ANNUAL SHOT REPORT 2016

BMS Education Day - Transfusion reactions

Hema Mistry: SHOT Laboratory Incidents Specialist

SHOT recommendations

- Some recommendations have been repeated many times – **almost 50% recommendations are repeats**
- Many have been actioned:
  - SHOT contributed to at least 18 different British Society for Haematology (BSH) guidelines
  - Changes to Blood Service practices: reduced TRALI & bacterial infection
  - Transfusion training and competency assessments
  - Widespread appointment of transfusion practitioners
  - Patient blood management

Haemovigilance definition

Blood is a living transplant

Collection, transport, processing and testing
Delivery to the patient

Is the donor safe?

Is the process safe?

Is a transfusion the most appropriate treatment?

Recipient characteristics

Donor characteristics

What is reportable

- Incorrect blood component transfused (IBCT)
  - WCT/SRNM
- Avoidable, delayed or under transfusion (ADU)
- Handling & Storage (HSE)
- ‘Near-miss’ events (NM)
- Right blood right patient (RBRP)
- Anti-D Ig

Clinical reactions

- Transfusion-associated circulatory overload (TACO)
- Transfusion-related acute lung injury (TRALI)
- Transfusion-associated dyspnoea (TAD)
- Acute transfusion reactions - allergic/febrile (ATR)
- Haemolytic transfusion reactions (HTR)

Additional categories...

- Transfusion-transmitted infections including bacterial contamination (TTI)
- Cell salvage incidents
- Post-transfusion purpura (PTP)
- Transfusion-associated graft-versus-host-disease (TA-GVHD)
- New or unclassifiable complication of transfusion (UCT) includes necrotising enterocolitis (NEC) and prothrombin complex concentrate (PCC) errors

Adverse clinical events & reactions when & how...

When...

- **Immediate** and life-threatening: ABO incompatibility; anaphylaxis
- **Hours**: pulmonary complications, bacterial infections, transfusion reactions
- **Days**: Delayed haemolytic reactions
- **Late** (months or years): viral infections; iron overload

What clinical features suggest a patient is reacting adversely to a transfusion?

Symptoms

- Fever, chills, rigors
- Dyspnoea, stridor
- Itch, rash, swelling of lips
- Shock, collapse
- Nausea, general malaise
- Pain
- Feeling of impending doom

Signs

- Change in temperature
- Hypoxia
- Change in BP, pulse
- Raised venous pressure, pulmonary signs
- Reduced urine output, change in urine colour
- Change in conscious level

What to do at the bedside...

- Stop the transfusion, maintain IV access with saline
- Check the bag and patient ID
- Rapid medical assessment
- **Inform the transfusion laboratory**
- **Take samples and return blood bag to laboratory**
- Renal function
  - Monitor fluid balance (input and output)
  - Collect first and subsequent urine samples

*BSH Guideline on the investigation and management of acute transfusion reactions (2012)

Acute transfusion reactions

What do you know about acute transfusion reactions?

- Acute transfusion reactions can be serological, but usually are not
- They are mostly unexplained, unpredictable, pathological reactions

Acute Transfusion Reactions (ATR)

- SHOT ATR cases in 2016 n=253 – many reactions
- Seldom serological
- Reaction to any component
- Non-haemolytic reactions:
  - Anaphylaxis
  - Allergic
  - Febrile
  - Hypotension

Haemolytic Transfusion Reactions (HTR)

- SHOT HTR cases in 2016 n=35 (acute n=17 – not many)
- Often serological
- Reaction to red cells
- Patient has haemolysis
  - can be acute (AHTR)
  - or delayed (DHTR)
  - haemolysis usually within 14 days

Acute Haemolytic Tx Reaction

- Dramatic & severe: this type most likely to be fatal
- [ ] Haemolysis: red cells destroyed in patient's circulation
- Major complications: DIC & renal failure, irreversible shock, death!
- Antibodies
  - cause rapid activation of Complement
    - to membrane [ ]
  - Most likely to be ABO blood group system

- Incidence: 0.00001 %

Delayed Haemolytic Tx Reaction

- Approximately between [ ] days post transfusion
- Denoted by [ ] & ↑ [ ]
  - Serum / plasma pinkish
  - Patient becomes jaundiced and / or anaemic
  - Occasionally fever; rarely renal failure & death
- [ ] clearance of red blood cells
- Antibodies
  - Reactive at 37°C by IAT
  - Usual suspect? [ ]
- Incidence: 0.00001 %

Delayed ‘Serological’ Tx Reaction

Clinically benign

- Haemolysis is not detectable
- Serum/Plasma ‘usual’ colour
-
- Evidence of newly formed in plasma and /or eluted*
- Only detected when patient has a repeat work -up
- Antibodies – active at
- Incidence - ???

Laboratory Investigation

Check paper work

Samples

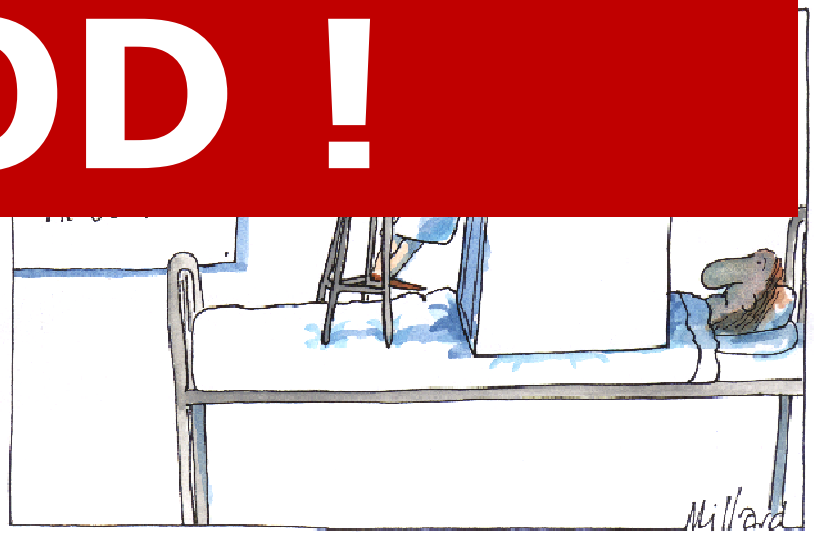
I

T

Elution

Donor cells

BAG, BAND, BLOOD !



Summary

In investigating a suspected transfusion reaction

- You are trying to rule out / detect
  - ABO incompatibility first
  - Reduced red cell survival (ab active @ 37°C)
  - Screening / XM failure
    - dosage
    - antigen deterioration
    - poor technique
    - user error
- **ALWAYS REMEMBER THE PATIENT'S SYMPTOMS**
- Senior scientific staff & the consultant haematologist should review case(s) & decide on further action(s)
  - Further investigations
  - Referral
  - Reporting to SHOT/SABRE

Electronic issue…

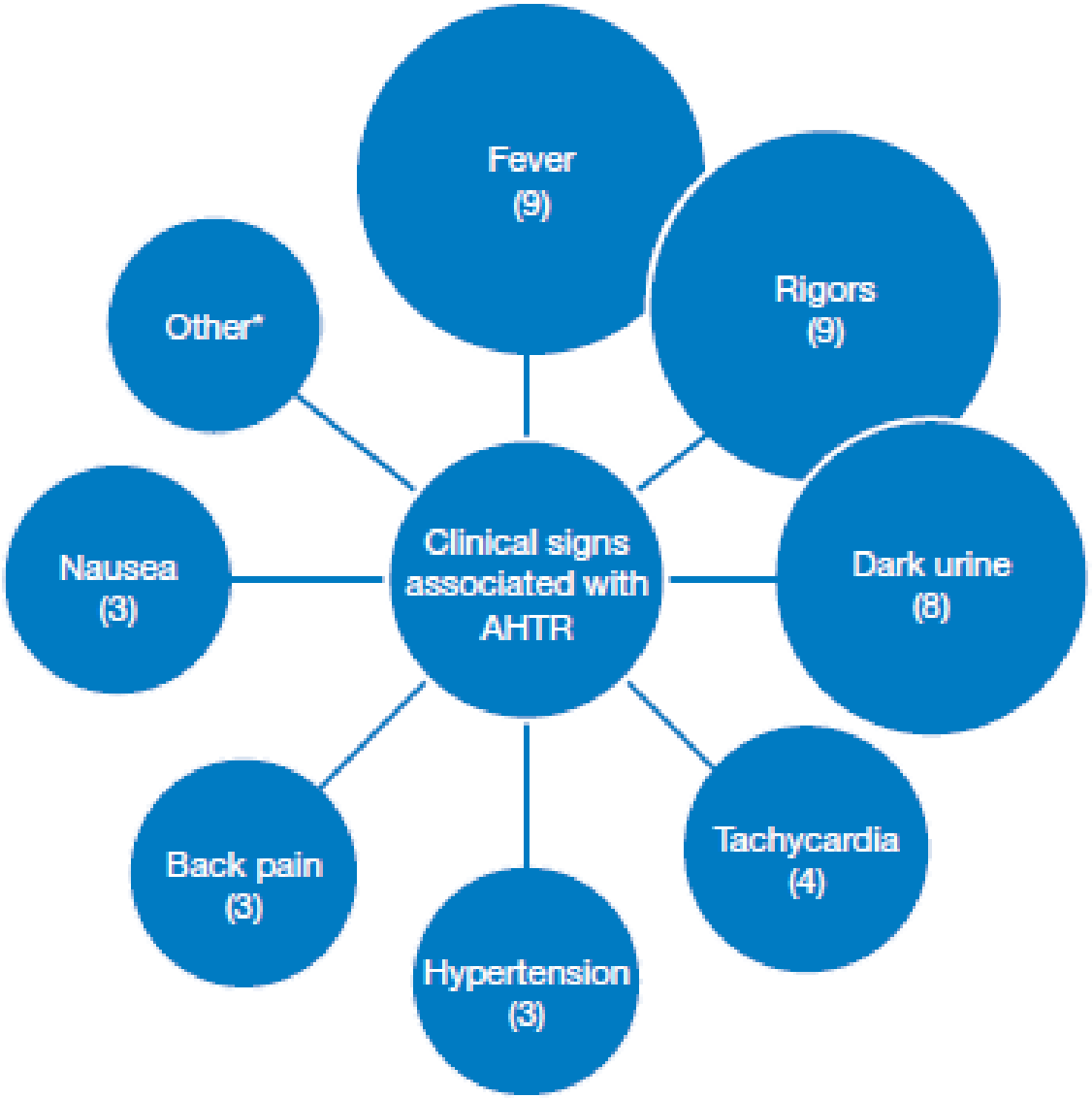
- Elderly man with myelodysplastic syndrome, comorbidities (COPD)
- Ba… lls,
- Tr… h
- W… i-Wr^a
- Re…
- 10 cases SHOT 2012-2015, none 2008-2011
- Increasing use of EI: 36% in 2008, 61% in 2016

