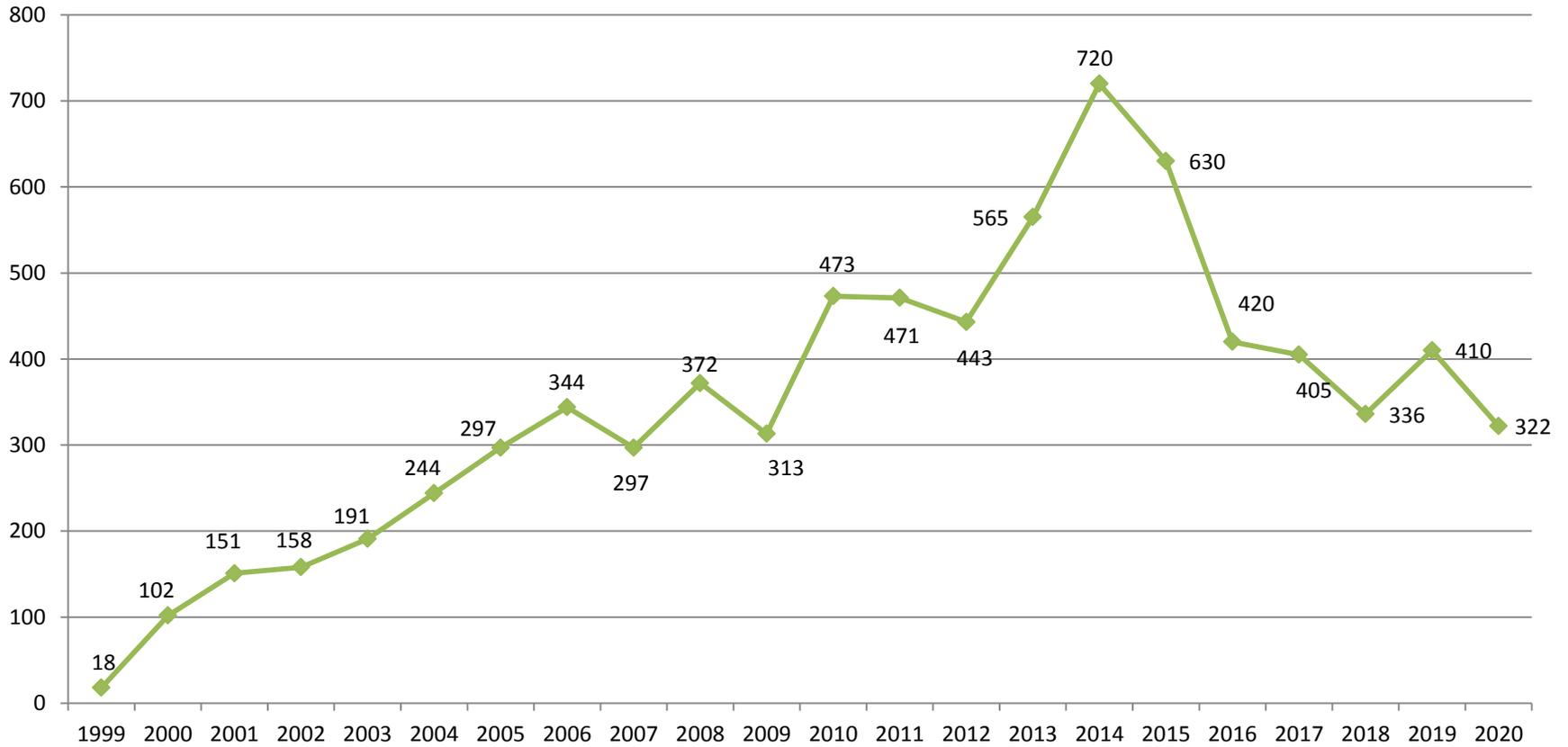


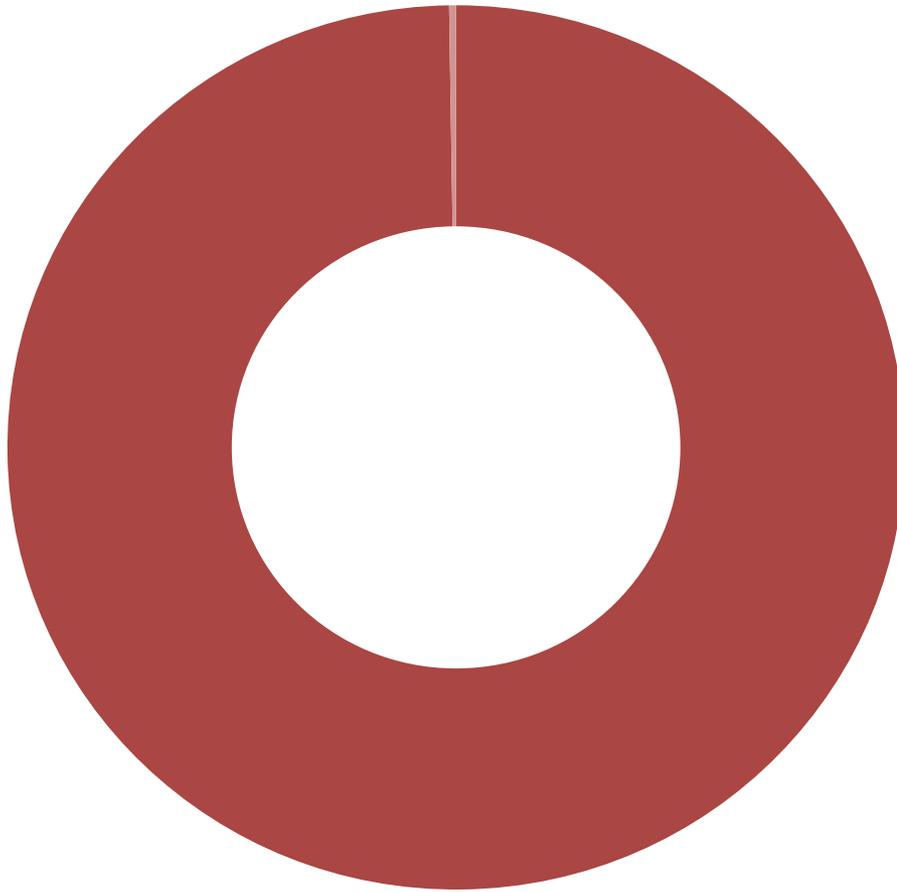
NHO Serious Adverse Reactions 2019- 2020

