Lessons from SHOT

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Haemovigilance definition

- Surveillance procedures from the collection of blood and its components to the follow up of the recipients
- To collect and assess information on unexpected and undesirable effects resulting from the therapeutic use of labile blood components
- And to prevent the occurrence or recurrence

Haemovigilance in the UK MHRA SHOT

Medicines & Healthcare products Regulatory Agency

- Competent Authority' for the BSQR 2005
 - QMS in blood establishments and hospital blood banks.
- Competent Authority for the Medicines Act 1968
- Competent Authority for the Medical Devices Regulations 2008
- STATUTORY reporting

Serious Hazards of Transfusion

- Confidential enquiry
- Serious adverse reactions/events AND near misses all of which occur in BOTH a laboratory and CLINICAL environment.
- PROFESSIONALLY MANDATED reporting



What is SHOT?

- Serious Hazards of Transfusion (Est 1996)
- Collect data on serious adverse reactions and events
- Data reviewed by transfusion experts to produce Annual SHOT Report www.shotuk.org
- Participation is professionally mandated
 - a requirement of quality, inspection and accreditation organisations
- Small core team based in Manchester



SHOT aims

- IMPROVE standards of transfusion practice by EDUCATING users on transfusion hazards and their prevention
- INFLUENCE clinical guidelines for the use of blood components
- INFORM policy within transfusion services

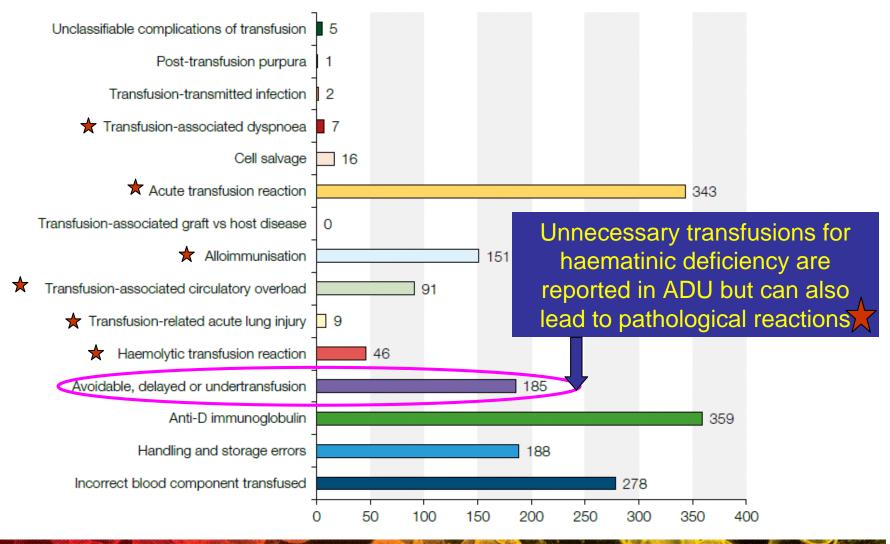
Serious Hazards Of Transfusion



SHOT Headlines 2014

- Deaths n=15
 - 2 definitely related to the transfusion (1 haemolytic transfusion reaction,1 TACO)
 - 3 deaths as a result of delayed transfusion
- Major morbidity n=169
 - Mainly acute transfusion reactions
- TACO was associated with 36 major morbidities and contributed to 6 deaths (42/91 cases of TACO had poor outcomes)

Cases reviewed 2014 n=1681



Haematinic Case Studies

SHOT category – avoidable transfusion (ADU)

- A 78 year old man felt unwell and had a Hb of 58g/L
- He was otherwise asymptomatic and was known to have iron deficiency anaemia
- The attending doctor authorised a 3 unit red cell transfusion
- The post transfusion Hb was 76g/L

SHOT Category – Avoidable transfusion (ADU)

- Following iron deficiency during pregnancy, a female delivered with a Hb of 78g/L
- A decision was taken in conjunction with the patient not to transfuse her, but to discharge her on oral iron
- Nine days later, her Hb was checked by the midwife and found to have risen to 89g/L
- Two weeks later, without a further check on her Hb, she was admitted to the community hospital for a blood transfusion at the GP's request

