European Haemovigilance Seminar
Zürich 2004

Workshop II

Haemovigilance and
Clinical Usage of Blood
Components

Haemovigilance in Denmark

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A Reporting System for Serious transfusion risks and complications

Danish Medicines Agency (DMA)

- Consider blood components as a drug
- It is a legal obligation to report drug complications to DMA
- Consequently a transfusion complication should be reported to DMA

The Danish Medicines Agency received no reports on adverse events

This was accepted both by the health authorities and the transfusion centres
Reports from UK and France (1998)
Serious Hazards of Transfusion

- **SHOT**
  Love, Williamson, Cohen et al.
  *Serious Hazards of Transfusion. Annual Report 1996/97*

  Williamson and Love: *Reporting Serious Hazards of Transfusion*
  Morel and Hervé: *Surveillance of Blood Transfusion Safety: Contribution of the Hemovigilance Strategy in France*

A Reporting system for Serious transfusion risks and complications

**Danish Society of Clinical Immunology (DSKI):**
- Was allowed to do the practical work:
  Collect data on serious events
  in a voluntary and confidential reporting system.
  Analyze and publish the data.
- On condition that the Danish Medicines Agency:
  Should be supplied with accumulated data.
  Should be contacted immediately if a new kind of events appeared.
Danish Registration of Transfusion Risks (DART)

Danish Society of Clinical Immunology (DSKI)

- The responsible body is DSKI
- The Committee on Transfusion Medicine, DSKI will be the steering group for the organization
- The National office was placed in the Transfusion Centre in Aarhus
- National coordinators: Jørgensen and Taaning
- Name: DART

It was decided to copy an existing system in order to
- Save time
- Not repeat work already done

SHOT was chosen because
- It was described in details in the annual report
- The results were exiting
Danish Registration of Transfusion Risks (DART)

Decision was made: September 1998
DART was implemented: January 1999

Implementation in a few months possible because:

- Copy of an existing system
- Persons responsible for the practical work in the Transfusion Centres were informed at meetings
- All involved in the process were very enthusiastic
- Number of persons involved was small
Danish Registration of Transfusion Risks (DART)

Reporting system

The Reporting system actually consists of two steps:

- Transfusion report
  Used for registration of all transfused blood components

- DART report
  Used only for registration of risks and complications
Danish Registration of Transfusion Risks (DART)
Reporting system: Transfusion report

1. Transfusion report

- A report form is attached to all blood component delivered from the hospital blood bank to the clinical department.
- The clinical department has to answer the questions in the report and send it back to the blood bank within 24 hours after transfusion.

If the transfusion report is not returned, the blood bank will ask for it.

The Danish Medicines Agency inspect the blood banks every other year. During that procedure they control that most of the reports have been returned.

Therefore, the return rate is very high (>99%).
Danish Registration of Transfusion Risks (DART)
Reporting system: DART report

2. DART report

- The local hospital blood bank fill in the report form.
- Forward the report to the Regional Blood Transfusion Centre.
- RBTC accept the report or add further information.
- The RBTC forward the report to DART.
- RBTC is responsible to the DART (secure validity of data).

Danish Registration of Transfusion Risks (DART)

Results & Validation of data
### Occurrence of Adverse Events

Comparison of cumulative data of SHOT and DART

<table>
<thead>
<tr>
<th></th>
<th>NUMBER</th>
<th>PER CENT</th>
<th>RATIO*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SHOT</td>
<td>DART</td>
<td>SHOT</td>
</tr>
<tr>
<td>IBCT</td>
<td>699</td>
<td>55</td>
<td>61</td>
</tr>
<tr>
<td>IMM</td>
<td>410</td>
<td>45</td>
<td>35</td>
</tr>
<tr>
<td>TTI</td>
<td>32</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>TOTAL</td>
<td>1141</td>
<td>104</td>
<td>99</td>
</tr>
</tbody>
</table>

