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 life saving therapy
• 20th 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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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
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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

<table>
<thead>
<tr>
<th>Country/region</th>
<th>*Reports/1000 units</th>
<th>What is reportable</th>
<th>Type of system</th>
</tr>
</thead>
<tbody>
<tr>
<td>UK</td>
<td>0.20</td>
<td>Serious reactions + IBCT</td>
<td>Voluntary</td>
</tr>
<tr>
<td>Ireland</td>
<td>1.22</td>
<td>Serious reactions + IBCT</td>
<td>Voluntary</td>
</tr>
<tr>
<td>France</td>
<td>2.83</td>
<td>All reactions</td>
<td>Mandatory</td>
</tr>
<tr>
<td>Netherlands</td>
<td>2.90</td>
<td>All reactions</td>
<td>Voluntary</td>
</tr>
<tr>
<td>Québec</td>
<td>7.07</td>
<td>All reactions</td>
<td>Voluntary</td>
</tr>
</tbody>
</table>
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
Irrespective of the structure of the system

Haemovigilance may provide data for priority settings and evaluation of preventive strategies
Haemovigilance systems have documented that:
- blood transfusion is safe
- 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

- Diversion pouch
- Bacterial detection

<table>
<thead>
<tr>
<th>Year</th>
<th>N</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>7</td>
<td>43.8</td>
</tr>
<tr>
<td>2001</td>
<td>4</td>
<td>24.7</td>
</tr>
<tr>
<td>2002</td>
<td>7</td>
<td>44.1</td>
</tr>
<tr>
<td>2003</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>2004</td>
<td>1</td>
<td>8.3</td>
</tr>
<tr>
<td>2005</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>2006</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
The rise and fall of TRALI documented by SHOT

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

RRP de Vries

SHOT Manchester 06-07-10
Haemovigilance in the UK and beyond

- Many ways to Rome
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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)
- 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
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

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Questions

Bloodtransfusion: worth the risk?

Safer products: worth the money?
Should we watch for more than safety of blood transfusions?

<table>
<thead>
<tr>
<th>Risk</th>
<th>Benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication</td>
<td>1: 100</td>
</tr>
<tr>
<td>Blood Transfusion</td>
<td>1: 10,000</td>
</tr>
<tr>
<td>Blood component</td>
<td>1: 1,000,000</td>
</tr>
<tr>
<td>Blood saving procedures</td>
<td>???</td>
</tr>
<tr>
<td>Blood transfusion</td>
<td>???</td>
</tr>
</tbody>
</table>
Many ways to Rome
A global affair
More than safety?

It’s amazing what one can accomplish when one doesn’t know what one can’t do.
Annual SHOT Symposium

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

RRP de Vries