SHOT category-Transfusion-associated circulatory overload

- An 82 year old woman was admitted to hospital with chronic iron deficiency anaemia, Hb 45g/L
- Four units of red cells were transfused, each over 2.5 hours
- Following this she developed acute shortness of breath, O₂ saturations dropped to 54% associated with pulmonary oedema, pulse 110bpm, BP 200/99 which fell to 50/20 the following day
- She was stated to be fluid overloaded
- Intubated and ventilated for 2 days in ITU
- She was treated with noradrenaline and frusemide and made a full recovery



SHOT Category-Avoidable transfusion (ADU)

- An 87 year old female was admitted to hospital via her GP with Hb 58g/L but she was asymptomatic
- She had known macrocytic anaemia with B12 less than 30pg/mL
- She was given an urgent 3 unit red cell transfusion on the Medical Assessment Unit which had been prescribed by the Fy2 doctor

SHOT category – Avoidable transfusion (ADU) leading to alloimmunisation)

- A 57 year old woman attended preoperative clinic prior to elective hip replacement
- The Hb was reported as 62g/L
- A routine red cell transfusion was requested and prescribed by the orthopaedic trainee and the patient was planned to attend the haematology day care unit for transfusion

Case 5 (2)

- The junior haematology doctor did not review the patient before accepting her for transfusion and there had been no request for consultant haematology review
- The results prior to transfusion, which took place 5 days later, showed clear evidence of iron deficiency - Hb 56g/L, MCV 62fl, ferritin 2microg/L (folate and B12 levels normal)

Case 5 (3)

- Two pre-transfusion antibody screens were negative
- 1 month after transfusion and following iron therapy and endoscopy to check for GI bleeding (no abnormalities detected) results were Hb 105g/L, MCV 77fl, ferritin 25microg/L
- A further pre-op group and screen sample 2 months later identified that the patient had developed anti-S, anti-E and anti Lua

SHOT category – avoidable transfusion (ADU)

- A 45.1 Kg, 91 year old female patient presented via GP with recent deterioration
- Community blood tests were communicated to the GP showing severe anaemia
- The GP blood tests showed profound B12 and folate deficiency with levels of 75pg/mL and 3.1ng/mL respectively
- Macrocytosis noted and blood film reported as likely due to haematinic deficiency
- The patient was seen by medical SpR in A&E and had documentation stating that the receiving doctor was to speak to the on call haematologist before transfusion

Case 6 (2)

- Patient proceeded to have 4 units of packed red cells transfused (20:00)
- Patient was seen by the haematology SpR the following day (11:55) who advised of the risk of cardiac overload and severe thrombocytopenia
- Clinical observation was recommended and B12 and folate replacement commenced

Learning points:

- Good patient history taking and full clinical assessment are essential
- Effective communication and handover
- The underlying cause of the anaemia should be established and treated
- Severe megaloblastic anaemia can cause impaired cardiac muscle function. Transfusion should be avoided where possible due to the increased risk of these patients developing fluid overload*
- If transfusion is essential in non-bleeding patients, consider single unit transfusions with close monitoring, observation and diuretic cover to reduce the risk of TACO*



^{*} Handbook of Transfusion Medicine (2014) Norfolk, D (Ed)

Key recommendation (2013)

Don't give two without review:
Transfusion-associated circulatory
overload (TACO) is a significant hazard,
particularly when elderly or other patients
at risk receive several units of blood
without review and a check Hb level

*advice inspired by a campaign devised by NHSBT's Patient Blood Management team

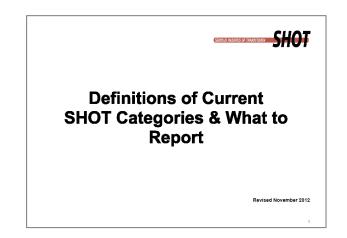
Additional Information

Following documents available on website to help with reporting:
www.shotuk.org

- SHOT reporting definitions
- SHOT reporting toolkit
- Clinical Lessons
- Laboratory Lessons

Also available:

- SHOT annual reports
- SHOT summaries
- Supplemental data





Acknowledgements

- SHOT Team in Manchester
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- UK NHS Organisations for reporting
- You for listening