Twenty five years of Haemovigilance in Ireland

Dr Kieran Morris

NHO Conference

25 March 2025

Krever Commission Report (Canadian Blood Services)

- The report described a public health disaster in Canada in the 1970s and 1980s
- The report detailed the events leading to the tainted blood crisis
- The report estimated that 85% of hepatitis C infections from blood transfusions between 1986 and 1990 could have been prevented
- The report concluded that the Canadian government failed to take precautionary measures to protect the blood supply
- The report found cost cutting attempts, cover ups and political interference
- The report found the negligent importation of blood from high risk American donors

Penrose Inquiry (Scottish Blood Service)

Recommendation

The Inquiry recommends: That the Scottish Government takes all reasonable steps to offer a HCV test to everyone in Scotland who had a blood transfusion before September 1991 and who has not been tested for HCV

Infected Blood Inquiry (UK Blood Services)

Several hundred findings (the following are selected)

- A patient needs to be able to access their records with ease
- Any failure of record keeping is likely to result in some loss of trust in the system
- There is no place for gratuitous comments in records
- Complacency is the enemy of safety
- Patient safety should have been the paramount guiding principle
- A search for certainty can be, and in this case was, the enemy of achieving progress

Infected Blood Inquiry (UK Blood Services)

- Risks to public health need to be addressed with speed, consistency, and an objective look, at such evidence as there is without making unjustified assumptions
- What aids the process is a clear structure for decision making. Instead of effective decision making here, there was ‘decision paralysis.’
- Cost, though a relevant factor, should not be the starting point. Patient safety should be.

Sadly, these principles were honoured more in the breech than in the observance

Infected Blood Inquiry (UK Blood Services)

Over 100 recommendations (the following are selected)

- Change the culture, such that safety is embedded as a first principle, and is regarded as an essential measure of the quality of care
- A more rational approach to regulation and safety management, resolving the problems created by the current systems for trying to deliver safer care which are fragmented, overlapping, confusing and poorly understood

Infected Blood Inquiry (UK Blood Services)

Harm and risk of harm go unaddressed because:

- **Patients and service users are not listened to**
- **Data is not collected**
- **Information/intelligence/data is held in the wrong place and/or not shared with the appropriate bodies**
- **The extent of a risk is not identified because bodies are not pooling their intelligence/data**
- **Trends that can be only be spotted by taking a bird's eye view are not identified**
- **A joined up response is required but none is forthcoming as a result of remit apathy ('not my responsibility') and/or lack of accountability for joint working**

Regulatory aspects of blood transfusion

- Guiding principles and law
- EU Blood Directive 2002/98/EC
- Inspection/accreditation/licensing
- Enforcement and threat surveillance
- Professional organisations within the blood transfusion professional community
- **The precautionary principle**

The Role of Haemovigilance in Transfusion Safety

- Confidentiality of submitted data
- Broad participation, supported by education
- Use of standardized definitions and terminology
- Nonpunitive evaluation of data
- Reporting of rates of occurrences
- Sufficient detail to make effective recommendations for improved practices
- Focus on improved safety and outcomes
- Simple and efficient operations
- Sustainable organization

Medicolegal aspects of transfusion practice

- Ethical principles/regulatory framework/quality guidelines/duty of care/consent to transfusion
- EU Blood Safety Directive 2002/98 – standards related to blood collection testing, processing, and storing
- EU Blood Safety Directive 2004/33 – technical requirements
- EU Blood Safety Directive 2005/61 and 2005/62 – traceability, reporting adverse reactions and events, and specifications for quality systems

Dipping into the Archives (NHO annual reports)

Annual report 2000

Haemovigilance has been defined as

“A set of surveillance procedures, from the collection of blood and its components to the follow up of recipients, to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products, and to prevent their occurrence or recurrence”

Annual report 2000

The remit of the NHO is to:

- Receive, collate and follow up reports of adverse reactions/events to transfusion of blood components/products
- Advise on the follow up action necessary
- Report adverse reactions to the Irish Medicines Board (IMB) according to an agreed procedure
- Provide ongoing support to hospital based Transfusion Surveillance Officers (TSOs) and as appropriate to medical, nursing and technical staff

Annual report 2000

- Advise on improvements in safe transfusion practice based on the data supplied by hospitals
- Support the development of clinical guidelines for hospitals
- Support the audit function of hospitals
- Promote the development of fully traceable transfusion records
- Report to National Blood Users Group (NBUG) an a periodic basis with a view to developing national transfusion practice

Annual report 2000

Definition of adverse event/reaction

Adverse event: an undesirable experience occurring following administration of a blood component/product

Adverse reaction: a reaction which is harmful and unintended and which occurs following a transfusion of therapeutic volume of a blood component/product

Annual report 2000

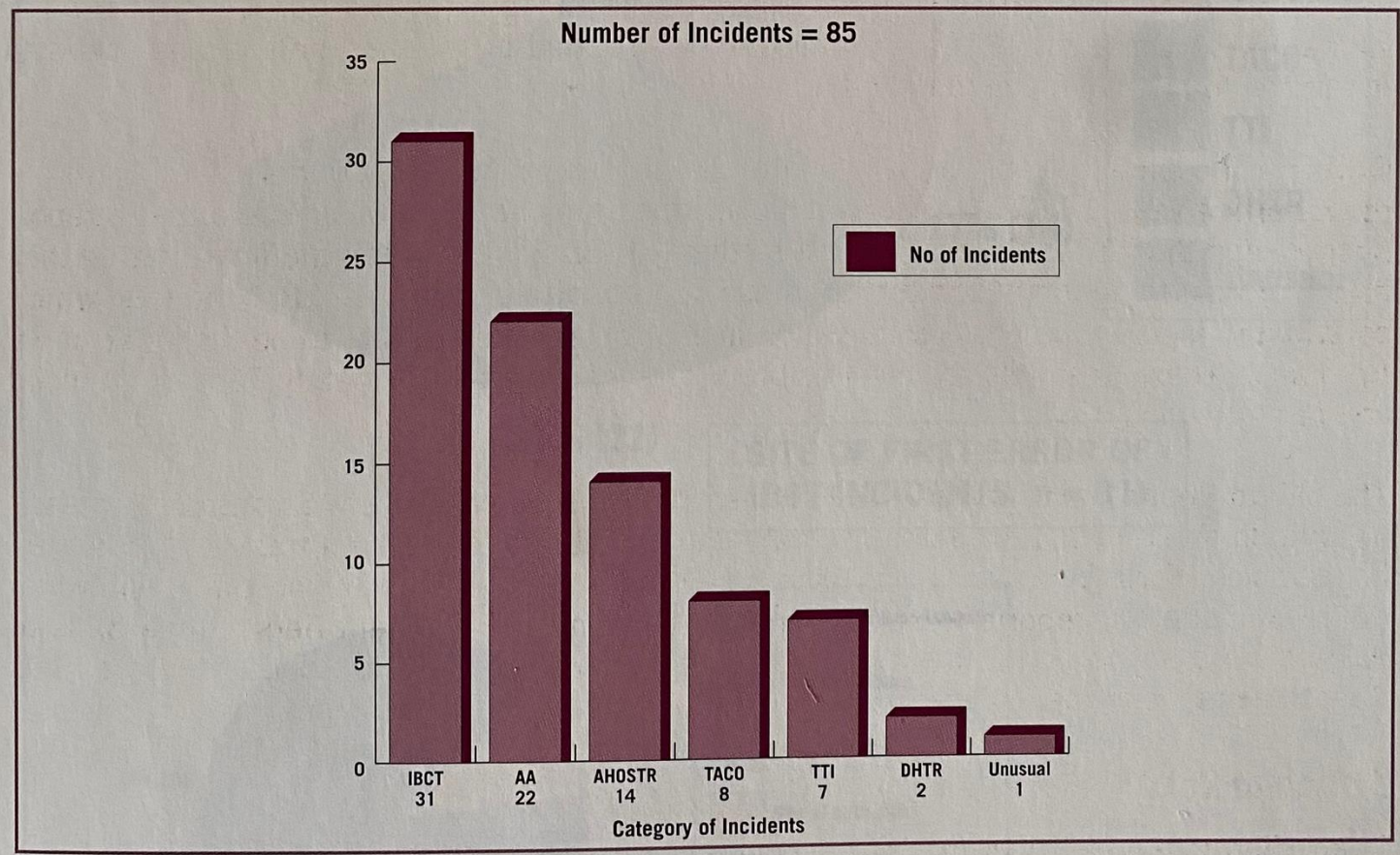
Reporting forms

- Initial report form
- Incorrect blood component/blood product transfused
- Acute haemolytic or other severe acute transfusion reaction
- Delayed haemolytic transfusion reaction
- Transfusion related acute lung injury
- Severe acute anaphylaxis/anaphylactoid reactions
- Transfusion related circulatory overload
- Post transfusion purpura
- Transfusion associated graft versus host disease
- Unusual transfusion reactions

Table 1: Number of units issued by IBTS January – December 2000

Component	Total Issues
Red Cells	124,291
Platelets	41,207
Fresh Frozen Plasma	24,811
Cryoprecipitate	1,848
Whole Blood	506
Combined total	**192,663**

