study in 15 volunteering countries

- Athens, Jan. 2009: 2nd meeting of the working group for evaluation of first results
- Rome, Feb. 2009: EHN

Going ahead with the second phase of the pilot study

Purpose of Database

**Information
sharing**



Analysing data

Surveillance

Data Potential Uses

- **International, beyond the EU and Europe**
- **Benchmarking for countries**
- **Risk assessment**

Data analysis and dissemination

Areas to be covered

- Data on contributing systems/sites (% coverage)
- Event rates per 1,000 or 100,000 overall and by product type
- Type of reaction and total/ severe/ deaths
- Distributions of types of event
- Averages for global regions
- 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

Participation in Database

International, beyond EHN membership

Coverage

All ARs and AEs, regardless of level of severity and extent of harm (if any), that threaten the recipient's health status and also monitoring effects on the donor's health and well-being

Data collection for 2006 and 2007

Collected by the OCP's representative to EHN/ ISBT

Participation to STARE pilot project

- 2006
 - 10 countries
 - 1 region
 - From EU-Europe, Asia-Pacific, North-America
- 2007
 - 12 countries
 - 1 region
 - From EU-Europe, Asia-Pacific, North-America
- For confidentiality purpose codes were given to countries
- We thank all participants for their prompt and extensive cooperation

STARE Pilot Study

What data

- General information
 - Haemovigilance reporting system and coverage
 - Reporting system on transfusion medical device/reagents
 - Percentage of blood components with full traceability

General Denominators

Donors	Whole blood
Donations	Aphaeresis (RBCs, Pts, FFP)
Blood components issued /transfused	

Specific denominator data

Whole blood	
Platelets (WBD-PRP, WBD-PRP/5, WBD-BC, Aphaeresis)	Pathogen inactivated (%)
Plasma	Leukoreduced (%)
Cryoprecipitate	Apheresis (%)
Granulocytes	
Others	

of transfused patients (if available)

Results

General information

- All participating countries have national haemovigilance systems
- Coverage 99-100% with two exceptions (85%, 90%)
- 10/13 have a system for reporting on transfusion medical devices and reagent problems
- 9/13 claim 99-100% traceability

Denominators

- 11/13 (85%) full information on donations but only 6/13 (46%) also on donors
- 12/13 (92%) on blood components issued but only 3/13 (23%) on blood components transfused

Donor adverse events

Categories

With local symptoms

- Haematoma
- Arterial puncture
- Delayed bleeding
- Nerve irritation
- Nerve injury
- Painful arm

Severity levels

- Mild/Moderate
- Severe
 - Symptoms > 1 year
 - All severe

Vasovagal

- Immediate type
- Immediate, accident
- Delayed type
- Delayed, accident

Citrate reaction

Haemolysis

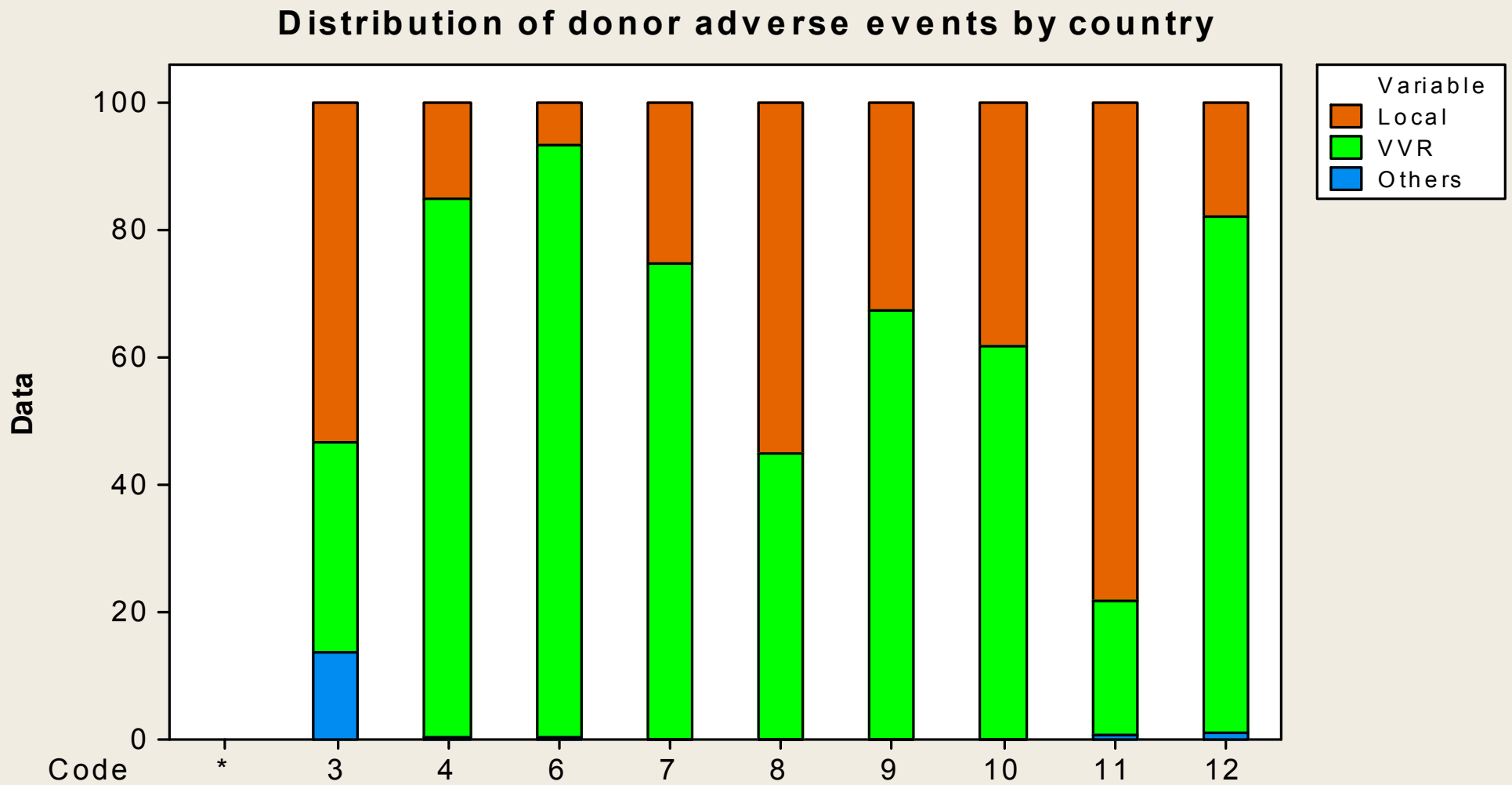
Generalised allergic reaction

Air embolism

Donor adverse events by type and severity

- 3/13 (23%) complete
- 2/13 (15%) complete but some deviation in recording
- 4/13 (31%) not broken down by severity
- 4/13 (31%) not provided

Data 2007



Adverse events associated with transfusion

Serious (EU definition)

Near miss (definition from CoE Guide)

Uneventful (definition from Guide)

