

# the Scilly naval disaster



# Harrison's solution

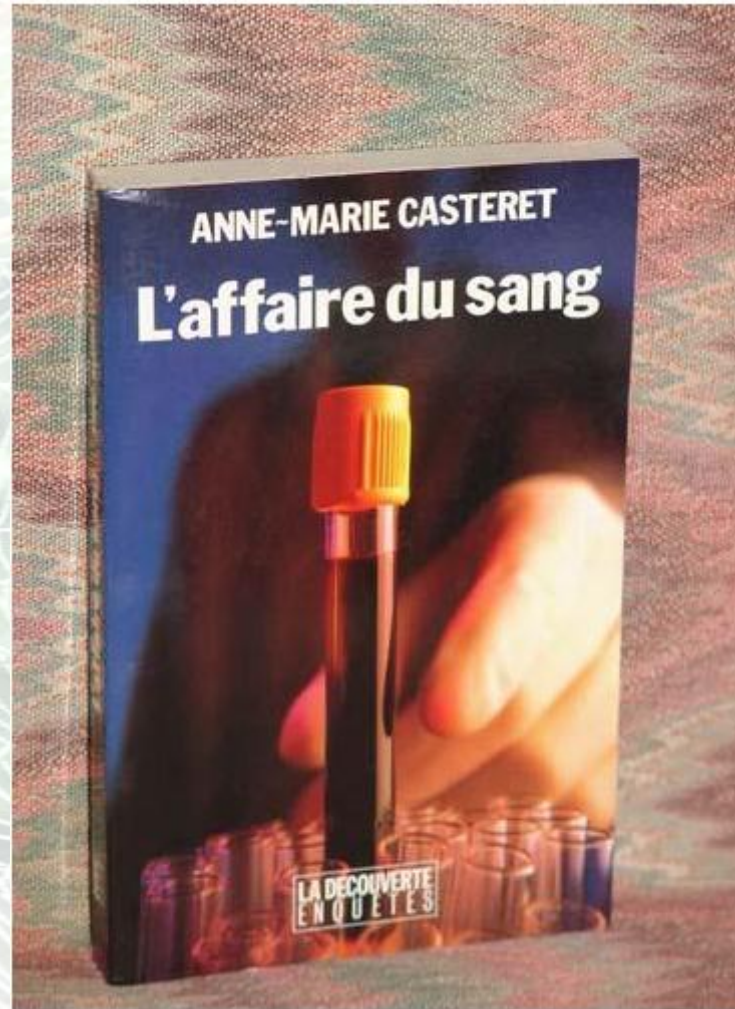


# Transfusion safety: early history



- 17<sup>th</sup> century: animal blood
- 18<sup>th</sup> century: forbidden by law ( too dangerous)
- 19<sup>th</sup> century: human blood as live saving therapy
- 20<sup>th</sup> century: 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



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- 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?

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# 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



## *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	<i>Serious reactions + IBCT</i>	Voluntary
Ireland	1.22	<i>Serious reactions + IBCT</i>	Voluntary
France	<b>2.83</b>	All reactions	<b><i>Mandatory</i></b>
Netherlands	<b>2.90</b>	All reactions	<b>Voluntary</b>
Québec	7.07	All reactions	Voluntary

# First year of reporting to the European Commission



**Total SAR**

(serious adverse reactions)