Joanne Scanlon

Total number of reports received in the NHO 1999 -2020 (n= 7682)



SAE's/SAR's V's Components issued (0.002%)



- Components issued 2019-2020: 278.889
- SAE's/SAR'S reported: 695



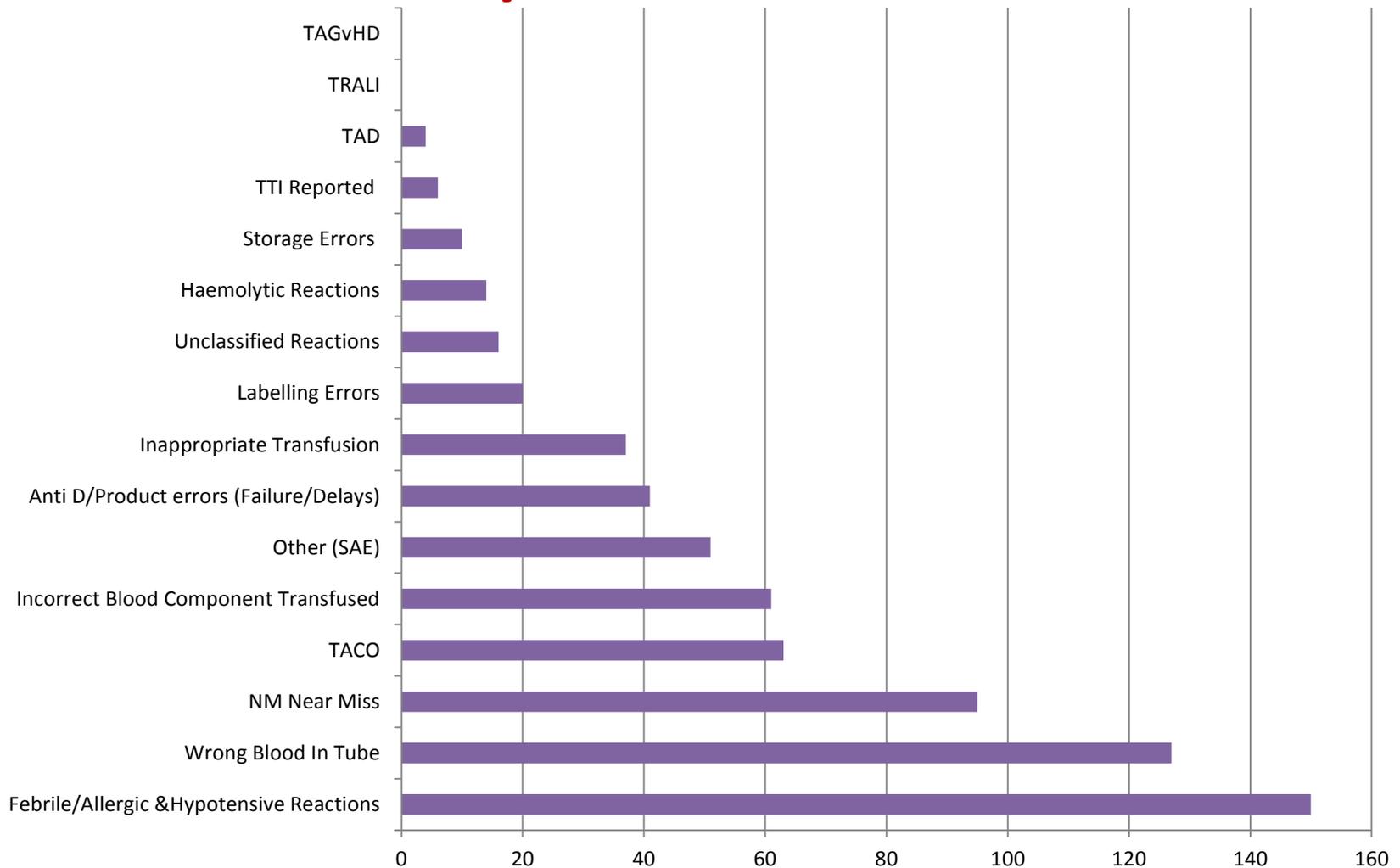
NATIONAL
HAEMOVIGILANCE OFFICE
CONFERENCE FEB 2022

Overarching Transfusion Committees



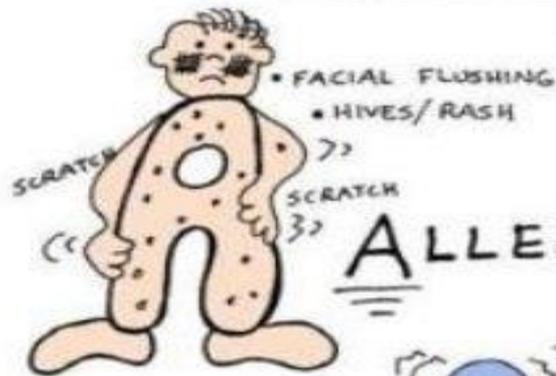
- ❖ West
- ❖ South and Mid West - Munster
- ❖ Dublin and East
- ❖ Dublin and Midlands
- ❖ Dublin and North East
- ❖ Maternity Hospitals
- ❖ Paediatric Hospitals