Due to a deviation in

WB collection

Aphaeresis

Testing

Processing

Storage

Distribution

Materials

Others

Specification

Product
defect

Equipment
failure

Human error

Others

Errors-IBCT 2007

Countries responding

7/13 (54%) Yes

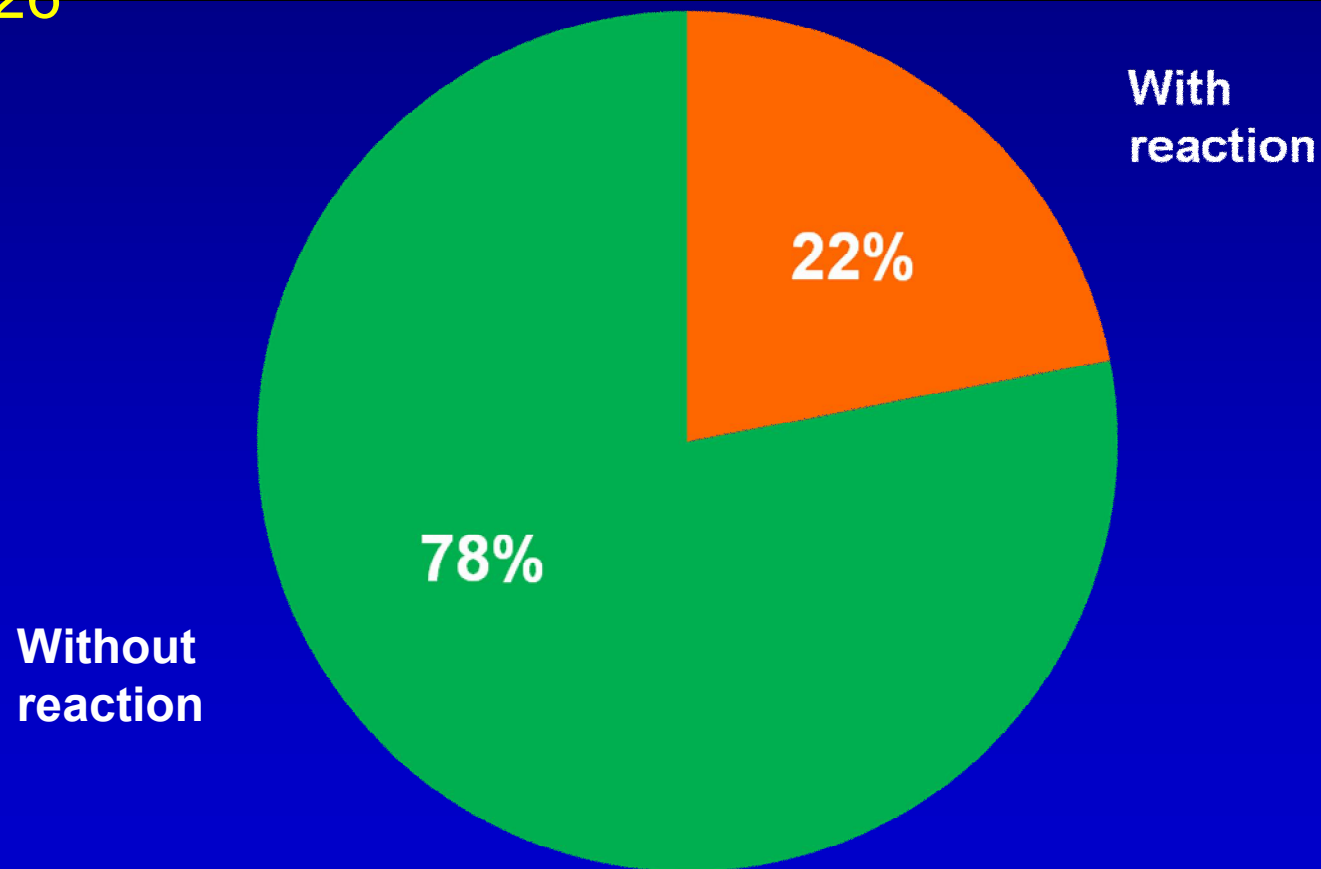
4/13 (31%) Partial

2/13 (15%) No

IBCT 2007

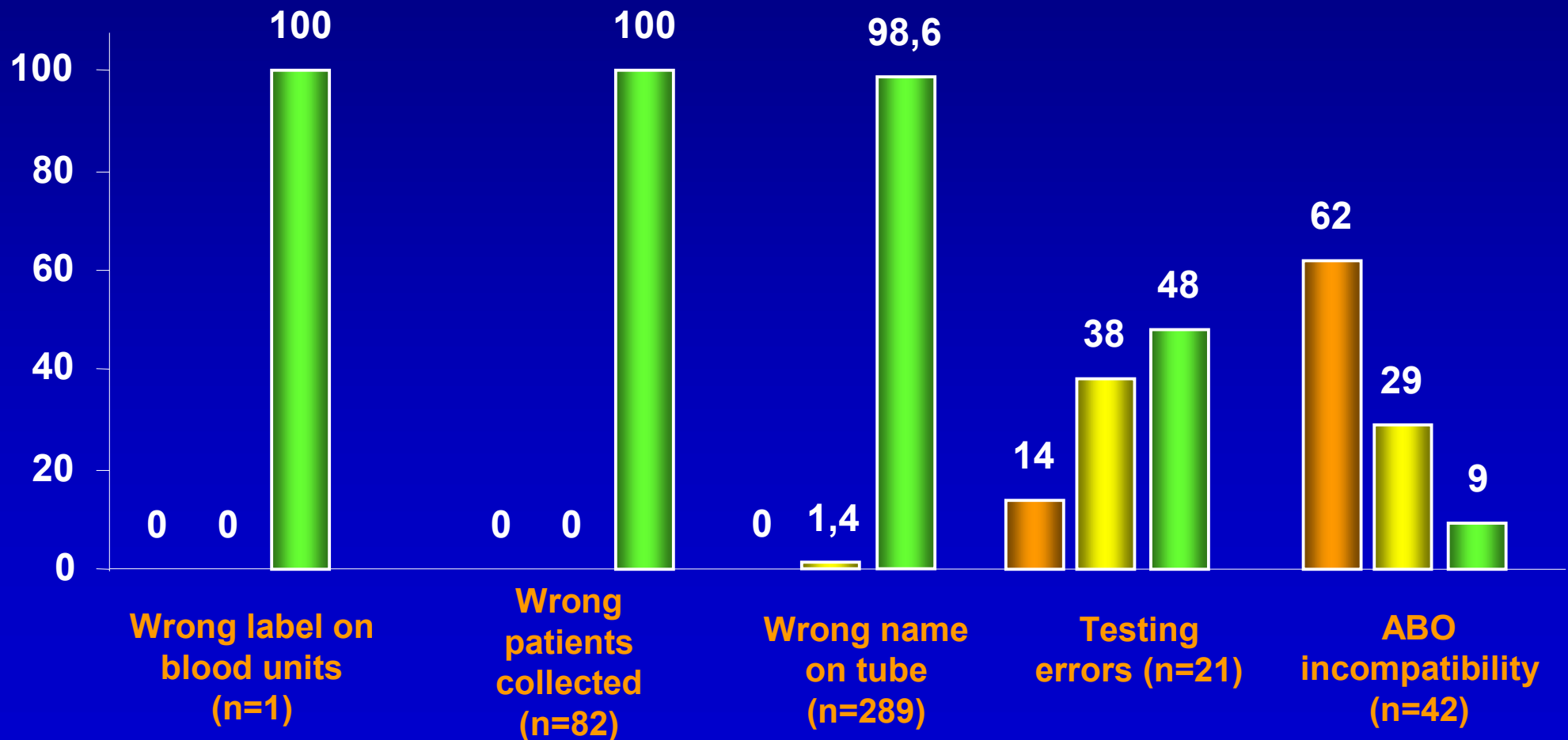
Data from 12 countries

n=126



Incorrect Blood Component Transfused

 Transfused with reaction  Transfused without reaction  Component not transfused (Near Miss)



All Adverse Reactions in Patients

By component:

RBC	
WBC-PRP	
WBD-BC	Platelets
Apheresis	
Plasma	
Cryoprecipitate	
Others	
Multiple components	

By imputability levels:

- Possible
- Probable
- Certain/definite

Levels 0 Excluded/unlikely / unassessable are not reported

By severity grades:

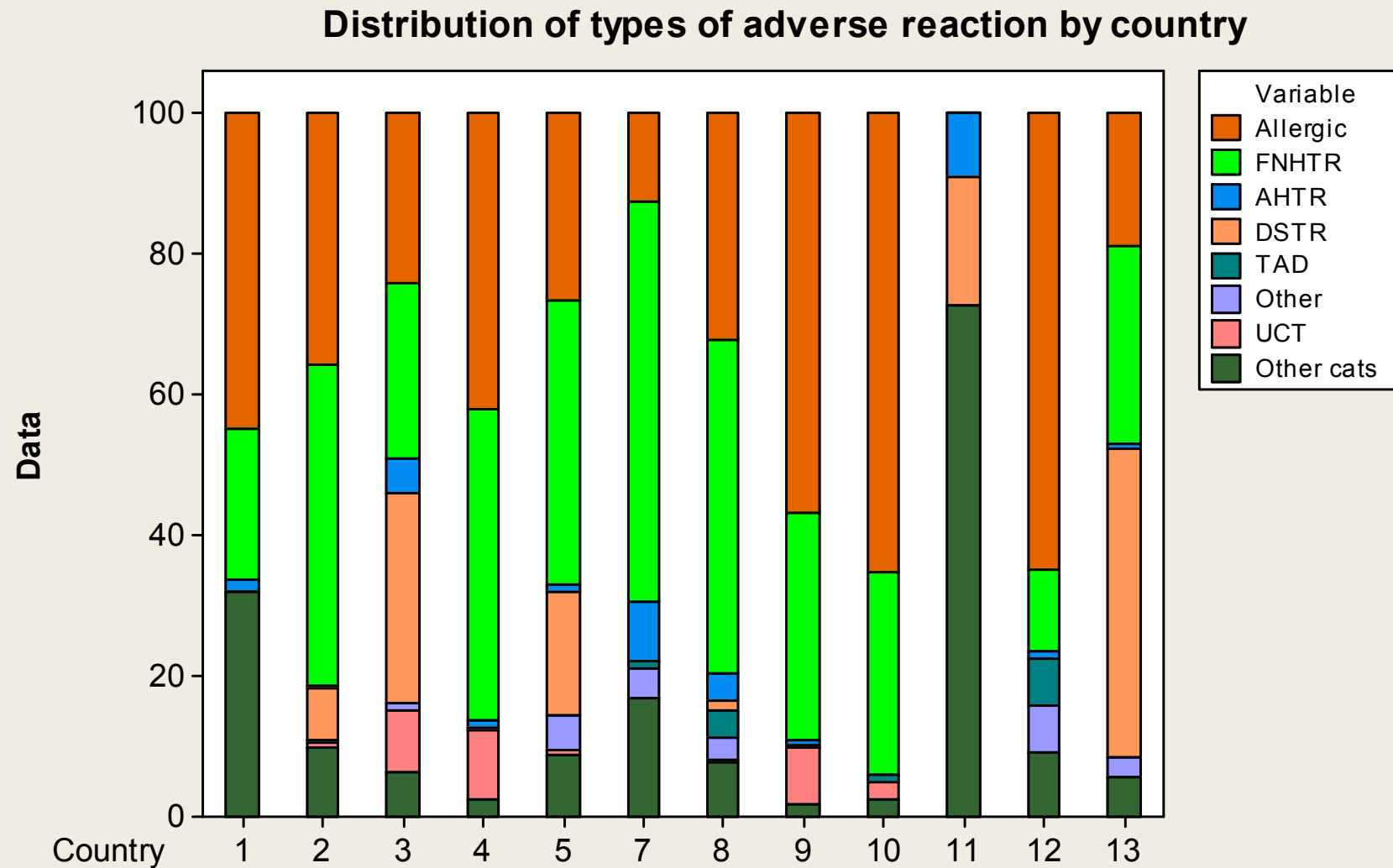
- 1 Non-severe
- 2 Severe
- 3 Life-threatening
- 4 Death