**2201 (1/10.000)**

**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



*Irrespective of the structure of the system*

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

# 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**

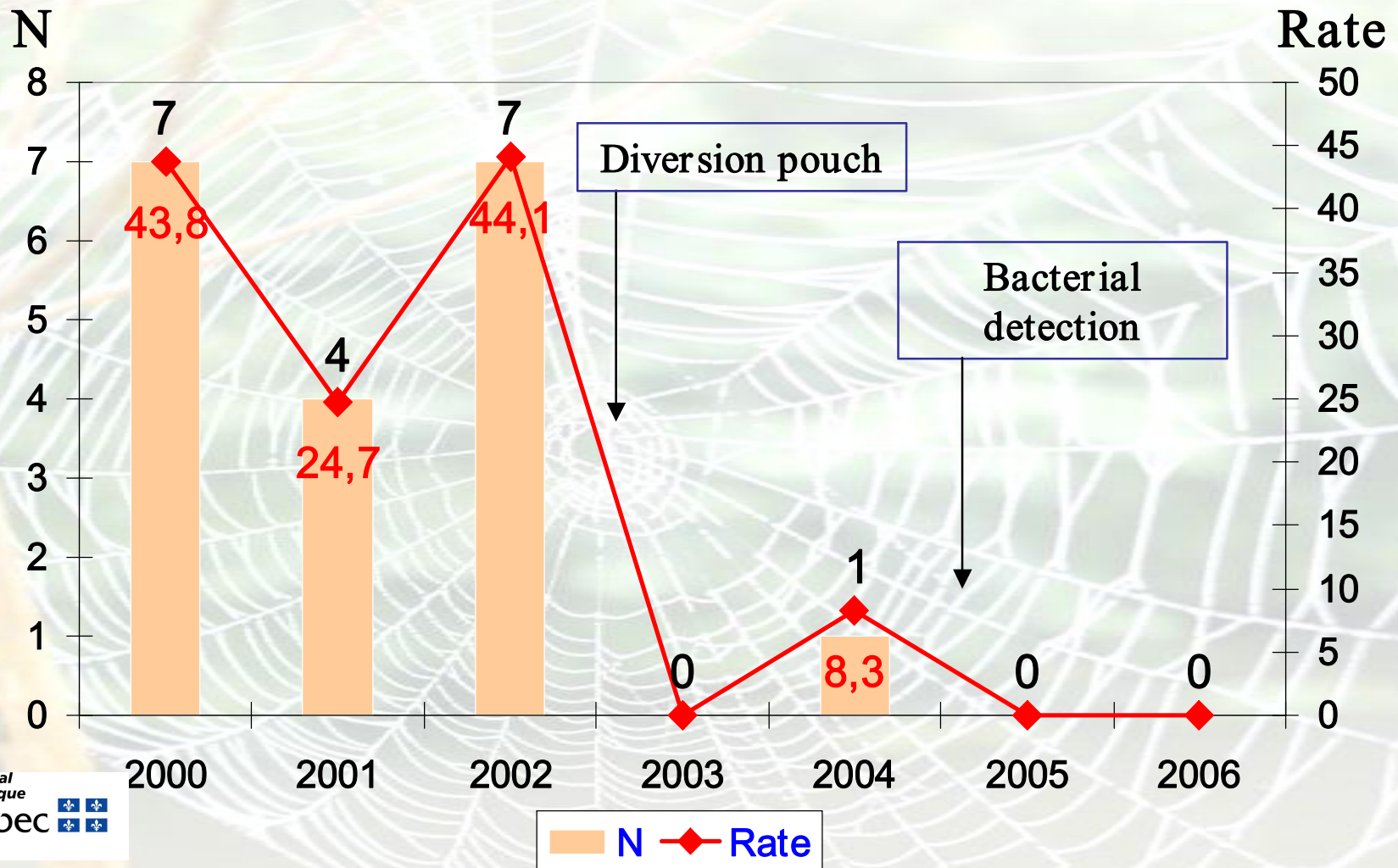
***Many serious reactions are not (yet) preventable***