Summary of Data 2019-2020



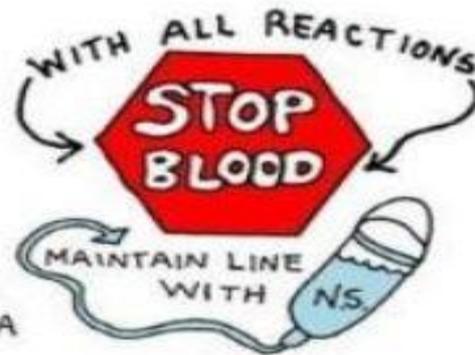
TRANSFUSION REACTIONS:

(OCCURS IN THE FIRST 10-15 MIN OR FIRST 50cc OF BLOOD)



- FACIAL FLUSHING
- HIVES/RASH

ALLERGIC



- FEVER
- CHILLS
- ANXIETY

- HEADACHE
- TACHYCARDIA
- TACHYPNEA

FEBRILE



- HEADACHE
- CHEST PAIN
- APPREHENSION
- LOW BACK PAIN

- CHILLS
- FEVER
- TACHYCARDIA

HEMOLYTIC

- ↓ BP
- ↑ RESP RATE

Acute Hemolytic Transfusion Reactions (AHTR)

AHTR is defined as a reaction occurring within 24 hours of a transfusion where clinical and/or laboratory features of haemolysis are present (ISBT definition). Acute haemolysis may be caused by ABO incompatibility, other antigen incompatibility or to non-immunological factors.



Acute Transfusion reactions

Acute Transfusion Reactions (n=148)	Immunological Haemolysis due to ABO incompatibility	0
	Febrile Non Haemolytic Transfusion Reaction	72
	Anaphylaxis/Hypersensitivity	61
	Hypotensive Transfusion Reactions	3
	Unclassified Reaction	12

Febrile Reactions (n=72)

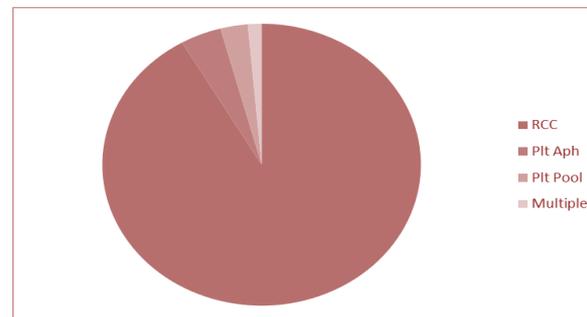
Findings

- 78 Reports received
- 72 Reports accepted
- 10 Reports Mandatory

Demographics

- 1-4 yr: 2
- 12-17 yr: 1
- 18-30 yr: 5
- 31-50 yr: 16
- 51-70 yr: 20
- 70+: 28

Components



Clinical Outcome

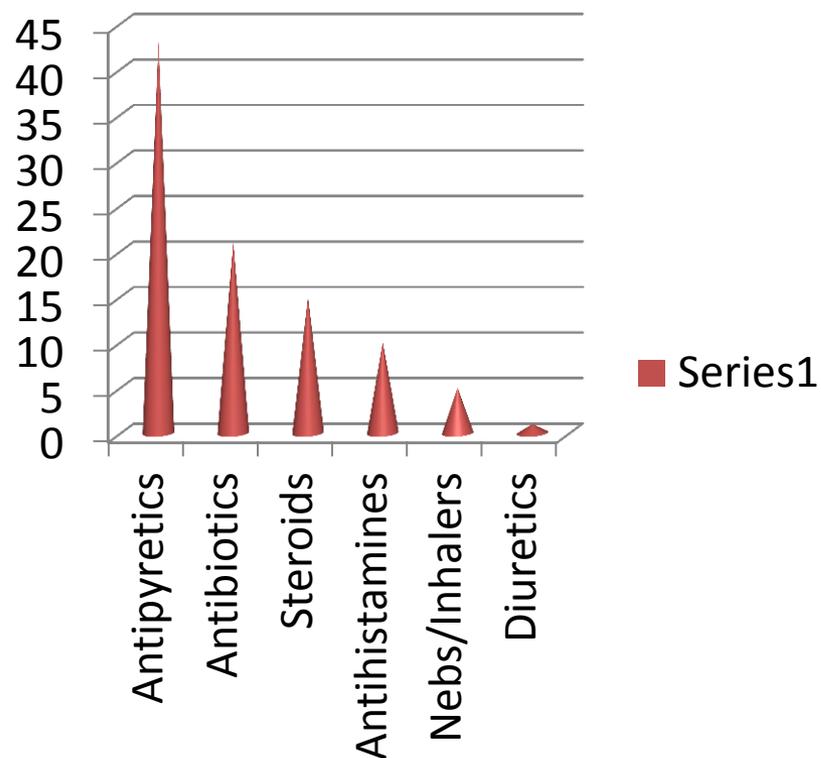
- Complete Recovery: 64
- Minor Sequelae: 7
- Death: 1(unrelated to transfusion)

