ANNUAL SHOT REPORT 2016

The Oscar factor and transfusion complications

Paula Bolton-Maggs
Medical Director
Synopsis

• Overview of findings in 2016
• ABO-incompatible transfusions
• Near miss incidents
• Key recommendations (2)
• IT issues
Overview

3091 total reports

Errors 87.0%

Near miss 1283
RBRP 227
All errors

1178 (74.5%)

1581 incidents

Pathological reactions 385 (24.4%)
Others (CS & UCT) 18 (1.1%)

Debbi Poles
Data analyst
All incidents reported in 2016 n=3091

- NM: Near miss
- RBRP: Right blood right patient
  - Possibly preventable
  - Unpredictable

- UCT: Unclassifiable complications of transfusion
- PTP: Post-transfusion purpura
- TTI: Transfusion-transmitted infection
- CS: Cell salvage
- ATR: Acute transfusion reaction
  - Unpredictable
  - Possibly preventable
  - Errors

- TAD: Transfusion-associated dyspnoea
  - Possibly preventable

- TRALI: Transfusion-related acute lung injury
- TACO: Transfusion-associated circulatory overload
- TA-GvHD: Transfusion-associated graft vs host disease
- HTR: Haemolytic transfusion reaction

- ADU: Over or undertransfusion and PCC
  - ADU: Delayed transfusion
  - ADU: Avoidable transfusion

- HSE: Handling and storage errors
- Anti-D: Anti-D immunoglobulin errors
- IBCT: Incorrect blood component transfused

Total incidents: 1283
Cumulative data for SHOT categories 1996-2016 n=18258

- UCT: Unclassifiable complications of transfusion
- PTP: Post-transfusion purpura
- TTI: Transfusion-transmitted infection
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- TACO: Transfusion-associated circulatory overload
- TA-GvHD: Transfusion-associated graft vs host disease
- Allo: Alloimmunisation

Failure to provide irradiated components: n=1310 patients since 1999
Clinical failures 76.8% in 2016
1 patient missed for 486 components

Adverse incidents due to mistakes
Updated reporting* – First 6 months 2017
(Red is month from end of May to end of June 2017)

<table>
<thead>
<tr>
<th>Condition</th>
<th>Number of reports</th>
</tr>
</thead>
<tbody>
<tr>
<td>Withdrawn</td>
<td>170</td>
</tr>
<tr>
<td>TTI</td>
<td>1</td>
</tr>
<tr>
<td>TRALI</td>
<td>2</td>
</tr>
<tr>
<td>TAD</td>
<td>2</td>
</tr>
<tr>
<td>TACO</td>
<td>33</td>
</tr>
<tr>
<td>RBRP</td>
<td>57</td>
</tr>
<tr>
<td>PUCT</td>
<td>6</td>
</tr>
<tr>
<td>PTP</td>
<td>0</td>
</tr>
<tr>
<td>NM</td>
<td>462</td>
</tr>
<tr>
<td>IBCT-WCT</td>
<td>29</td>
</tr>
<tr>
<td>IBCT-SRNM</td>
<td>84</td>
</tr>
<tr>
<td>HTR</td>
<td>3</td>
</tr>
<tr>
<td>HSE</td>
<td>86</td>
</tr>
<tr>
<td>CS</td>
<td>2</td>
</tr>
<tr>
<td>ATR</td>
<td>99</td>
</tr>
<tr>
<td>ANTID</td>
<td>135</td>
</tr>
<tr>
<td>ADU</td>
<td>78</td>
</tr>
</tbody>
</table>

* May be subject to change after review by experts
MHRA submitted SAR and SAE reports 2007 to 2016

SHOT experts define SAR
The risk of infection transmitted from blood components is very low n=1

Platelets
3 S. aureus
1 S. marcescens
Possibly preventable: 121 (3.9%)
Not preventable: 282 (9.1%)
Errors: 2688 (87.0%)
Errors in Transfusion Medicine

Dorothy Stainsby, FRCP, FRCPath

National Blood Service, Holland Drive, Barrack Road, Newcastle upon Tyne NE2 4NQ, UK

Analysis of incorrect blood component transfused:
  Multiple errors
  70% clinical area
  Failure of bedside check