# Results III

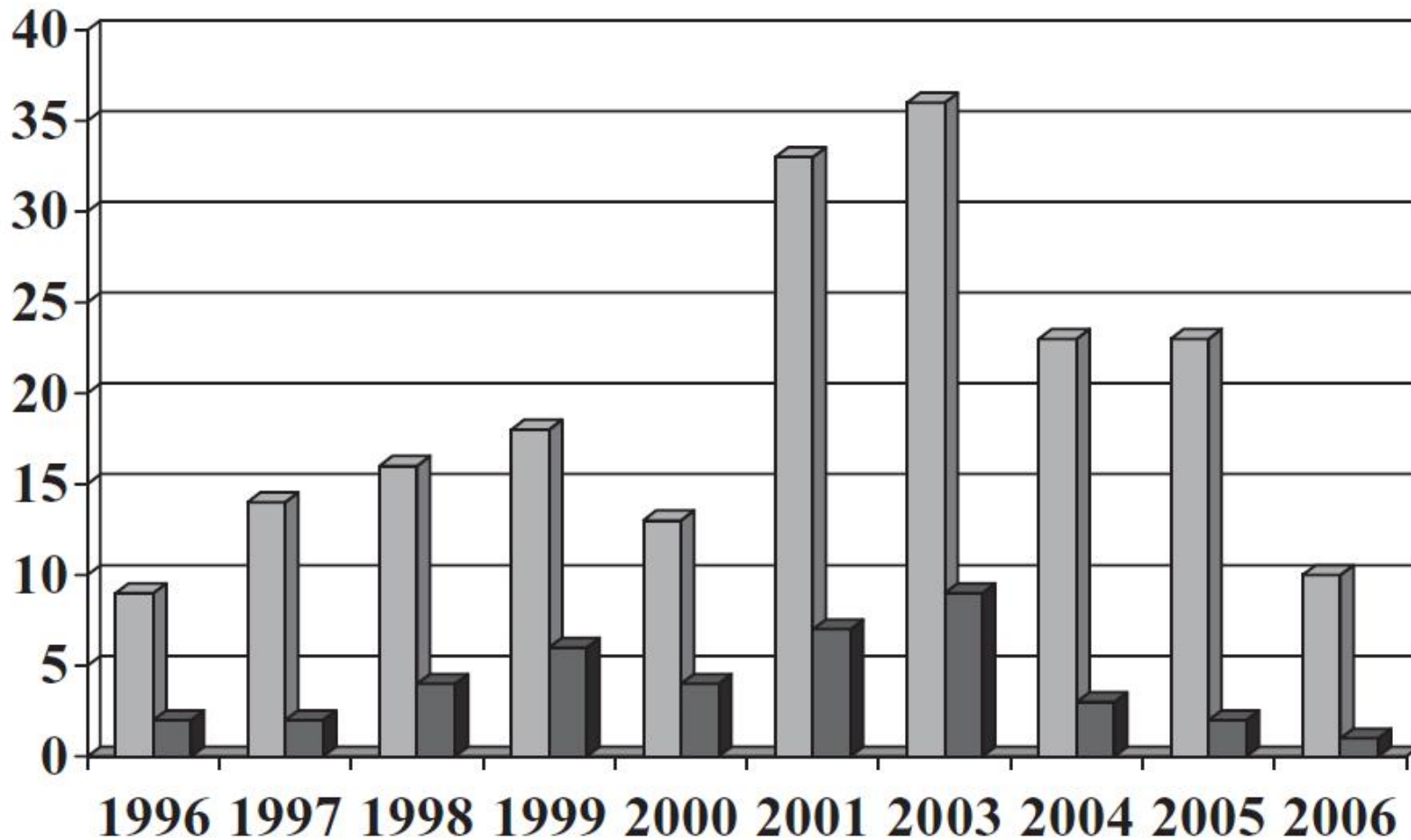


**Well functioning Haemovigilance systems contribute significantly to evidence-based blood transfusion medicine, in particular the introduction of measures that improve the safety, such as**

# 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

SHOT Manchester 06-07-10

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# 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



INTERNATIONAL HAEMOVIGILANCE NETWORK

WWW.IHN-ORG.NET



# IHN: main activities



- Website ( [www.ihn-org.net](http://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