Febrile Reactions

Investigations

- Bact screening of unit: 46
- Bact screening of pt: 62
- Bact screening of both pt and unit: 41

Interventions



Anaphylaxis/hypersensitivity (n=61)

- Number of reports received: n =68
- No. of reports accepted: 61

Clinical Outcome:

- Deaths: 0
- Complete Recovery: 54
- Minor Sequelae: 6
- Serious Sequelae: 1

Demographic Data

♂ 30 ♀ 31

Adults: 58

Less than 4 Years: 3

Components:

Red Cells n= 18

Apheresis Platelets n= 29

Pooled Platelets n=8

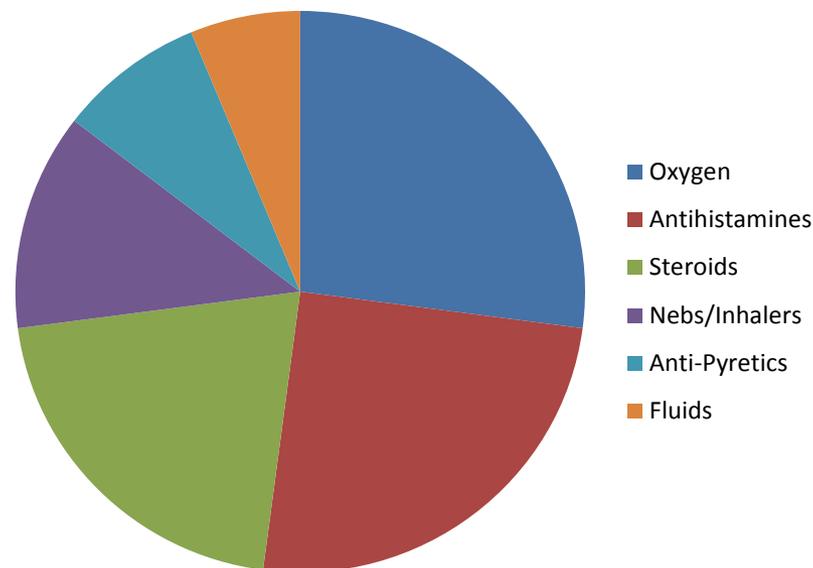
Plasma n= 3

Multiple Components n=3

Anaphylaxis/hypersensitivity

Investigations and Treatment

- IgA levels: 26 (all NAD)
- Bact screening unit: 20
- Bact screening pt: 30
- Bact screening both product and patient: 17



Case Study - AA

Background

- 12 yr old male pt with a diagnosis of Ewings Sarcoma admitted with febrile neutropenia.
- Plt count: 16 and received 1 unit of apheresis platelets

15 mins into transfusion pt developed:

- Temp rise 36.5^{0c} - 38.3^{0c}
- Urticaria to face and neck
- Tachycardia 92 – 149 bpm
- Rigors
- Resp rate increased to 28 from 22, Falling O2 sats and wheeze

Case Study - AA

Investigations

- IgA Levels: 0.8g/l
- Chest Xray NAD
- Bilateral wheeze identified on auscultation of chest

Intervention

- Transfusion stopped
- Pt treated with O₂, Antihistamines, Anti-Pyretics, Steroids, Adrenaline nebuliser

Clinical Outcome:

- Major Sequelae

Future Requirements for this pt:

- Pooled Platelets

Hypotensive Transfusion Reactions (n=3)

- The NHO received 3 reaction under the category of Hypotensive transfusion reaction

Case	Age Group	Gender	Imputability	Red Cells	Platelet Apheresis
1	Elderly (70+)	Female	Possible	Yes	
2	Elderly (70+)	Female	Possible	Yes	
3	Adult (51 - 70 years)	Female	Possible		Yes

Hypotensive Transfusion Reactions (n=3)

- Case 1: 81 yr old pt post fall transfused 1 unit RCC for anaemia post op. 15 mins into transfusion BP dropped from 111/45mmHg – 75/35 mmHg. Patient treated with IV Fluids, made a complete recovery within 40 mins
- Case 2: 79 yr old pt post op knee replacement transfused for anaemia. Bp dropped from 127/71 mmHg to 98/59 mmHg 10 mins into transfusion. Pt treated with Beta Blockers and made complete recovery
- Case 3: 60 yr old AML received 1 unit of apheresis platelets for count of 19, 15 minutes into transfusion Bp dropped from 100/20 mmHg to 67/70 mmHg

Key Messages

- Assessment of signs and symptoms when a reaction occurs is critical in the provision of treatment. Education in relation to this is fundamental
- For febrile reactions paracetamol is key treatment
- If anaphylaxis is suspected adrenaline should be available
- Steroids may take several hours to have an effect
- The common cocktail of paracetamol, steroids and antihistamines should be avoided
- Pooled platelets in PAS/HLA matched platelets should be considered with patients with recurring reactions

Unclassified Reaction (n=12)

Definition

- Unclassified SAR is the occurrence of an adverse symptom / sign with no risk factor other than the transfusion and which on its own does not allow the reaction to be classified within the defined categories of SAR.

Findings

- Reports of **12** unclassified reactions were received which is an increase on previous reporting years.