HAEMOLYTIC TRANSFUSION REACTION (HTR)

Death due to anti-Wr^a following electronic issue

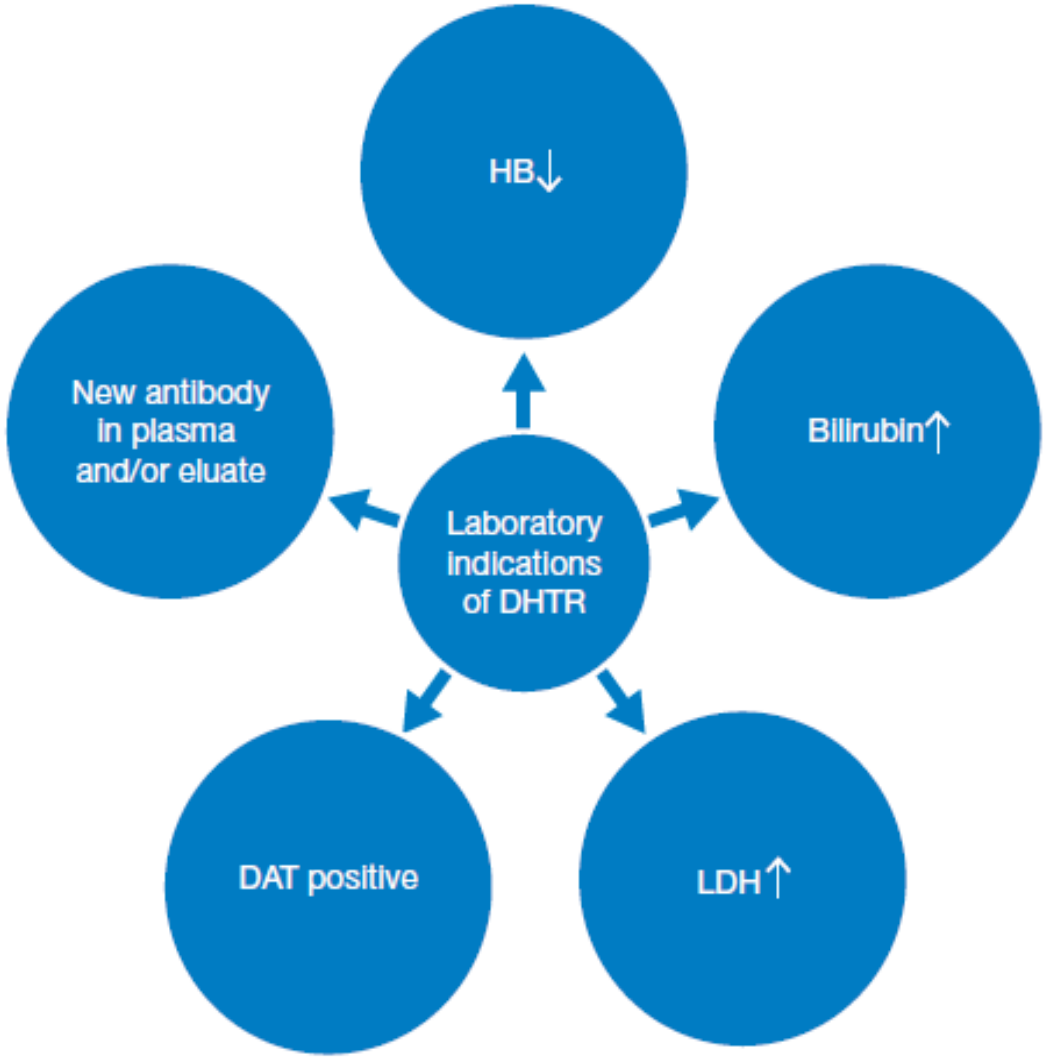
Clinical signs and symptoms

Clinical signs associated with AHTR



Laboratory signs

Laboratory indications of DHTR



Fever, chills and rigors during or soon after transfusion: possible causes

- Febrile non-haemolytic transfusion reaction
- Acute haemolytic reaction
- Bacterial contamination
- Underlying condition

Case 1

- A patient with myelodysplasia has a 2 unit red cell transfusion as a day case
- History of complex red cell antibodies
- With the second unit, she complains of feeling unwell, with mild nausea and chills
- Her temperature rises from 37.8 to 39°C, BP and pulse both increase
- The transfusion is stopped and symptoms and signs improve within 30 minutes

What is this most likely to be?

A. A haemolytic transfusion reaction due to complex red cell antibodies

B. A haemolytic reaction due to incorrect component transfused

C. A febrile transfusion reaction

D. Bacterial contamination of the unit

Case 2

- Patient with haematuria being transfused with platelets
- 20 minutes into transfusion:
  - 2.2°C rise in temperature, vomiting, tachycardia, chest pain
  - Hypoxia
- Rigors prevented BP measurement
- Urine positive for haemoglobin but patient has haematuria

Which investigations would you do?

A. Blood cultures of the patient, send the platelet unit for culture

B. Repeat group and antibody screen the patient

C. All the above

D. None of the above

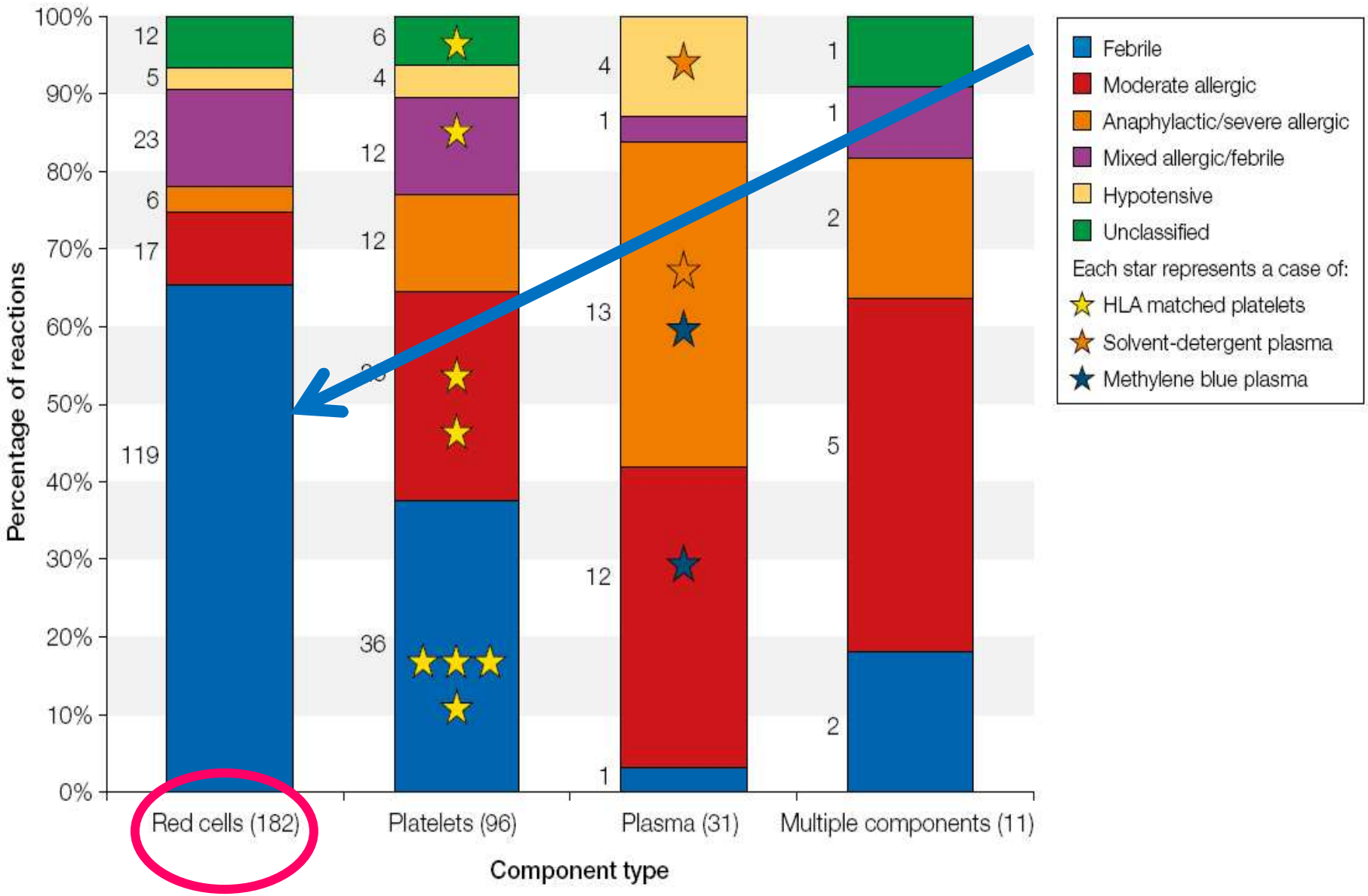
Culturing the platelet unit:

A. Perform culture in hospital lab, refer to blood service if positive result

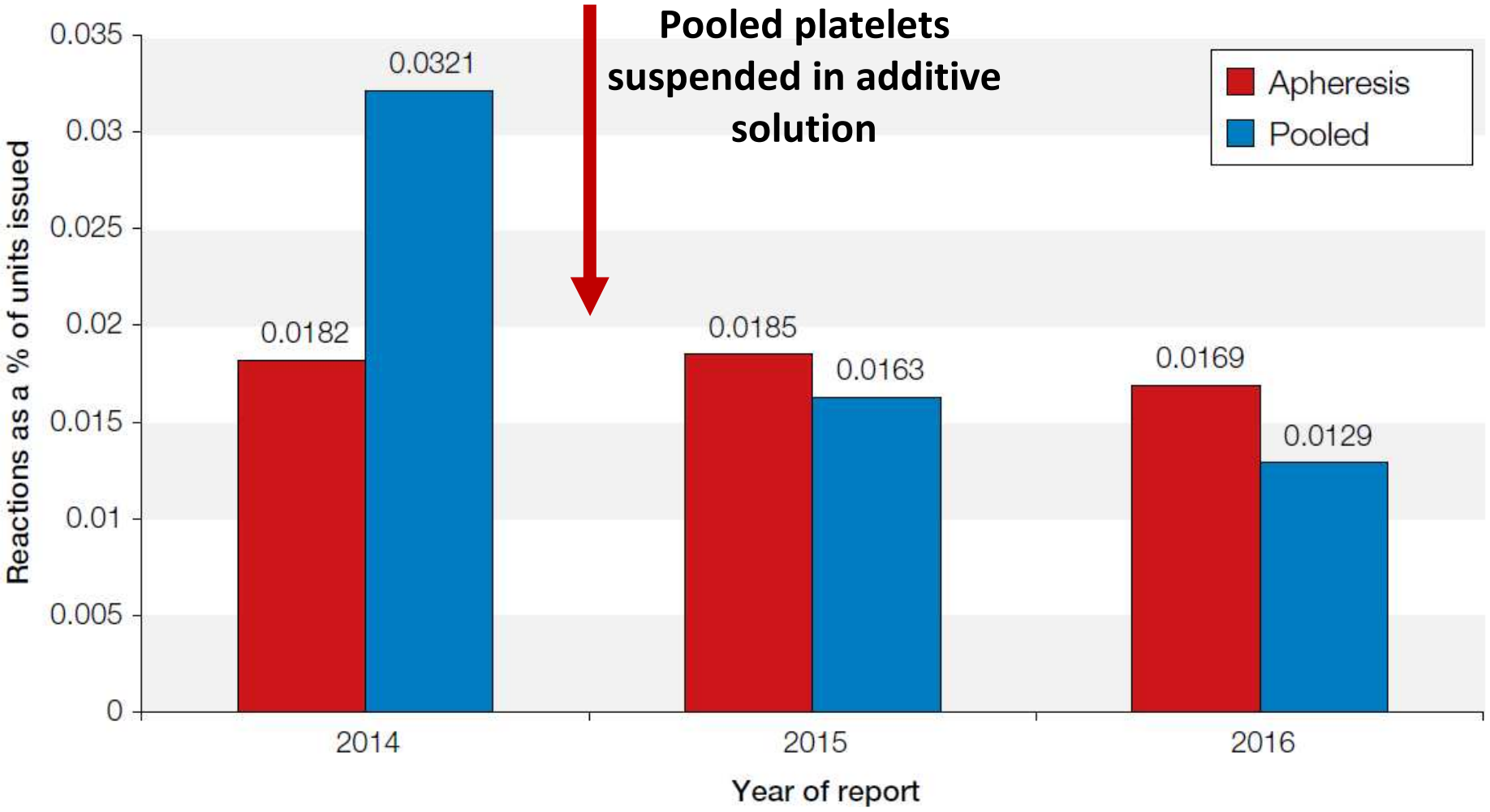
B. Contact nearest blood service to discuss next steps

With a severe febrile reaction such as this, the most important step is to contact the blood service

