Haemovigilance in Europa, to risk management in transfusion medicine

Paul Strengers, M.D.
Sanquin, Amsterdam; CAF, Brussels
Past-President European Haemovigilance Network

Symposium “Hemovigilantie”
Wetenschappelijke Vereniging Transfusie Vlaanderen
17 November 2006 - Gent
**Blood is ‘NEWS’**

**Italy:** Blood transfusion doctor accused of corruption with industry, committed suicide.  
*Italian news papers, May 2004*

**USA:** Wife of man who died from unordered and IBCT, filed lawsuit against hospital.  
*ABC newsletter, 5-11-2004*

**USA:** Recall of Ortho-Clinical Diagnostics Fetal Cell Screening Kit.  
*ABC newsletter, 21-1-2005*

**Netherlands:** Dutch government urged to inform public of blood mistakes.  
*Lancet, 25-6-2005*

**USA:** A woman whose 81-year-old mother died after IBCT, is suing an Anaheim hospital for the fatal error.  
*ABC newsletter, 13-1-2006*

**China:** Ban on use of transfusion appliances of the same lot due to severe transfusion reactions.  
*ABC newsletter, 20-1-2006*

**Spain:** Blood doping of famous cyclists by Spanish blood transfusionist, Dr. Fuentes.  
*Worldwide news agencies, July 2006*
Over the last 25 years:
Focus on blood safety of products

- Attention to voluntary, non-remunerated blood donors.
- Progressive exclusion of high risk donor groups.
- Progressive introduction of new / improved screening tests.
- Progressive introduction of viral inactivating and reducing production techniques.
- Increased interest of regulatory bodies in blood, resulting in directives, guidelines, notes for guidance, etc.
- Reorganisations of blood transfusion organisations.
- Public inquiries and court cases.
- Media attention on blood safety.

Hospital transfusion practice stayed a neglected area
The blood/plasma chain

risks

potential blood donor ➔ donor ➔ donation ➔ product ➔ recipient ➔ adverse event

adverse event ➔ adverse reaction

blood centres ➔ fractionators ➔ hospitals

General public and Authorities (policy makers, inspectorate, regulators)
## Residual risk from 1997-2003 in The Netherlands

(source Sanquin)

<table>
<thead>
<tr>
<th>Type of virus</th>
<th>Mean incidence among repeat donors (per mill. donor yrs)</th>
<th>Detection window (days)</th>
<th>Window risk</th>
<th>Probability of infected donation (per mill.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV 1/2</td>
<td>5.5</td>
<td>11</td>
<td>0.03</td>
<td>0.2</td>
</tr>
<tr>
<td>HBV</td>
<td>32</td>
<td>59</td>
<td>0.16</td>
<td>5</td>
</tr>
<tr>
<td>HCV</td>
<td>2.6</td>
<td>10</td>
<td>0.03</td>
<td>0.1</td>
</tr>
<tr>
<td>HTLV I/II</td>
<td>1.5</td>
<td>51</td>
<td>0.14</td>
<td>0.2</td>
</tr>
</tbody>
</table>
In The Netherlands, daily life is safer than 50 years ago  
(source: CBS, 2005)

<table>
<thead>
<tr>
<th></th>
<th>1954</th>
<th>2004</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhabitants</td>
<td>10.6 mill.</td>
<td>16 mill.</td>
</tr>
<tr>
<td>Risk on death by cancer</td>
<td>80,000</td>
<td>136,500</td>
</tr>
<tr>
<td>Risk on death by cardiovasc. disease</td>
<td>41 %</td>
<td>32 %</td>
</tr>
<tr>
<td>Risk on death by flue</td>
<td>0.55 %</td>
<td>0.09 %</td>
</tr>
<tr>
<td>Risk on death by suicide</td>
<td>0.88 %</td>
<td>1.1 %</td>
</tr>
<tr>
<td>Risk on death by tuberculosis</td>
<td>1 %</td>
<td>0.05 %</td>
</tr>
<tr>
<td>Risk on accidental drowning</td>
<td>0.5 %</td>
<td>0.07 %</td>
</tr>
<tr>
<td>Risk on death by traffic accident</td>
<td>2.1 %</td>
<td>0.6 %</td>
</tr>
<tr>
<td>Risk on death of a neonate, till year 2</td>
<td>2.26 %</td>
<td>0.44 %</td>
</tr>
<tr>
<td>Risk on death of a baby</td>
<td>3.12 %</td>
<td>0.66 %</td>
</tr>
<tr>
<td>Number of diseased</td>
<td>80,000</td>
<td>136,000</td>
</tr>
</tbody>
</table>
How safe is medical care?

