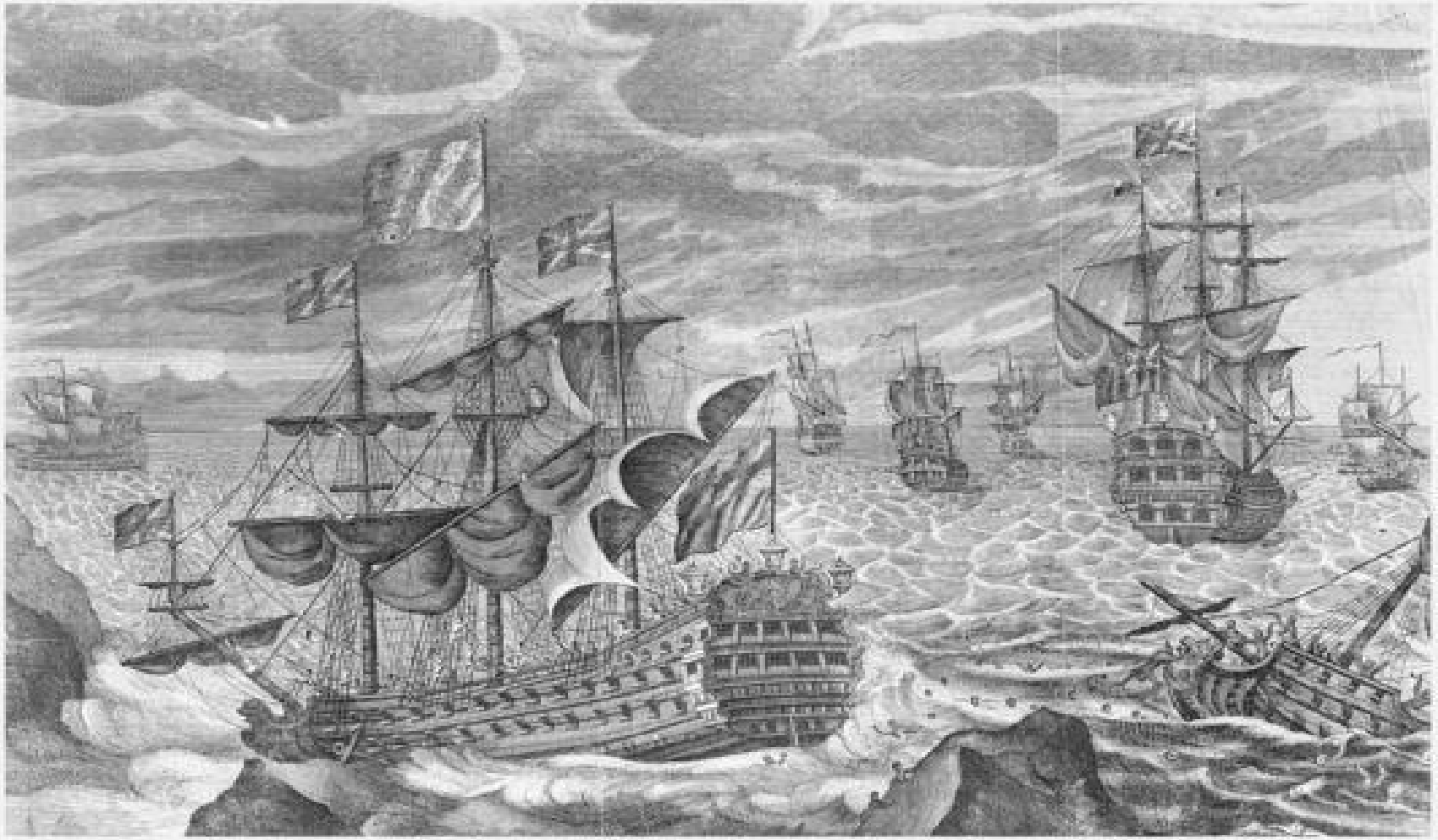
the Scilly naval disaster

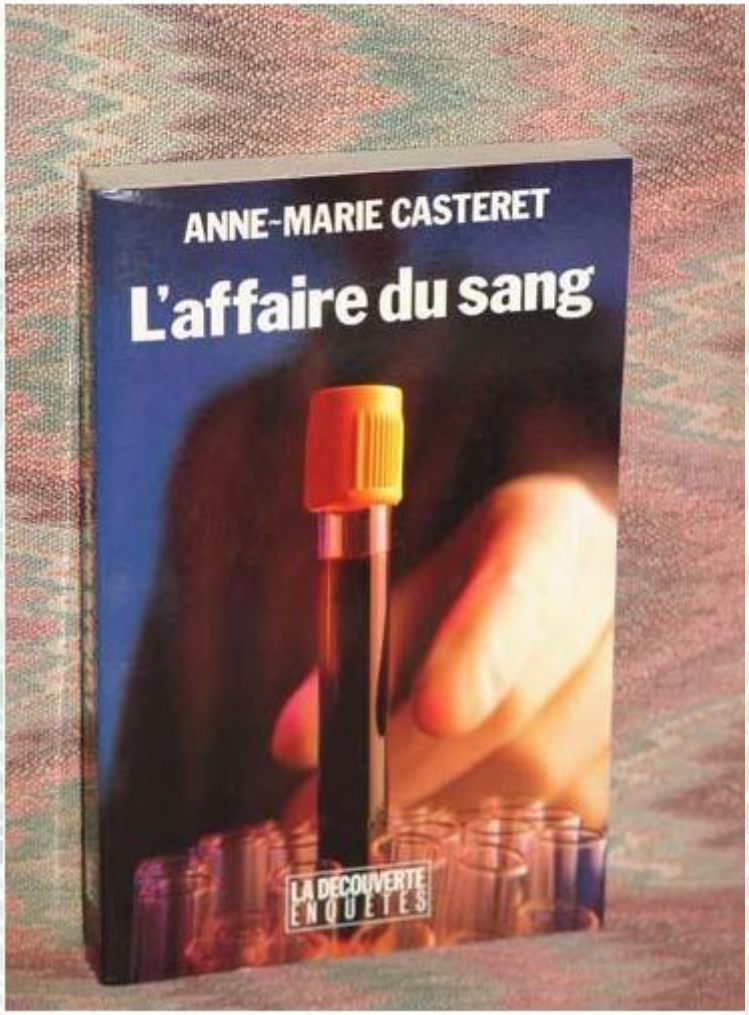


Harrison's solution

Transfusion safety: early history

- 17th century: animal blood
- 18th century: forbidden by law (too dangerous)
- 19th century: human blood as live saving therapy
- 20thcentury: more indications, relatively safe ?
- 1991:

The French blood disaster



Haemovigilance: short CV

- Haemovigilance was born and baptised in France in 1994 and grew up in the AFSSAPS family
- After two years she got a brother in the UK which was named SHOT
- stepwise other national systems appeared in Europe and beyond

Haemovigilance: short CV

- Haemovigilance was born and baptised in France in 1994 and grew up in the AFSSAPS family
- After two years she got a brother in the UK which was named SHOT
- stepwise other national systems appeared in Europe and beyond

Haemovigilance in the UK and beyond

- Many ways to Rome
- A global affair
- More than safety?

Haemovigilance in the UK and beyond

- Many ways to Rome
- A global affair
- More than safety?

HV: Concepts and models I

What is reported and when ?

- Only Adverse reactions (AR) or also Adverse Events (AE)
- All vs only serious AR
- Only in recipients or also in donors
- All or only product related AR and AE
- " Hot" vs "Cold" vigilance

HV: Concepts and models II

INTERNATIONAL HAEMOVIGILANCE NETWORK
WWW.IHN-ORG.NET

How is the system organised?

