

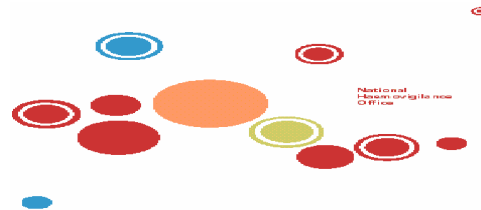


Serious Adverse Reactions

NHO Annual Report

2010

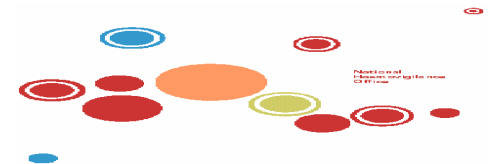
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Haemovigilance Officer
National Haemovigilance Conference
November 2011



Serious Adverse Reactions (SAR)

- Introduction
- Overview of SAR received
- Acute Haemolytic Transfusion Reactions
- Delayed Haemolytic Transfusion Reaction
- Transfusion Associated Circulatory Overload
- Recalls from the IBTS.

11.11.11



Serious Adverse Reactions (SAR)

151 SAR reports accepted ↑2009 Figures

No reports:

- Transfusion Associated Graft versus Host Disease (TA v GHD),
- Post Transfusion Purpura (PTP)
- Adverse donor reactions related to predeposit autologous transfusion (PAD).
- TRALI



Serious Adverse Reactions accepted by the NHO in 2010		151
Acute Transfusion Reactions	Immunological haemolysis due to ABO incompatibility	2
	Immunological Haemolysis due to other alloantibody (Acute)	4
	Febrile Non Haemolytic Transfusion Reaction	46
	Anaphylaxis Hypersensitivity	51
	Unclassified	4
	Hypotensive Reaction	2
Delayed Haemolytic Transfusion Reactions	Immunological Haemolysis due to other alloantibody (Delayed)	11
Respiratory Complications of Transfusions	Transfusion Associated Circulatory Overload	24
	Transfusion Associated Dyspnoea	2
Suspected Transfusion Transmitted Infection	STTI Bacterial	3
	STTI Viral	2

Overall Data of SAR n=151

Implicated components		Age Profile		Imputability		Clinical Outcome	
Red Cells	89	Infant (1 - 12 months)	1	Excluded	1	Complete Recovery	133
Platelets Apheresis	41	Infant (1-4 years)	6	Unlikely	3	Minor Sequelae	10
Platelets Pooled	10	Child (5-11 years)	6	Possible	60	Serious Sequelae	1
FFP	1	Adolescent (12-17 years)	4	Likely/Probable	76	Death unrelated to transfusion	6
Solvent Detergent (SD) Plasma	1	Adult (18-30 years)	13	Certain	11	Unknown	1
Multiple Components	9	Adult (31-50 years)	28	Emergency/Routine transfusion		Transfusion start time	
		Adult (51 - 70 years)	42	Yes	18	In core hrs	111
		Elderly (70+)	51	No	113	Outside core hrs	35
				Unknown	20	Non emergency transfusions administered outside of core hrs	27



Transfusion start time

Of the 151 reactions accepted,

- 35 reactions occurred in transfusions commenced after 8pm.
- 27 (77%) of the transfusions were not emergency.
- Within this group of non emergency transfusions - 18 (67%) involved RCC.
- 11 of these cases all non emergency situations - the transfusion actually took place between midnight and seven am.
- Most common group of patients effected (48%) were elderly patients and most common reaction within this group - TACO.



Recommendation on transfusion time

- Elective transfusions should normally be carried out during the day (NBUG 2004)
- Transfusion should only take place if there are sufficient competent staff available to monitor the patient and the patient can be readily observed throughout the transfusion episode (SHOT 2010)



Overall AHTR Data Summary n=6

Implicated components		Age Profile		Imputability		Clinical Outcome	
Red Cells	4	Infant (1-4 years)	1	Possible	2	Complete Recovery	6
Platelets Apheresis	1	Child (5-11 years)	1	Likely/Probable	3	Transfusion start time	
Multiple Components	1	Adult (31-50 years)	1	Certain	1	In core hrs	6
		Elderly (70+)	3	Emergency/Routine transfusion		Outside core hrs	
				Yes	No 5		
				Unknown 1			

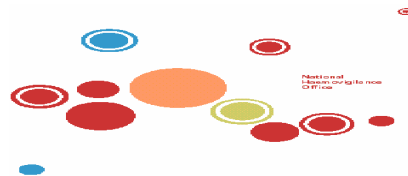


AHTR (n=2) Immunological Haemolysis due to ABO Incompatibility - Case 1 – *imputability - possible*

Background:

A group AB Rh D positive child with an underlying haematology/oncology condition was transfused with a unit of group A Rh positive apheresis platelets followed immediately by a group specific unit of RCC.

