



# **Serious Adverse Reactions**

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# **NHO Annual Report**

# **2008**

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# **Serious Adverse Reactions (SAR)**

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- Introduction
- Overview of SAR received
- Paediatric Reactions
- Recommendations



# Serious Adverse Reactions (SAR)

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196 SAR reports during the reporting year 2008.

- After review 143 SAR reports accepted – increase 36 reports on last year - 19(13%) reports involved paediatric patients
- **No reports of:**
  - Transfusion Associated Graft versus Host Disease (TAvGHD)
  - Post Transfusion Purpura (PTP).
  - No reports of donor adverse reactions related to Predeposit Autologous Donation (PAD) category

**Points to Note: 10 reactions occurred as a result of an error – 2 occurring in paediatric patients**

<b>Serious Adverse Reactions accepted by the NHO</b>		<b>2008</b>
<b>Acute Transfusion Reactions</b>	<b>Immunological Haemolysis due to other alloantibody (Acute)</b>	<b>2</b>
	<b>FNHTR</b>	<b>38</b>
	<b>Anaphylaxis Hypersensitivity</b>	<b>41</b>
	<b>Unclassified</b>	<b>6</b>
	<b>Hypotensive Reaction</b>	<b>2</b>
<b>Delayed Haemolytic Transfusion Reactions</b>	<b>Immunological Haemolysis due to other alloantibody (Delayed)</b>	<b>4</b>
<b>Respiratory Complications of Transfusions</b>	<b>Transfusion Related Acute Lung Injury</b>	<b>1</b>
	<b>Transfusion Associated Circulatory Overload</b>	<b>39</b>
	<b>TAD</b>	<b>2</b>
<b>Suspected Transfusion Transmitted Infection</b>	<b>STTI Bacterial</b>	<b>6</b>
	<b>STTI Viral</b>	<b>2</b>
<b>Total</b>		<b>143</b>



## **AHTR (n=2) Immunological Haemolysis due to other allo-antibody- Case 1**

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- Patient who had required transfusion post operatively required further transfusion support
- Pretransfusion sample DCTpositive
- Anti D and Anti FyA previously reported but a non specific antibody reacting in ICT and Enzyme panels was also detected.
- Anti D Anti FyA least incompatible red cells transfused.
- Three hours 40 minutes into the transfusion the patient developed hypertension, pyrexia and chills.
- On investigation -raised bilirubin level, DCT was negative and antibody specificity on the post transfusion sample remained undetermined.



# AHTR - Immunological Haemolysis due to other allo-antibody- Case 1

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- Ten days later the patient was readmitted -fall in haemoglobin - elevation of bilirubin.
- DCT was negative,
- Antibody investigation - inconclusive
- Samples sent to Reference Laboratory for further investigation .
- Anti k Anti Jka, and Anti S were identified. No Anti D detected.
- Patient had acute and delayed reaction – captured as AHTR.

## **Outcome**

Complete recovery



## AHTR - Immunological Haemolysis due to other allo-antibody- Case 2

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- Patient with a history of anti -Fya antibodies required a transfusion of red cells
- Within 1 hour developed – Temp rise chills+ rigors and restlessness/anxiety
- On investigation – patient transfused in error with Fya positive unit due to an error in antigen typing.

### **Error Cause:**

Human and System errors identified

- On call- over weekend MS rotated through the hospital blood bank
- Carried out the antigen typing incorrectly. (Human Slip)



# AHTR - Immunological Haemolysis due to other allo-antibody- Case 2

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Error could have occurred in:

1. Transfer of RCC unit segments once cut from packs ,into test tubes for typing procedure
2. Possibility of Cross pipetting error of RCC when making dilutions for testing
  - Insufficient documentation of the technical results during the procedure to enable checking of the scientist technique and results.(System failure – policies and procedures)

## **Changes to practice;**

- retraining of staff in amended procedures
- Update of SOP's
- new stepwise recording system for all technical work was implemented.



# Febrile Non-Haemolytic Transfusion Reactions(FNHTR) (n=38)

## Findings

- 38 reports received increase of eight reports on 2007.

## Patients:

- 37 adults,
- the majority of these being elderly (>70 years).
- 1 child .

## Components Implicated

- 35 were associated with red cells - 1 each with apheresis platelets, pooled platelets and leucocytes.

## Imputability

- Possible 20 cases Likely/probable 18 cases

## Investigations

- majority of the cases were investigated for bacterial contamination :
- 31 (81.5%) patients had blood cultures taken,
- 29 (76%) cases the pack cultured
- 26 cases both the patient and pack were cultured.
- 15 (39%) cases were investigated for haemolysis
- 13 (34%) cases in total were investigated for both haemolysis and bacterial contamination.