- Local, regional/national,international
- Passive vs active
- Voluntary vs mandatory
- Centralised vs decentralised
- Governance:
  - regulator, manufacturer, professional societies,Public Health

Reporting in haemovigilance systems

Country/ region	*Reports/ 1000 units	What is reportable	Type of system
UK	0.20	*Serious reactions + IBCT*	Voluntary
Ireland	1.22	*Serious reactions + IBCT*	Voluntary
France	2.83	All reactions	*Mandatory*
Netherlands	2.90	All reactions	Voluntary
Québec	7.07	All reactions	Voluntary

First year of reporting to the European Commission

INTERNATIONAL HAEMOVIGILANCE NETWORK
WWW.IHN-ORG.NET

Total SAR 2201 (1/10.000)

(serious adverse reactions)

Attributable to quality and safety of blood components 22 (1/1.000.000) = 1%

From Thomas Brégeon, European Commission
Directorate general for Health and Consumers

CONCLUSION

INTERNATIONAL HAEMOVIGILANCE NETWORK
WWW.IHN-ORG.NET

Irrespective of the structure of the system

Haemovigilance may provide data for priority settings and evaluation of preventive strategies

Institut national de santé publique Québec

HV: Results 1

Haemovigilance systems have documented that

- blood transfusion is safe and that
- labile blood components are extremely safe

HV: RESULTS II

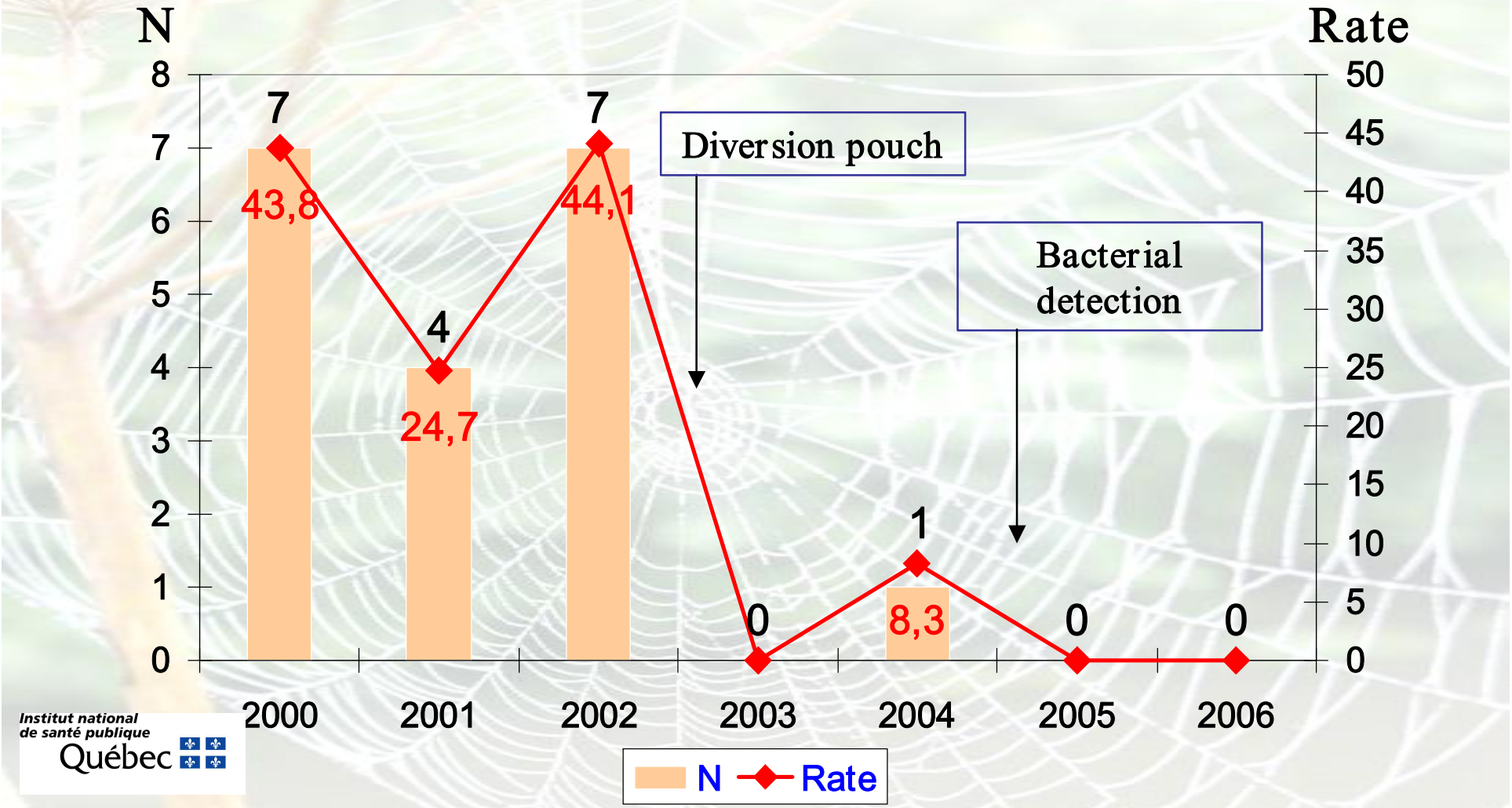
Administrative errors in the hospital still constitute an important category of preventable serious reactions,however