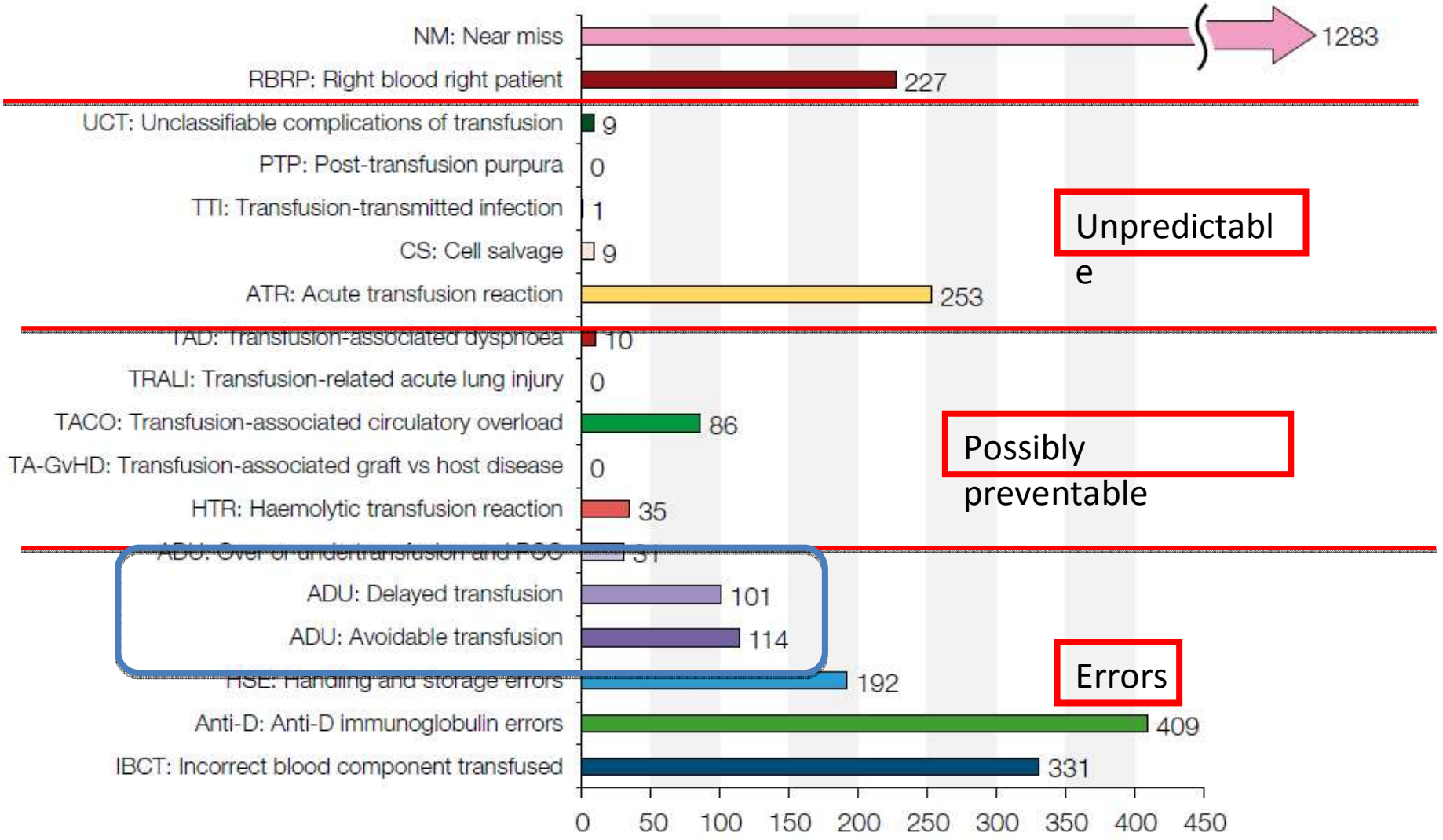
same time inform blood service



Pooled & apheresis platelets

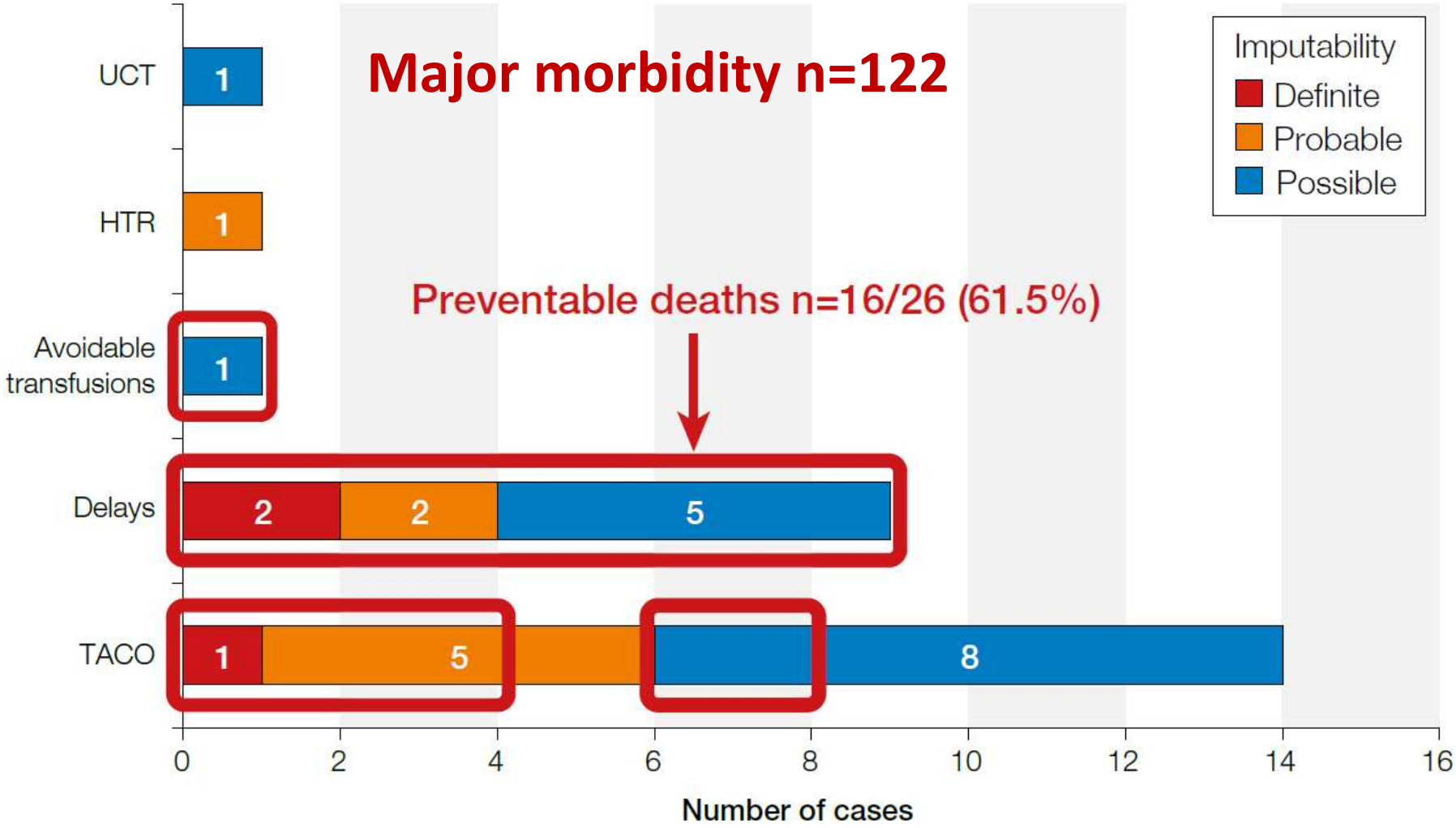


All incidents reported in 2016 (n=3091)



Deaths & Major morbidity

Bad news: 26 patients died where transfusion was implicated



Fatal TACO as a result of transfusion following spurious result

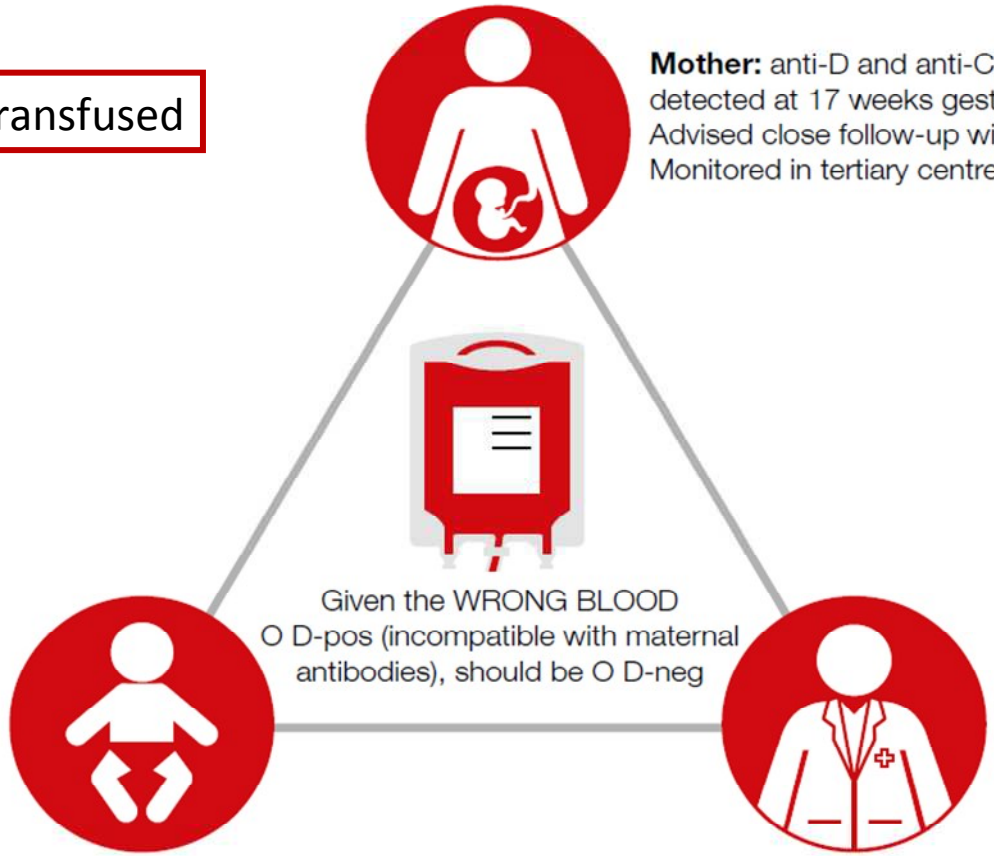
- 96 year old woman admitted with a GI bleed
- FBC sample sent to the laboratory underfilled and gave Hb result of 50 g/L
- Result telephoned to ward and authorised in the computer with a text comment “sample underfilled, result subject to error”
- No repeat sample was sent but a 6 unit crossmatch was ordered
- Three units were transfused and the post-transfusion Hb was 200 g/L
- Patient developed TACO and an emergency venesection was requested but she died the following day

Over-transfusion due to lack of monitoring of response to transfusion

- Elderly patient admitted to the Medical Admissions Unit with haematemesis and initial Hb 106 g/L
- No details provided of her observations or the findings on endoscopy but she had further episodes of vomiting blood
- Five units of red cells were transfused before a repeat Hb was performed which was 204 g/L
- The patient was recognised to have circulatory overload and died shortly afterwards

Laboratory error and poor communication

Wrong component transfused



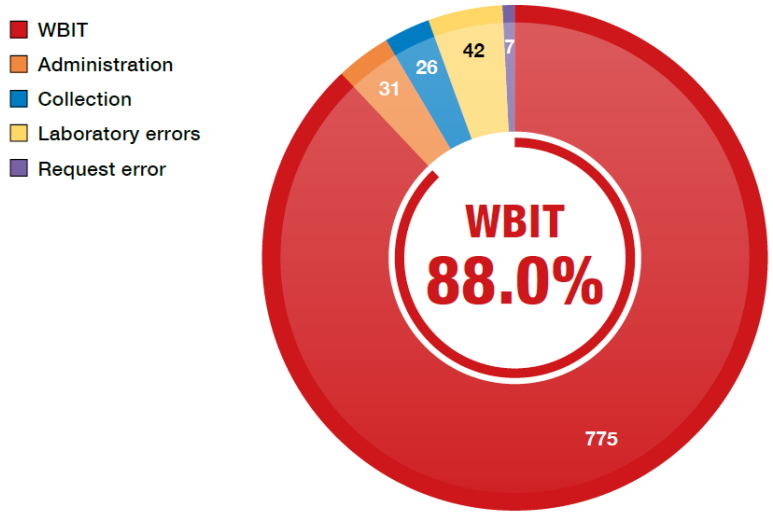
The baby required repeat exchange transfusion with O D-negative on day 6

What went wrong….

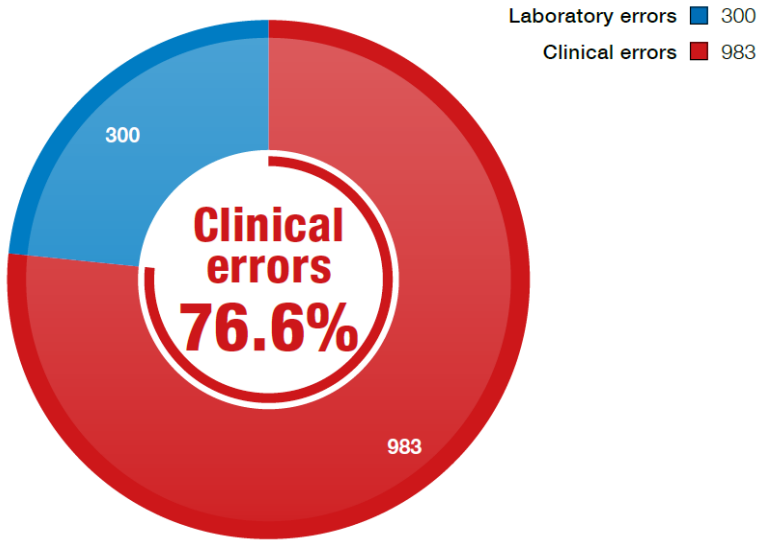
- Day 3 – clinician alerted laboratory, BMS did not review maternal details and issued O+ red cells
- All requests were by telephone, handover not effective and no follow up request form received by laboratory
- On several occasions BMS did not check mothers blood group and antibody results and issued 2 O+ red cells without crossmatching against the mother's sample
- Multiple other human factors contributed
- Kleihauer test was inappropriate due to the mothers antibody status and laboratory staff should not have issued anti-D Ig