Data on adverse reactions 2007

Analysis by type, blood component, severity, imputability

- One country did not provide data
- 12/13 (92%) by type
- 12/13 (92%) had breakdown by component
- 10/13 (77%) by severity
- 11/13 (85%) by imputability

Data from 12 countries 2007



General results – Year 2007

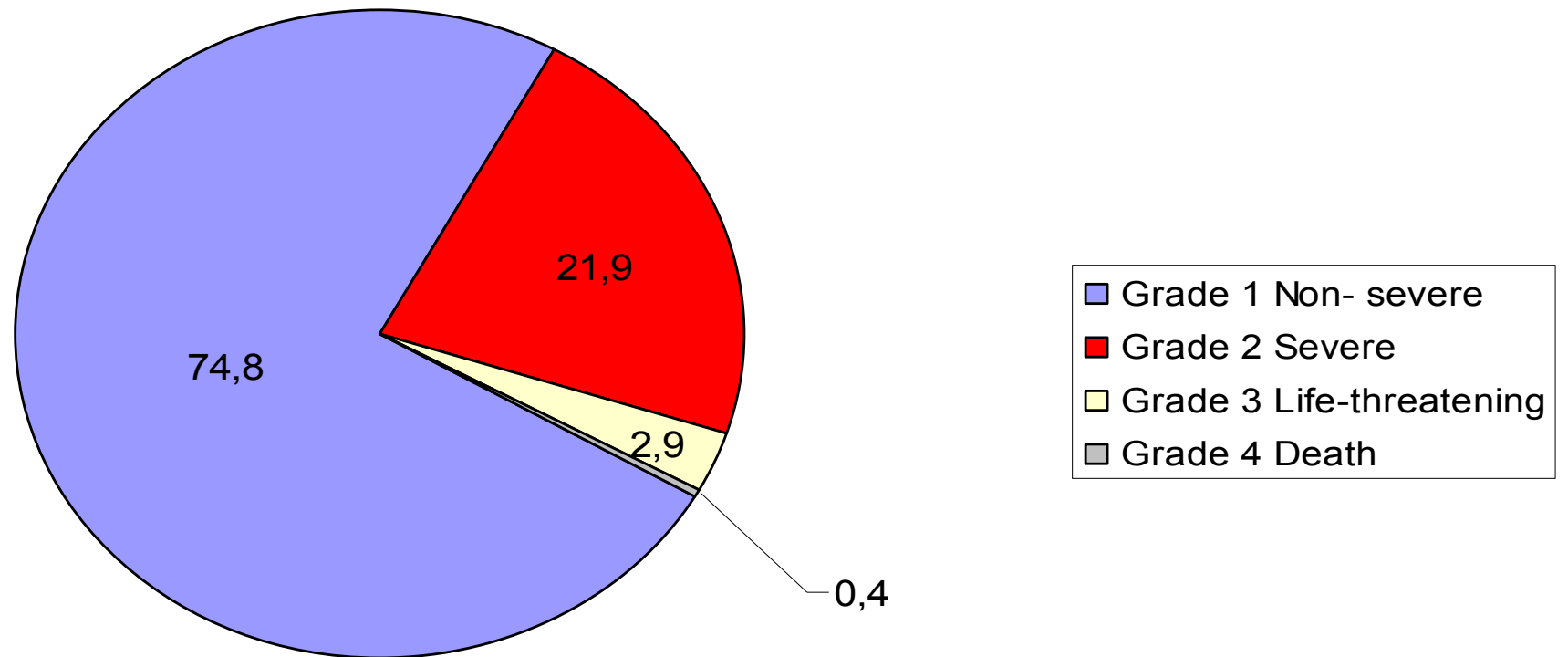