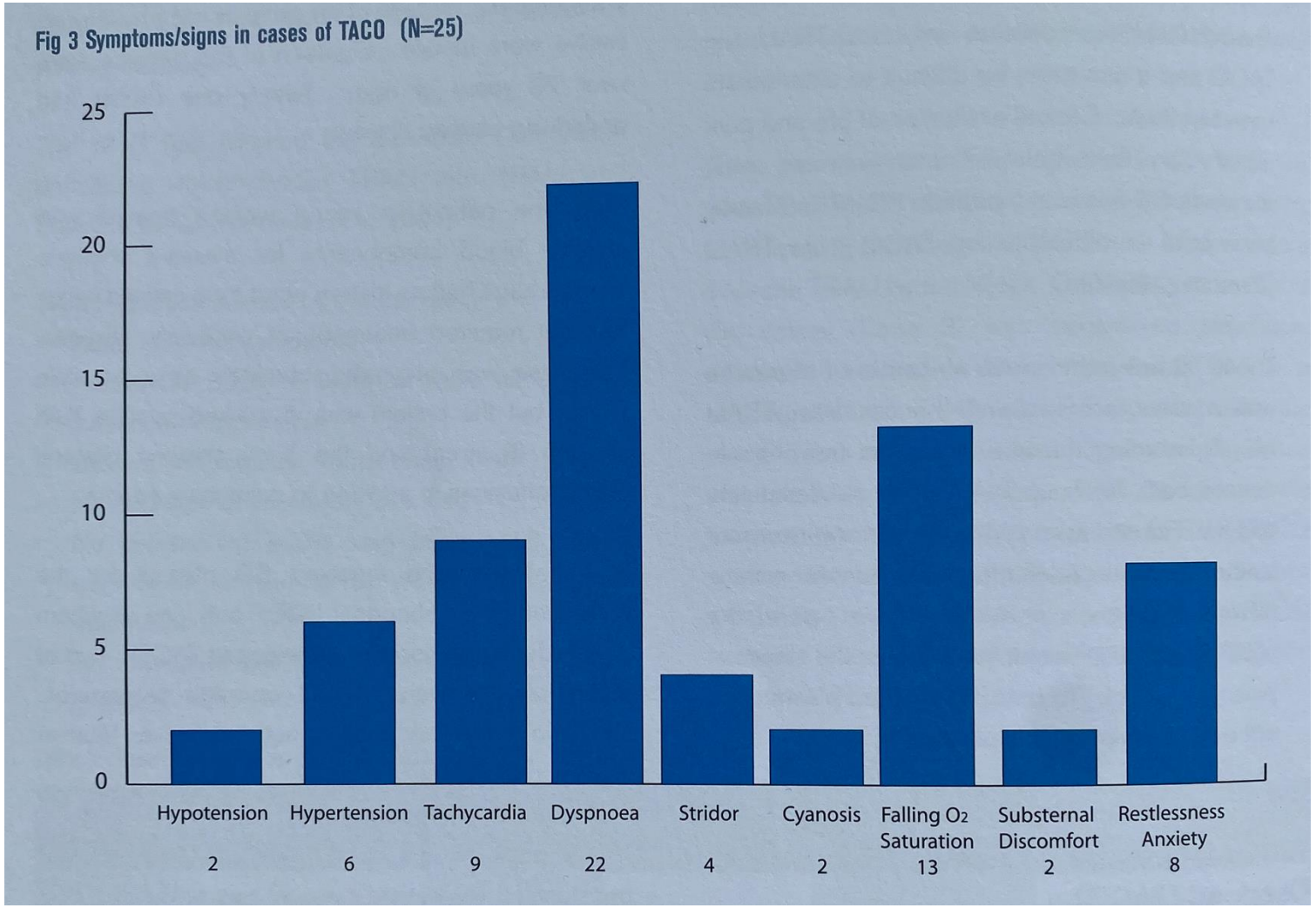
Graph 1 NHO Incidents by Category



There were no reports received in the categories of:

- Post Transfusion Purpura, (PTP)
- Transfusion Related Acute Lung Injury (TRALI)
- Transfusion Associated Graft versus Host Disease (TAGvHD).

Annual report 2005



- Two patients required ongoing cardiac support and four patients died later of their underlying condition
- One of the patients given SD plasma to correct an abnormal INR developed TACO and subsequently died. This was a severely ill patient with underlying liver disease but the transfusion was considered unnecessary as the patient was not bleeding. The death was considered possibly related to the transfusion

Annual report 2010/2011

During 2010, 451 reports were received - an increase of 30% (n=137) compared to the 314 reports received in 2009.

Table 5: Reports Received by the NHO 2009-2010 (n=765)

Reports	2009		2010	
	n	%	n	%
Accepted reports	267	85	391	87
Reports not progressed	46	15	56	12
Duplicate reports received	1	0	4	1
Total number of reports received	314	100	451	100

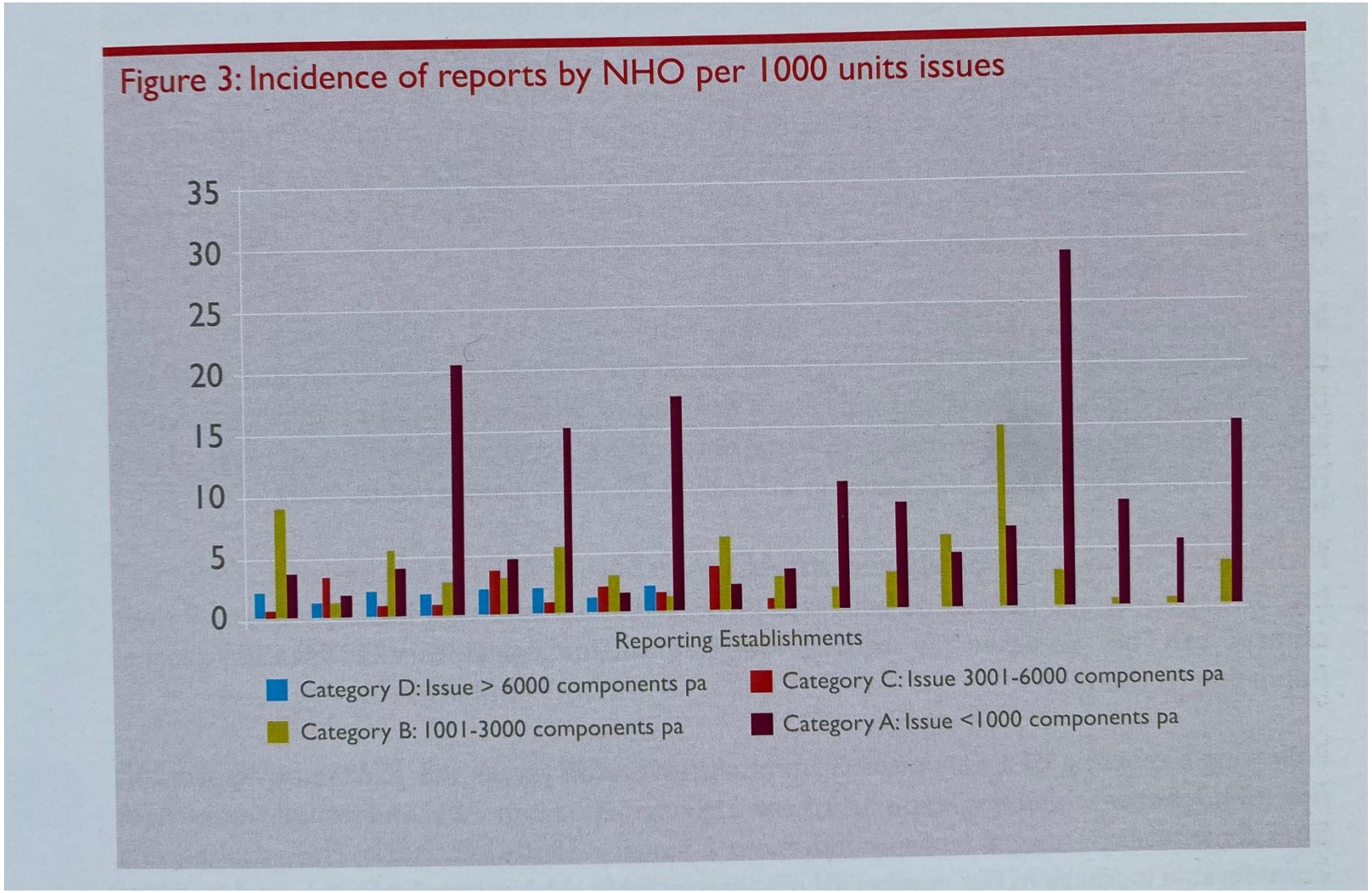
Annual report 2010/2011

Table 8: Mandatory and Non-Mandatory Reports by Hospital Category (n=71*)

Category	Components issued (p.a).	No of Reporting Establishments	Near Miss	SAE	SAR	Not accepted	Total	Range
A	0-1000	37	5	26	15	10	56	0-11
B	1000 -3000	18	6	69	43	29	147	1-26
C	3000-6000	8	9	17	23	7	56	2-21
D	> 6000	8	15	49	70	12	146	13-33

(* Reports from two supply centres and duplicate reports were not included).
This represents a haemovigilance participation rate of 73% (n=52).