Approximately 50mls of the RCC had transfused



AHTR (n=2) Immunological Haemolysis due to ABO Incompatibility – Case 1

imputability - possible

Symptoms:

- temperature rise
- chills and rigors.

Investigations

- Bacterial Screening – negative.
- Direct Antiglobulin Test (DAT) –positive post transfusion (Negative pre transfusion) No eluate carried out.
- LDH (lactate dehydrogenase) slightly elevated
- Bilirubin – normal

Clinical Outcome

- The patient made complete recovery.





AHTR (n=2) Immunological Haemolysis due to ABO Incompatibility - Case 1

imputability - possible

- The use of A platelets is standard practice in AB group patients where AB platelets are not available.
- However occasionally group A apheresis platelets may contain significant anti B antibodies which may be a problem if group AB RCC are transfused shortly afterwards or transfused into a small child.
- Changes to practice. IBTS commenced collection of group AB apheresis platelets
- Also currently under consideration is the provision of apheresis platelets suspended in Platelet Additive Solution (PAS)



AHTR (n=6) Immunological Haemolysis due to other alloantibody - Case 1

- An elderly female patient with a history of cardiac disease required a transfusion Hb 7.9g/dl

Background:

- She had a history of antibodies during her pregnancy. In addition it was noted that this patient had anti- Cw, anti-E and anti C identified at the beginning of 2009.
- Subsequently in late 2009 she developed a possible further antibody. This was not confirmed at that time.





AHTR (n=6) Immunological Haemolysis due to other alloantibody - Case 1

Transfusion Episode

On this occasion over a weekend patient was crossmatched. Historical antibody record showed

- anti Cw anti E anti c and ? anti K + ? Undetermined antibody.
- Unit of least incompatible blood was issued.
- Medical staff were informed that patient had multiple antibodies and unit should only be transfused if absolutely necessary
- Decision was made to transfuse with out consultation with the lab or Consultant Haematologist



AHTR (n=6) Immunological Haemolysis due to other alloantibody - Case 1

Symptoms

- Patient developed a raised bilirubin and LDH within 24 hours of transfusion together with a failure to have an increment post transfusion .

Investigation

- Following failure of the Hb rise on this occasion, a sample was sent to the reference laboratory and a anti Fy^a and anti S were identified
- The unit transfused was not Fy^a typed.

Comment:

- No Hb increment and a raised bilirubin occurring within 24hrs usually indicates the antibody were present pretransfusion.

Recommendation:

- Although it may be necessary to issue least incompatible blood, in an emergency, samples should be sent to a reference laboratory for confirmation



AHTR (n=6) Immunological Haemolysis due to other alloantibody - Case 2

Background

- A male patient with a known anti E+K+auto antibody developed a reaction four hours after the transfusion of RCC commenced,

Symptoms

- temperature rise,
- hypertension,
- tachycardia,
- nausea and vomiting.



AHTR (n=6) Immunological Haemolysis due to other alloantibody - Case 2

Investigations:

- bilirubin increased significantly.
- DAT was positive pre/post transfusion.
- Bacterial Investigation of patient –no growth.
- LDH not checked post transfusion

A sample was referred to the reference laboratory and testing in IAT with a range of rare cells detected an anti-Wr^a



AHTR (n=6) Immunological Haemolysis due to other alloantibody - Case 2

- Anti-Wr^a has been implicated in transfusion reactions and the antibody may have been too weak to detect on crossmatch but still may have contributed to the transfusion reaction.
- It is possible that one of the units was Wr^a+ however as less than 1% of the population is Wr^a + the units transfused to the patient were not previously typed for the antigen



Immunological haemolysis due to other allo-antibody (Delayed > 24 hrs)

Findings

- 11 reports

Patients

- Elderly > 70 years – 4
- Adult 51-70 years – 4
- Adult 31-50 years – 3

Imputability

- Certain 2
- Likely/Probable 8
- Possible 1

Previous Transfusion History

- Unknown in 5 case if previously transfused
- Previous transfusion in 6 cases

Investigations

- Most common antibodies identified
Anti E, anti Jk^a, anti Jk^b anti Fy^a
anti c.
- Unusual antibodies identified
Lu^a, Yta (identified at IBGRL)