- 12 haemovigilance systems
 - 11 national
 - 1 regional

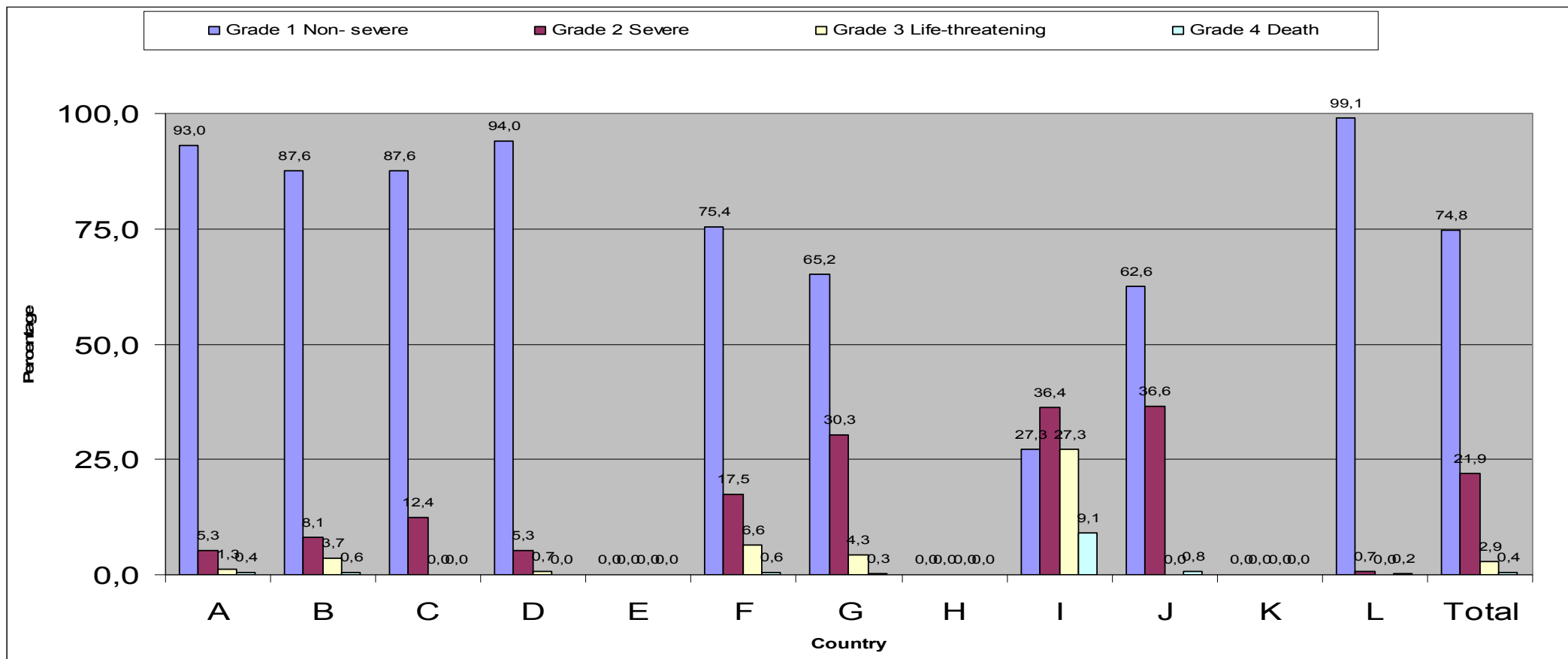
 - 13,142 adverse reactions

 - 14,391,424 units issued (11 systems)
-

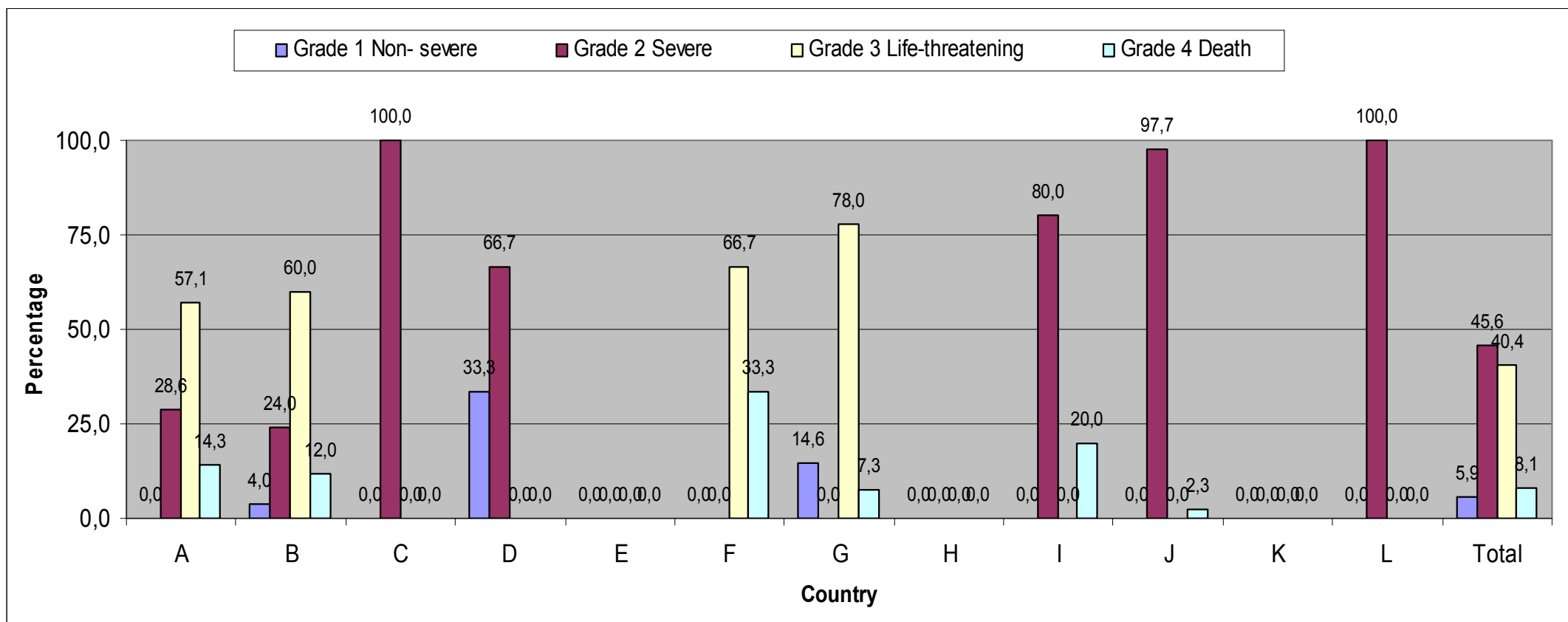
Severity of adverse reactions all countries 2007



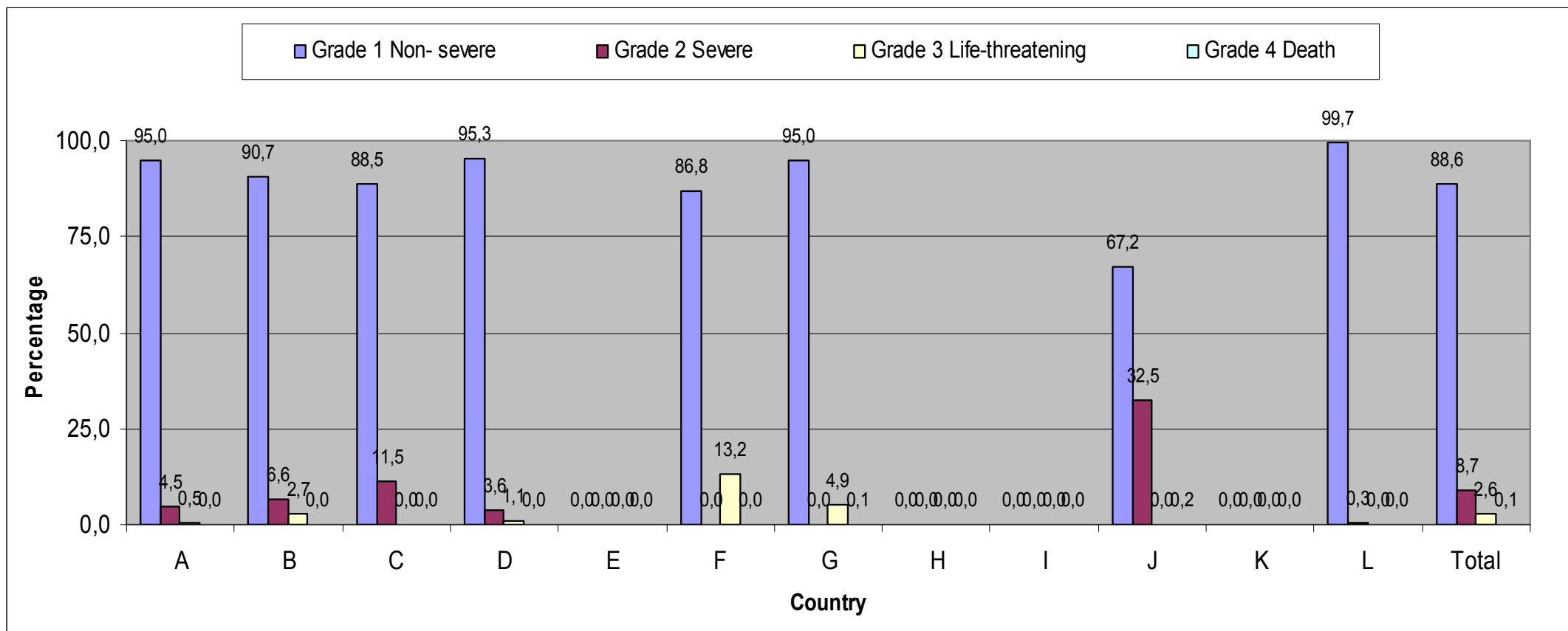
Severity of adverse reactions by country - 2007