Errors in prescribing or clinical use of medication more common than expected

USA (1999):
Every year: 44,000 – 98,000 patients die because of medical failures
4,000 – 7,000 patients die because of failures with medicinal products.
(Report of Institute of Medicine” To err is human”)

USA (2001):
6.7 % of patients in hospitals encounter errors in medication;
incidence of fatal Adverse Drug Reactions: 0.32 %

USA (2004):
More medical mistakes by sleep deprivation
(NEJM 2004:351:1838-48)
Medical errors in the U.K.

- Every year, 850,000 medical errors in hospitals run by National Health Service
- Direct result: 40,000 people die
- More likely in men, in elderly people and in emergency admissions
- Very largely preventable
- Clearly steps can be taken to massively reduce the risk
- ‘It is staggering that not more is done’

Taylor, Foster. BMJ, 2004
8 years of SHOT data 1996 - 2004
Adverse events and reactions
Incorrect Blood Component Transfused
(SHOT data 1996-2004)

Definition:
When a patient receives a blood component that did not meet appropriate specifications or was intended for another patient

- 1996-2004: 1,832 reports

- 20 deaths and 92 major morbidity: all preventable

- ‘no-harm’ events and near-misses give clue to underlying causes
SHOT Multiple errors in IBCT cases (1996 – 2003)
(totals cases = 1393; total errors = 2340; 69.7 % of reports; 1996-2004)
Response of authorities is changing (Dutch example)

Case: Incorrect Blood Component Transfusion (IBCT)

Identification product: 10 minutes before infusion by nurse together with resident nurse.

Identification patient: mentioning the name of patient, only.

Mistake discovered: after 5 minutes

Immediate actions: disconnection of bag; patient informed; ward manager informed.

Any harm to patient: none.
Position of authorities

**Inspectorate**: Nurse acted not in conformity with protocol.

a. Bedside check by two persons (one official registered) of patient identification data (name, birth date and PID) with identification data on blood bag and blood support form.

b. Question to patient is name and birth date (not: are you Mrs. Jones?)

**Response of nurse**: She had realized that she had acted against safety measures.
Reason:
She thought check with resident nurse was done;
She knew the patient;
It was busy on the ward where a patient had just died;
Beside check with colleague nurse was not possible.
Position of authorities

Regional Disciplinary Tribunal on Health Care

- Shortages in professional conduct are considered as serious.

- Person is to be blamed due to not acting following protocols, in particular by not checking compatibility of patient name with name on blood bag.

- Conclusion:
  Nurse has not acted in conformity with the care required to the patient.

Disciplinary action:
Official warning and publication in The Netherlands State Journal and in major journals on nursing

Official verdict June 2, 2005.

- **Case:** male, 55y, given FFP for reversal of coumadin effect prior to elective knee surgery. after 45 min.: cardiac arrest, death 6 hours later.

- **Donor:** female, 54y. 15 years of frequent donation: 290 donations. 3 pregnancies, resulting in 2 births and 1 abortion. donor’s plasma strongly positive for granulocyte 5b antibody ( >90% of white cells granulocyte-specific 5b antigen positive)

- This donor never implicated in case of TRALI before.

- FDA requested look-back study
- Study performed over 2 years prior to fatality
- Donor had made 73 donations
- 54 patients received 63 blood products.
- 36 patient charts could be evaluated for TRALI

Results:

13 patient charts (36.1%) indicated a transfusion reaction.

- 15 TRALI injuries temporarily associated with FFP:
  - 7 mild/moderate reactions in 6 (16.7%) recipients.
  - severe reactions in 8 (22.2%) recipients.