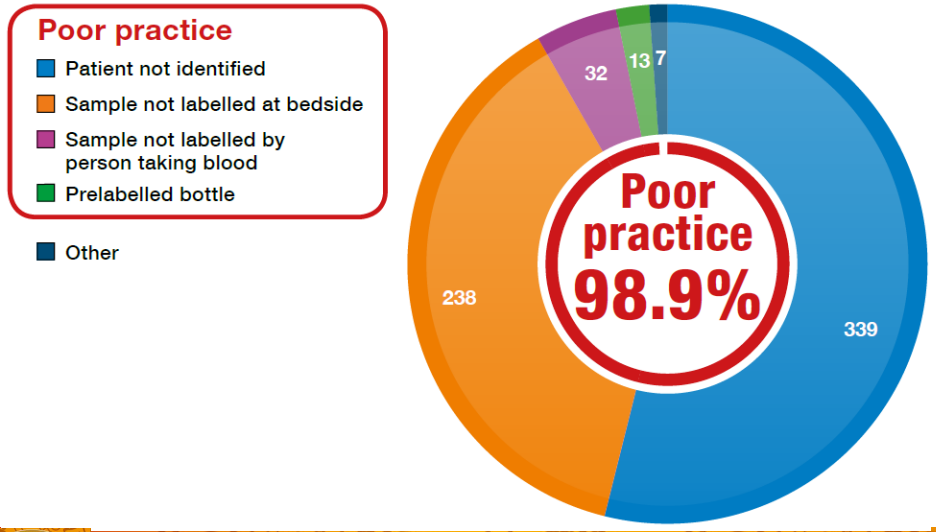
ABO-incompatible red cell transfusions (n=3)

Near miss IBCT-WCT cases n=881

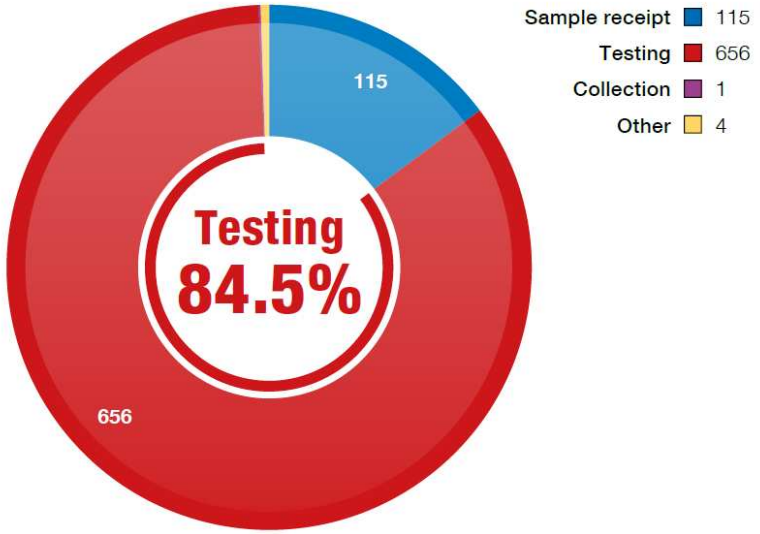


Overall source of near miss errors



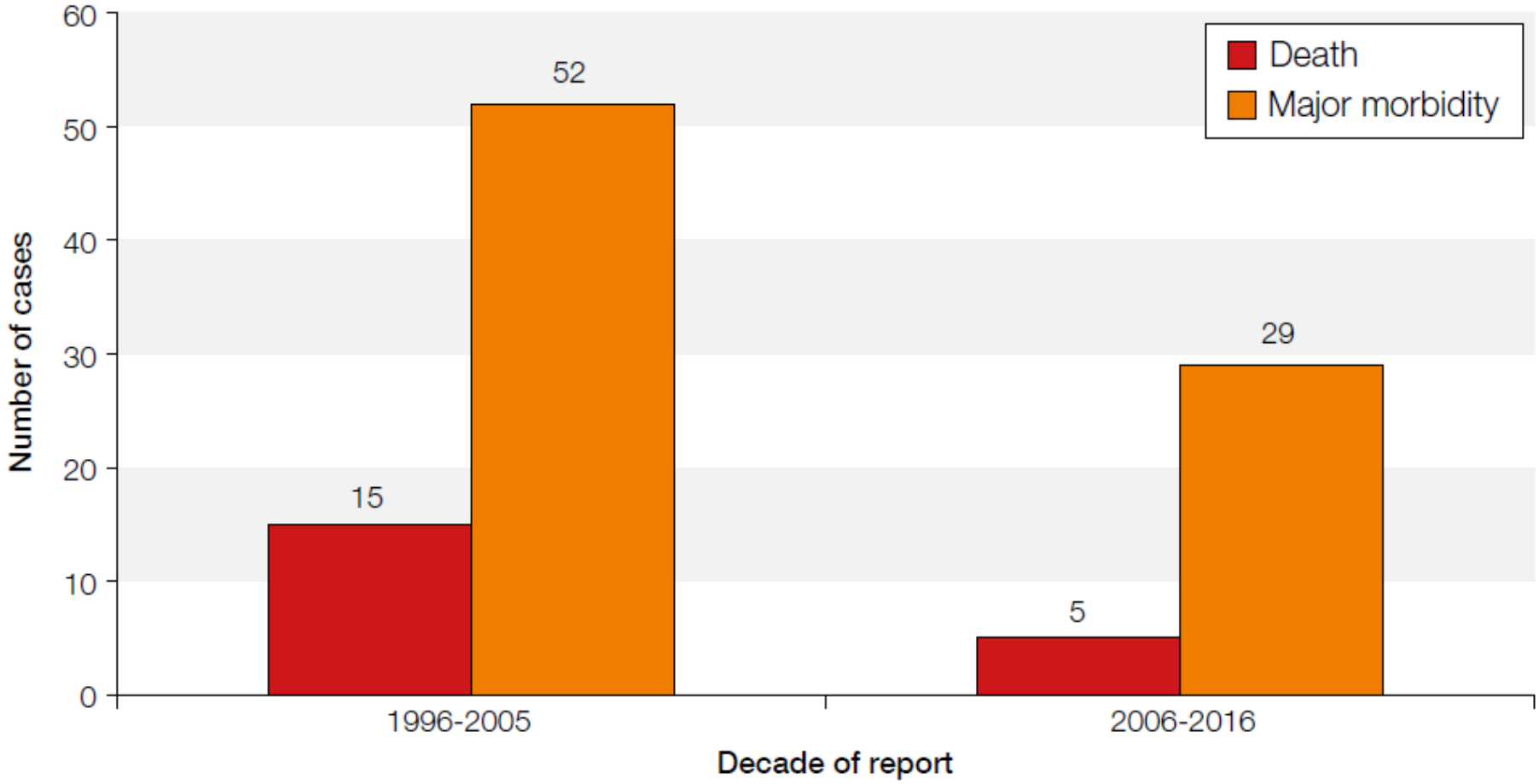


Point in the process where a wrong blood in tube incident was detected



Good news..

reduction in ABO-incompatible transfusions



Key recommendation 1

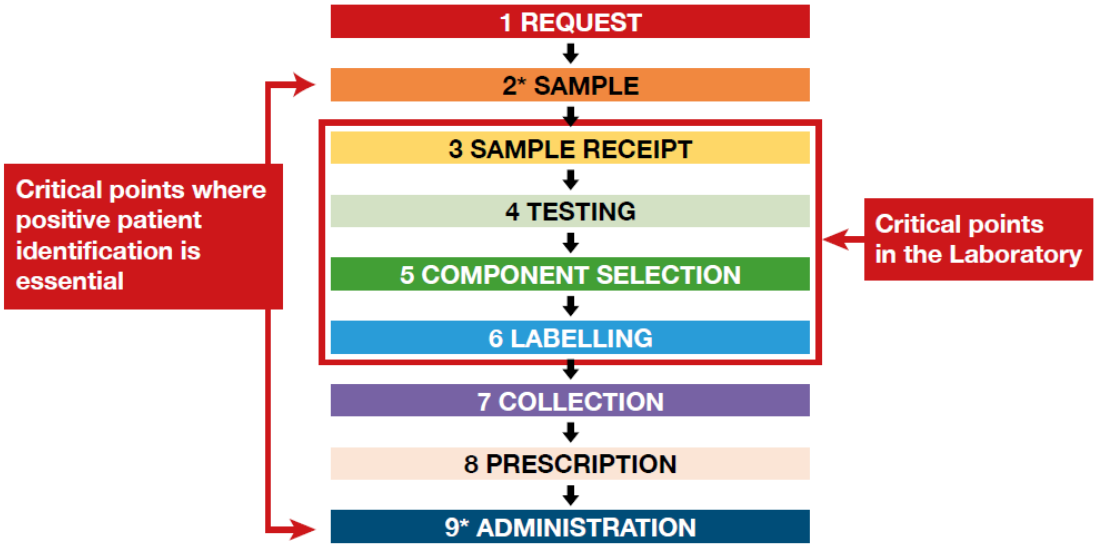
be like a pilot – **use a bedside checklist** as standard of care. It will prevent administration errors and is the final opportunity to detect errors made earlier

No amount of experience or years of practice will remove the risk of misidentification if you are interrupted or distracted

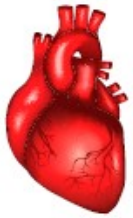
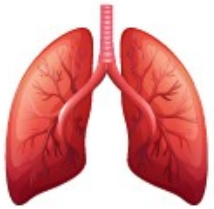
The bedside check will not detect a wrong blood in tube incident

All samples must be labelled at the bedside from the wristband details.
Unlabelled blood samples MUST NOT leave the SAMPLE CIRCLE.
Unlabelled blood samples outside the circle should be disposed of.