Category

- Group 2(+DAT, Fall in Hb) - 10
- Group 3 (jaundice) – 1

Immunological haemolysis due to other allo-antibody (Delayed >24 hrs)

Case History 1

Background

- Adult female patient with a complex medical history required an intraoperative transfusion for estimated blood loss of 1.3 litres. Her pretransfusion antibody screen detected a anti Lu^a and a non specific antibody. Antigen negative units for the antibody detected were issued and transfused.
- The patient had a previous history of a anti- Fy^a identified in another hospital however the current hospital was unaware of this and this antibody was not detected on the pre transfusion sample
- Four days post transfusion the patient showed evidence of haemolysis with a falling haemoglobin level, rising bilirubin, a positive DAT which was negative pre transfusion and a subsequent elevation in the LDH level.
- A sample referred to the reference laboratory identified an auto-antibody, anti Jk^a and anti Fy^a.





Immunological haemolysis due to other allo-antibody (Delayed >24 hrs) Case History 2

- The patient was admitted and transfused with two units of RCC for an underlying GI bleed.
- When a further sample was received 18 days later anti e was detected and the patients DAT was positive.
- A sample was referred to the reference laboratory and the antibody was confirmed.





Immunological haemolysis due to other allo-antibody (Delayed >24 hrs)

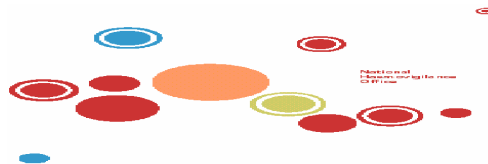
Case History

- On retrospective review bilirubin was elevated over the preceding days, along with an elevated LDH and a falling Hb level.
- However the patient had also developed a large haematoma five days post the original transfusion and this possibly complicated the picture for investigating the possibility of a delayed haemolytic transfusion reaction.
- On investigation it was established that the antibody was previously identified in this patient however due to failure in verification the result was posted to the patient record but the date of birth was incorrect and this was not identified by the medical scientist when the laboratory system was interrogated.



DHTR – Recommendations

- Reporting of DHTR have increased however it is essential that any patient presenting with unexplained anaemia some days after a transfusion should be investigated for immunological haemolysis.
- Consideration to the development of a national patient antibody register for patients with red cell antibodies. This would only be feasible with the implementation of a national UHI, a recommendation made by the HIQA (2009) and supported by the NHO. A UHI would facilitate improved and safer access to patients' records on a national antibody register thereby ensuring safer transfusion practice for patients.





Transfusion Associated Circulatory Overload

Findings

- 24 reports fulfilled the criteria for TACO

Implicated Components

- 21 RCC
- 1 SD Plasma
- Only 2 cases involved multiple components

Patients

- 19 elderly (>70 years)
- 5 adults (51-70 years)

Transfusion start time

In core hrs 15

Outside core hrs 8

Non emergency transfusion outside of core hrs 7

Most frequently occurring symptoms

- Falling O₂ Sats (14 cases) Dyspnoea (18 cases) Hypertension (6 cases) Tachycardia (8 cases)

Underlying conditions

- Cardiac - 17 Renal – 8 Respiratory – 5
- 22 patients had more than one underlying condition
- 2 patient had all three underlying conditions

Fluid balance

- Complete fluid balance 54%
- Incomplete/No record 46%

TACO with Single Unit Transfusions

Single unit transfusions can also result in TACO and therefore should be monitored as closely as multiple unit transfusions (Andrzejewski and Popovsky, 2005).

Findings:

14 patients developed TACO after one unit.

- 6 patients had incomplete/no fluid balance
- 8 had complete fluid balance – all were in a positive balance ranging from 460mls – 3020 mls
- 6 patients on regular diuretics – 3 received diuretics pre/during transfusion
- 9 patients had not received any other component in the previous 24 hrs.



TACO – Recommendations

- At risk patients should be given a diuretic prior to transfusion particularly those on regular diuretic therapy
- Careful estimation of the patient's hydration and cardiac status prior to the transfusion
- Particular attention should be paid to patients with underlying conditions which may increase their susceptibility to TACO.
- Nurses should monitor the rate of transfusion and fluid balance as these factors influence the risk of a patient developing TACO (SHOT 2010)



TACO case history - multiple components

Background

Elderly male patient (estimated weight > 70kgs) with a history of ongoing GI bleeding and septicaemia received three units of red cells and five units of solvent detergent (SD) plasma.