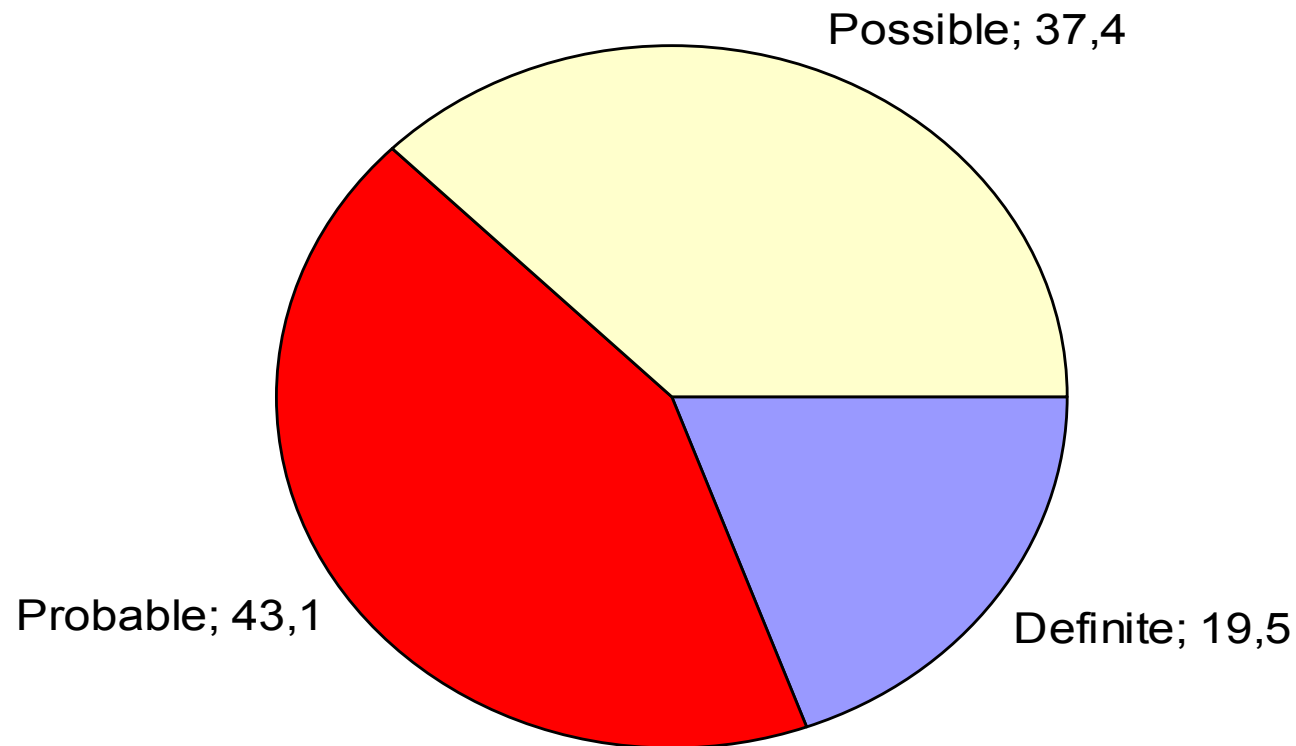
Severity of TRALI by country 2007



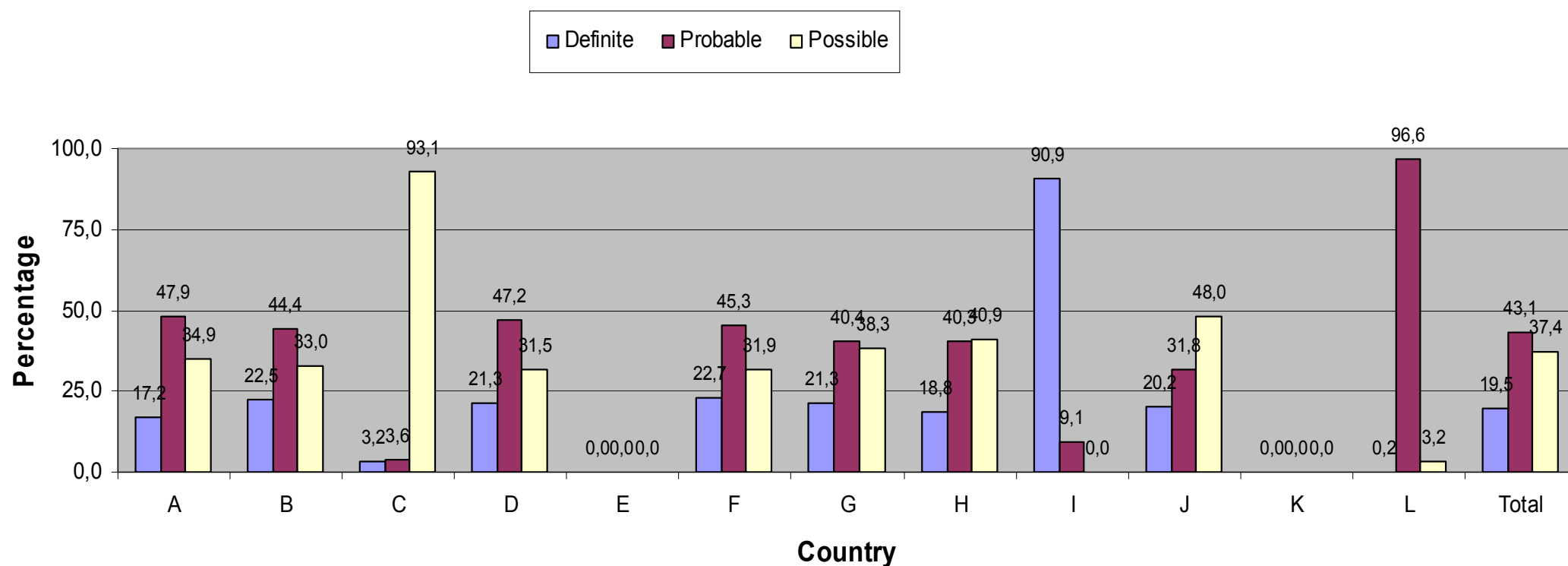
Severity of allergic reactions by country 2007



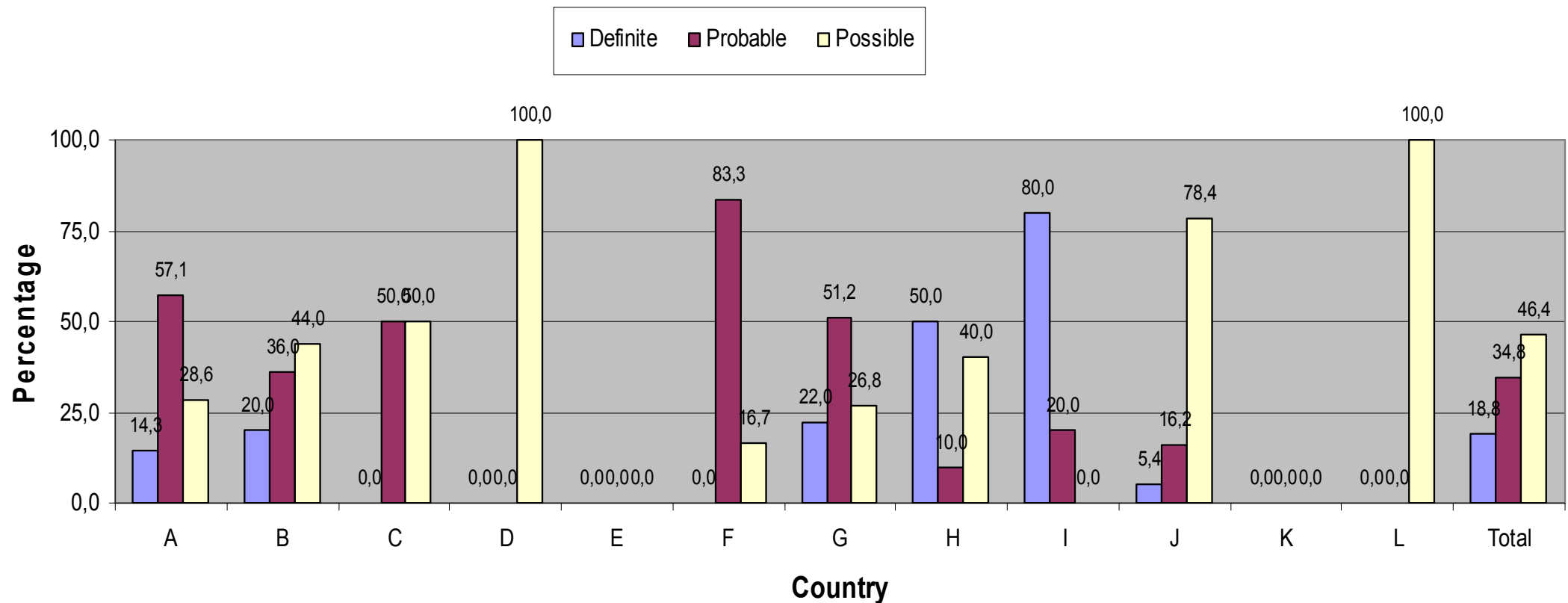
Imputability of adverse reactions all countries 2007



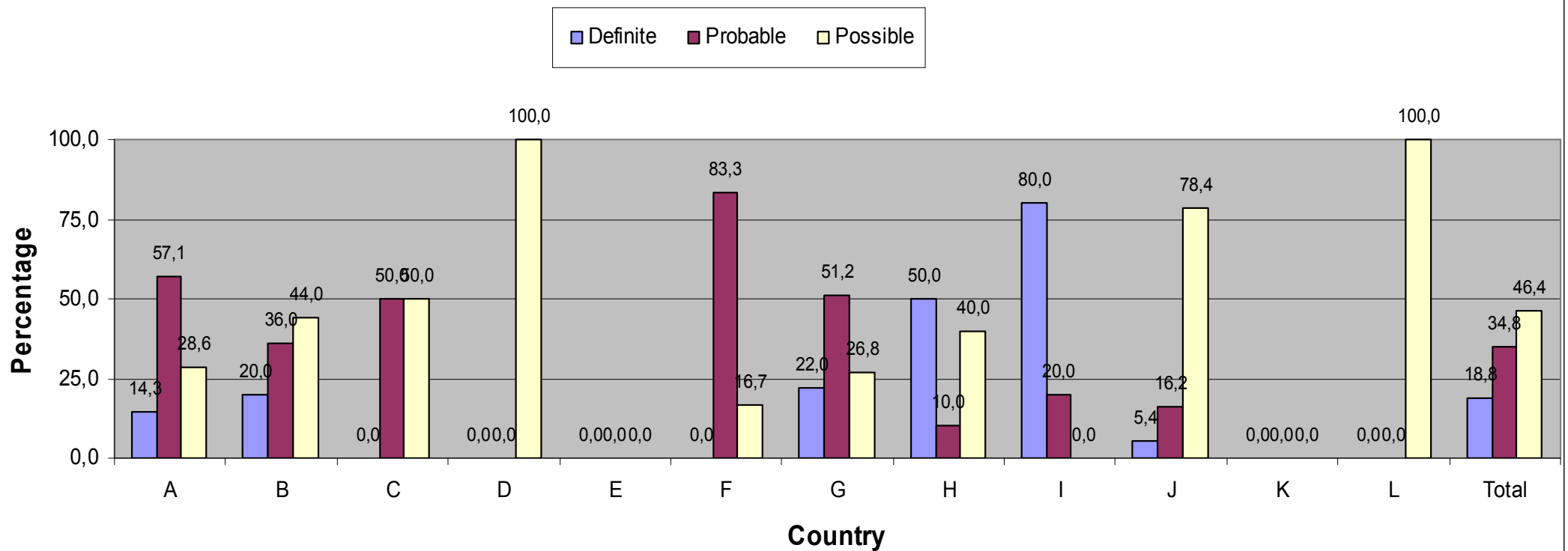
Imputability of adverse reactions by country - 2007