Many serious reactions are not (yet) preventable

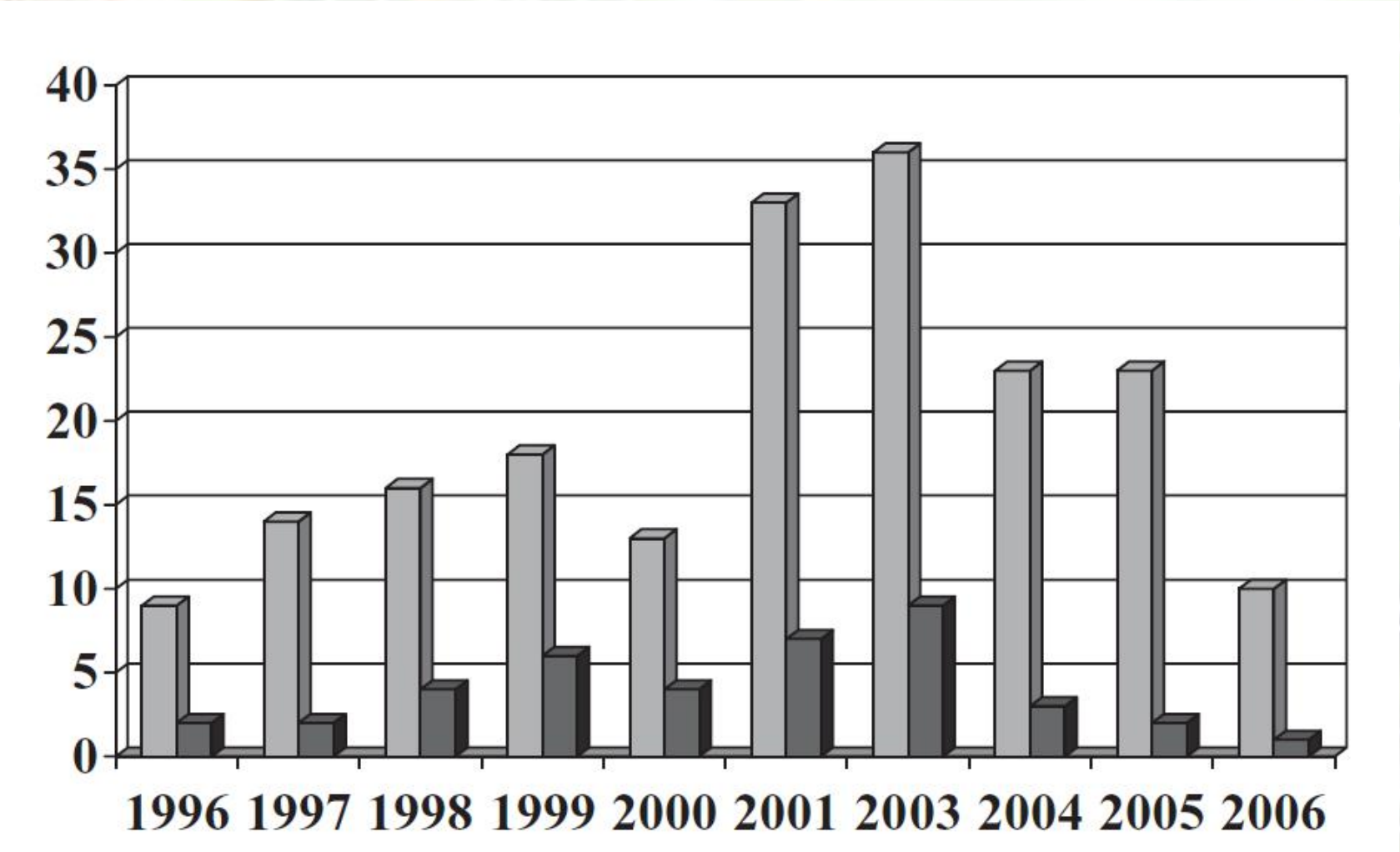
Results III

Well functioning Haemovigilance systems contribute significantly to evidence-based blood transfusion medicine, in particular the introduction of measures that improve the safety,such as

Frequencies and Ratios/100,000 Bacterial Infections - Platelet pools



The rise and fall of TRALI documented by SHOT



Chapman et al. Transfusion, 2009; 50: 440-452

Haemovigilance in the UK and beyond

- Many ways to Rome
- A global affair
- More than safety?

EHN: members

- Australia
- Austria
- Belgium
- Canada
- Croatia
- Denmark
- Finland
- France
- Germany
- Greece
- Iceland
- Ireland
- Italy
- Japan
- Luxembourg
- Malta
- Netherlands
- New Zealand
- Norway
- Portugal
- Singapore
- Slovenia
- South Africa
- Spain
- Sweden
- Switzerland
- United Kingdom
- United States

From EHN to IHN

IHN: main activities

- Website (www.ihn-org.net)
- Annual business meeting
- Annual Seminar (IHS)
- Working parties
- Database

IHS XIII Amsterdam

- Dates: 9-11 february 2011
- Venue: Royal Tropical Institute
- Program will include :
  - US HV program: first data
  - Risk management (vulcano ashes)
  - WS on quality indicators
  - morning for HV officers/nurses
  - IHN Award II

IHN: results

- Transfer of knowledge and experience: not readily measurable
- Standardisation: uniform definitions
- Database

Standardisation

The IHN and the *ISBT Working Party for Haemovigilance* have made two important contributions:

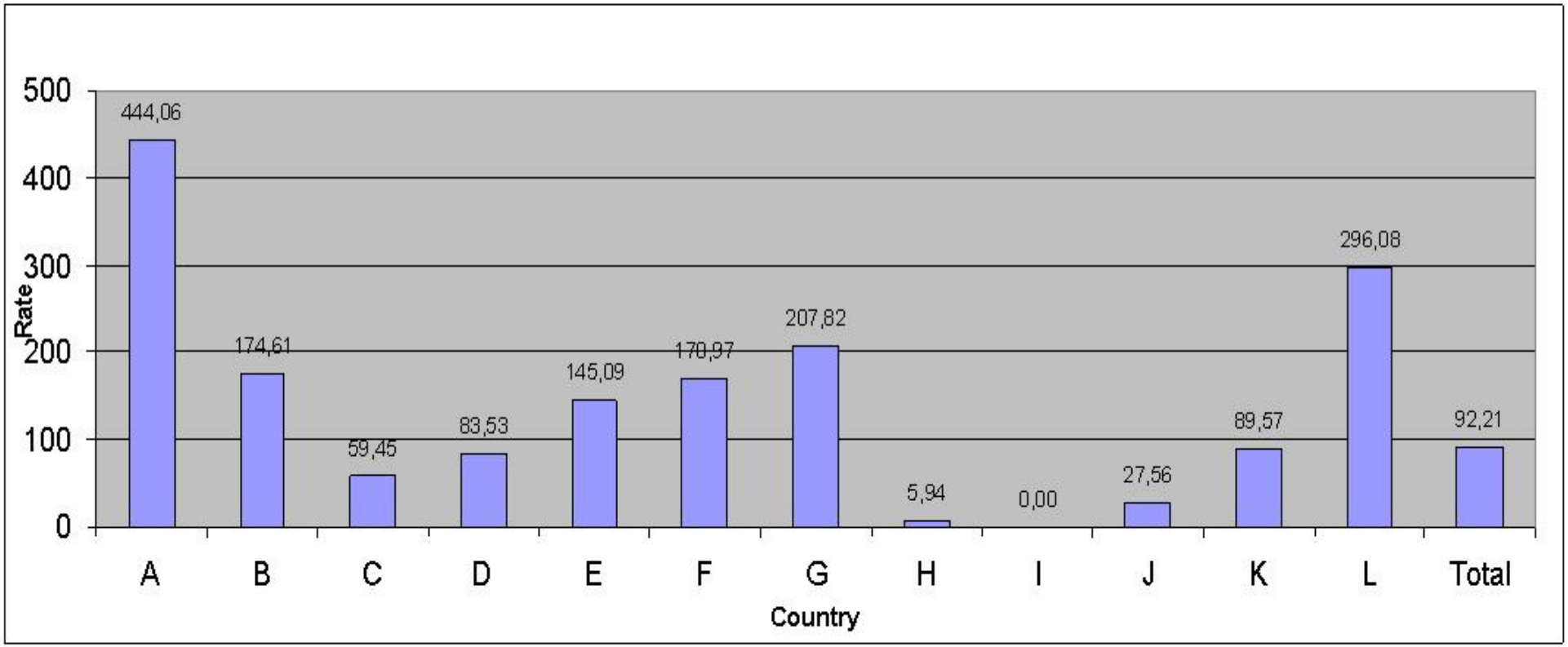
1. definitions of adverse reactions and adverse events in patients
2. definitions of complications and adverse events in donors

IHN database

General results – Year 2007

- 12 haemovigilance systems
  - 11 national
  - 1 regional
- 13,142 adverse reactions
- 14,391,424 units issued (11 systems)