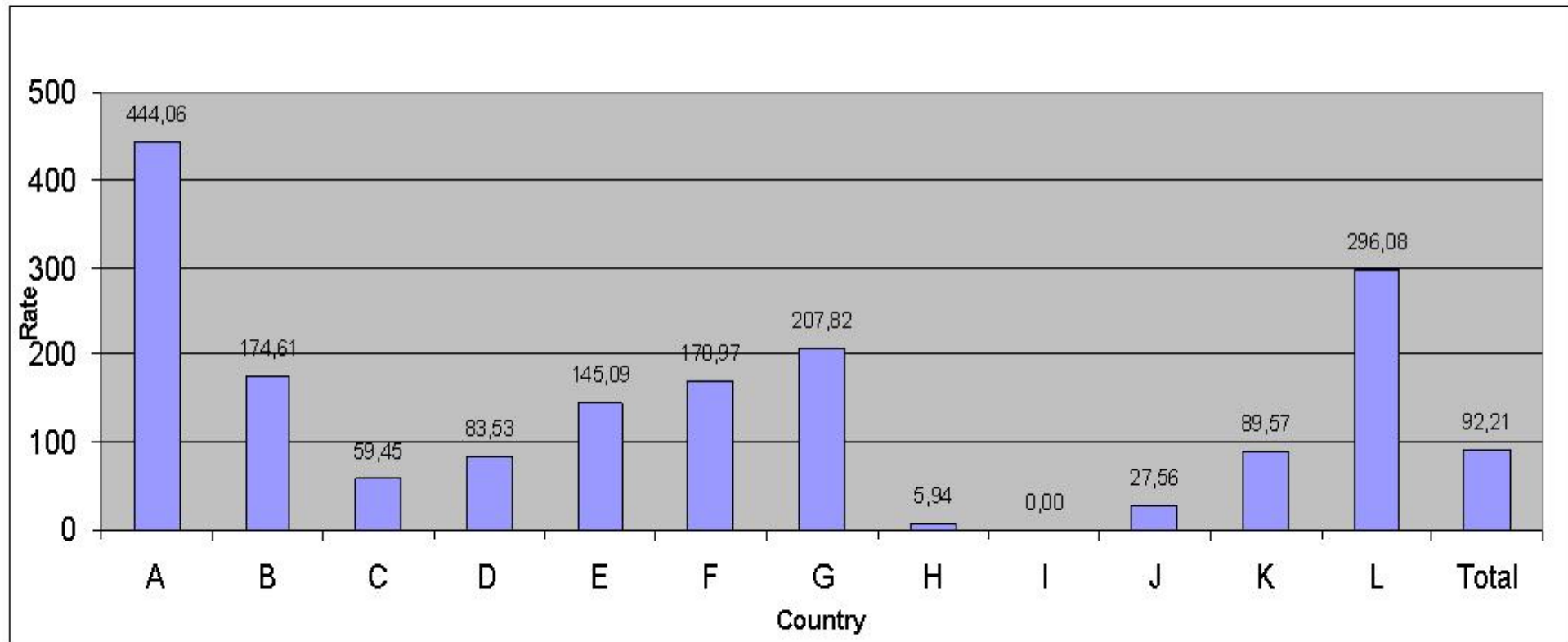


## General results – Year 2007



- 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

