SHOT 2010 and improving patient safety through interventions based on SHOT data

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SHOT

• Serious
• Hazards
• Of
• Transfusion
SHOT Aims

- To improve standards of hospital transfusion practice
- To inform policy with UK Blood Services
- To aid production of clinical guidelines
- To educate users on transfusion hazards and their prevention

SHOT’s mission is to improve patient safety
This talk....

- Improvements in patient safety through interventions based on SHOT data

- SHOT 2010
Deaths definitely attributed to transfusion
1996/97 - 2010
Deaths and major morbidity (i.e. serious outcomes): percentage of total reports 1996/97 - 2010

<table>
<thead>
<tr>
<th>Year of report</th>
<th>Number of reports</th>
</tr>
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<tbody>
<tr>
<td>1996/97</td>
<td>34%</td>
</tr>
<tr>
<td>1997/98</td>
<td>27%</td>
</tr>
<tr>
<td>1998/99</td>
<td>15%</td>
</tr>
<tr>
<td>1999/00</td>
<td>12.5%</td>
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<tr>
<td>2000/01</td>
<td>8.5%</td>
</tr>
<tr>
<td>2001/02</td>
<td>7.9%</td>
</tr>
<tr>
<td>2003</td>
<td>11%</td>
</tr>
<tr>
<td>2004</td>
<td>5.2%</td>
</tr>
<tr>
<td>2005</td>
<td>5%</td>
</tr>
<tr>
<td>2006</td>
<td>2.8%</td>
</tr>
<tr>
<td>2007</td>
<td>12.4%</td>
</tr>
<tr>
<td>2008</td>
<td>4.4%</td>
</tr>
<tr>
<td>2009</td>
<td>5.9%</td>
</tr>
<tr>
<td>2010</td>
<td>7.8%</td>
</tr>
</tbody>
</table>
1. **Reduction in mortality and major morbidity**
   - hallmark of an effective haemovigilance system
Recommendations 1997-1998

- SHOT reporting should be made a requirement of CPA

Participation is the key to successful haemovigilance
Reporting to SHOT: now a requirement

- Clinical Pathology Accreditation (CPA UK) Standard H2
- National Patient Safety Agency (NPSA) Safer Practice Notice SPN 14
- Health Service Circular (HSC) 2007/001 Better Blood Transfusion, Standard 4b.3
- Welsh Assembly Government, Healthcare Standards for Wales, Standard 16
PARTICIPATION

1996/97
- 94/424 hospitals 22%
- Issued with 3.16 million blood components from UKTS
- 141 analysed reports

2010
- 208 hospitals/trusts 94.7%
- Issued with 2.9 million* blood components from UKTS
- 1464 analysed reports +863 near misses +137 RBRP

*Includes 57,487 SD-FFP
IBCT

Largest reporting category
SHOT 1996-97

141 analysed reports

- IBCT: 47%
- ATR: 16%
- DTR: 16%
- TA-GvHD: 2%
- TRALI: 7%
- PTP: 7%
- TTI: 5%
IBCT events 1996/97 n = 63

Source of error

- Patient sampling and request
- Hospital transfusion laboratory
- Collection and administration

- 54%
- 29%
- 17%
1996/97 recommendations

- National standard for minimal formal identification requirement when component is collected and staff training

- The bedside check is vital in preventing error

BCSH guidelines on administration of blood components 1999 and 2009

‘Better Blood Transfusion’ initiatives – NBTCs

Health Service Circulars 1998 - 2007
2087 incidents reported to SHOT 1996/97 - 2003
Professor Sir John Lilleyman
Professor Sir John Lilleyman

1. ~70% of IBCT due to clinical errors
2. Failure to check the patient identity at the bedside is the commonest single point of failure

SHOT 1999 – 2003:
221 errors in 130 ABO incompatible transfusions:
59% (131):
• collection of the wrong unit of blood and/or
• administration to the wrong patient
1 Training and competency assessment for all staff involved in blood transfusions

2 Compatibility form and patient notes **not** used as part of the final identity check – match blood pack with the patient’s wristband (or identity band/photo identification card)

3 Appraise the feasibility and relevance of using:
NPSA Safer Practice Notice 14

Patient identification

Photo identification cards for patients having regular blood transfusions

If you have to go to hospital for regular blood transfusions, you can now have a permanent identification card.