Annual report 2010/2011



Annual report 2010/2011 (key points – selected)

- Decision making in an emergency is very difficult and retrospective review can appear harsh however this patient did receive unnecessary transfusions
- As noted in earlier sections of this report there is little evidence to support the ‘two person check’
- 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
- Testing an eluate is an important part of investigating a haemolytic transfusion reaction and may be the only way of identifying any and all of the antibodies present

Annual report 2010/2011 (key points – selected)

- All patients receiving transfusion should have regular clinical review and assessment of their needs
- Every clinician who signs a transfusion prescription should be satisfied that the reason for every transfusion is known, evidence based and documented in the case notes. Patients with a low body mass index (BMI) will have a smaller blood volume and will require a smaller blood transfusion to achieve the same increment in haemoglobin and are at risk of TACO
- Hospital blood banks are expected to provide a quality based transfusion service underpinned by procedures and staff training. Such procedures must be put in place. Failure to provide these is considered system and not human error

Annual report 2010/2011 (key points – selected)

- The availability of instructions and multiple documents can only lead to error. Pre transfusion instructions should be in one document and not dispensed as over compatibility report forms and prescription documents.
- As a minimum blood cultures and investigations for haemolysis should be taken on patients suffering an FHTR to exclude red cell incompatibility or bacterial contamination. A recheck should be taken to confirm the component was intended for that patient.
- Careful attention to fluid balance is essential and must be documented

SERIOUS Adverse Events 2019 to 2020

National Haemovigilance Office

Caroline Casey

Components issued in 2019 and 2020

	RCC	Platelets	Other (Granulocytes)
Total Number of components issued 2019	122,582	21,237	163
Total Number of components issued 2020	113,766	21,049	92

Table 1: The number of components issued in 2019 and 2020

What happened 2019?

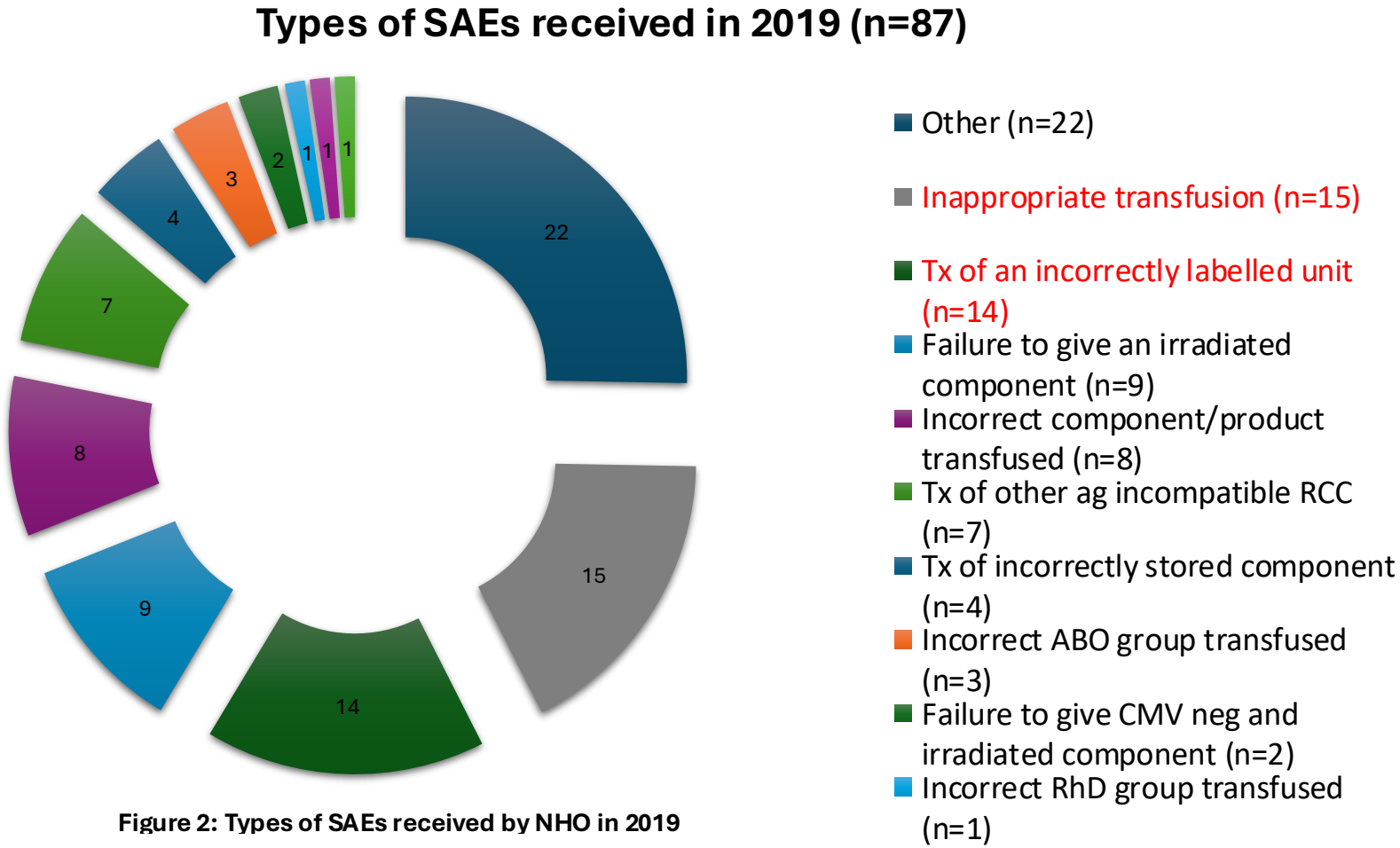


Figure 2: Types of SAEs received by NHO in 2019

What happened 2020?

Types of SAEs received in 2020 (n=67)

- Inappropriate transfusion (n=21)
- Other (n=14)
- Incorrect component/product transfused (n=7)
- Tx of incorrectly stored component (n=6)
- Tx of other ag incompatible RCC (n=5)
- Failure to give an irradiated component (n=4)
- Tx of an incorrectly labelled unit (n=3)???
- Incorrect RhD group transfused (n=3)
- Blood or blood product given to wrong patient (n=1)
- Failure to give CMV neg and irradiated component (n=1)
- Tx of expired component (n=1)
- Failure to give CMV neg component (n=1)

Figure 3: The number and type of SAEs received at the NHO in 2020

Wrong Blood in Tube (WBIT)

Reports accepted 2019 – (n = 46)

Reports accepted 2020 - (n = 71)

	No. of reports 2019 (n = 46)	No. of reports 2020 (n =71)
Sample taken from intended patient but labelled with another patient's details	36	61
Sample taken from wrong patient but labelled with intended patient's details	10	10

Table 6: Classification and number of WBIT reports accepted by the NHO in 2019 and 2020

What happened in 2019 and 2020?

Patient Identification errors reported to NHO	2019 (n = 47)	2020 (n=77)
Detail on sample not transcribed from ID band	4	4
Patient not correctly ID at phlebotomy	19	21
Patient not correctly ID at admission	4	4
Sample not labelled by person taking sample	4	15
Sample remotely labelled	9	21
Other	6	10
Unknown		2
Pre-labelling	1	

Table 6: the number and type of patient ID errors reported in 2019 and 2020

WBIT and electronic identification systems (EIS) 2020

- EIS in use in 24 out of 30 sites that reported WBIT events to the NHO in 2020.
- 92.2% of reported events were from sites which stated that an electronic system was in use at the time of the WBIT event.
- 26% of reported events an electronic ID system was not used during the sampling procedure.
- Of the remaining WBIT reported 34 used EBTS, 15 used MNCMS and it was unknown if an electronic sampling system was used in two incidences.

What can we do?

- Address environmental factors?
- Stop scanning bands from charts??
- Address issues with printers?
- Get phlebotomists to take samples?

Key Recommendations from current WBIT data

Things to consider:

- Removing wristbands from charts
- Employing phlebotomists for out of hours sampling
- Address issues with printers

Key Recommendations from 2019 and 2020

- We need to address the human factor principle
- We need more detail in our descriptions
- We need to learn from excellent practices
- We need to ensure our systems are robust and we are resilient

‘To make no mistakes is not in the power of man; but from their errors and mistakes the wise and good learn wisdom for the future.’