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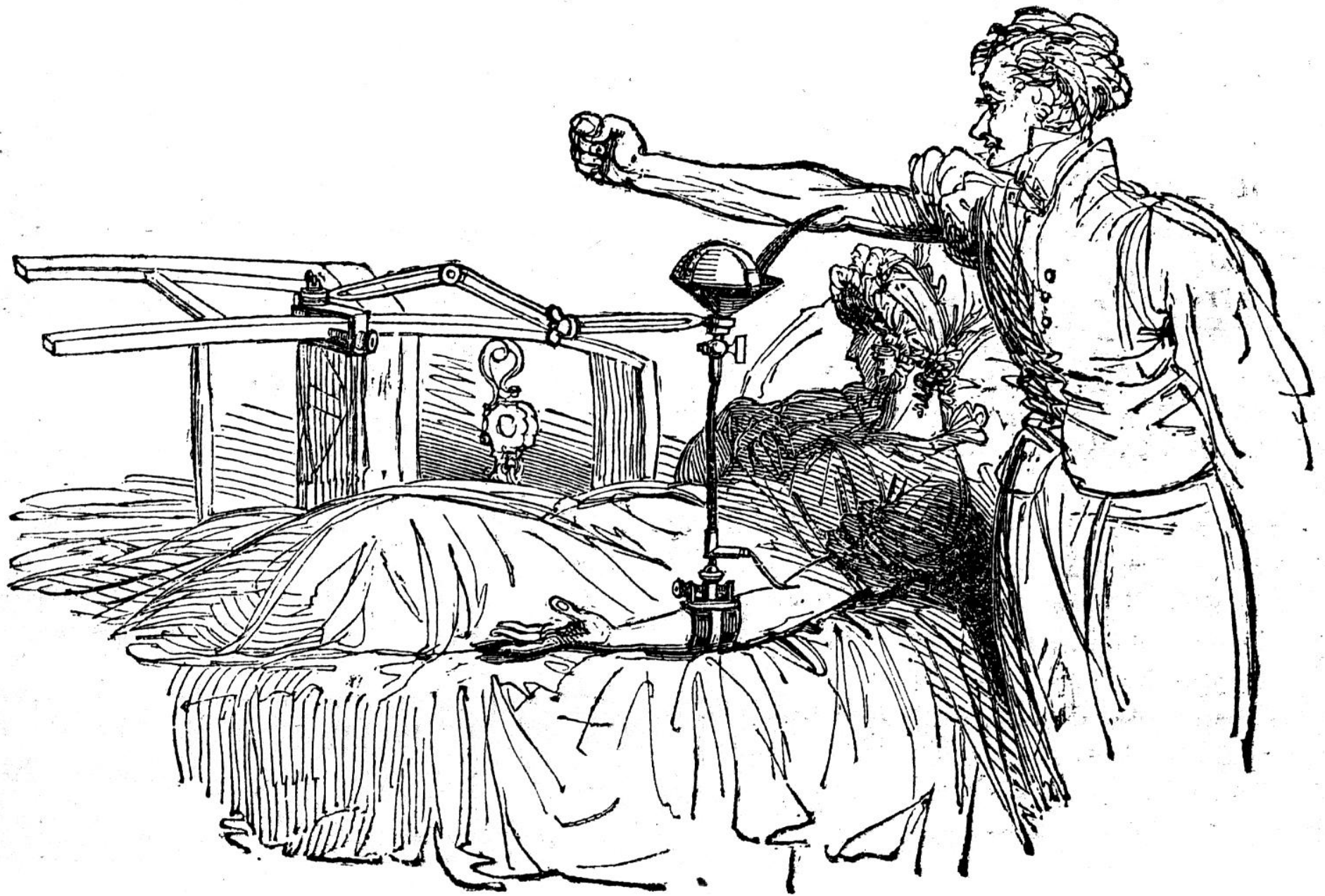
# Conclusions