Serious Hazards of Transfusion:
A Decade of Hemovigilance in the UK

Dorothy Stainsby, Hilary Jones, Deborah Asher, Claire Atterbury, Aysha Boncinelli, Lisa Brant, Catherine E. Chapman, Katy Davison, Rebecca Gerrard, Alexandra Gray, Susan Knowles, Elizabeth M. Love, Clare Milkins, D. Brian L. McClelland, Derek R. Norfolk, Kate Soldan, Clare Taylor, John Revill, Lorna M. Williamson, and Hannah Cohen, on behalf of the SHOT Steering Group

Transfusion Medicine Reviews, Vol 20, No 4 (October), 2006: pp 273-282
Outcome of ABO-incompatible transfusions

66% have no adverse effect

15 deaths to 2005
5 deaths 2006-2016

No or minor adverse reaction
Major morbidity
Deaths def/prob/poss

Year of report
*15 months in 01/02

BSQR=Blood Safety and Quality Regulations
Good news: reduction in ABO-incompatible transfusions
Death in 2014 from ABO-incompatible transfusion

Filipina nurse who killed a pensioner when she mixed up his name with another patient and gave him the wrong blood during a transfusion is facing jail

- Lea Ledesma was working at London Heart Hospital as a nurse
- She injected Ali Huseyin, 76, with blood meant for Irfan Hussain
- Her blunder caused Mr Huseyin to have a heart attack and die
- She was today found guilty of manslaughter and cried at verdict

By ANTHONY JOSEPH FOR MAILONLINE

She was respected and experienced and known as ‘the mother’ of the intensive care unit. She received a suspended sentence
ABO-incompatible red cell transfusions 2016 n=3

This case is a mirror-image of the fatal case

- Patient group O+ Donor group A+
  Wrong blood in tube
  Major morbidity
  Case 10.3

- Patient group O+ Donor group A+
  Wrong blood in tube
  Case 10.4

- Patient group B+ Donor group A+
  Collection & administration
  Major morbidity
  Case 10.5
ABO-incompatible red cell transfusions

Near miss ABO-incompatible transfusions

3

264

(On a building site in Cardiff)
Wrong blood in tube incidents

Overall source of near miss errors

Point in the process where a wrong blood in tube incident was detected
Practices leading to near miss WBIT incidents n=629

**Poor practice**
- Patient not identified
- Sample not labelled at bedside
- Sample not labelled by person taking blood
- Prelabelled bottle
- Other

**Poor practice 98.9%**
Wrong component transfused

Mother: anti-D and anti-C detected at 17 weeks gestation
Advised close follow-up with titres
Monitored in tertiary centre
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Given the WRONG BLOOD. O D-pos (incompatible with maternal antibodies), should be O D-neg.

Baby: induced delivery at 36 weeks in local centre. Hyperbilirubinaemia. Group O D-pos. NICU staff were not aware of this baby prior to delivery; not discussed in obstetric high risk meeting.
Laboratory error and failure of communication

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Policies not followed:
Day 3: Verbal requests for urgent blood for exchange
2 BMS did not look at maternal results so provided wrong group

The baby required repeat exchange transfusion with O D-negative on day 6
The Oscar factor

**Envelopegate**
PwC, one of the best-known accountancy firms in the world, has supervised counting the ballots and the announcements, for the majority of Academy Awards ceremonies. Its employees wait in the wings, passing the results to the presenters. The failure of a system that was supposed to be foolproof, checked and counterchecked repeatedly, could not have been more public – watched by Hollywood stars and millions of people across the world on television.
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The Oscar factor

Failure of the 2-person check
Warren Beatty and Faye Dunaway
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Failure of the 2-person check
Warren Beatty and Faye Dunaway

Tweeting disaster
Key recommendation 1

be like a pilot – **use a bedside checklist** as standard of care. It will prevent administration errors and is the final opportunity to detect errors made earlier.

No amount of experience or years of practice will remove the risk of misidentification if you are interrupted or distracted.

The bedside check **will not detect a wrong blood in tube** at sampling.