- 1st unit of the first unit red cells administered over four hours early in the morning.
- Following this intravenous fluids were recommenced.
- Later that day five units of SD Plasma administered over 45 mins - patient was scheduled for a minor surgical procedure shortly after the transfusion. (Vitamin K had already been administered x 2 doses)
- Following this, two further units of red cells were administered each over 4 hrs.
- O₂ saturations were satisfactory, initially on nasal prongs and then on face mask.



TACO case history- multiple components

- O₂ saturations decreased to 82% when he intermittently took off the mask. He was in a positive fluid balance of +1265mls
- Just over three hours later it was noted that when on oxygen therapy 40% via face mask, his oxygen saturation dropped to 81% and he had a respiratory rate of 32-36. No other symptoms noted, but his condition now sufficiently concerned staff to seek a medical review
- Reviewed by a medical intern and IV hydrocortisone was administered – patient had no signs of an allergic reaction.
- Chest x-ray was requested which on review 40 minutes later showed overload.

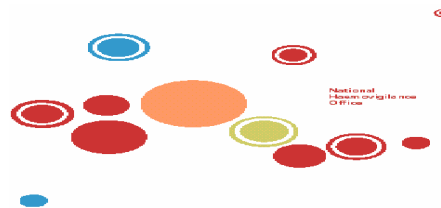


TACO case history- multiple components

- At 07.00am, he was commenced on BiPAP his O₂ sats continued to fluctuate again but it would appear that frusemide was not administered until 10.00am
- He had a diuresis of approximately 2000mls over next five hours.
- However, his condition continued to deteriorate and he was ventilated later that evening for respiratory failure.

Testing for Brain Natriuretic Peptide

- An increased ratio of 1.5 is suggestive of transfusion associated overload - almost a 10 fold increase in this patient .





TACO

Comment

- Two features of particular concern Although the TACO was clearly not solely due to the SD plasma it would appear that unless the patient was actively bleeding the SD plasma was given over a very short period of time for an INR of 1.4 which was unlikely to correct.
- In addition from other TACO cases reported it is noted that a number of NCHD's prescribe corticosteroids for reactions which presumably are initially misdiagnosed as allergic reactions and diuretics are not given.
- NHO has previously issued guidelines on indications and transfusion rates for SD plasma and the numbers of TACO reactions associated with plasma dropped dramatically
- In some incidents the amount of time given for Haemovigilance at induction for new medical staff is very short.



Recommendations

- Doctors and nurses should receive education aimed at recognition and avoidance of TACO
- In addition NCHD's should receive specific training in the area of transfusion medicine to ensure safe and appropriate decision making regarding transfusion and prescription of blood components and products



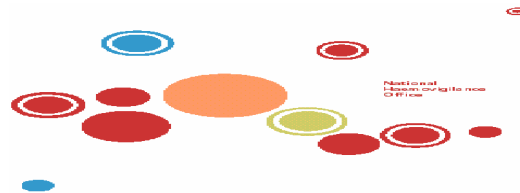
STTI – Recall

- Where a recall involves blood components which have been transfused, hospitals should have a system in place which includes a review of a patient to ensure a complete follow-up.



Confirmed/Unconfirmed BacT Alert- What does the NHO collect from HBB?

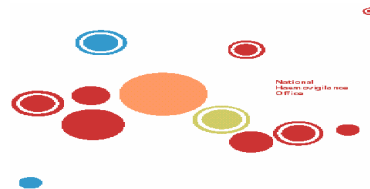
- Confirmed and Unconfirmed positive BacT Alert - If the patient has a reaction - this will be collected as an ***SAR - STTI Bacterial.***
- Confirmed and Unconfirmed positive BacT Alert - if the patient is commenced on antibiotics or their antibiotic is changed as a result of the recall but there is no reaction detected this will be collected as an ***SAE.***
- Confirmed and Unconfirmed positive BacT Alert. If there is no sequelae for the patient - ***not reportable.***

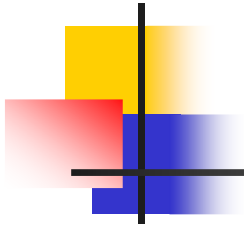




False Positive BacT Alert – What does the NHO collect from HBB?

- False positive BacT Alert where the patient is commenced on antibiotics will be collected as ***SAE – Other***
- False positive BacT Alert where there is increased donor exposure as a result of the BacT Alert will be collected as ***SAE - Incorrect Component Transfused***
- False positive BacT Alert - no sequelae for the patient - ***not reportable.***





Thank You

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