- 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
-

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# Questions



***Bloodtransfusion:  
worth the risk?***

***Safer products:  
worth the money?***

# Should we watch for more than safety of blood transfusions?



## Risk

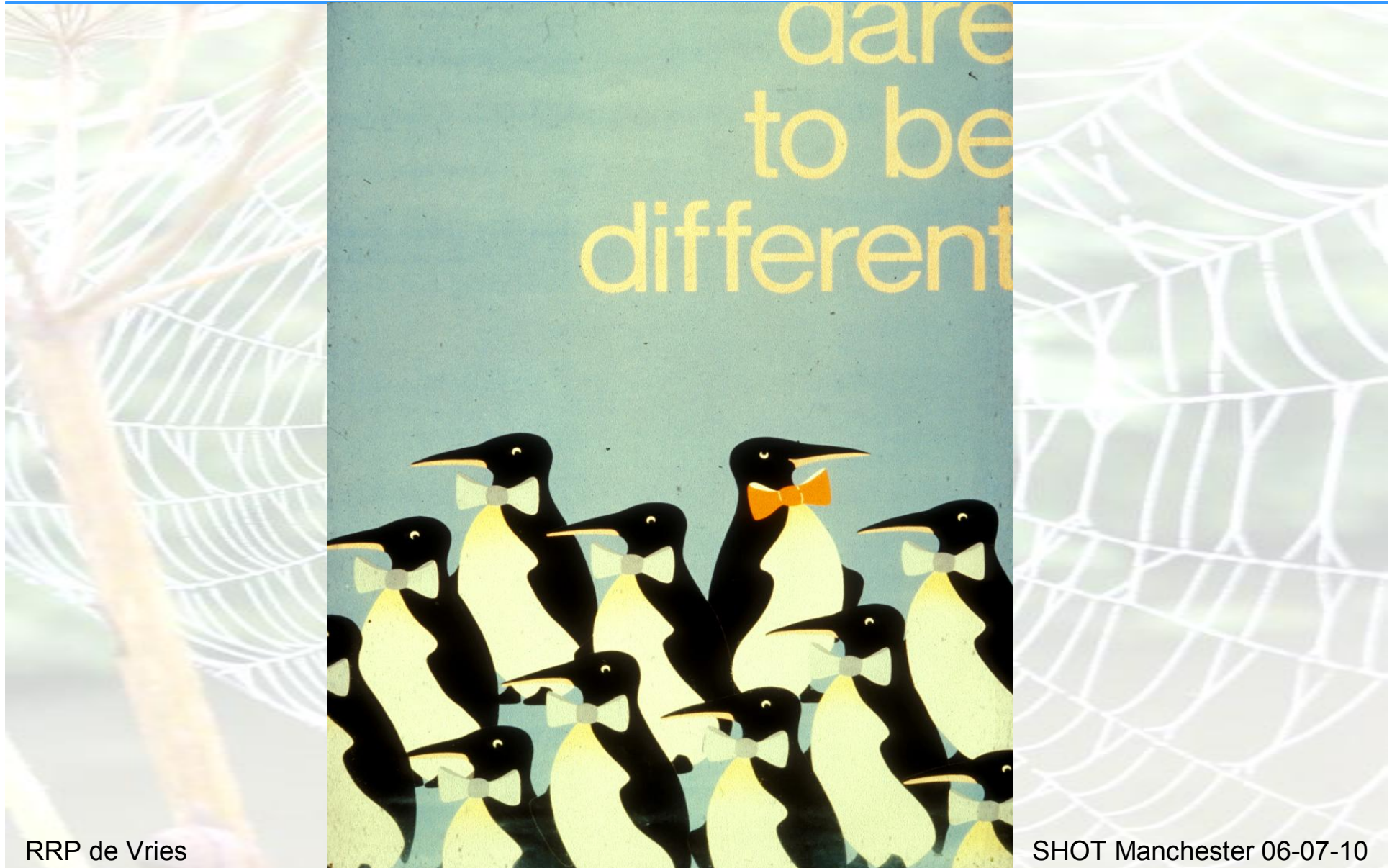
- Medication 1: 100
- Blood Transfusion 1: 10.000
- Blood component 1: 1.000.000

- Blood saving procedures ???

## Benefit

- Blood transfusion ??????????

# Many ways to Rome



RRP de Vries

SHOT Manchester 06-07-10

# A global affair



RRP de Vries

SHOT Manchester 06-07-10

# More than safety ?



# Annual SHOT Symposium



**I wish you  
a very vigilant,  
highly informative  
and pleasant day**