## Clinical Outcome

- 32 Complete recovery
- 4 minor sequelae
- 1 death unrelated to transfusion
- 1 clinical outcome not given



# Acute Allergic and Anaphylactic Transfusion Reactions (AA) (N=41)

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## Findings

### **41 reports received**

- **No cases of AA due to IgA deficiency with antibodies were reported**
- **Immunoglobulin IgA levels were reported in 25 cases.**

### **Patients:**

- **27 adults**
- **14 paediatric/adolescents.**

### **Components Implicated**

- **RCC 11,**
- **Apheresis Plts 15, Pooled Plts 13**
- **SD Plasma 1, Cryoprecipitate 1,**

### **Imputability**

- **35 cases likely/probable**
- **5 possible**
- **1 unlikely**

### **Clinical Outcome**

- **35 Complete recovery**
- **3 minor sequelae**
- **3 outcome not given**



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

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## Findings

- 4 reports

## Patients

- All elderly > 70 years

## Imputability

- Likely/Probable 2
- Possible 2

## Previous Transfusion History

- Unknown in 3 case if previously transfused

- Final case – previous Jka detected – emergency O neg antigen pos unit administered

## Investigations

- Antibodies identified  
Anti M, Anti Kell, Anti Jka, Anti Fya Anti S

## Category

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



# Transfusion Associated Circulatory Overload (n=39)

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## Findings

- › 39 reports fulfilled the criteria for TACO
- › 27% of total SAR received

## Implicated Components

- › 33 RCC
- › 1 SD plasma
- › 1 Apheresis Platelets
- › Only 4 cases involved multiple components

## Patients

- › 26 elderly (>70 years)
- › 7 adults (51-70 years)
- › 5 adults (31-50 years)
- › 1 adult (18-30years)

## Imputability

- › 27 Likely/probable
- › 10 Possible
- › 1 Certain

## Most frequently occurring symptoms

- › Dyspnoea (29 cases) Falling O<sub>2</sub> Sats (20 cases) Hypertension (15 cases) Tachycardia (14 cases)

## Underlying conditions

- › Cardiac - 26 Renal – 12 Respiratory – 9
- › 20 patients had more than one underlying condition
- › 1 patient had all three underlying conditions

## Investigations

- › Occurred in four cases where the volume transfused was between 50-100mls.
- › Only 12 patients had completed fluid balance
- › Only 10 patients had Chest X Rays



# TACO occurring in patients as a result of an error (n=7) (18%)

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- Transfusion time too short – 3
- Prescribed and transfused too quickly – 1
- Transfusion based on an old Hb result and no prophylactic diuretic administered – 1
- Unnecessary Transfusion -1
- Units administered too close together in a patient with underlying cardiac disease -1

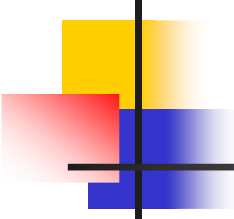
## **Human failure**

- Failure to adhere to policies/procedures 4
- Knowledge 1
- Co-ordination/communication 2
- Verification 2
- **Total 9**

## **System failure**

- Management priorities 1
- Culture 2
- Policies/procedures 1
- **Total 4**

# TACO case history

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- Low weight (52kg) elderly patient
  - Haemoglobin was 3.9 g/dl.
  - No history of underlying cardiac or renal disease
  - not on regular diuretics.
  - Transfused with 4units RCC – uneventfully over previous 2 days
  - Received 4 litres of fluids with klean-prep for gastro-intestinal investigations
  - IV fluids continued 60mls per hour,
  - No fluid balance
  - HB was 9g/dl further 2 units RCC were given.
  - 5th unit - BP started to rise, no diuretic before or during the transfusion but given post transfusion.
  - 6<sup>th</sup> unit commenced, the patient remained hypertensive with tachycardia, pedal oedema and bi-basal crepes
  - Transfusion discontinued, diuretics, anti-hypertensive administered
  - complete recovery within 12 hours.
  - 5th and 6th units - unnecessary and a contributing factor to the overload.