Incidence of adverse reactions by country - 2007



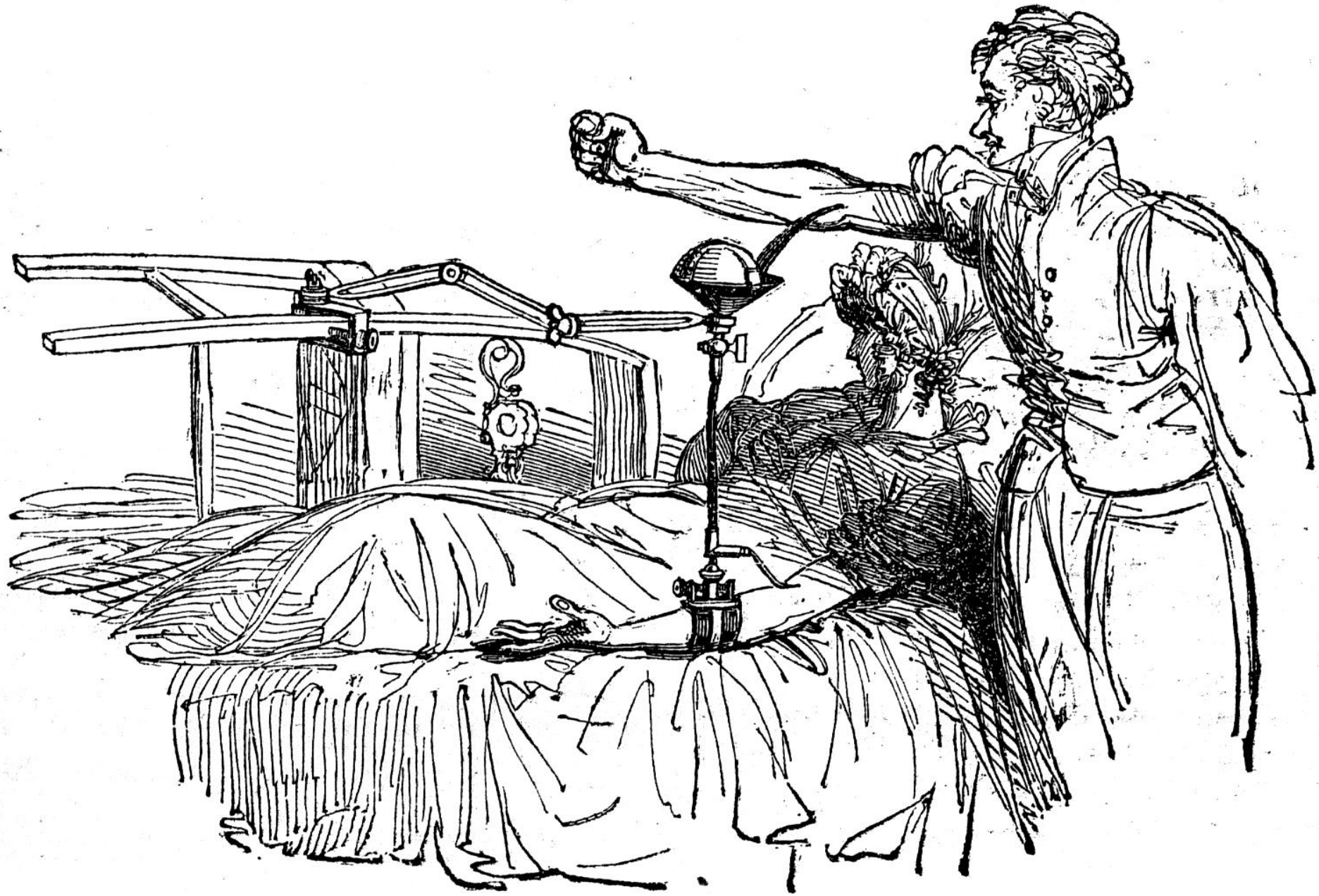
Per 100,000 units issued

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

Haemovigilance in the UK and beyond

- Many ways to Rome
- A global affair
- More than safety?



Questions

INTERNATIONAL HAEMOVIGILANCE NETWORK
WWW.IHN-ORG.NET

Bloodtransfusion:

worth the risk?