Commentary

- ***Reporting establishments are advised to continue reporting cases with unusual symptoms or those reactions which may not fit into the criteria already in place***

Mandatory Unclassified Serious Adverse Reactions 2019-2020 (n=12)

	Component Transfused	Age Profile	Imputability	Description
Case 1	Platelets Apheresis	Adult (51 - 70 years)	Likely / Probable	Nausea, Back Pain, Chills/Rigors, Sub sternal Discomfort
Case 2	Red Cells	Adult (51 - 70 years)	Possible	Dyspnoea, ↓ O2 Sats, GI Symptoms, Sub sternal Discomfort
Case 3	Red Cells	Adolescent (12-17 years)	Likely / Probable	Tingling sensation in both arms and legs, 1 hr later severe pain both legs and ankles
Case 4	Red Cells	Adult (31-50 years)	Possible	Nausea/Vomiting, Sub sternal Discomfort, Hypotension, Tachycardia, Patient profoundly unwell
Case 5	Red Cells	Adult (31-50 years)	Likely / Probable	Tachycardia
Case 6	Red Cells	Adult (51 - 70 years)	Likely / Probable	Hypertension, Anxiety, Dyspnoea, Chills/Rigors
Case 7	Red Cells	Elderly (70+)	Likely / Probable	Cyanosis, ↓ O2 Sats, Tachycardia, Restlessness, Back pain, Chills/Rigors
Case 8	Red Cells, Platelet Apheresis	Adult (51 - 70 years)	Possible	DCT Positive, Anti A present, Falling Hb
Case 9	Red Cells	Elderly (70+)	Possible	Joint Pains
Case 10	Red Cells	Adult (18-30 years)	Likely / Probable	Nausea, Vasovagal episode, Tachycardia
Case 11	Platelets Apheresis	Adult (31-50 years)	Possible	Dyspnoea, Chest/Abdominal Pain, Back Pain, Chills/Rigors
Case 12	Platelets Pooled	Elderly (70+)	Likely / Probable	Dyspnoea, Back pain, Hypertension

Delayed Transfusion Reactions: Immunological Haemolysis due to other allo- antibody (delayed n=8)

- 11 Reports received
- 8 Reports accepted

Age Range

All reactions ranged from 51 years to 70 years age group with one reaction in the 70+ age group

Clinical Outcome

- 7 out of the 8 reported reactions made a complete recovery
- There was 1 report of death which was unrelated to transfusion (Patient gravely unwell pre-transfusion)

Case No.	Age	Gender	Findings	Antibody identified	Outcome	Timeframe for developing antibody	Reaction caused by error
1	Adult (51 - 70 years)	Male	↓HB + DAT	Anti Jk ^a	Death *	8 Days	No
2	Adult (51 - 70 years)	Female	↑LDH, ↑Bilirubin	Anti Fy ^a	Complete Recovery	6 Days	No
3	Adult (51 - 70 years)	Female	↓Haptoglobins	Anti Jk ^a	Complete Recovery	9 Days	No
4	Adult (51 - 70 years)	Male	+DAT, ↑Bilirubin	Anti C Anti e	Complete Recovery	7 Days	No
5	Adult (51 - 70 years)	Male	↓Hb, ↓Haptoglobins	Anti c Anti E Anti Jk ^a	Complete Recovery	9 Days	No
6	Adult (51 - 70 years)	Female	↓Haptoglobins ↑LDH, +DAT	Anti Jk ^a	Complete Recovery	20 Days	No
7	Adult (51 - 70 years)	Male	↑LDH ↑Bilirubin ↓Hb	Anti Jk ^a	Complete Recovery	8 Days	No
8	Elderly 70+ years	Female	↑Bilirubin ↓Hb, +DAT	Anti E	Complete Recovery	21 Days	No

****Death unrelated to transfusion***

Delayed Transfusion Reactions

Most commonly implicated antibody =
Anti Jk^a

Recommendations

- Lifesaving transfusion should not be withheld due to a history of alloantibodies.
- Robust methods of recording patients antibody history should be developed and supported with patient education

Transfusion Transmitted Infection (n=1)

	Year	Serious Adverse Reaction	Age	Gender	Imputability	Red Cells	Platelets Apheresis	Platelets Pooled
1	2019	Transfusion transmitted bacterial infection	Adult (51 - 70 years)	Male	Excluded			Yes
2	2019	Transfusion transmitted viral infection - Other	Adult (31-50 years)	Male	Possible	Yes		
3	2019	Transfusion transmitted viral infection (HCV)	Adult (51 - 70 years)	Male	Excluded	Yes		
4	2019	Transfusion transmitted viral infection (HCV)	Adult (31-50 years)	Female	Excluded	Yes		
5	2020	Transfusion transmitted viral infection (HBV)	Adult (51 - 70 years)	Male	Likely / Probable	Yes		
6	2020	Transfusion transmitted viral infection (HBV)	Adult (51 - 70 years)	Female	Possible	Yes	Yes	

Possible Transfusion transmitted viral infection (Parvovirus)

Background

- 1995: Diagnosed Type 1 Diabetic
- 2014: Pt having routine haemodialysis
- Nov 2017: Received a simultaneous pancreas kidney transplant. Also received 12 units RCC
- March 2018: First identified as having Parvovirus as part of investigation of neutropenia
- May 2019: investigated for atypical parvovirus B19
- Archive samples from time of transplant tested and a high B19 was detected (14 days post transplant)

Possible Transfusion transmitted viral infection (Parvovirus)

- NHO notified July 2019
- QC Dept. in IBTS aware and HPRA informed
- Transfusion Transmitted Parvovirus was posed as a potential route of transmission
- IBTS do not screen the blood supply for Parvovirus DNA or antibody
- No regulatory or legal requirement for the IBTS to provide Parvovirus screened blood
- Both the NHO and IBTS take any reports of Transfusion Transmitted Infection very seriously, an investigation was carried out