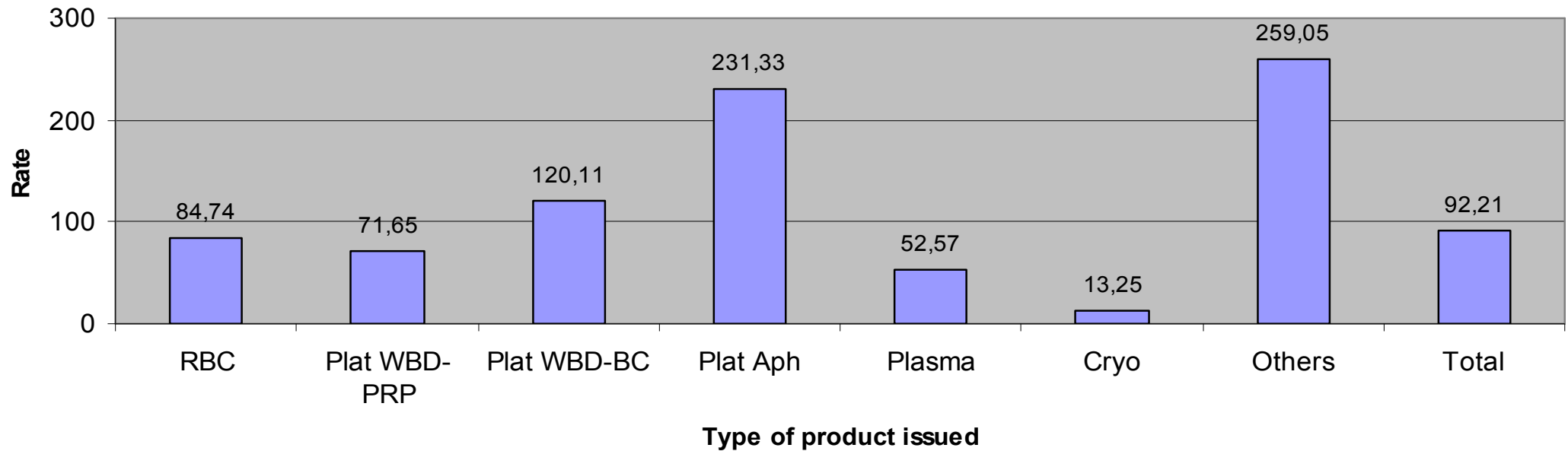
Imputability of TRALI by country - 2007



Imputability of allergic reactions by country - 2007

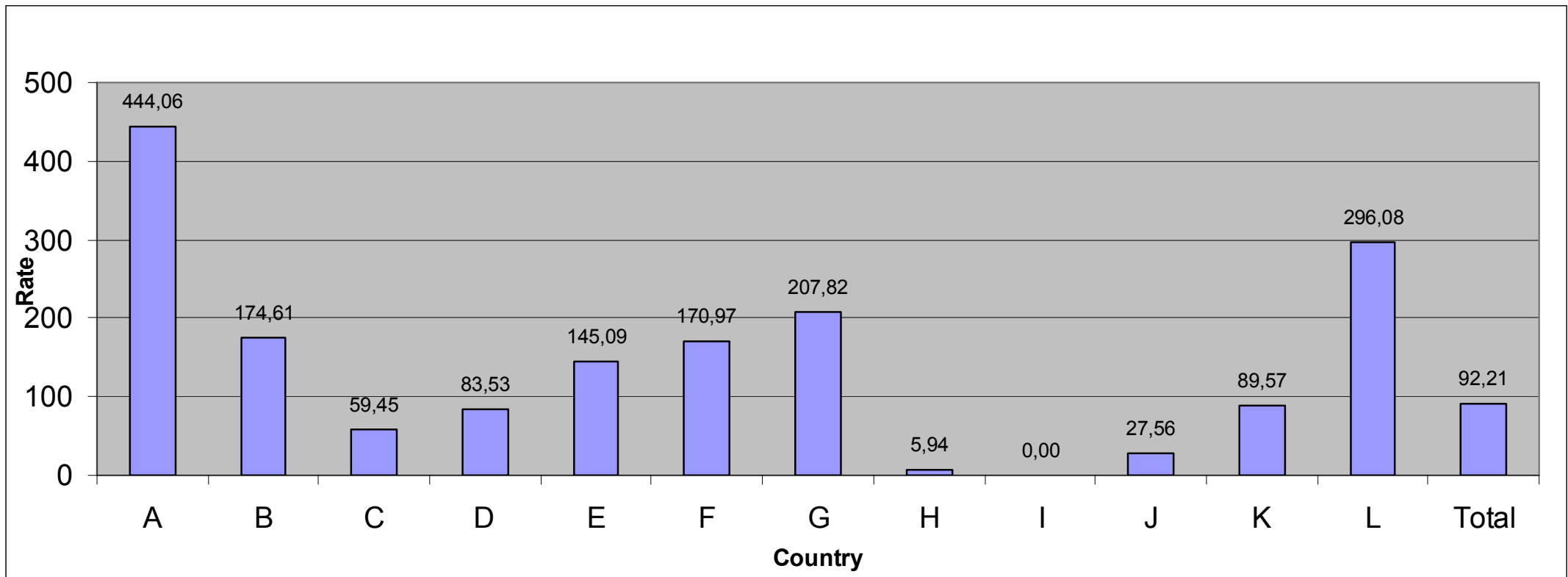


Incidence of adverse reactions by type of products - 2007



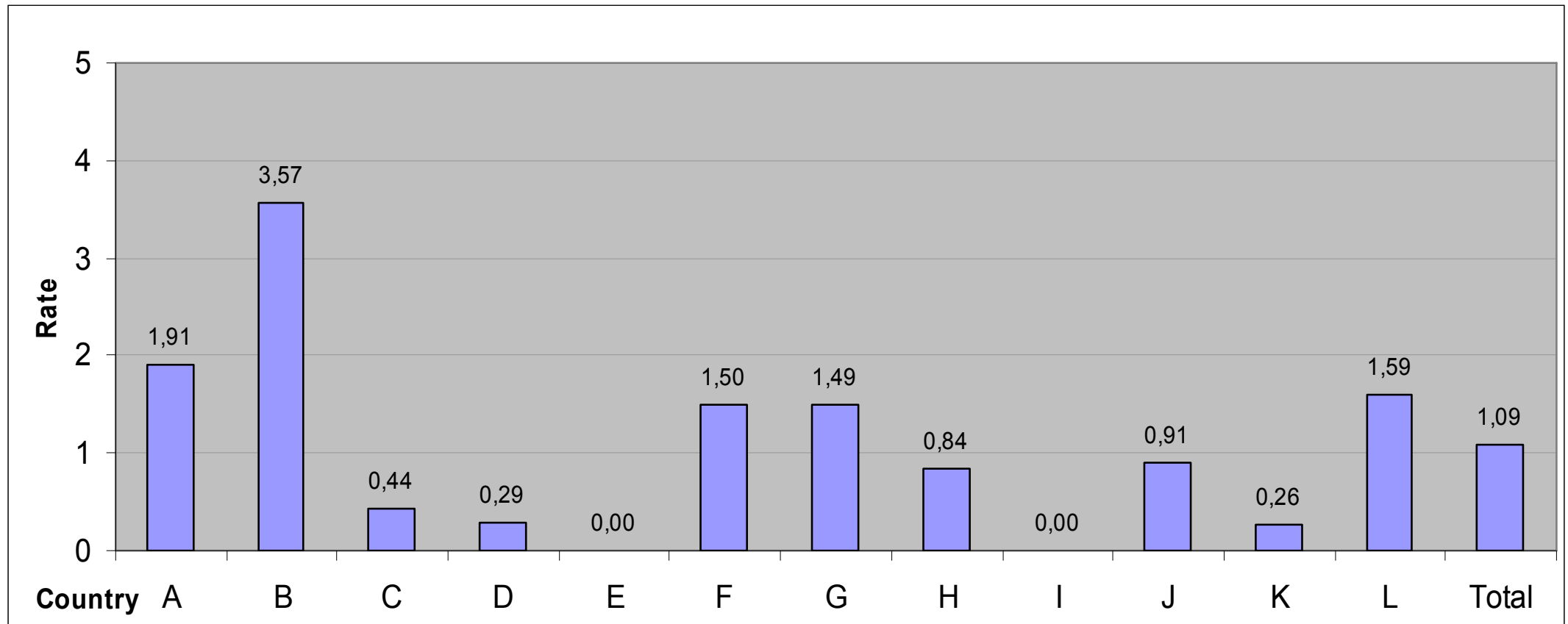
Per 100,000 units issued

Incidence of adverse reactions by country - 2007



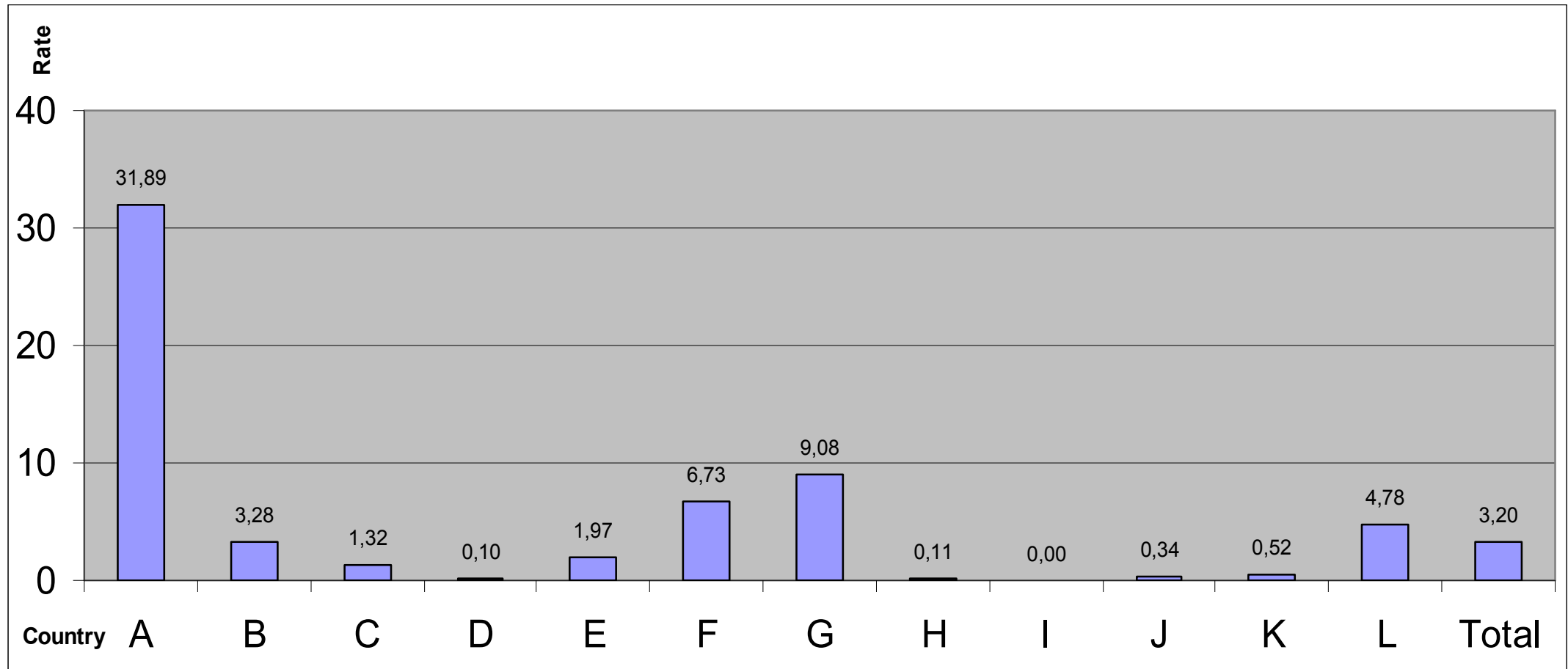
Per 100,000 units issued

Incidence of TRALI by country 2007



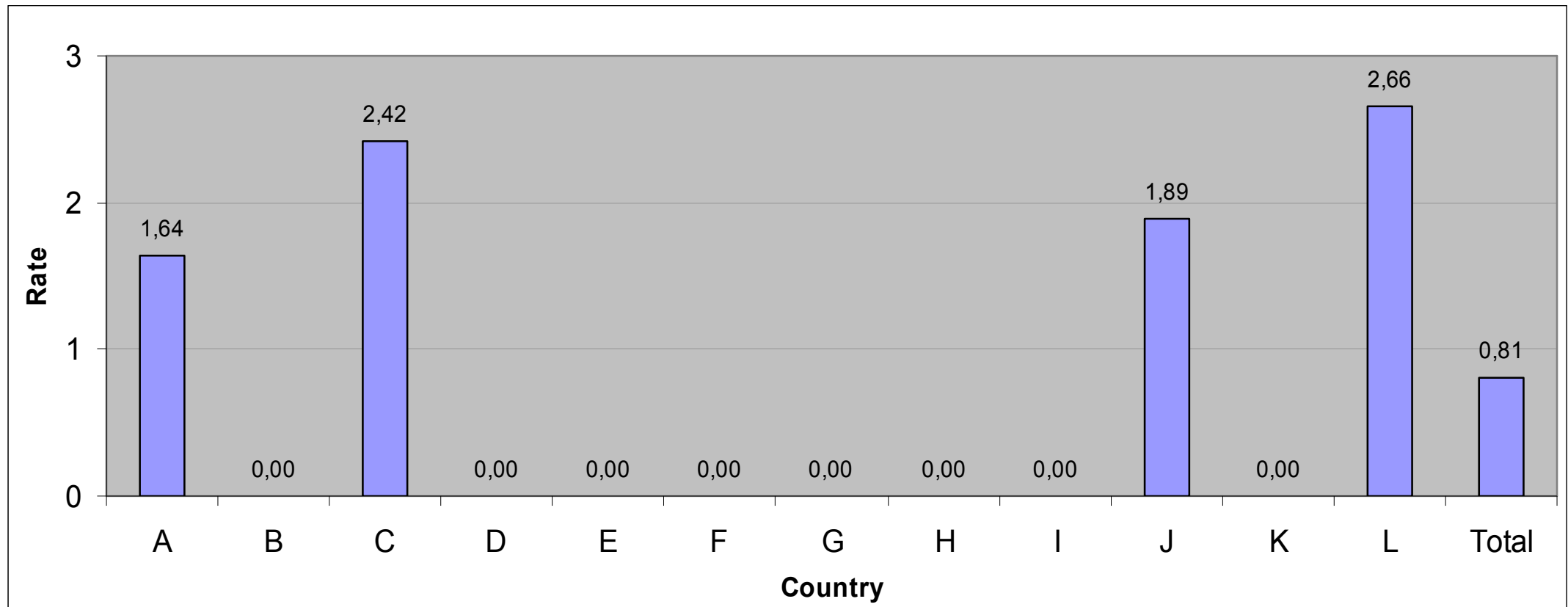
Per 100,000 units issued

Incidence of TACO by country 2007