Plutarch

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NHO Serious Adverse Reactions 2019-2020

Joanne Scanlon

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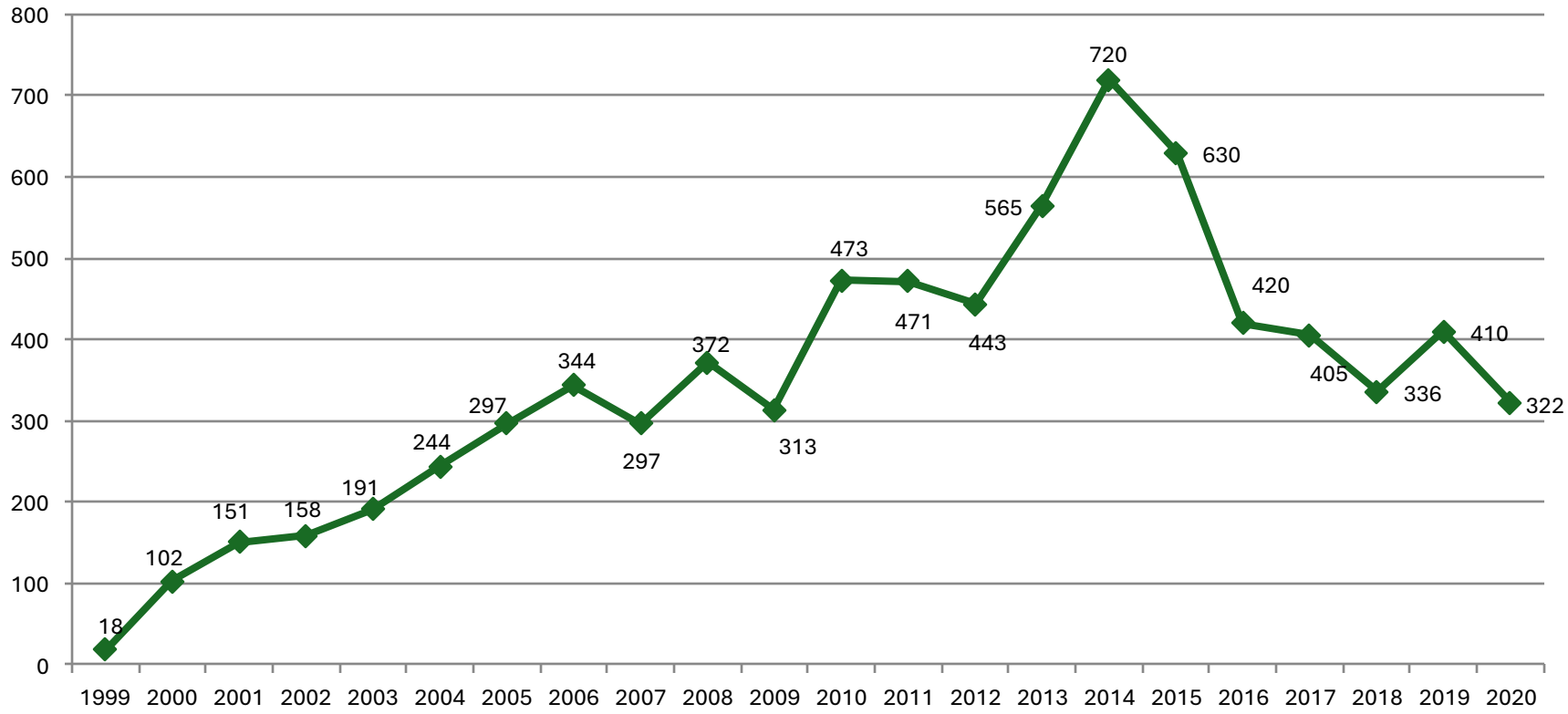
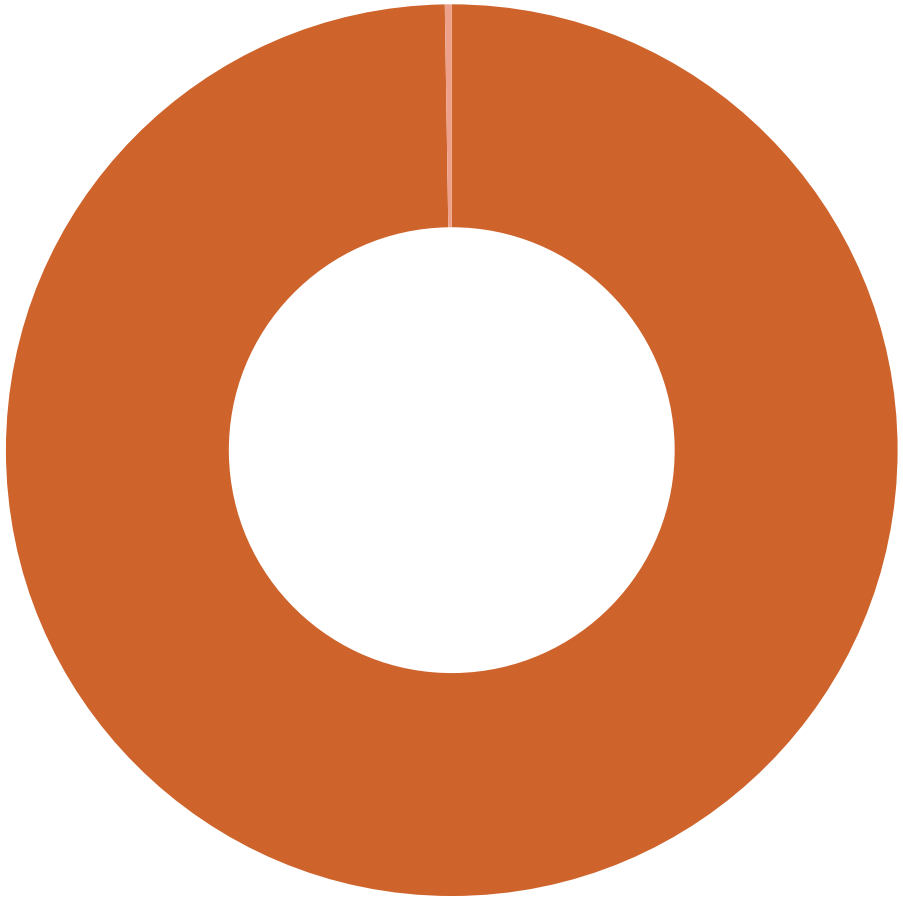
Total number of reports received in the NHO 1999 -2020 (n= 7682)