Further information

For further information and advice, please contact:

Insert trust contact details including trust blood transfusion practitioner and the blood transfusion department.

Blood transfusion red label system: the process of matching blood sample to patient

Staff guidance on group and save, and cross-match sampling

Blood Transfusion Department (Insert contact numbers)
NPSA SPN 14
Right patient, right blood

Main aims
IBCT
ABO incompatible transfusions
Over 5 years
Figure 4
IBCT cases 1996–2010 showing ABO-incompatible red cell transfusions

Key
- All other IBCT cases
- ABO-incompatible red cell transfusions

NPSA SPN 14
29%
Clinical ‘wrong blood’ reports
2001/02 - 2010

Clinical ‘wrong blood’ reports reduced by 57% from 2009 to 2010
Total laboratory errors
1996/97 - 2010

28% fall in IBCT cases where primary error occurred in the laboratory: 107 in 2010 vs. 149 in 2009
Recommended minimum standards for hospital transfusion laboratories 2009

- Address staffing, technology, training and competence
Improvements in patient safety

• Reduction in mortality and major morbidity
  - hallmark of an effective haemovigilance system

• Reduction in ABO incompatible transfusions; 29% reduction in IBCT: 57% in clinical areas and 28% less in the laboratory
TRALI
Transfusion-related acute lung injury
TRALI

- Leading cause of transfusion-related mortality and major morbidity
- Caused by HLA/HNA abs – main source is donor plasma:
  - A donor with a history of transfusion (excluded since April 2004 unless Tx pre 1980 only)
  - A female donor with a history of pregnancy – abs in 10-15%
## TRALI – relative risk from different components 1996-2003

<table>
<thead>
<tr>
<th></th>
<th>Red cells</th>
<th>Cryoppt</th>
<th>FFP / Cryosup</th>
<th>Platelets</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRALI cases</td>
<td>33</td>
<td>2</td>
<td>31</td>
<td>27</td>
</tr>
<tr>
<td>Components issued</td>
<td>18,370,000</td>
<td>634,000</td>
<td>2,515,000</td>
<td>1,842,000</td>
</tr>
<tr>
<td>Risk/ component issued</td>
<td>1:556,000</td>
<td>1:317,000</td>
<td>1:81,000</td>
<td>1:68 000</td>
</tr>
<tr>
<td>~Relative risk compared to red cells</td>
<td>-----</td>
<td><strong>2</strong></td>
<td><strong>7</strong></td>
<td><strong>8</strong></td>
</tr>
</tbody>
</table>
Recommendations 2001-2002

- UK transfusion services should take all steps possible to reduce the risk of TRALI from blood components especially FFP and platelets
Intervention to reduce the risk of TRALI
Intervention to reduce the risk of TRALI
‘Please- no more new questions for donors!!’

Decision ‘Male FFP as far as possible’.

October 2003

- Male donations marked M - to FFP
- Female donations marked F- to ‘plasma discard’
- Did NOT swap out female FFP stocks
- April 2004-previously transfused donors excluded (vCJD)
Figure 13
Number of TRALI cases by year of transfusion
TRALI – effect of male FFP 2003 - 2010

Cases with concordant donor antibody

Number cases

- FFP
- Platelets

Improvements in patient safety

• Reduction in mortality and major morbidity
  - hallmark of an effective haemovigilance system
• Reduction in ABO incompatible transfusions; 29% reduction in IBCT: 57% in clinical areas and 28% less in the laboratory
• Observed rates of TRALI consistently lower since 2003/04
  – But in 2010 female donors implicated in all 4 cases where concordant donor HLA abs found
TTI
Transfusion-transmitted infection
Current estimated risks in the UK for HBV 1.5, HCV 0.01, HIV 0.20 and HTLV-1 0.06 per million donations
Bacterial transmission

• In 6 years from 1996 to 2002, 24 bacterial transmissions (6 fatal) were reported to SHOT
Strategies to prevent transfusion transmitted bacterial infections should be given priority

- Diversion of first 20mL of blood commenced in 2002
Other measures to reduce bacterial sepsis

- Donor selection
- Improved donor arm cleaning
- Visual inspection of units
- Screening of platelet donations for bacterial contamination
  - All UKBS screen platelet donations for bacterial contamination

Currently the greatest risk of TTI is associated with bacterial contamination. Bacterial screening unlikely to prevent all transmissions and current high standards of collection, processing and vigilance should be maintained.