(idea courtesy of Joy Murphy)

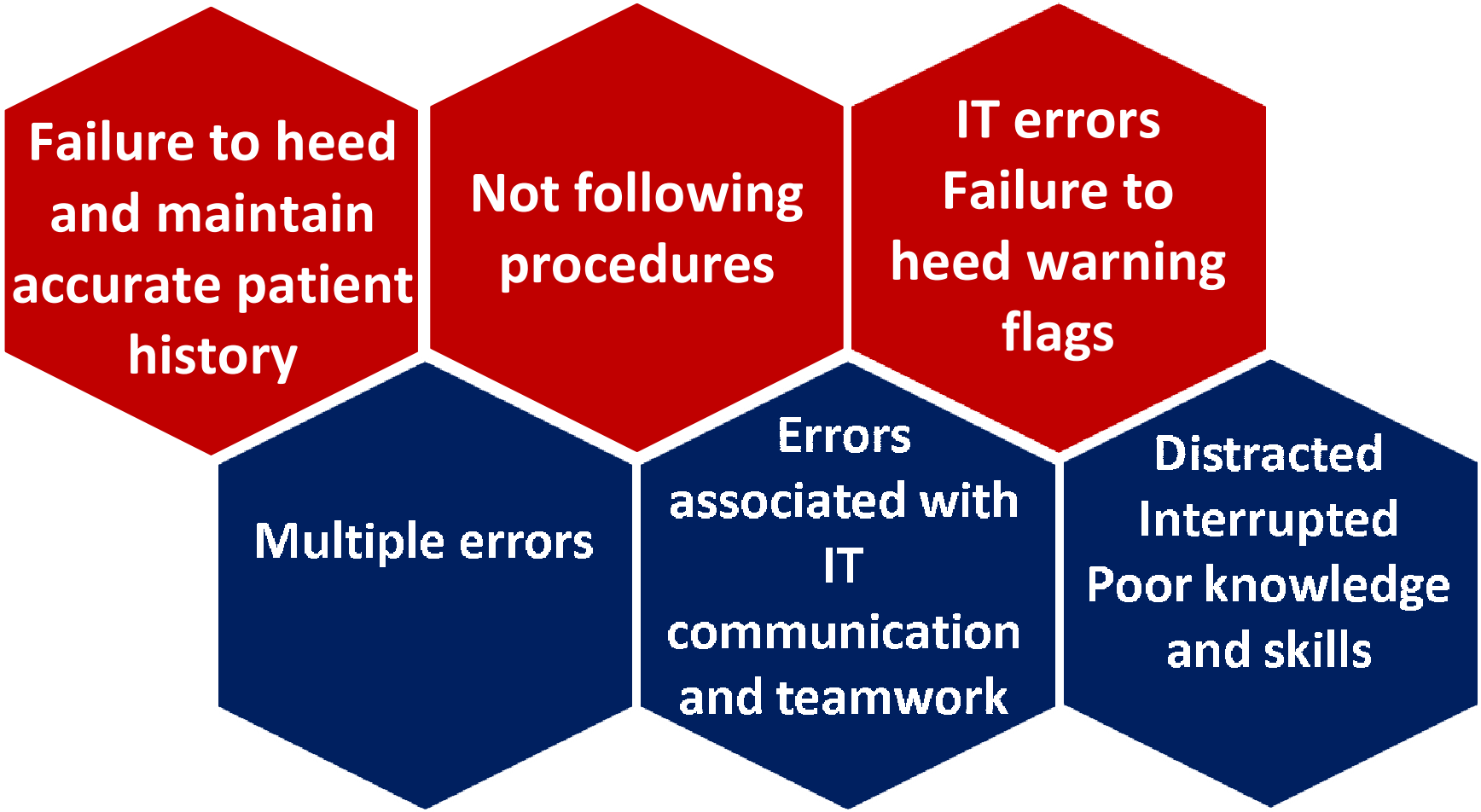


Key recommendation 2

TACO Checklist	Red cell transfusion for non-bleeding patients	If 'yes' to any of these questions
	Does the patient have a diagnosis of 'heart failure' congestive cardiac failure (CCF), severe aortic stenosis, or moderate to severe left ventricular dysfunction? Is the patient on a regular diuretic?	1 • Review the need for transfusion (do the benefits outweigh the risks)?
	Is the patient known to have pulmonary oedema? Does the patient have respiratory symptoms of undiagnosed cause?	2 • Can the transfusion be safely deferred until the issue can be investigated, treated or resolved?
	Is the fluid balance clinically significantly positive? Is the patient on concomitant fluids (or has been in the past 24 hours)? Is there any peripheral oedema? Does the patient have hypoalbuminaemia? Does the patient have significant renal impairment?	3 • Consider body weight dosing for red cells (especially if low body weight) • Transfuse one unit (red cells) and review symptoms of anaemia • Measure the fluid balance • Consider giving a prophylactic diuretic • Monitor the vital signs closely, including oxygen saturation

Due to the differences in adult and neonatal physiology, babies may have a different risk for TACO. Calculate the dose by weight and observe the notes above.

Recurring laboratory errors



UK NEQAS
Haematology and Transfusion

Errors in antibody identification

Claire Whitham

- Similar errors noted across 3 exercises
  - A process of exclusion not followed where antibodies were masked
  - Antibodies excluded with inappropriate cells
  - Making positive identification with only one example of an antigen positive cell

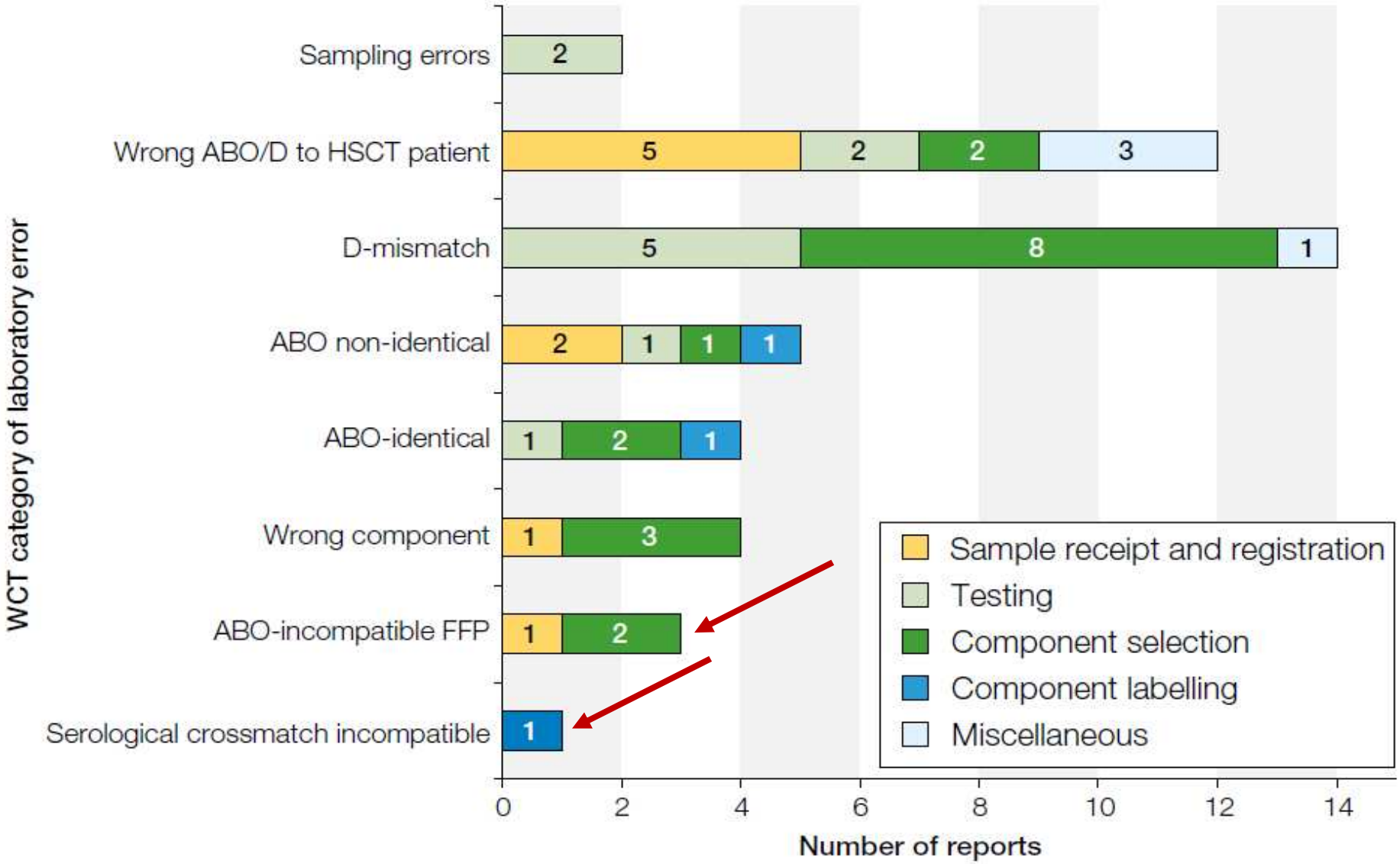
UK NEQAS
Haematology and Transfusion

Learning Points

Claire Whitham

- Every antibody investigation should include a systematic process for exclusion and positive identification of antibody specificities
- All reactions should be accounted for before a conclusion is reached
- Errors in antibody identification cannot be detected at the bedside