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



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

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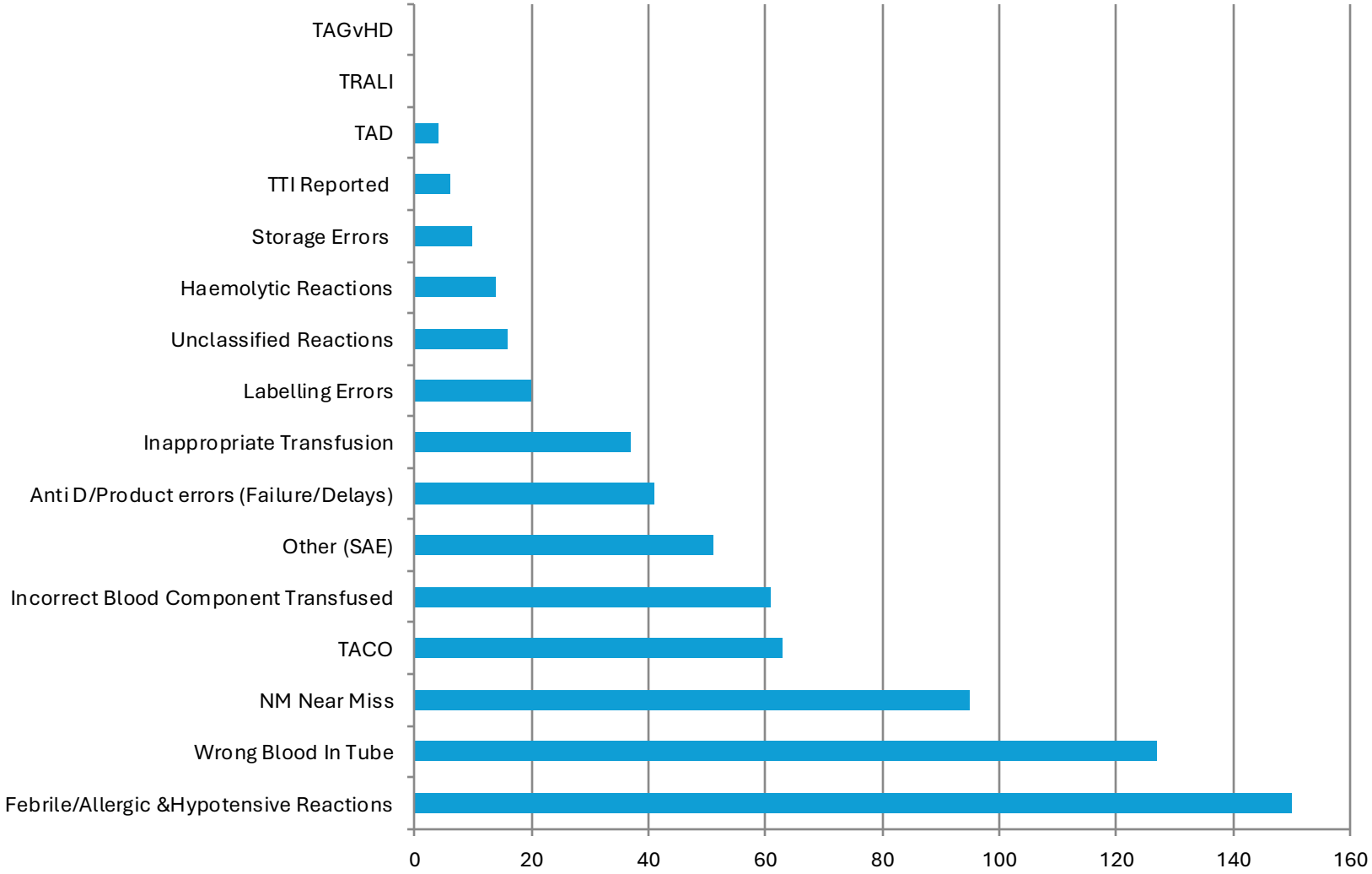
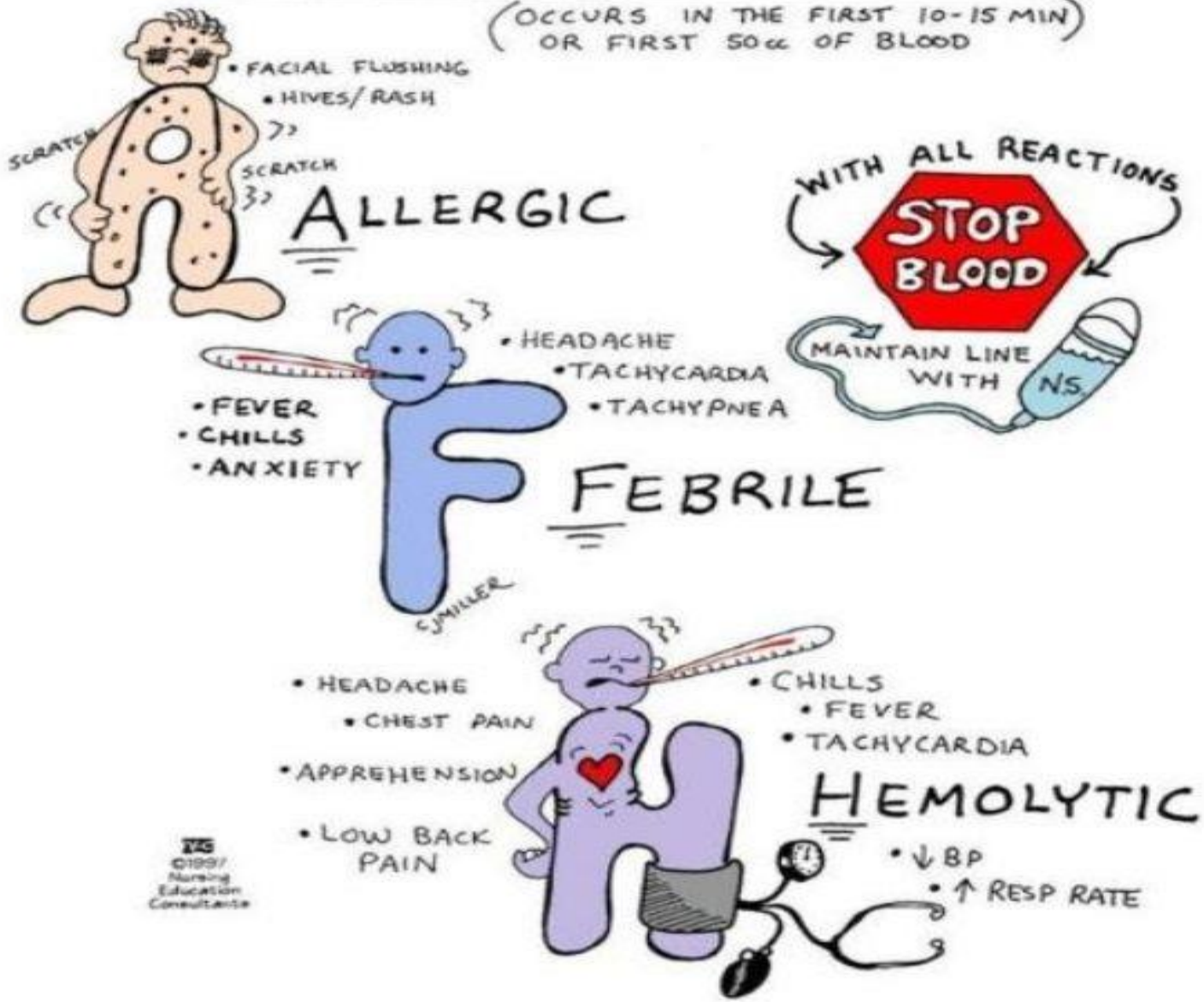
Summary of Data 2019-2020



TRANSFUSION REACTIONS:

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



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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

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Febrile Reactions (n=72)

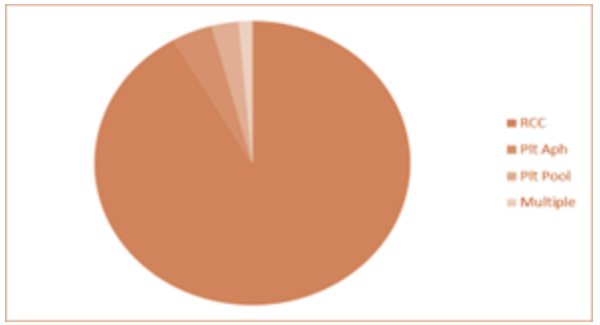
Findings

- 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)

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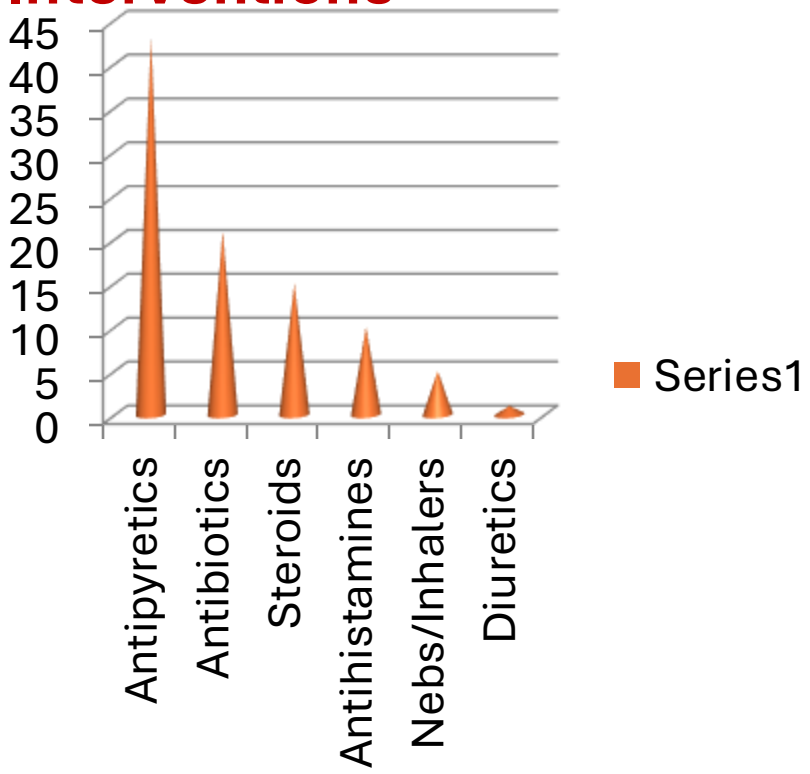
Febrile Reactions

Investigations

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

Interventions



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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 Sequleae: 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

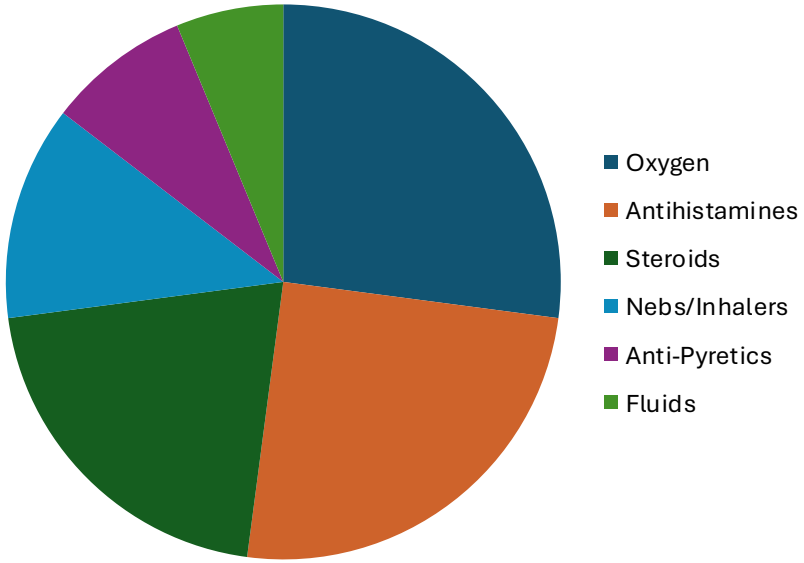
Plasma n= 3

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



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Case Study - A

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

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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

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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 affect
- 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

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Un l 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 1**2** 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

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 viral infection (HCV)	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:

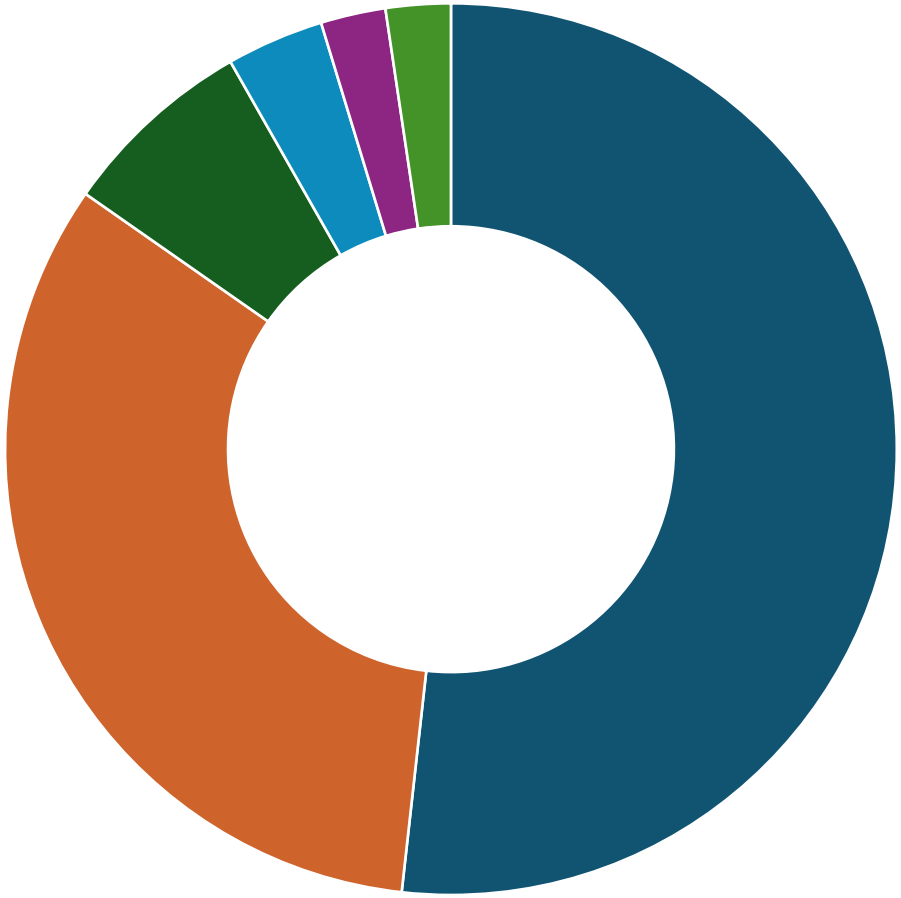
- Further review form the organ donation perspective
- Parvovirus is transmitted most commonly via droplet. The possibility of direct person to person transmission should be out ruled

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.***

Clinical Features TACO



- Fluid Overload
- Repiratory Distress
- Other
- Cardiac Problems
- Electrolyte Imbalance
- Deteriorating Renal Function

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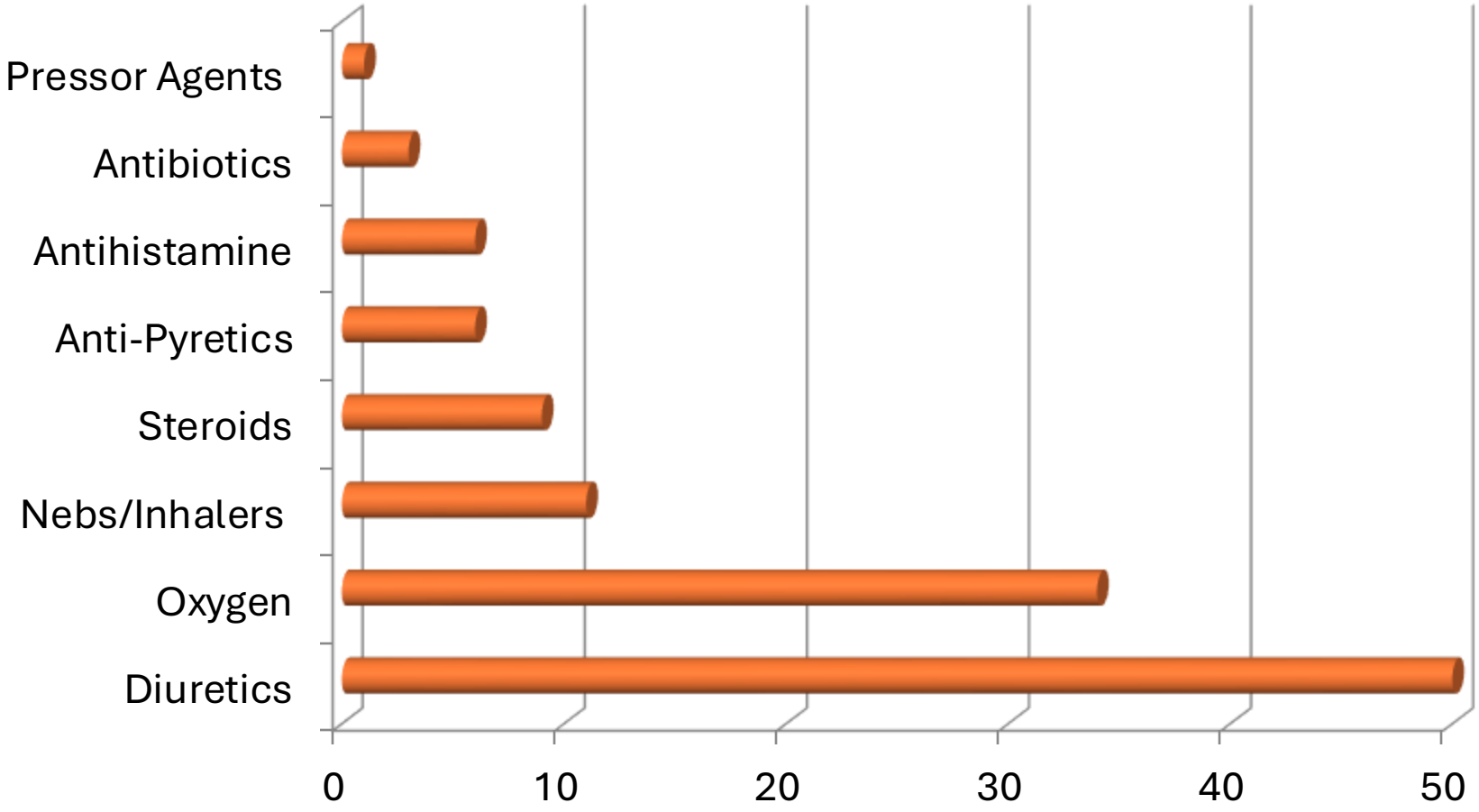
Interventions



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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

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CONFERENCE FEB 2022

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

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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 2-4 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 stenosism 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

Mortality and morbidity data by category 2019-2020

	Death (unrelated to transfusion)	Death probably related	Death possibly related	Major Sequlae	Minor Sequlae	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**

National Haemovigilance Office

Transfusion Associated Circulatory Overload 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 chronic anaemia?		
Pulmonary	Is the patient known to have Pulmonary Oedema?		
	Has the patient any respiratory symptoms?		
Fluid Therapy/ Metabolic	Is the pre-transfusion fluid balance positive?		
	Is the patient receiving other fluids?		
	Does the patient have low body weight? Is there hypoalbuminaemia? 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 patient's need for transfusion		
Can the transfusion be safely deferred?		

If proceeding with the transfusion, please ensure the following steps are completed:

- Check Body Weight of patient and correct component dosing
- Transfuse a single unit of RCC and review
- Monitor Fluid Balance
- Are prophylactic Diuretics required?
- Monitor observations including O_2 saturation closely

Serious adverse reactions: 2013-2015

Joanne Scanlon

National Haemovigilance Office

Serious Adverse Reactions (SAR)- Main findings 2013-2015

In total 1,079 SAR reports submitted to NHO with 952 reports accepted
200 Reports Mandatory (21%)

50 Reports were reclassified following submission

121 Reports Did not progress

61 reports involving paediatric patients received and 58 accepted

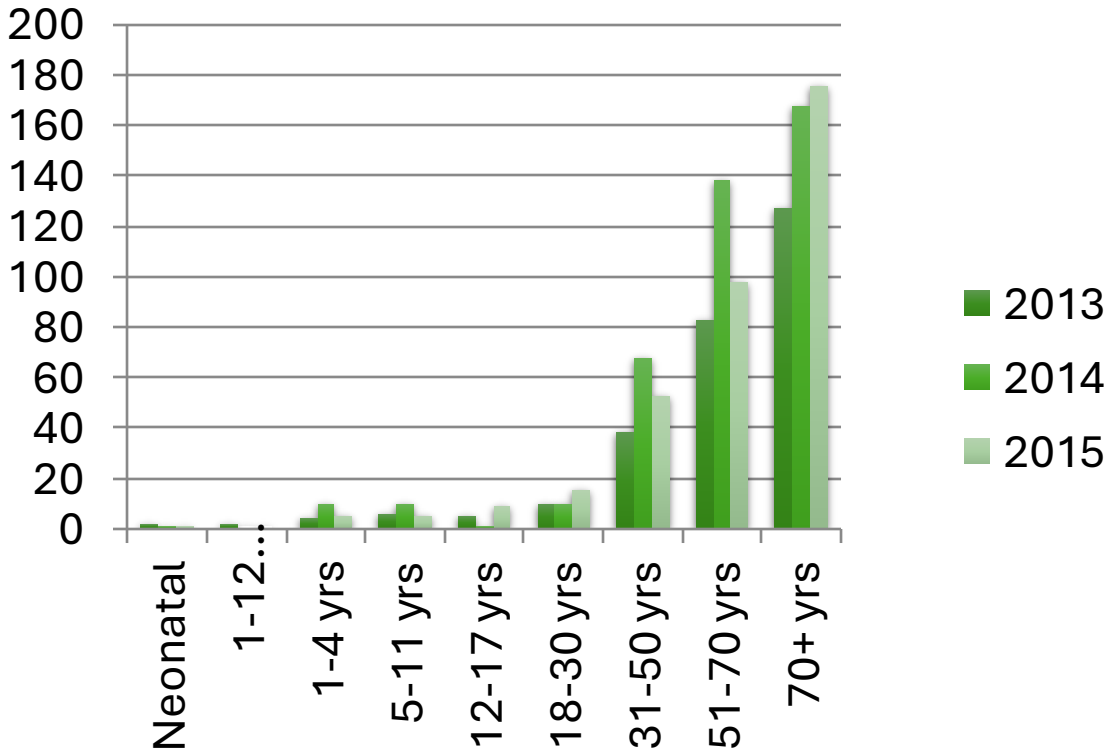
No reports accepted in relation to:

- ***Suspected transfusion transmitted infection (bacterial)***
- ***Transfusion Associated Graft versus Host Disease (TAvGHD),***

Serious Adverse Reactions accepted by the NHO		2013	2014	2015
Acute Transfusion reactions	Immunological haemolysis due to ABO Incompatibility	0	1	1
	Immunological haemolysis due to other allo-antibody (Acute < 24 hrs.)	0	1	0
	Anaphylaxis/hypersensitivity (AA)	**37**	**35**	**41**
	Febrile Non Haemolytic Transfusion Reaction	**65**	**70**	**65**
	Unclassified SAR	7	9	5
	Hypotensive Transfusion Reaction	2	3	0
Delayed Haemolytic Transfusion Reactions	Immunological haemolysis due to other allo-antibody (Delayed > 24 hrs.)	11	11	8
Delayed Serological Transfusion Reaction	Delayed Serological Transfusion Reaction	**102**	**220**	**168**
Post transfusion purpura	Post transfusion purpura	0	**2**	0
Transfusion Transmitted viral infection (HBV)	Transfusion Transmitted viral infection (HBV)	**2**	0	0
Respiratory Complications of transfusion	Transfusion Associated Circulatory Overload (TACO)	**21**	**23**	**38**
	Transfusion Associated Dyspnoea	1	0	2
	Transfusion related acute lung injury (TRALI)	0	**1**	0
Totals		**248**	**376**	**328**

Subject to change

Age groups involved in Reportable SAR's 2013-2015



Immunological Haemolysis due to ABO Incompatability

Findings:

Two reports have been accepted between 2013-2015, both with an imputability of ‘Certain’.

Immunological Haemolysis due to ABO Incompatability n=2 Case Study

Background

- Elderly patient with a haemoglobin of 7.4g/dl required a transfusion

Symptoms

- Temperature rise within 90 mins
- Hypotension
- Haematuria – new onset

Treatment

- Transfusion stopped

On investigation

- Incorrect unit had been administered (O+ pt. received A+ unit)
- DAT: Negative
- Bilirubin: ↑from 17umol/L to 44 umol/L within 4 hours after transfusion
- Abnormal Renal function
- LFT's back to normal 2 days post transfusion
- LDH, Haptoglobins not done

Case Study

Clinical Outcome:

- Patient required dialysis for 4 weeks and ICU admission as a result of this reaction

Error Details

- 2 Female patients with same name, same month and year of birth
- Both pts had blood in Issue fridge
- Incorrect unit collected by hospital porter – ***failure to verify***
- Compatability label and unit not checked against pts ID band by 2 nurses – ***failure to verify, failure to adhere to policies and procedures***

Corrective Action

- Re-education and re-training of staff involved
- Introduction of a new label for patients with same /similar names
- The Blood Track electronic scanning system is being introduced to improve safety during the *Pre-transfusion Checking Procedure(Phase 3)*

Recommendation

Initial treatment of Acute Transfusion Reaction is not dependent on classification but should be directed by symptoms and signs. Treatment of severe reactions should not be delayed until the results of investigations are available (BCSH 2012)

There is no substitute for Correct Patient Identification at all stages in the transfusion process (Key SHOT message 2015)

Acute Allergic and Anaphylactic Transfusion Reactions

Implicated components:

	2013	2014	2015
Red Cells	12	10	11
Apheresis Platelets	17	20	21
Pooled Platelets	8	3	6
LG Octaplas	n/a	2	1
Multiple	n/a	n/a	2
Total	37	35	41

AA Reaction – Case Study

Reaction due to IgA deficiency

- Elderly male patient group A RhD Positive transfused with one unit of RCC following orthopaedic surgery. His antibody screen was negative pre transfusion
- Approx. 10 mls of the unit had transfused when the patient developed a temperature rise, lower back pain, vomiting and dyspnoea.

Treatment

The transfusion was stopped. The patient was treated with an antipyretic, antihistamines, steroids and IV fluids.

AA Reaction – Case Study

On investigation:

- ***IgA levels was less than 0.07g/l***
- Bacterial investigation of patient and pack – no bacterial infection after 6 days
- Serological investigations were negative.

Clinical Outcome

- Complete recovery

Comment

This case was originally reported as a FNHTR but due to the IgA deficiency in the patient it was re-categorized as an AA reaction.

AA Reaction – Case Study Points to note

- Irish donors are not tested for IgA deficiency
- IBTS supply washed red cells and platelets, which have reduced IgA levels
- In this case red cells from an IgA deficient donor were imported from the UK and transfused following further reactions with washed red cells

Recommendations

Recommendation (BCSH 2012)

For patients with recurrent moderate or severe allergic reactions, other than those in which the patient is IgA deficient, options for further transfusion include:

- Use of directly monitored transfusion of standard components in a clinical area with resuscitation facilities
- Anaphylaxis should be treated with intramuscular adrenaline
- Transfusion of washed red cells or platelets
- Consider antihistamine prophylaxis (although the evidence for efficacy is low, the risks are also low)

Febrile Non-Haemolytic Transfusion Reactions(FNHTR) n =216

Findings

- 216 reports received
- 200 accepted (13 mandatory)

Patients:

- Neonatal (1-12 months) - 1
- Infant (1-4 years) - 4
- Child (5-11 years) - 4
- Adolescent (12-17 years) -2
- Adult (18-30 years) -14
- Adult (31-50 years) - 35
- **Adult (51 -70 years) – 62**
- **Elderly (70+) -78**

Components Implicated

- 181 - red cells
- 19 - apheresis platelets

Investigations

Majority of the cases were investigated for bacterial contamination

- 175 patients had bacterial investigations
- 136 cases both the patient and the pack were cultured
- A further 34 cases the patient only was cultured
- 5 remaining cases only the pack was cultured

Clinical Outcome

- 185 Cases :Complete Recovery
- 13 Cases :Minor Sequelae (majority due to admission required from day ward)
- 2 Cases :Death as a clinical outcome, however both were unrelated to transfusion

BCSH Guidelines 2012

Recommendation

- ***Patients with recurrent febrile reactions, recommend a trial of premedication with oral paracetamol given one hour before the reaction is anticipated (or nonsteroidal anti-inflammatory drugs in patients with predominant chills or rigors - but an assessment of the risks of medication against the severity of reaction should be made in each case)***

Transfusion Associated Circulatory Overload 2013-2015

Findings

- 89 Reports received and 82 accepted
- 10 (11%) reports fulfilled the criteria for Mandatory TACO
- 9 reactions as a result of errors – at risk patients, inappropriate transfusions

Patients

- 57 elderly (>70 years)
- 17 adults (51-70 years)
- 5 adults (31-50 years)
- 2 adult (18-30 years)
- 1 infant (1-12 months)

Implicated Components

- 78 RCC
- 6 Apheresis platelets
- 1 Pooled Platelets
- 2 LG Octaplas

Clinical Outcome

- 59 (69%) made a Complete recovery
- 11 Reports of Minor Sequelae
- 3 Reports resulted in Major Sequelae (ventilated)
- 9 Reports resulted in death, all of which were unrelated to transfusion

Reporting TACO to the NHO

NHO collect

- Reports of TACO where patients exhibit clinical signs and symptoms of overload following transfusion and which do not meet the very strict criteria of the ISBT definition either in terms of the time line or evidence of four characteristics.

Proposed ISBT revised definition TACO

Current Mandatory Definition(any 4 of the following)

- Acute Respiratory distress
- Tachycardia
- Hypertension
- Pulmonary oedema
- Positive Fluid Balance

Draft ISBT (ISBT, 2014) Primary features

- Pulmonary oedema
- Enlarged cardiac silhouette (on Cxray)
- Evidence of fluid overload

Features to support diagnosis:

- Elevated BNP
- Increase in mean arterial pressure or increased pulmonary wedge pressure

Rationale for the revision

At the Amsterdam(2014) meeting of the haemovigilance working party(ISBT & IHN), a number of members requested revision of the TACO definition.

Notably, strict application of the revised definition may lead to non-acceptance of cases and a decrease in non-mandatory reports which would be accepted as TACO by clinicians and by some haemovigilance systems.