Possible Transfusion transmitted viral infection (Parvovirus)

Investigations:

- Relevant archived samples were referred to the NVRL for Parvovirus DNA PCR and Public Health England for genotyping
- 12 implicated donors

Results

- One of implicated donors had a reactive parvovirus DNA result

Possible Transfusion transmitted viral infection (Parvovirus)

Outcome

- Overall the blood donation could not be excluded, the NHO accepted this case with an imputability of possible

Further considerations:

- Further review from the organ donation perspective
- Parvovirus is transmitted most commonly via droplet. The possibility of direct person to person transmission should be out ruled

STTI Recommendations

- *Inform NHO, IBTS Quality Department, IBTS Consultant on call or Medical Scientist on call ASAP in cases of STTI to protect the blood supply*
- *Where a recall involves blood components which have been transfused, hospitals should have a robust system in place which should include a review of the patient.*

Transfusion-associated circulatory overload (TACO)

Definition (2018)

*International Society of Blood Transfusion
Working Party on Haemovigilance*

*in collaboration with
The International Haemovigilance Network*

And AABB (formerly the American Association of Blood Banks)

Change to Definition

- 2018 definition represents a revision of the previous international TACO definition published by the International Society for Blood Transfusion Haemovigilance working party and International Haemovigilance Network:
http://www.isbtweb.org/fileadmin/user_upload/Proposed_definitions_2011_surveillance_non_infectious_adverse_reactions_haemovigilance_incl_TRALI_correction_2013.p



International Society
of Blood Transfusion



International
Haemovigilance
Network

TACO – Points to note

- The NHO continue to collect reports of TACO where patients exhibit clinical signs and symptoms of overload following transfusion and do not meet the strict criteria of ISBT Definition
- The NHO following review and discussion will make a decision if the reaction fits the ISBT Definition criteria