## **Error causes.**

Verification, failure to adhere to policies/procedures and monitoring all highlighted



## Possible TRALI (n=1)

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- Elderly female patient – low weight
- Became acutely unwell – GI bleed – required surgery.
- Transfused - 2 RCC, 2 SD Plasma 1.5 Litres fluids
- Returned from OT –extubated
- 30 mins later – developed acute pulmonary oedema
- Reventilated and diuretic given with no noticeable diuresis
- Was in pos fluid balance



## Possible TRALI (n=1)

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- BNP not available
- Patient remained ventilated for 8 days
- Female donor investigations for HLA or granulocyte antibodies – negative
- Captured as Possible TRALI – underlying ALI – TACO
- Clinical Outcome – patient recovered



# Transfusion Associated Dyspnoea (TAD n=2)

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- **Definition.** TAD is characterized by respiratory distress within 24 hours of transfusion that do not meet the criteria of TRALI, TACO or allergic reaction. Respiratory distress should not be explained by the patient's underlying condition or any other known cause.(ISBT)

# TAD

## Case 1

- originally submitted as an unclassified transfusion reaction
- patient with underlying renal disease
- drop in oxygen saturation with an associated tachycardia within 15 minutes of commencing the transfusion.
- no evidence to suggest overload /allergic type reaction
- symptoms resolved within one hour following administration of oxygen therapy.

## Case 2

- originally submitted as a TACO
- One hour 15 minutes post the transfusion the patient became acutely short of breath, distressed and agitated.
- A diffuse wheeze was noted but not considered an allergic type reaction.
- no changes on the patients chest x ray
- treated with nebulisers and iv medication and subsequently required CPAP
- CPAP was discontinued six hours later and the patient made a complete recovery.



# Suspected Transfusion Transmitted Infection

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## FINDINGS:

- 8 reports in 2008
- 2 Viral
- 6 Bacterial



## Bacterial Infections (n=6)

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**Components** – RCC 4 Pooled Platelets 2

**Imputability**- 4 possible 2 unlikely

- Both cases in platelets due unconfirmed pos “BactAlert” where patient did not have reaction - commenced on antibiotics
- 2 cases associated with RCC -considered contamination during culturing process - considered unlikely

Final two cases both involving RCC - bacterial infection could not be excluded

- coagulase negative staphylococcus was identified in the patient, but the segment line from the unit was cultured with no growth
- last case pantoea species was cultured from the patient, the pack and administration set. - segment line cultured negative.



## Viral Infections (n=2)

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- First case- HBV involved multiple components
- large number of donors – 98
- transfusion transmitted infection considered unlikely.
- Second case - HIV
- Involved three donors
- Returned and retested HIV negative
- transfusion transmitted infection excluded

# Paediatric Reactions (n=19)

<b>Anaphylaxis/hypersensitivity (AA)</b>	<b>14</b>
Neonate (< 28 days)	1
Infant (1 - 12 months)	1
Young Child (1-4 years)	4
Child (5-11 years)	7
Adolescent (12-17 years)	1
<b>Febrile Non Haemolytic Transfusion Reaction</b>	<b>1</b>
Child (5-11 years)	
<b>Hypotensive Transfusion Reaction</b>	<b>2</b>
Neonate (< 28 days)	2
<b>Unclassified SAR</b>	<b>2</b>
Neonate (< 28 days)	1
Child (5-11 years)	1

# Paediatric Reaction to Cryoprecipitate (n=2)

## Findings

- 2 cases
- Both Hypotensive reactions

## Patients

- 2 Neonates

## Imputability

- Certain 1
- Likely Probable 1

## Investigations

- reaction which was related to the cryoprecipitate was due to citrate toxicity

## Clinical Outcome

- Complete Recovery 1
- Serious sequelae – but subsequently recovered 1



# Paediatric Reactions occurring as a result of an error (n=2)

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AA = 1

- Premed prescribed but not administered
- Human Failure – verification
- System failure – management priorities

Unclassified SAR = 1

- Over transfused
- 15mls/Kg ordered
- 50mls/kg prescribed and given
- Human Failure – communication and knowledge

# Recommendations

## **FNHTR**

- **Whenever possible as a minimum, blood cultures and investigations for haemolysis should be taken on patients suffering a FNHTR to exclude red cell incompatibility or bacterial contamination.**

## **Anaphylaxis/hypersensitivity**

- **Reaction Alerts – in patient charts and on the hospital IT system can be valuable in those patients with a previous AA reaction to ensure appropriate component selection and pre medication prior to future transfusions**

## **TACO**

- **Particular attention should be paid to identifying patients at risk of developing TACO, high risk patients include patients of low body weight, elderly, infants and children and physiologically compromised patients especially those with chronic anaemia and cardiac, renal and respiratory conditions.**

## **DHTR**

- **Consideration to the development of a national patient antibody register for patients with red cell antibodies**
- **Patients presenting with unexplained anaemia some days after a transfusion should be investigated for immunological haemolysis (Bilirubin, LDH DAT and antibody screen)**