NOTE

Mandatory Definition of TACO remains unchanged (ISBT 2011)

TACO – Paediatric Patients n=1

Case history

Background

- Infant recently diagnosed with a haematological condition required an invasive procedure
- Platelet count 22 x 10^9
- Transfused with one unit of apheresis platelets

Baseline obs

Temp: 36.2, P 152, BP 087/46

30 mins later - (220mls transfused)

- Hypertension BP 119/43,
- Tachycardia – 174,
- Dyspnoea,
- falling O_2 sats

Treatment:

- Commenced on CPAP, and treated with diuretics

On review:

- Weight – 7kgs
- Transfused 33mls/kgs (10-20mls per Kg)
- Positive fluid balance > 250mls

Comment

- Incorrect volume prescribed and transfused

TACO – Paediatric Patients (case history)

Error Causes

- NCHD prescribed the platelets without noting patients weight
- RGN presumed this was the correct amount even though hesitated before commencing the transfusion thinking it was too much but went ahead as consultant wanted a good rise in platelet count

Corrective/Preventative action

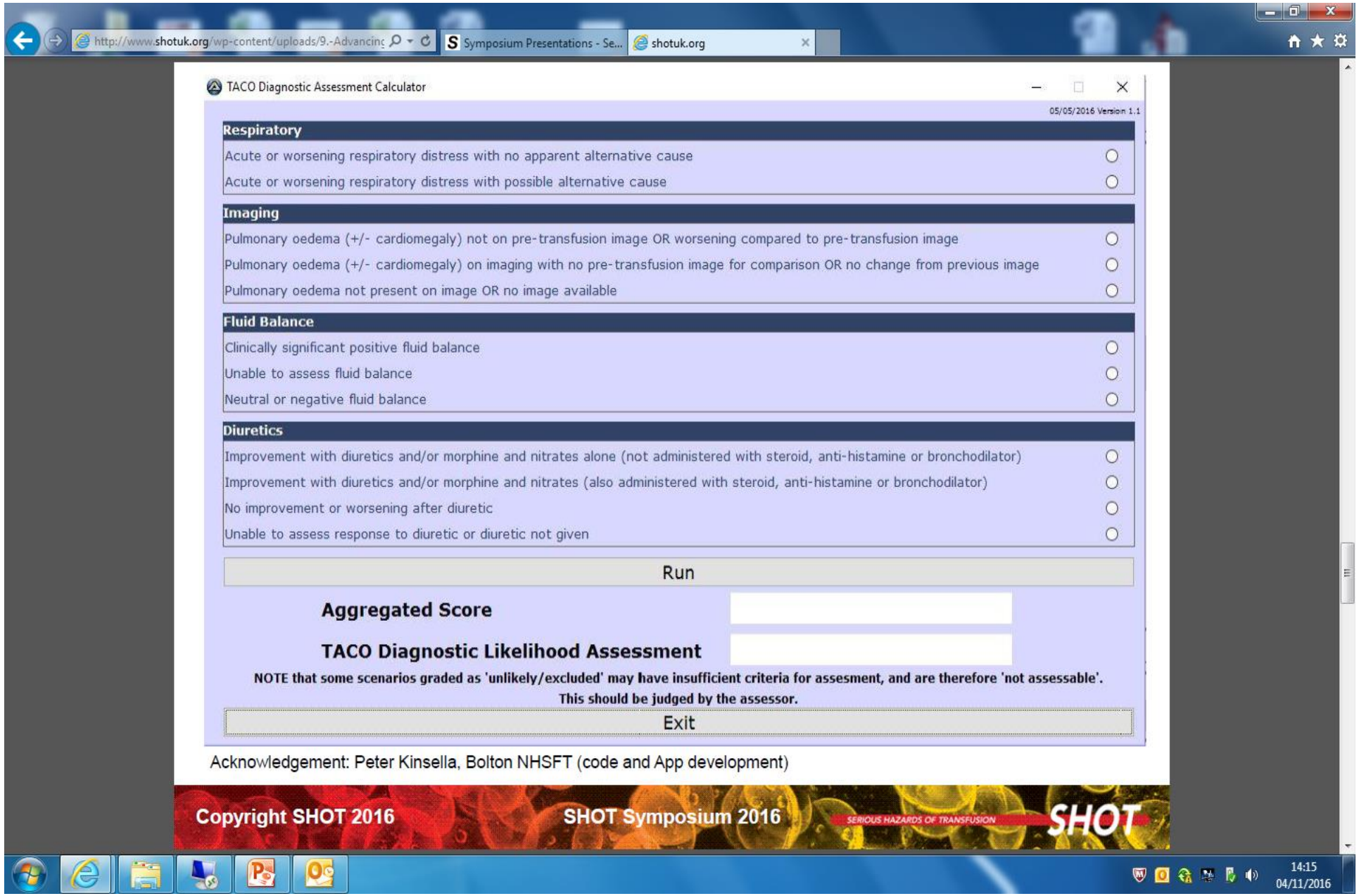
- Re-education and change in procedure – only a member of patients direct medical/oncology team could prescribe or cancel components.

Clinical Outcome

Initially required CPAP but made a full recovery.

SHOT Recommendation (2015)

A formal pre-transfusion Risk assessment for Transfusion-associated circulatory overload (TACO) should be performed wherever possible as TACO is the most commonly reported cause of death and major morbidity


http://www.shotuk.org/wp-content/uploads/9.-Advancinc
Symposium Presentations - Se...
shotuk.org
TACO Diagnostic Assessment Calculator
05/05/2016 Version 1.1
Respiratory
Acute or worsening respiratory distress with no apparent alternative cause
Acute or worsening respiratory distress with possible alternative cause
Imaging
Pulmonary oedema (+/- cardiomegaly) not on pre-transfusion image OR worsening compared to pre-transfusion image
Pulmonary oedema (+/- cardiomegaly) on imaging with no pre-transfusion image for comparison OR no change from previous image
Pulmonary oedema not present on image OR no image available
Fluid Balance
Clinically significant positive fluid balance
Unable to assess fluid balance
Neutral or negative fluid balance
Diuretics
Improvement with diuretics and/or morphine and nitrates alone (not administered with steroid, anti-histamine or bronchodilator)
Improvement with diuretics and/or morphine and nitrates (also administered with steroid, anti-histamine or bronchodilator)
No improvement or worsening after diuretic
Unable to assess response to diuretic or diuretic not given
Run
Aggregated Score
TACO Diagnostic Likelihood Assessment
NOTE that some scenarios graded as 'unlikely/excluded' may have insufficient criteria for assesment, and are therefore 'not assessable'.
This should be judged by the assessor.
Exit
Acknowledgement: Peter Kinsella, Bolton NHSFT (code and App development)
Copyright SHOT 2016
SHOT Symposium 2016
SERIOUS HAZARDS OF TRANSFUSION
SHOT
14:15
04/11/2016

Post Transfusion Purpura n=2, Case Study

Treatment

- Patient was treated with HPA 1a Negative products, IVIG, Plasma exchange and Rituximab

Investigations

- Serological investigations resulting in identification of HLA antibodies, Anti HPA 1a identified and other platelet specific alloantibody identified

Outcome

- Major Sequelae
- This patient had thrombocytopenia due to underlying condition so therefore complete recovery was impossible
- However, 1 week post reaction patient had no acute bleeding or no new subcutaneous or mucosal bleed

Suspected Transfusion Transmitted Infections (n=2)

Findings

Between 2013-2015 the NHO have received 18 Reports of Suspected Transfusion Transmitted Infections and in all but two cases transfusion transmitted infection has been excluded or considered unlikely as a result of investigations carried out by the IBTS.

In the final two cases (HBV infection) as all of the unit numbers transfused were not available (1976, 1986, 1990) transfusion transmitted infection could not be excluded and both cases were accepted by the NHO

Delayed Serological Transfusion Reactions (DSTR's) n=490

Why did NHO begin to accept DSTR reports?

- Following on from hospital inquiries and review of other European Haemovigilance systems, we commenced collection in Jan 2013
- Prior to this we advised hospitals to maintain local records
- Non-Mandatory reports

Findings:

➢2013: 102 Reports accepted (40% of total SAR's)

➢2014: 220 Reports accepted (59% of total SAR's)

➢2015: 168 Reports accepted (57% of total SAR's)

Issues Identified with Reporting

- Patient history is sometimes unknown- both Transfusion and Antibody history
- Investigate history in other facilities?
- Difficult to out-rule haemolysis completely
- Time consuming

Conclusion

- Did DSTR analysis by hospitals lead to investigation of possible DHTRs and subsequent increase in reporting?
- Not really…

2013	2014	2015
10/102	11/220	10/168

NHO Decision Jan 2016

- Following collection of DATA for 3 years, no new findings were identified
- NHO decided to follow our UK colleagues and we ceased the acceptance of reports from Jan 2016
- HPRA informed
- **Comment**: If a decision at European level is made for these reports to become mandatory, it may be necessary to report in the future

The next twenty five years

- Personal responsibility
- Holding to account
- Shift from adverse event reporting to improvement and innovation
- Shared decision making, patient empowerment and full open disclosure
- Develop the trust relationship
- Sentinel hospitals which will be the engines for real change