- SaBTO
  - Pathogen inactivation not recommended until further data on cost and benefit available
Figure 18
Number of bacterial TTI incidents, by year of report and type of unit transfused (Scotland included from 10/1998)
SHOT recommendations

1996/97

Need for a national body with relevant expertise and resource to advise government of priorities for improvement in blood safety

MSBTO → SaBTO 2007

SHOT aspires to integrated risk-based decision making with patient safety at its core
This talk....

- Improvements in patient safety through interventions based on SHOT data

- SHOT 2010
Figure 2
Cases reviewed in 2010 $n = 1464$

- HSE 239 (16.3%)
- Anti-D 241 (16.5%)
- ATR 510 (34.8%)
- TRALI 40 (2.7%)
- TACO 15 (1.0%)
- TAD 35 (2.4%)
- PTP 1 (0.1%)
- Autologous 15 (1.0%)
- I&U 110 (7.5%)
- IBCT 200 (13.7%)
SHOT 2010 Headlines

- Participation 94.7%
- No confirmed cases of TTI
- 29% reduction in IBCT: 57% in clinical areas and 28% less in the laboratory
- TACO and I&U responsible for the majority of cases of mortality and major morbidity with imputability ≥2
- 3 deaths directly caused by transfusion, and transfusion probably or possibly contributed in a further 10
- 101 cases of major morbidity with ATR the single highest cause (57 cases)
- i.e. Serious outcome in 7.8% of cases reported
SHOT 2010: deaths

• 13 transfusion-related deaths, 7 due to TACO
• 3 imputability 3
  – Sudden unexpected death ATR
  – TACO
  – Hyperhaemolysis in child with SCD
• Remainder
  – 6 due to TACO
  – 1 under-transfusion
  – 2 ATR
    • Septic neonate: cardiac arrest during tx apheresis plts
    • Adult with cerebral tumour developed hypertension and rigors during tx apheresis plts and bled into the tumour
  – 1 TRALI in patient with massive GI bleed who died the same day of cardiorespiratory failure. No serology.
SHOT 2010 major morbidity

- 101 cases, majority due to ATR
  - 57 cases, 34 with anaphylactic and 1 angioedema, 11 allergic reactions with bronchospasm and 10 severe hypotensive reactions and 1 SVT with a fever

- Pulmonary complications of transfusion
  - 15 patients with TACO, 19 with TRALI and 6 with TAD

- I&U (covered by SK)

- IBCT: 2 cases where ‘wrong blood’ contributory

- HTR: 2 cases

- Development of anti-D after failure to administer anti-D

- Autologous: Severe coagulopathy after reinfusion of 1110 mL of salvaged blood
Lessons and recommendations from the 2010 SHOT report - 1

The medical assessment and management of patients receiving blood transfusions

• Numerous reports in TACO and I&U chapters have shown that there is inadequate medical assessment of patients during the prescription and monitoring of transfusion episodes
15 TACO-related deaths and 33 cases of major morbidity 2007 - 2010

*Includes 3 deaths and 5 cases of major morbidity from I&U
TACO: lack of attention to fluid balance.....

A confidential chart with data about fluid balance has been removed from the published version of this presentation, because it forms part of a Poster to be presented at the BBTS ASM 2011.
....particularly in elderly patients >70 years

57% of patients with TACO >70 years
An 84-year-old male with congestive cardiac failure (CCF) associated with IHD, on oral furosemide, isosorbide mononitrate and enalapril, was admitted with melaena. The Hb was 7.9 g/dL. He was transfused 3 units of RBC, each over 3 hours. However, because he was nil by mouth for endoscopy, his oral medication was withheld. No parenteral diuretic was substituted. He developed pulmonary oedema with pO2 6.3 kPa, and received CPAP and diuretic therapy, but he died.
2010 main recommendation

• The existing British Committee for Standards in Haematology (BCSH) guidelines for the Administration of Blood Components should be supplemented by an amendment dealing with measures to avoid the development of TACO and over-transfusion, particularly in vulnerable patients, including
  – pre-transfusion clinical assessment
  – rate of transfusion
  – fluid balance, regular monitoring of Hb
  – prescription of diuretics

Action: BCSH Transfusion Taskforce
Lessons and recommendations from the 2010 SHOT report - 2

Recognition and management of acute transfusion reactions

Learning point

- Transfusion should only take place if there are sufficient staff available to monitor the patient and the patient can be readily observed throughout the transfusion.