Wrong component transfused n=45 Wrong blood component transfused n=170



Selection error leads to transfusion of incompatible FFP

- *83 year old male, blood group A, required 3 units of FFP*
- *3 units of group O FFP were issued and 1 unit was transfused*
- *Post transfusion Hb fell from 80g/l to 72g/l, bilirubin was 19µmol/L and DAT was negative* **Component selection**
- *BMS was following the SOP for platelets rather than FFP during a busy period of the day* **Component labelling**
- *There was no warning flag within the LIMS to prevent ABO-incompatible plasma components* **Administration**

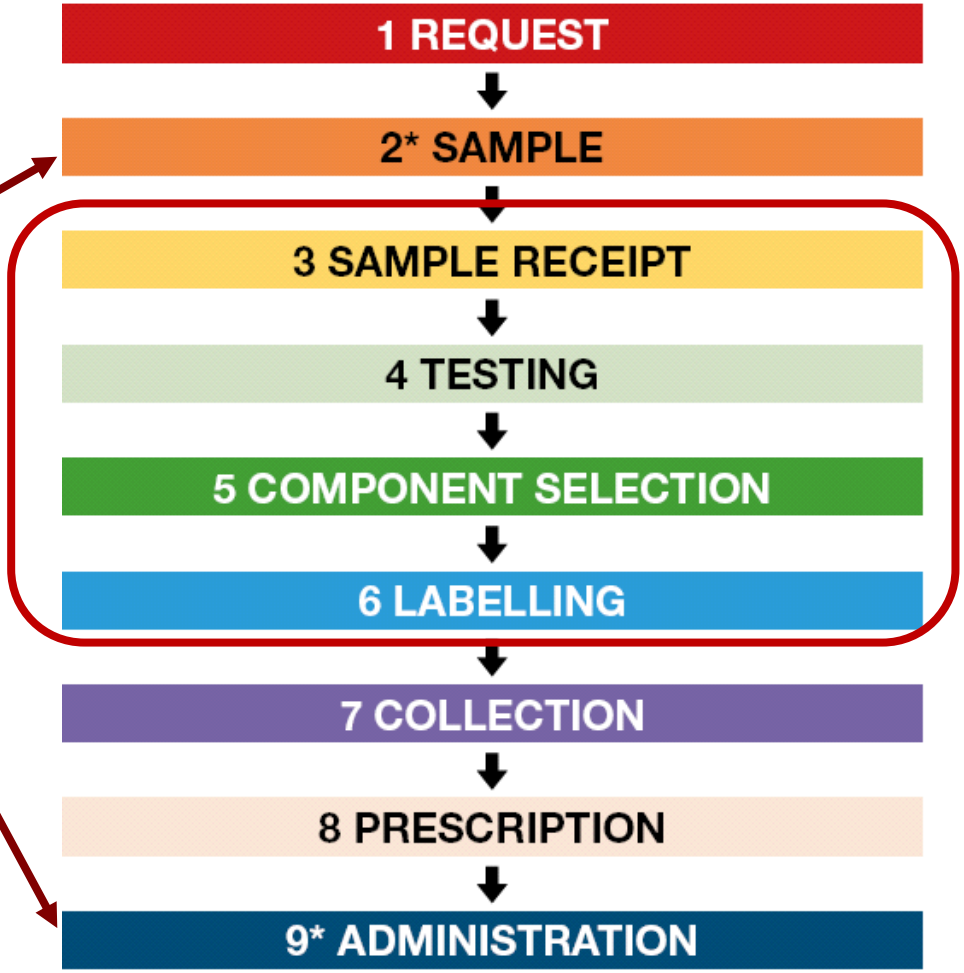
Laboratory: In an emergency, or if the group was unclear, the safe group of FFP to give is group AB or group A (as group AB is often in short supply), but not group O. Group O FFP should be reserved for patients confirmed to be group O and is not suitable for use in the emergency setting where the blood group is unknown.

Clinical staff: Should have sufficient knowledge to identify if there is a ABO-incompatible component that has been issued by the laboratory during the pre-administration checks, and not assume that this is only the responsibility of the laboratory.

Change management and validation protocols must challenge the new system or equipment to ensure it is fit for purpose

Critical points in the transfusion process

Critical points: Positive patient identification essential



7.21. The compatibility tag

7.21.1. The labelling of blood components is a critical step,

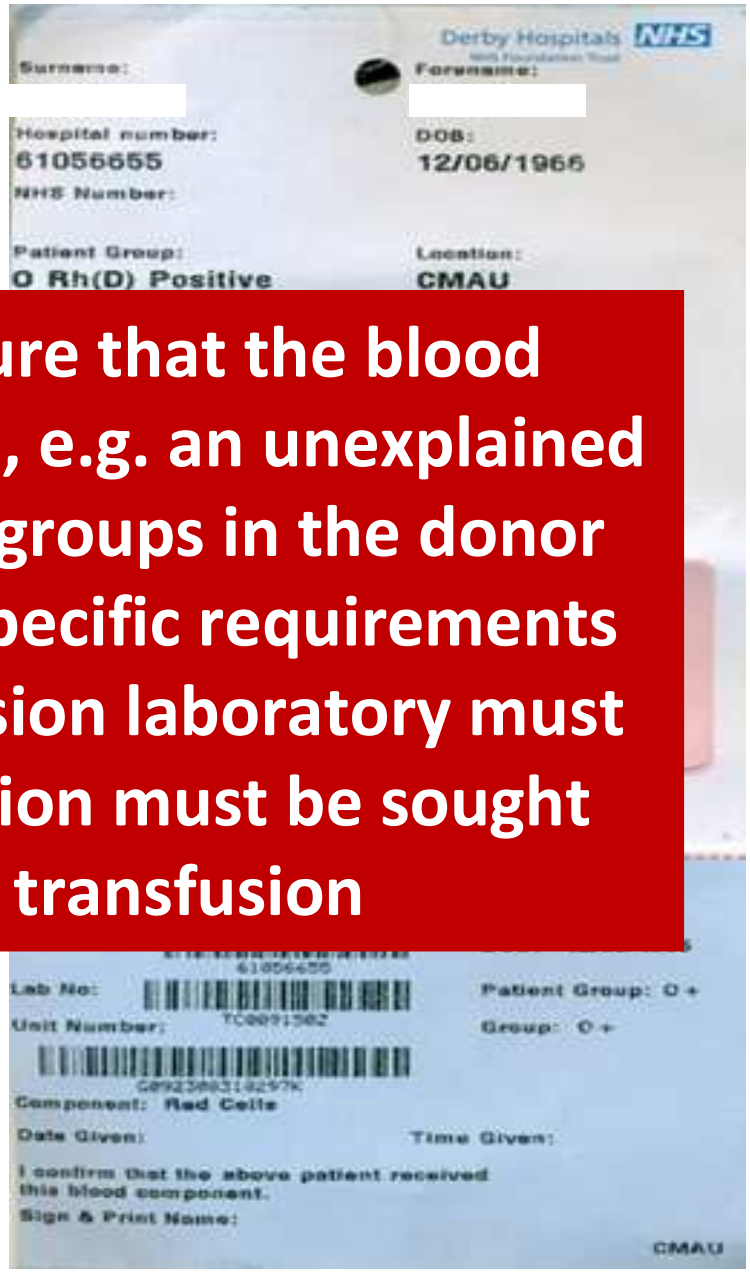
7.21.2.

viii. Donation number;

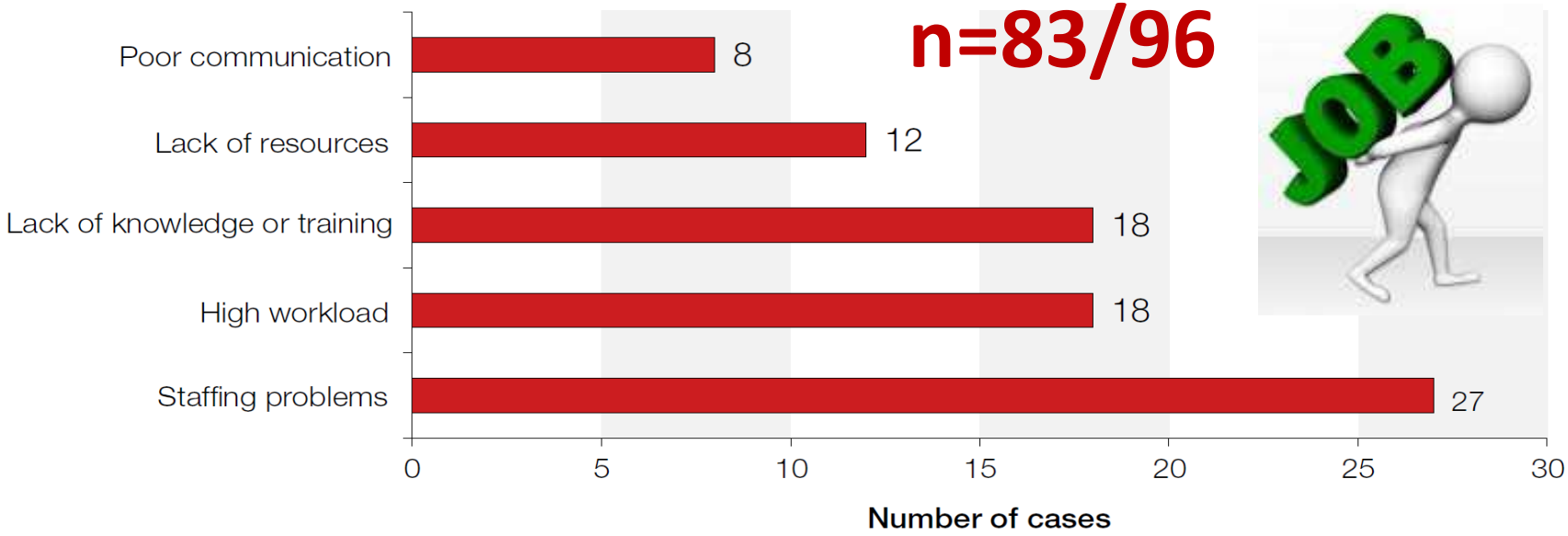
ix. Component type;

x. Donor ABO and D group.