(idea courtesy of Joy Murphy)
Deaths and major morbidity 2016
Bad news: 26 patients died where transfusion was implicated
Transfusion-related deaths 2010 to 2016 n=115

Delays 21.7% of deaths

Pulmonary complications 53.1%

- TTI: 1
- TA-GvHD: 1
- UCT: 7
- PTP: 1
- HTR: 8
- ATR: 5
- Anti-D: 1
- Avoidable: 3
- Delay: 25
- ABO-incompatible: 2
- TACO: 53
- TAD: 3
- TRALI: 5
The changing pattern of respiratory complications
Number of suspected TRALI cases and deaths at least possibly related to TRALI using revised criteria

![Bar chart showing the number of reported TRALI cases and deaths from 2003 to 2016. The x-axis represents the year of report, and the y-axis represents the number of reports. The chart indicates a notable increase in the number of cases and deaths in 2003, with a decline in subsequent years.](image-url)
National audit of TACO

- Patients over 60 years of age
- Transfused 1 March to end of April 2017
- Included risk factors for TACO
- Asked if reported to SHOT (as TACO or other)

Preliminary numbers:
- 3908 patients
  - 2146 inpatients, 10 TACO identified, 3 reported to SHOT
  - 1762 outpatients, no TACO identified

- SHOT increased reporting – by end of June
  53 TACO reports compared to 32 last year

(Thanks to John Grant-Casey)
Key recommendation 2

use a TACO checklist as standard of care.

This has been revised from last year
**TACO Checklist**

### Red cell transfusion for non-bleeding patients

<table>
<thead>
<tr>
<th>Condition</th>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart failure, congestive cardiac failure (CCF), severe aortic stenosis, or moderate to severe left ventricular dysfunction</td>
<td>Does the patient have a diagnosis of ‘heart failure’ congestive cardiac failure (CCF), severe aortic stenosis, or moderate to severe left ventricular dysfunction? Is the patient on a regular diuretic?</td>
</tr>
<tr>
<td>Pulmonary oedema</td>
<td>Is the patient known to have pulmonary oedema? Does the patient have respiratory symptoms of undiagnosed cause?</td>
</tr>
<tr>
<td>Fluid balance</td>
<td>Is the fluid balance clinically significantly positive? Is the patient on concomitant fluids (or has been in the past 24 hours)? Is there any peripheral oedema?</td>
</tr>
</tbody>
</table>

**If ‘yes’ to any of these questions**

1. Review the need for transfusion (do the benefits outweigh the risks)?
2. Can the transfusion be safely deferred until the issue can be investigated, treated or resolved?
3. Consider body weight dosing for red cells (especially if low body weight)
   - Transfuse one unit (red cells) and review symptoms of anaemia
   - Measure the fluid balance
   - Consider giving a prophylactic diuretic
   - Monitor the vital signs closely, including oxygen saturation

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**Due to the differences in adult and neonatal physiology, babies may have a different risk for TACO. Calculate the dose by weight and observe the notes above.**
Major morbidity for incidents reported in 2016

- ATR: 76 cases
- TACO: 18 cases
- IBCT: 8 cases
- HTR: 7 cases
- TAD: 6 cases
- CS: 2 cases
- Anti-D: 2 cases
- UCT: 1 case
- Delays: 1 case
- TTI: 1 case
Allergic reactions to platelets have reduced since the change to suspension of pooled platelets in platelet additive solution in 2015

Janet Birchall
Transplant-related errors continue to increase
N=298
Transplant-related ABO and D errors n=106
Impact of pressures on the NHS

• Increasing number of errors:
  – 87.0% SHOT reports
  – 98.1% of MHRA serious adverse event reports

• Human factors noted in 83 SHOT error reports
  – 27 (32.5%) staffing issues
  – 18 (21.7%) workload

• Human factors noted in 10% MHRA reports
Emergency departments: set up to fail?

Error reports over time from different departments

Emergency departments

<table>
<thead>
<tr>
<th>Year</th>
<th>RBRP</th>
<th>ADU</th>
<th>HSE</th>
<th>IBCT-WCT</th>
<th>IBCT-SRNM</th>
<th>% of total error reports</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>13</td>
<td>9</td>
<td>7</td>
<td>12</td>
<td>3</td>
<td>6%</td>
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<tr>
<td>2011</td>
<td>18</td>
<td>12</td>
<td>6</td>
<td>13</td>
<td>4</td>
<td>7%</td>
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<tr>
<td>2012</td>
<td>21</td>
<td>14</td>
<td>5</td>
<td>13</td>
<td>4</td>
<td>8%</td>
</tr>
<tr>
<td>2013</td>
<td>20</td>
<td>14</td>
<td>6</td>
<td>5</td>
<td>5</td>
<td>9%</td>
</tr>
<tr>
<td>2014</td>
<td>16</td>
<td>21</td>
<td>3</td>
<td>6</td>
<td>15</td>
<td>10%</td>
</tr>
<tr>
<td>2015</td>
<td>28</td>
<td>3</td>
<td>1</td>
<td>10</td>
<td>7</td>
<td>11%</td>
</tr>
<tr>
<td>2016</td>
<td>25</td>
<td>7</td>
<td>2</td>
<td>10</td>
<td>21</td>
<td>12%</td>
</tr>
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</table>