Transfusion Associated Circulatory Overload (TACO) n=59

Findings

- 63 Reports received
- 59 Accepted
- 44 Mandatory

Demographics

- 18-30 yr: 2
- 31-50 yr: 1
- 51-70 yr: 15
- 70+: 41

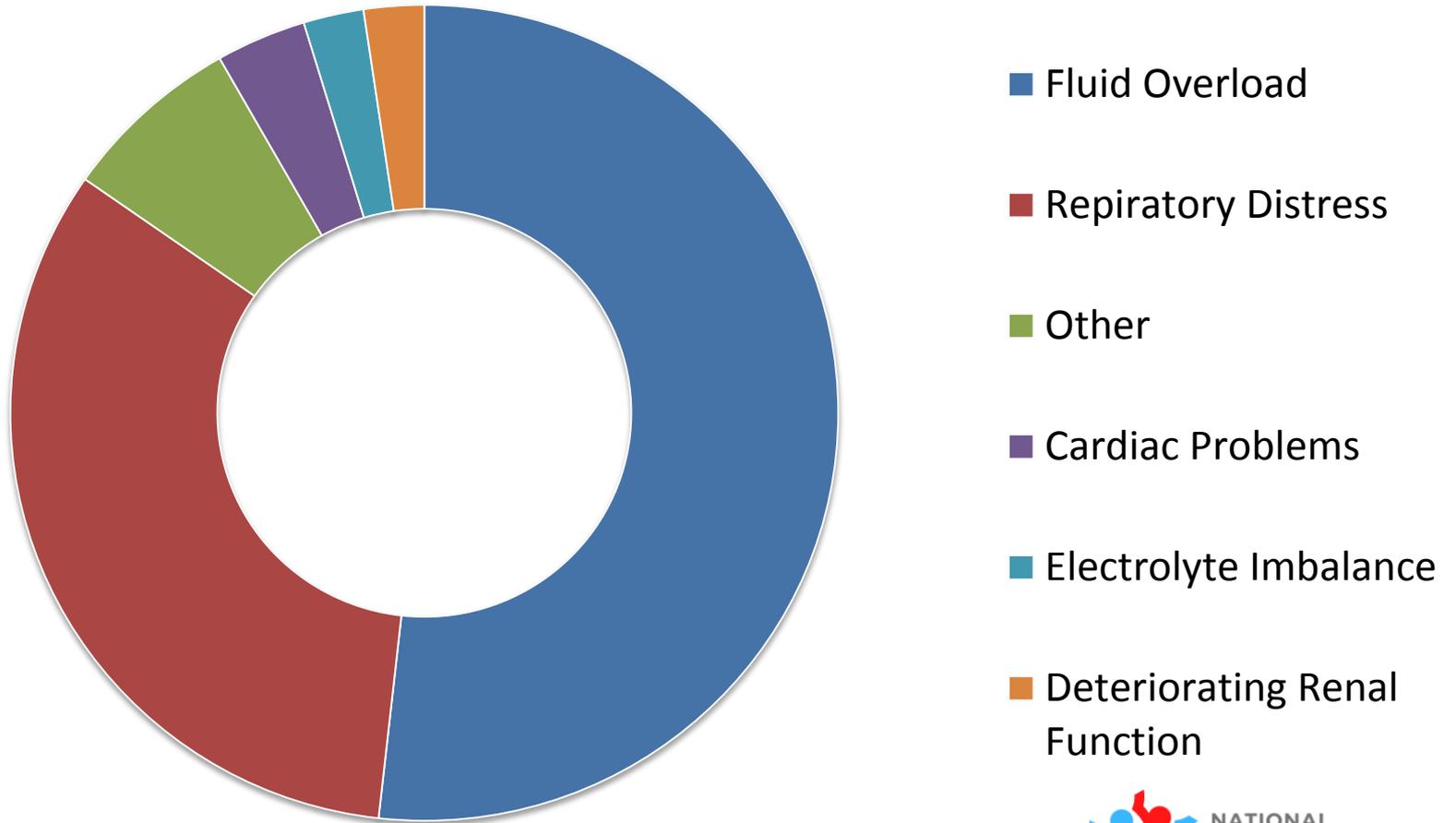
Components

- RCC: 58
- Platelets (pooled): 1

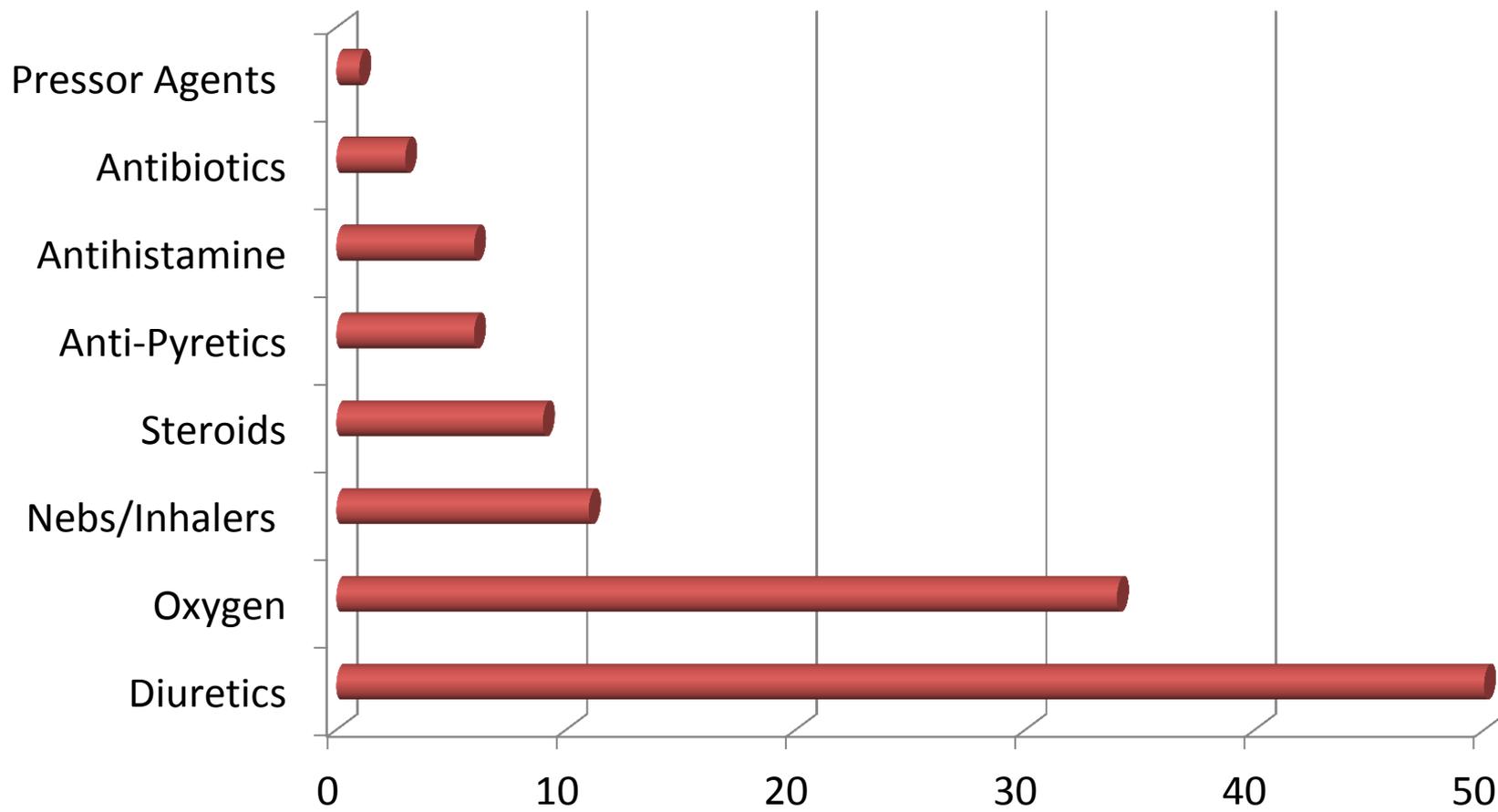
Clinical Outcome

- Complete Recovery: 43
- Minor Sequelae: 9
- Serious Sequelae: 2
- Death: 5 (1 possibly related to transfusion, 4 unrelated to transfusion)

Clinical Features TACO



Interventions



TACO Case Study

- 76 yr old pt with history of COPD (acutely unwell), Cardiomyopathy, htn, Recent RTI
- Hb 6.8g/dl pre transfusion
- Pt prescribed RCC X 2
- First unit transfused in the afternoon over 4 hours and second later that evening
- Pre transfusion obs
prior to second unit:
HR: 80bpm,
BP:162/73mmHg

Symptoms (15 mins into 2nd transfusion)

- Hypertension 162/73 – 180/114
- Tachycardia 80 – 129bpm
- Dyspnoea
- O2 sats 96% - 88%
- Metabolic acidosis
- Chest Xray changes

TACO Case Study

- Transfusion stopped
- Patient became very unwell and unresponsive
- Positive Fluid Balance
- Diuretics administered with effect
- O2 and nebs also used
- Sadly pt passes away following day

NHO queried as to why this already unwell patient with multiple co-morbidities was transfused RCC x 2

Questions: Was the Hb correct!