Recommendation

- Transfusions should only be performed where there are facilities to recognise and treat anaphylaxis, according to the UK resuscitation Council guidelines.

Action: Hospital transfusion committees (HTTs)
Lessons and recommendations from the 2010 SHOT report - 3

Clinical knowledge and handover

Main recommendations

- Transfusion medicine must be part of the core curriculum for doctors in training
  \textbf{Action: Education working groups of national transfusion committees}

- To avoid inappropriate and unnecessary transfusions due to lack of adequate clinical handover, decisions made concerning the need for transfusion support should be documented in the handover templates
  \textbf{Action: Trusts/hospitals}
Lessons and recommendations from the 2010 SHOT report - 4

DH ‘never events’ list 2011/12 now includes ‘death or serious harm as a result of the inadvertent transfusion of ABO-incompatible blood components’

NPSA SPN 14 is having an impact, but

- Only 77% of Trusts have provided competency-based training and assessment for blood administration for 50-91% of staff
- National TP survey: TPs spending vast majority of their time on NPSA SPN 14 and BSQR to detriment of other aspects of transfusion safety or inappropriate use - critical factor in 25% being dissatisfied with their role
Lessons and recommendations from the 2010 SHOT report - 4
DH ‘never events’ list 2011/12 (contd).

Main recommendation

- There should be a review of the practical aspects of the implementation of NPSA SPN 14 with a view to new guidance being issued and that Trusts should ensure that individual transfusion practitioners are fully supported with the allocation of additional link nurses in the escalation of training and assessment.

Action: NBTC, Trust/hospital chief executive officers (CEOs)
Lessons and recommendations from the 2010 SHOT report - 4
DH ‘never events’ list 2011/12 (contd).

Recommendations

• Trusts should implement the recommendations of the UK Transfusion Laboratory Collaborative
  Action: trusts/hospitals

• Work should continue with suppliers of LIMS to improve the capability of IT systems to generate warning flags and implement component selection algorithms based on data incorporated in the component label. These improvements should be in line with the recommendations of the BCSH guidelines on laboratory IT systems currently in preparation
  Action: Manufacturers of laboratory IT systems
Lessons and recommendations from the 2010 SHOT report - 5

Rapid Response Report NPSA/2010/017

Recommendations

• All under- and delayed transfusions that have a significant impact on patient outcomes should be reported to SHOT

  
  **Action:** hospital transfusion teams (HTTs)

• The Dendrite database should be enhanced to fully capture the salient clinical features and details of the timeliness of blood component support

  
  **Action:** SHOT team
Haemolytic transfusion reactions in sickle cell disease

Learning points

• A hyperhaemolytic transfusion reaction (in which both autologous and transfused red cells are destroyed) should be suspected if the patient rapidly develops a more marked anaemia than was present pre-transfusion.

Further transfusion should be avoided if possible, since this may exacerbate the haemolysis and lead to a protracted course or even death. Expert advice should be sought from a specialist sickle cell disease unit or a Blood Service transfusion medicine specialist

• A delayed HTR should be considered in the differential diagnosis of patients with sickle cell disease presenting with an apparent haemolytic crisis up to 14 days post transfusion
Thanks

- Dr Sue Knowles, SHOT Medical Director
- Steering Group and Working Expert Group
- Writing Group
- Debbi Poles – Research Analyst
- Alison Watt – Operations Manager
- Hema Mistry – Laboratory Incidents Specialist
- Julie Ball – Clinical Incidents Specialist
- Tony Davies – SHOT transfusion liaison practitioner
- Kathryn Gradwell and Vicky Peake, SHOT office information officers
- UK Forum for funding
- *Hospital transfusion teams for reporting!*