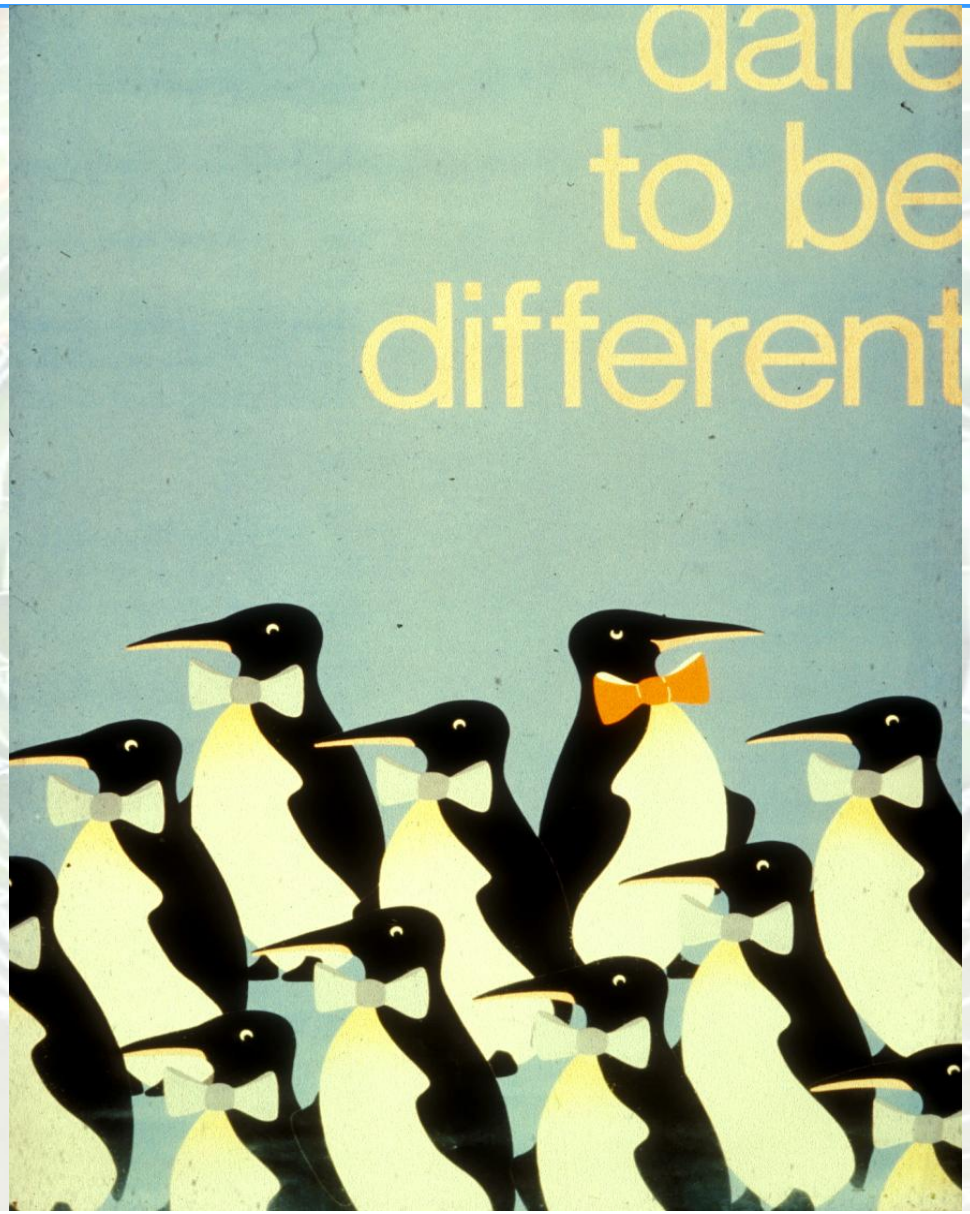
Safer products:

worth the money?

Should we watch for more than safety of blood transfusions?

	Risk
. Medication	1: 100
• Blood Transfusion	1: 10.000
• Blood component	1: 1.000.000
• Blood saving procedures	???
	Benefit
• Blood transfusion	????????

Many ways to Rome



A global affair

RRP de Vries

SHOT Manchester 06-07-10

More than safety ?

INTERNATIONAL HAEMOVIGILANCE NETWORK
WWW.IHN-ORG.NET

Annual SHOT Symposium

I wish you

a very vigilant,

highly informative

and pleasant day