Perhaps a dilute sample

Was Hb checked following first unit

Was the second unit appropriate

TACO Case Study

Feedback

- Possible samples were diluted – no proof
- Patients clinical condition combined with low Hb result – rationale for transfusion
- Agreed that a follow up Hb post first unit should have occurred

Transfusion Associated circulatory Overload (TACO)

- 52/59 patients transfused with a reason of transfusion categorised as anaemia (WHO defined Chronic anaemia as lower than 7-8g/dL in adults)
- 45 patients developed TACO following 1 component transfused
- 11 patients developed TACO following transfusion of 2 components
- 1 patient developed TACO following transfusion of 3 components
- 1 patient developed TACO following transfusion of 4 components (Massive Haemorrhage)

TACO as a result of an error

5 out of the total 59 accepted TACO cases reported occurred as a result of an error with **Human Failure** been identified as the cause of error

Case Number	Age	Imputability	Human Failure	System Failure	Error Cause
1	Adult (18-30 years)	Likely / Probable	Yes	Yes	Second unit prescribed and transfused in error - Lack of Knowledge
2	Elderly (70+)	Possible	Yes		Patient with pre-existing cardiac problems, unit transfused too quickly
3	Adult (51 - 70 years)	Likely / Probable	Yes		3 units prescribed, 4 units administered - SAH
4	Adult (18-30 years)	Likely / Probable	Yes	Yes	2 units of RCC transfused in a short period of time
5	Elderly (70+)	Possible	Yes		Patient with CCF, SOB, Pitting Oedema and prescribed 2 units RCC over 3-4 hours

TACO Checklist

	Patient Risk Assessment	Yes	No
Cardiac	Does the patient have any pre-existing co-morbidities i.e. Cardiac Failure, Hypertension, Severe aortic stenosis or moderate or severe left ventricular dysfunction?		
	Is this patient on regular Diuretics?		
	Does the patient have severe anaemia?		
Pulmonary	Is the patient known to have Pulmonary Oedema		
	Has the patient respiratory symptoms		
Fluid Therapy	Is the pre-transfusion fluid balance positive?		
	What other fluids is the patient receiving		
	Is there peripheral oedema present:		
	Does the patient have significant renal impairment?		

If any of the above risks have been identified PLEASE:

	Yes	No
Review the patients need for Transfusion		
Can the transfusion be safely deferred		

TACO Checklist

If Proceeding with the transfusion please ensure the following steps are completed:

- Body Weight of patient and correct component dosing
- Transfuse a single unit of RCC and review
- Monitor Fluid Balance
- Is prophylactic Diuretics required?
- Monitor observations closely

Transfusion Associated Dyspnoea (TAD)

TAD (ISBT 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 cause”

Findings

- The NHO received 4 reports of TAD in 2019-2020 reporting period.

Transfusion Associated Dyspnoea (TAD)

Case No.	Age	Gender	Imputability	Components	Comments
1	2019 Elderly (70+)	Female	Likely / Probable	RCC	Dyspnoea approx. 90 mins into transfusion
2	2020 Adult (18-30 years)	Female	Possible	RCC	Dyspnoea approx. 2 hours into transfusion
3	2020 Elderly (70+)	Female	Likely / Probable	RCC	Dyspnoea approx. 1 hour into transfusion
4	2020 Elderly (70+)	Male	Possible	RCC	Dyspnoea and Hypotension approx. 1 hour into transfusion. Initially classified as Hypotensive Transfusion reaction, following review accepted as TAD.

TAD – Points to note

- There is still much work that needs to be done to understand cases reported
- Patients generally have multiple co-morbidities
- Risk factors need to be identified and acted on

Mortality and morbidity data by category 2019-2020

	Death (unrelated to transfusion)	Death probably related	Death possibly related	Major Sequae	Minor Sequae	Complete Recovery	Unknown
Anaphylaxis/hypersensitivity (AA)				1	6	54	
Immunological haemolysis due to other allo-antibody (Acute < 24 hrs)					1	1	
Immunological haemolysis due to other allo-antibody (Delayed > 24 hrs)	1					7	
Hypotensive Transfusion Reaction					1	2	
OSR - Febrile Non Haemolytic Transfusion Reaction	1				7	64	
OSR - Transfusion Associated Circulatory Overload (TACO)	4		1	9	2	43	
OSR - Transfusion Associated Dyspnoea					1	3	
OSR - Unclassified SAR	1				2	9	
Transfusion transmitted viral infection - Other							1
Total	7	0	1	10	20	183	1

Haemovigilance and COVID

- March 5th 2020: NHO Conference
- March 28th 2020: 2 week stay at home notice!!
- Staff worked phenomenally ensuring patient care was not compromised
- Haemovigilance reporting continued
- We seen accelerated transformations relating to education, electronic systems
- Everyone's ability to adapt has been extraordinary
- Introduction of Zoom, Microsoft teams etc.

COVID 19 – Impact on transfusions

- Elective Surgery postponed
- Haematology/Oncology patients moved
- Challenges on donors, staffing clinics etc.
- IBTS worked continuously to maintain supply
- Donor selection criteria continuously updated with international guidance
- To date no evidence of transmission of COVID-Cov-2 via blood transfusion