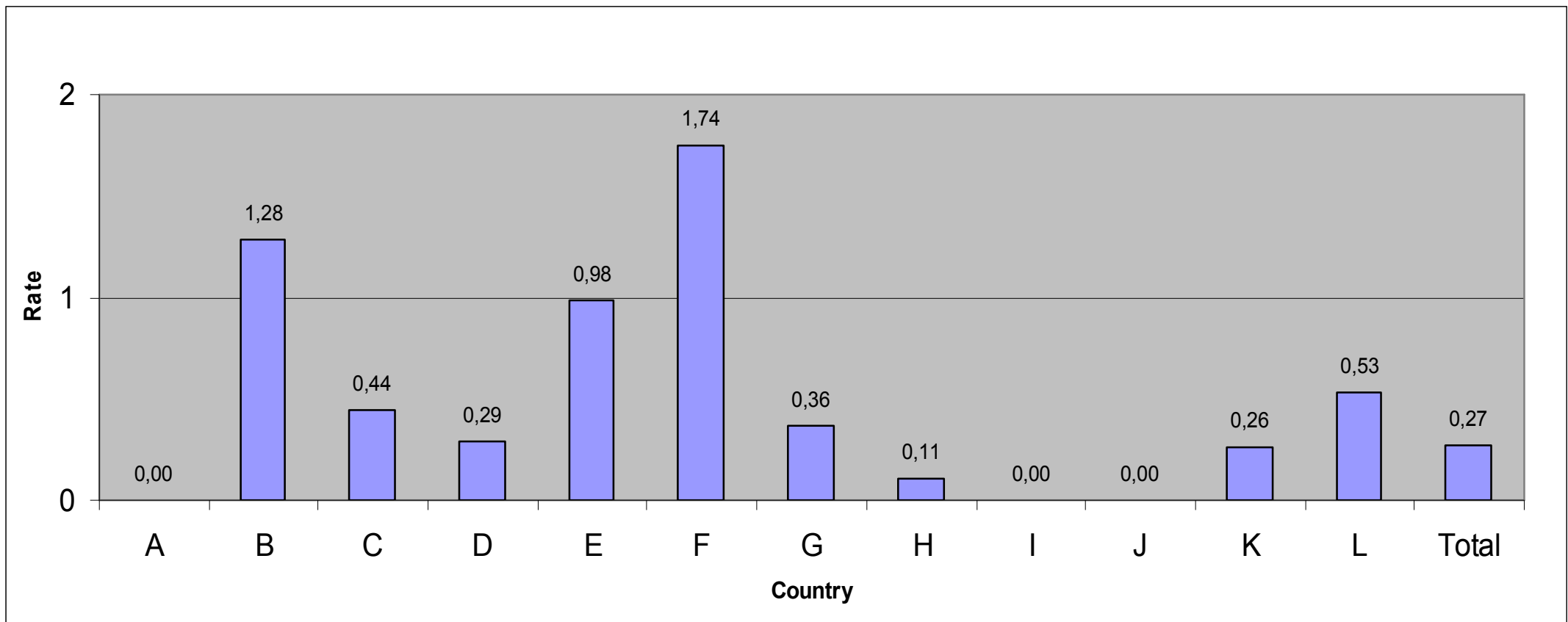
Per 100,000 units issued

Incidence of TAD by country 2007



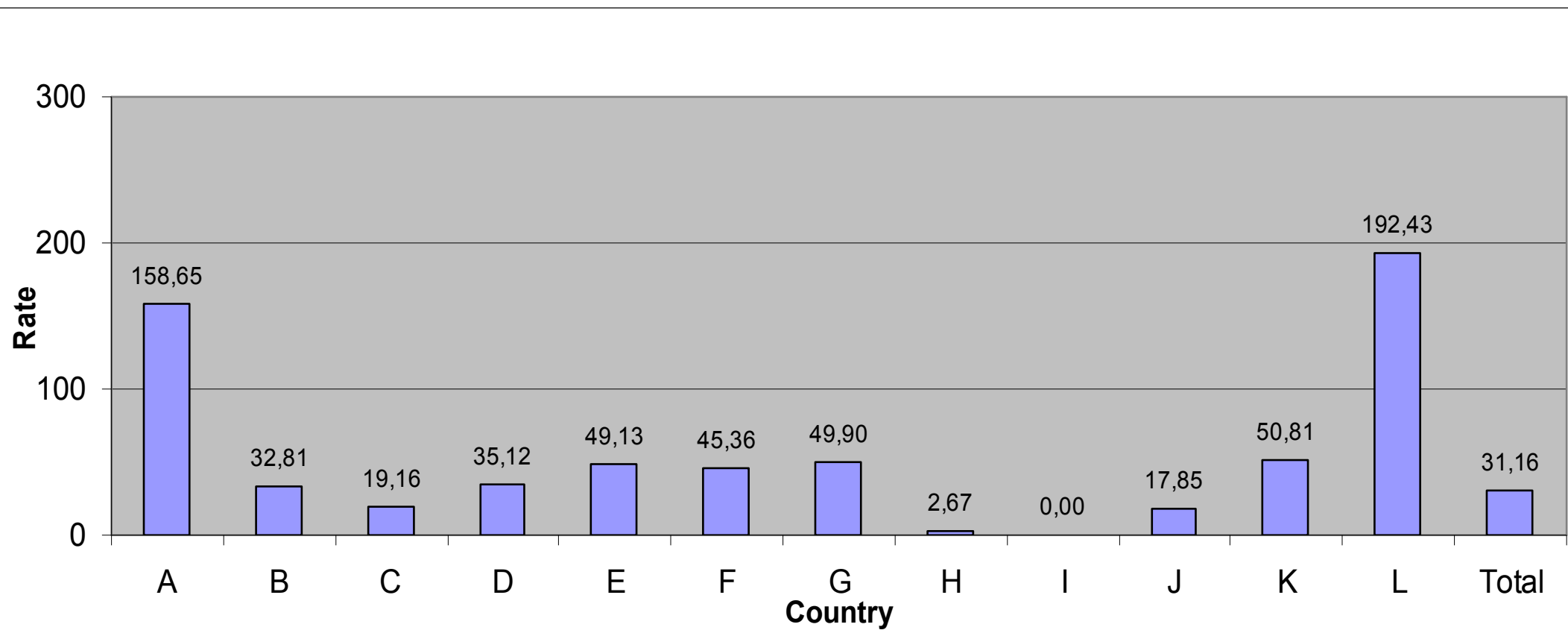
Per 100,000 units issued

Incidence of BaCon by country 2007



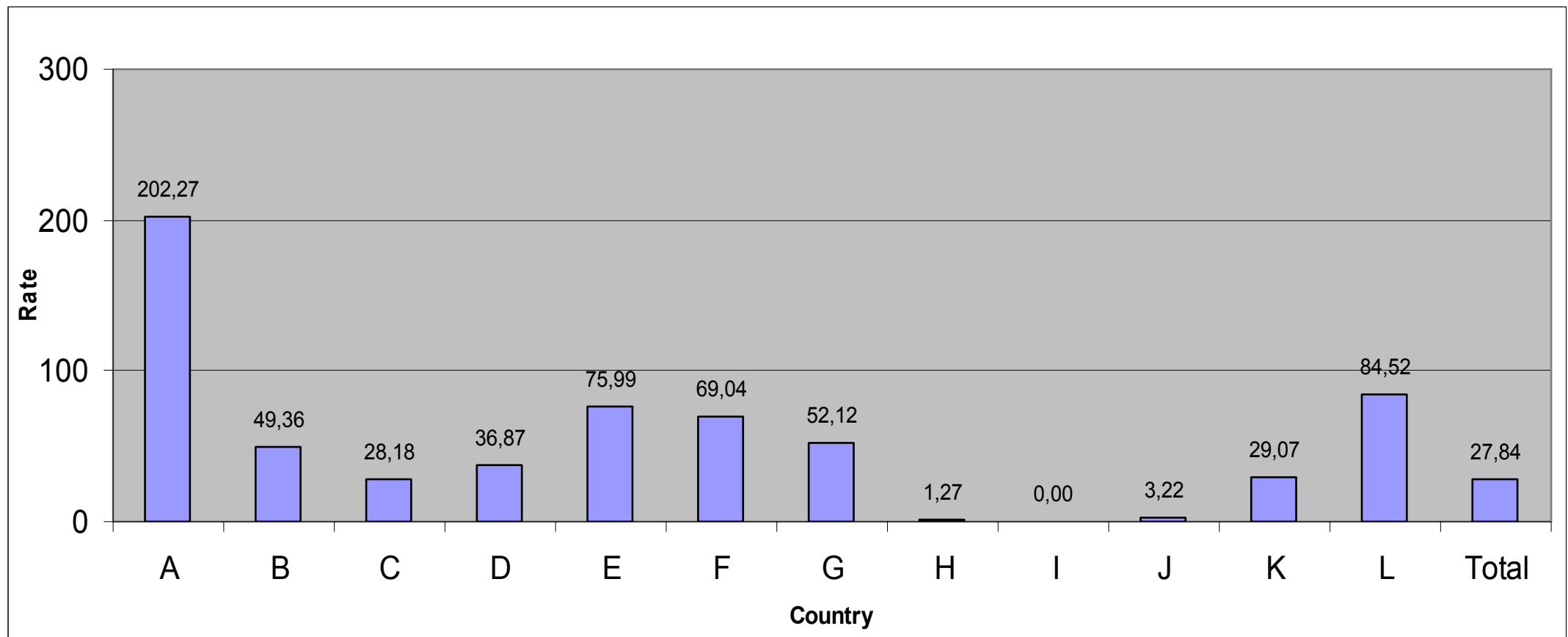
Per 100,000 units issued

Incidence of allergic reactions by country - 2007



Per 100,000 units issued

Incidence of FNHTR by country 200



Per 100,000 units issued

Conclusions

- It is possible to create an international database for ATR reporting
 - With relatively valid information
 - Incidence of ATR varies between countries
 - Reporting of ATRs varies
 - Estimation of imputability varies
 - Transfusion practices vary
 - Compliance to international definitions is not optimal
 - STARE will contribute to improve that situation
-

Conclusions

- There is a need to develop meaningful standardized definitions for adverse transfusion events (errors and near misses)
 - STARE adds value to regulatory based 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
 - surveillance of all events including minor ones instead of only serious ones allows better assessment of trends
-
- STARE has a future