*Adverse events per 100,000 transfused components

SHOT (1997-2001) 16 mill transfusions
DART (1999-2003) 2.3 mill transfusions

### Clinical Outcome after Adverse Events

Comparison of SHOT and DART

<table>
<thead>
<tr>
<th></th>
<th>NUMBER</th>
<th>PER CENT</th>
<th>RATIO*</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>SHOT</td>
<td>DART</td>
<td>SHOT</td>
</tr>
<tr>
<td>Death</td>
<td>61</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td>Major</td>
<td>166</td>
<td>29</td>
<td>16</td>
</tr>
<tr>
<td>Minor</td>
<td>819</td>
<td>71</td>
<td>78</td>
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<tr>
<td>Total</td>
<td>1046</td>
<td>104</td>
<td>100</td>
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</table>

*Clinical outcome per 100,000 transfused components

SHOT (1997-2001) 16 mill transfusions
DART (1999-2003) 2.4 mill transfusions
### Near Miss Events

Comparison of SHOT and DART

<table>
<thead>
<tr>
<th></th>
<th>NUMBER</th>
<th>PER CENT</th>
<th>RATIO*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SHOT</td>
<td>DART</td>
<td>SHOT</td>
</tr>
<tr>
<td>Sample</td>
<td>423</td>
<td>150</td>
<td>52</td>
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<tr>
<td>Request</td>
<td>62</td>
<td>0</td>
<td>8</td>
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<tr>
<td>Lab Fail</td>
<td>106</td>
<td>65</td>
<td>13</td>
</tr>
<tr>
<td>Comp 1</td>
<td>145</td>
<td>31</td>
<td>18</td>
</tr>
<tr>
<td>Comp 2</td>
<td>75</td>
<td>30</td>
<td>9</td>
</tr>
<tr>
<td>Misc.</td>
<td>1</td>
<td>2</td>
<td>0.1</td>
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<tr>
<td><strong>Total</strong></td>
<td>812</td>
<td>278</td>
<td>100</td>
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</table>

* Near Miss Events per 100,000 transfused components

**SHOT (1997-2001) 16 mill transfusions**

**DART (1999-2002) 1.8 mill transfusions**

### Registration of Transfusion Risks

### Conclusions & Consequences
Failures: Conclusion

Failures occur more often than expected  ratio  2.4

The clinical outcome was:

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Ratio</th>
</tr>
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<tbody>
<tr>
<td>Death</td>
<td>0.2</td>
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<tr>
<td>Major morbidity</td>
<td>1.2</td>
</tr>
</tbody>
</table>

Ratio = No/100,000 transfused components

Failures: Consequence of results

The data shows that in most of the cases

- The paperwork was done in the ward office (not bedside)
- The component was then given without control of identity
- Control of identity was not repeated bedside (“done already”)

Why?
Because:

1. It is not easy to handle the process physically
   
   There are so many pieces of something involved in the process that it is too complicated to handle it bedside
   - patient file, blood group answer, result of cross match
   - the patient and two nurses (stressed)
   - the component

2. It is difficult to handle the process mentally and therefore difficult to handle it with responsibility
   
   Together, two nurses must find out how they can control something they know only a little about and can not really control (written by other persons).
   - Blood groups written on different pieces of paper, and not always the same blood groups on these papers.
   - Cross match results when the patient has antibodies.
   - Component: When shall it be irradiated or leucodepleated?
   - Expire date of the cross match and the component.
DSKI will act to implement:

- A simplification of the standard operation procedure for the control of a blood component immediately before transfusion
- Bar codes on patient wristbands and blood components, used together with a computerised control of identity

DSKI: A new SOP for control of blood components before transfusion could be the following:

One nurse shall herself do a bedside control only of the identity between

- What she herself can read is written on the component about name and birthday of a patient and
- The patient in the actual bed

The blood bank is responsible for all the rest
**Danish Registration of Transfusion Risks (DART)**

**TRALI: Conclusions and Consequences**

- Occur more often than expected
- Education of hospital staff about the syndrome
- FFP for direct transfusion of patients should be only from male donors who have never been transfused with blood components
  
  *Standards of Transfusion Medicine (DSKI)*

**Danish Registration of Transfusion Risks (DART)**

**TTI: Conclusions and Consequences**

- The relative occurrence is only 3% of all risks
- The transmitted agent is normally a bacteria and hardly ever a virus
- Danish Health Authorities will nowadays not always follow the public opinion and initiate new virus screening, when possible
  
  They ask for and follow advise given by DSKI