If the practitioner is unsure that the blood component issued is correct, e.g. an unexplained difference between blood groups in the donor and recipient or whether specific requirements have been met,the transfusion laboratory must be contacted and verification must be sought before starting the transfusion



Human Factors (comments)



"The BMS was sick and should not have been at work, but there was no one else available to cover the night shift so they came in. Staffing levels are critically low and there is no give in the system to allow for sickness. All band 6 staff are locums, because the pay is better…"

UKTLC

TRANSFUSION MEDICINE Official Journal of the British Blood Transfusion Society

Transfusion Medicine | GUIDELINES

UK Transfusion Laboratory Collaborative: minimum standards for staff qualifications, training, competency and the use of information technology in hospital transfusion laboratories 2014

B. Chaffe,[1] H. Glencross,[2] J. Jones,[3] J. Staves,[4] A. Capps-Jenner,[5] H. Mistry,[6] F. Bolton-Maggs,[7] M. McQuade[8] & D. Asher[9]

[1] West Herts Hospitals NHS Trust, UK NEQAS BTLP, Watford, UK, [2] Portsmouth Hospitals NHS Trust, Cytology, Portsmouth, UK, [3] Welsh Blood Service, Quality Assurance, Cardiff, UK, [4] Oxford University Hospitals NHS Trust, Blood Transfusion, Oxford, UK, [5] UCL Pathology, Blood Transfusion, London, UK, [6] NHSBT Manchester Blood Centre, Serious Hazards of Transfusion (SHOT) Office, Manchester, UK, [7] Scottish National Blood Transfusion Service, Clinical Services Laboratory, Glasgow, UK, and [8] Norfolk and Norwich University Hospitals NHS Foundation Trust, Blood Transfusion, Norwich, UK

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SUMMARY

The SHOT Adverse Incident Reporting Scheme has consistently reported an unacceptably high level of errors originating in the laboratory setting. In 2006 an initiative was launched in conjunction with the IBMS, SHOT, BCHeh, BBTS, UK NEQAS, the NHSE NBTC and the equivalents in Scotland, Wales and Northern Ireland that led to the formation of the UK TLC. The UK TLC in considering the nature and spread of the errors documented by SHOT concluded that a significant proportion of these errors were most likely to be related to either the use of information technology or staff education, staffing levels, skill mix, training and competency issues. In the absence of any formal guidance on these matters, the UK TLC developed a series of recommendations using the results of two laboratory surveys conducted in 2007 and 2008.

In producing the initial (2009) recommendations the UK TLC had intended to provide guidance on 'best practice' in these areas. In doing so, it was anticipated by the UK TLC() that laboratories complying with these recommendations would see a fall in the errors reported to SHOT by them, thereby leading to an overall reduction of errors reported to SHOT by all laboratories. The UK TLC considered the expected level of error reduction and agreed that a 50% reduction in reportable errors originating in the laboratory could be achieved by September 2012.

This target was not met and in response, the UK TLC undertook a new survey of laboratories in 2013. Using the results of this new survey, the UK TLC has revisited its recommendations and developed them further into minimum standards for education, training, competency and the use of information technology for the hospital transfusion laboratory (the UK TLC standards).

Compliance with the UK TLC standards described below has now been accepted by both the United Kingdom Accreditation Service (UKAS) Clinical Pathology Accreditation (UK) Ltd (CPA) and the Medicines and Healthcare products Regulatory Agency (MHRA) as evidence to support their inspection programmes for laboratories.

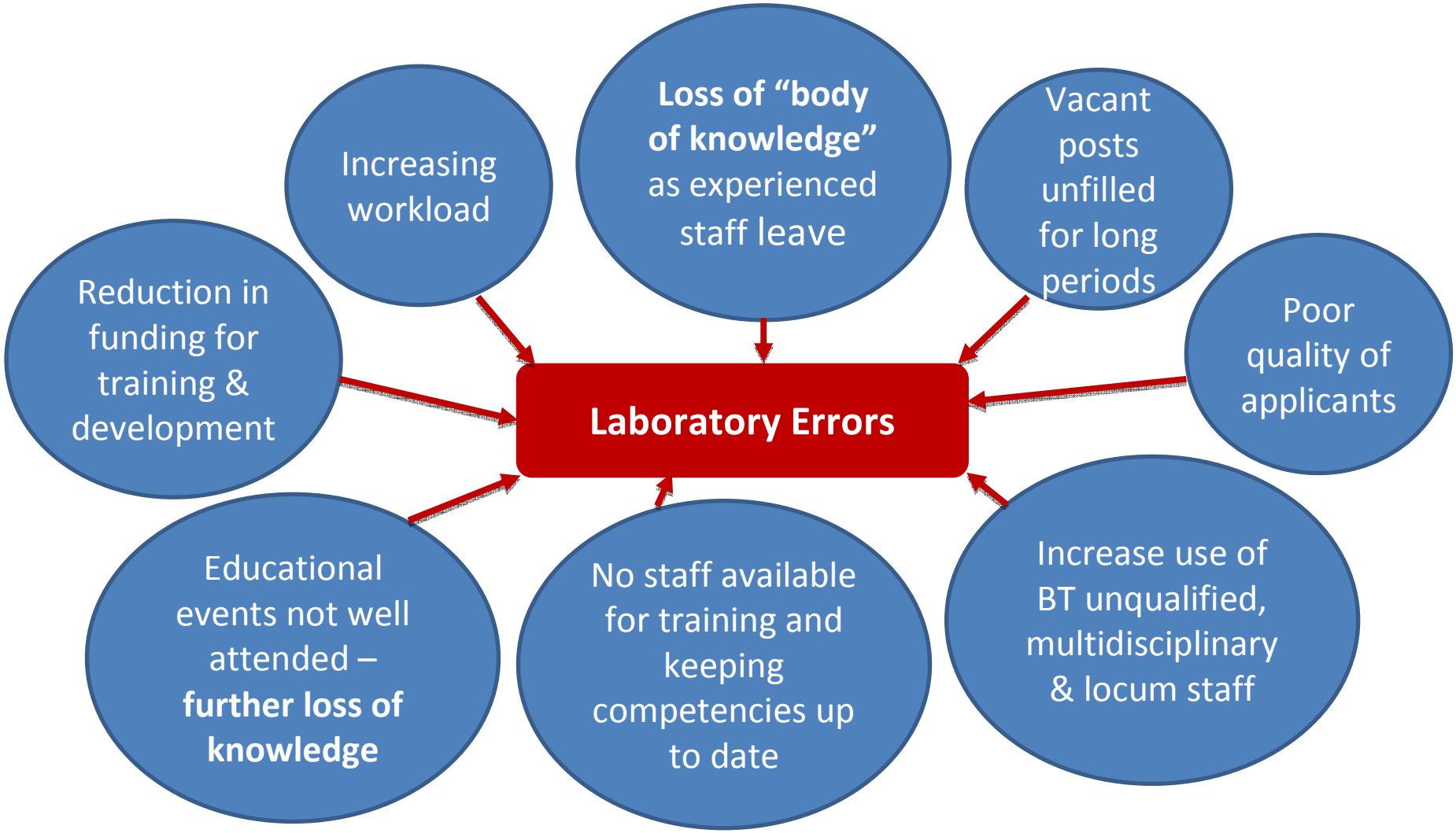
BACKGROUND

Prior to 2009 the SHOT Adverse Incident Reporting Scheme (SHOT, 1996–2013) consistently highlighted that 30–40% of 'wrong blood' incidents were due to errors originating in the hospital blood transfusion laboratory with a disproportionate number of these occurring outside core hours (core hours for these standards being defined as that period of the working day when the majority of the staff establishment are present).

In 2006, SHOT approached the IBMS to facilitate a meeting between themselves and other relevant stakeholders working in

- Collaboration of IBMS,SHOT,BBTS,NEQAS & RCPath formed in 2006
- Targeted with a 50% reduction of laboratory errors by 2012
- Identified problems with :- IT,Staff levels, Knowledge & skills
- 3 laboratory surveys 2011,2013,2015
  - 2014 UKTLC standards available

UKTLC 2017 Survey



General comments

Quality of service is suffering due to increased numbers of very inexperienced staff and the inability to recruit anyone with BT experience

As the technical transfusion lead I struggle to keep up with workload within my core 37.5 hours, and regularly work additional hours

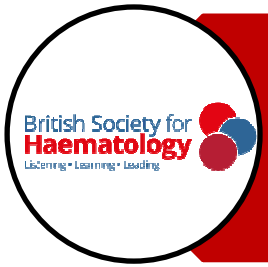
Lack of resource and support leads me to feel stressed and under considerable pressure regularly, and the only aspect that keeps me in this profession is my personal interest in the subject

Rotation of staff due to shift systems means less continuity

Key SHOT Messages 2016

Laboratories should always have adequate staffing at the appropriate grade to support those that require training

Appropriate use and management of Laboratory Information Management Systems (LIMS) are essential for patient safety



Gap analysis should be performed against national transfusion guidelines and SOPs amended to correct deficiencies

Conclusion

The standard of transfusion knowledge and education within laboratories is becoming a prevalent source of error

Anecdotal evidence that there is a national shortage of qualified BMS staff applying for vacant positions and vacancies being filled with less qualified staff

It is everyone's responsibility to ensure they complete their part of the process fully with care

Acknowledgements

- Clare Whitham – UK NEQAS
- Peter Baker – SHOT Working Expert Group
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