General wards

<table>
<thead>
<tr>
<th>Year</th>
<th>RBRP</th>
<th>ADU</th>
<th>HSE</th>
<th>IBCT-WCT</th>
<th>IBCT-SRNM</th>
<th>% of total error reports</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>62</td>
<td>68</td>
<td>198</td>
<td>64</td>
<td>63</td>
<td>6%</td>
</tr>
<tr>
<td>2011</td>
<td>74</td>
<td>66</td>
<td>137</td>
<td>74</td>
<td>63</td>
<td>7%</td>
</tr>
<tr>
<td>2012</td>
<td>69</td>
<td>79</td>
<td>102</td>
<td>40</td>
<td>103</td>
<td>8%</td>
</tr>
<tr>
<td>2013</td>
<td>76</td>
<td>74</td>
<td>100</td>
<td>25</td>
<td>110</td>
<td>9%</td>
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<tr>
<td>2014</td>
<td>73</td>
<td>85</td>
<td>93</td>
<td>40</td>
<td>114</td>
<td>10%</td>
</tr>
<tr>
<td>2015</td>
<td>78</td>
<td>104</td>
<td>102</td>
<td>40</td>
<td>102</td>
<td>11%</td>
</tr>
<tr>
<td>2016</td>
<td>102</td>
<td>106</td>
<td>126</td>
<td>31</td>
<td>126</td>
<td>12%</td>
</tr>
</tbody>
</table>

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Trend line (% total error reports)
Increasing number of specific requirements not met from laboratories
Anti-D immunoglobulin errors 2016

- Omission or late administration of anti-D Ig: 7
- Anti-D Ig given to a D-positive woman: 14
- Anti-D Ig given to a woman with immune anti-D: 11
- Anti-D Ig given to the mother of a D-negative infant: 15
- Anti-D Ig given to the wrong woman: 11
- Wrong dose of anti-D Ig given: 18
- Anti-D Ig handling and storage errors: 14

Late or missed: 81.4%

Total in 5 years: 1182

409 anti-D Ig-related incidents reported in 2016
2 women known to have developed immune anti-D

Lilian Parry
Clare Denison
Immune anti-D discovered in pregnancy

• Total 42 with no previous pregnancy (NPP)
• Total 115 who had a previous pregnancy (PP)
• 18/50 (36%) PP women found to be immunised at booking had apparently ideal management in the previous pregnancy
• Still worth giving anti-D Ig >72h and up to 10 days after a sensitising event (PSE)
Risk factors for sensitisation

• 14/61 (23%) weight >80kg
• 16/83 (19%) did not receive antenatal prophylaxis
• 19/28 (68%) PSE correctly managed
• 9/58 (16%) gestation beyond 40 weeks
  – National data: 17.5% pregnancies extend >40 weeks
• Postpartum prophylaxis correct in 62/102, missed in 8 and no information in 27
More questions than answers

- Should obese women receive increased dose?
- Should extra dose be given if pregnancy >40 weeks?
- Do twin pregnancies have increased risk?
- Is anti-D Ig required for medical termination without instrumentation?
Information technology
Information technology issues

- Global IT disruption May 2017 affecting 43 NHS sites
- Other incidents in Trusts November 2016
  - Leeds pathology IT system failure – 8 days
  - Ransomware attack in another region

75,000 passengers
170 airports
70 countries

May 26, 2017

Power surge, no backup
? Human error
IT incidents in SHOT

• IT is not error-proof
• 297/1405 (21.1%) error-related incidents were IT-related
• Recommendation:
  – Clinicians, laboratory scientists, IT professionals and IT providers should work together to develop an industry standard for flags, alerts and warnings that prevent harm from wrong blood but still ensure timely and accurate availability of blood components for clinical use
Additional Information

Following documents available on website www.shotuk.org

- SHOT report
- Teaching slide set
- SHOT cases
- SHOT reporting definitions
- SHOT Bites

Previous SHOT reports
SHOT summaries