- 5 patients received multiple transfusions:
  - two 2 reactions each
  - one 2 mild/moderate reactions
  - one a mild/moderate and a severe reaction.

- Only 7 (46.7%) reactions were reported to hospital’s transfusion service.
- Only 2 (13.3%) were reported to blood centre.
Defining risks

Generically: Risk = probability x magnitude of harm

Operational risk: effects of human performance, technology and external events

Reputational risk: impact of organizational behavior on trust in the system

Compliance risk: necessity to keep abreast with national and international standards, regulations and standard–of–practice

Governance risk: requirements for sound decision making and clear accountabilities of all relevant stakeholders.
Domains of risk

Risk assessment / risk analysis:
- attempts to provide scientific estimates of health risks, and to identify sources of uncertainty in the data
- “bottom line” presents the possible adverse effect in the form of a certain probability that there will be an increased risk for each segment of the exposed population

Risk perception:
- an impression or intuitive judgment about the nature and magnitude of a risk
- people tend to overestimate the frequency of rare events and underestimate the frequency of common ones
- influenced by the degree:
  - to which the hazard is understood
  - to which it involves feelings of dread
  - size and type of population (e.g. children)
What about perception of blood?

**Patients** think blood transfusion is special and beneficial, but have difficulty in accepting small risks they can’t control.

**Blood Donors** believe their contribution is a gift to the community that will be used appropriately and safely.

**Clinicians** think blood is ordinary, take blood transfusion for granted, the benefit is assumed and the risks regarded as minimal.

**Governments** view blood as a commodity and transfusion medicine as an expensive support service, which should be regulated and funded in a “McDonaldised” manner.
Transfusion medicine

- Burdensome regulations
- Quantity & Quality of Blood Product
- Medico legal threats
- Therapeutic efficacy
- Clinical need
- Safety
- Cost effectiveness
- Politics focus on demand, safety & cost
- Public Awareness & Community perceptions
Models to reduce the risks

- Risk analysis
- Analysis of blood errors

Primary prevention
Secondary prevention

Risk factors: 3 x ‘P’

- Process
- Patient
- Product

Blood safety projects
Conclusion: haemovigilance is...

- Issue identification
- Assessment of harms and benefits
- Analysis of risks
- Assessment of options to mitigate risk
- Implementation of chosen strategies
- Monitoring and evaluation of effectiveness of these strategies
Why?

...simply because,

- "You can not fix, what you do not know"

- If you do not know why failures are made, you can not prevent that they will not be repeated.
‘Near-miss’ identification

General aspects:

• At what time was the incident?
• Was it busy in the patient’s room?
• Did the telephone ring at the same time?
• Was the apparatus working appropriate?
• Are the right protocols used?
• Are the protocols rightly used?
‘Near-miss’ form

Failures at blood drawing and identification

- Was blood drawn under exceptional circumstances?
- Was blood drawn from a number of patients at the same time?
- Was blood drawn while the patient’s name was not known yet?
- Is checked whether the identification data are corresponding with the data of the blood drawn from that patient?
- Was the patient falsely identified?
Safe Incident Reporting

...should be not blame free, but:

- In an open and transparent culture
- Objective on reporting of incidents in order to improve quality and safety of care.
- Start with consulting of the person, who encountered the incident. He/she is often very disappointed because a failure has been made which could seriously harm the patient. Support is often needed.
- Realize that patient safety is partly employer safety.
Dealing with public perception

- Epidemiological concept of risk is being more and more confused with danger.
- Neither abstract epidemiological figures nor strict rules should be the standard when it comes to risk assignment.
- Haemovigilance bears the character of a clinical science and should therefore stay close to daily practice.
Conclusion: haemovigilance should also....

- Dealing with risk perceptions
- Defining levels of acceptable risk
- Ensuring effective communication
- Acceptance that risk is a socio-political decision

BUT:
- Zero risk should not be a mandate
- Zero risk is likely an unrealistic and unattainable goal
- Risk should be as low as reasonable achievable.