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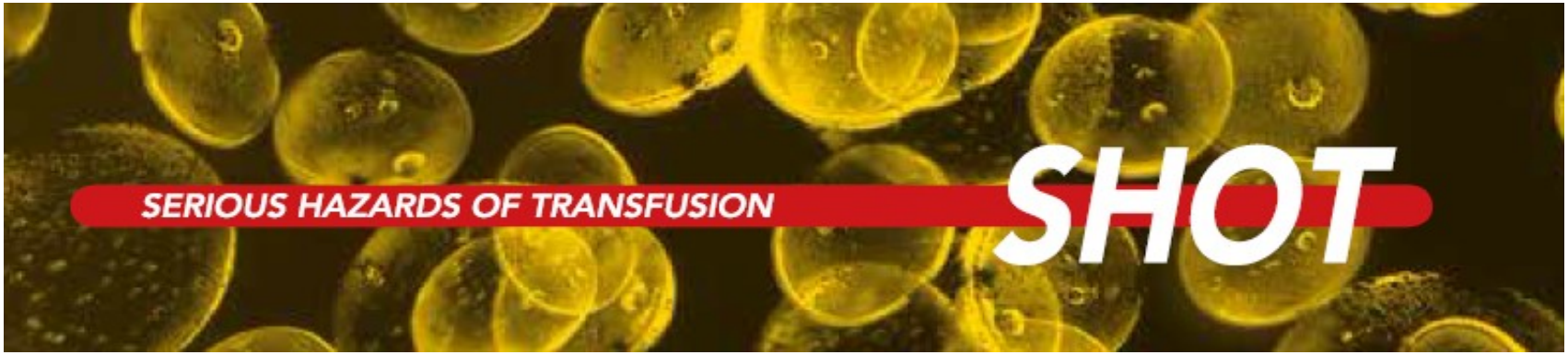
SHOT – Lab Errors 2014



Karen Mead
Specialist Practitioner of Transfusion

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SHOT Overview

- Launched in November 1996
- The UKs independent, professionally led, confidential enquiry into the serious hazards of transfusion
- Collects data on transfusion reactions and adverse events (including near miss events)
- Covers all NHS and private hospitals in the UK in addition to the 4 Blood Transfusion Services
- Reporting is confidential and professionally mandated

- a requirement of quality, inspection and accreditation organisations

Pathology Quality Assurance Review

Dr Ian Barnes

January 2014

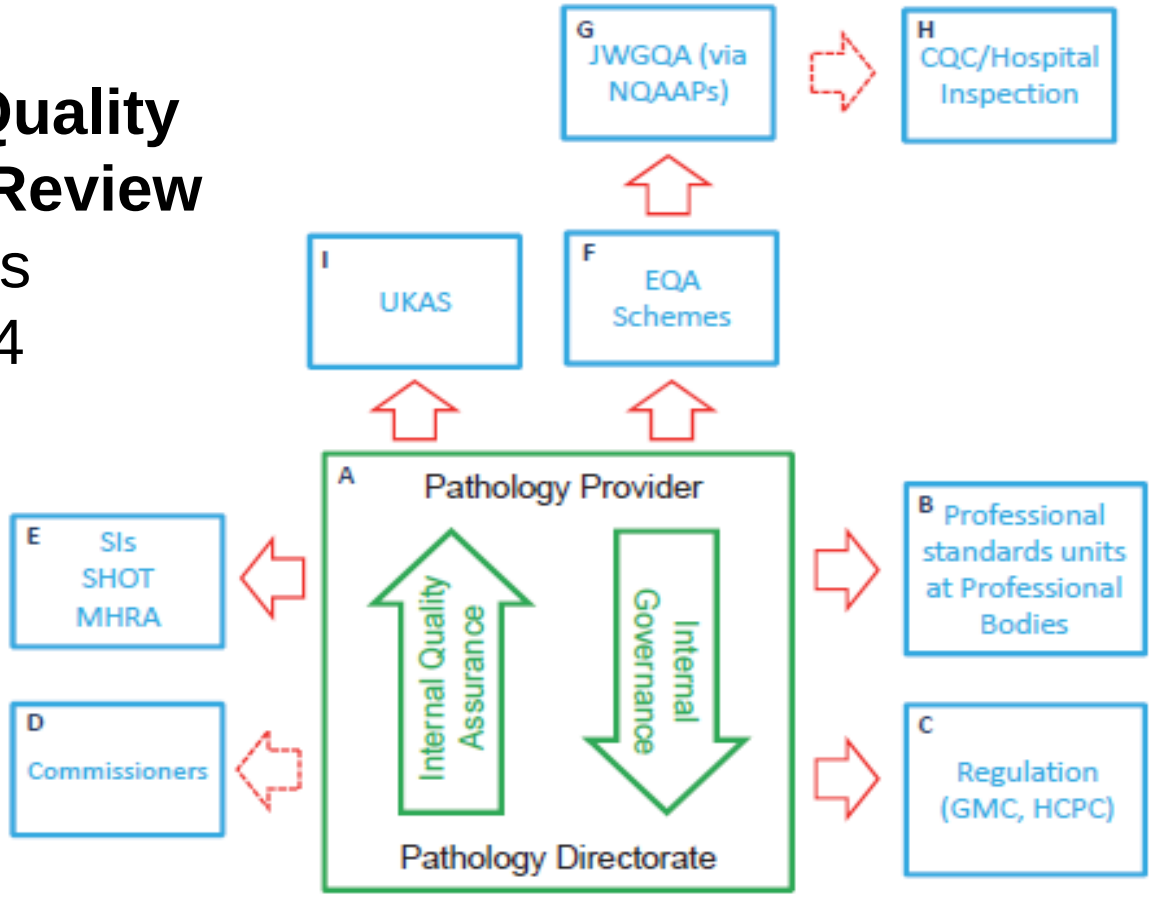


Fig 1: The above diagram gives a high-level view of the main roles of providers and laboratories, regulators, statutory bodies, commissioners, the accrediting body and professional organisations, in assuring the quality of pathology services. Activities shown in green are internal to laboratories and providers. Activities shown in blue are external processes of assurance. Red arrows indicate lines of reporting, and dashed arrows represent areas where this relationship exists in theory but is not extensively utilised.

Annual Report written by Transfusion Experts:

- Annual and cumulative statistics
- Examples of incidents
- Learning points
- Recommendations
- Summary report

Also resources:

SHOT definitions
SHOT information & teaching slides
Lessons for Laboratory / clinical staff
SHOT laboratory reporting guide
SHOT toolkit / RCA toolkit

Information obtained is used to:

- provide education on all facets of transfusion safety and management of transfusion reactions

- improve standards of hospital transfusion practice

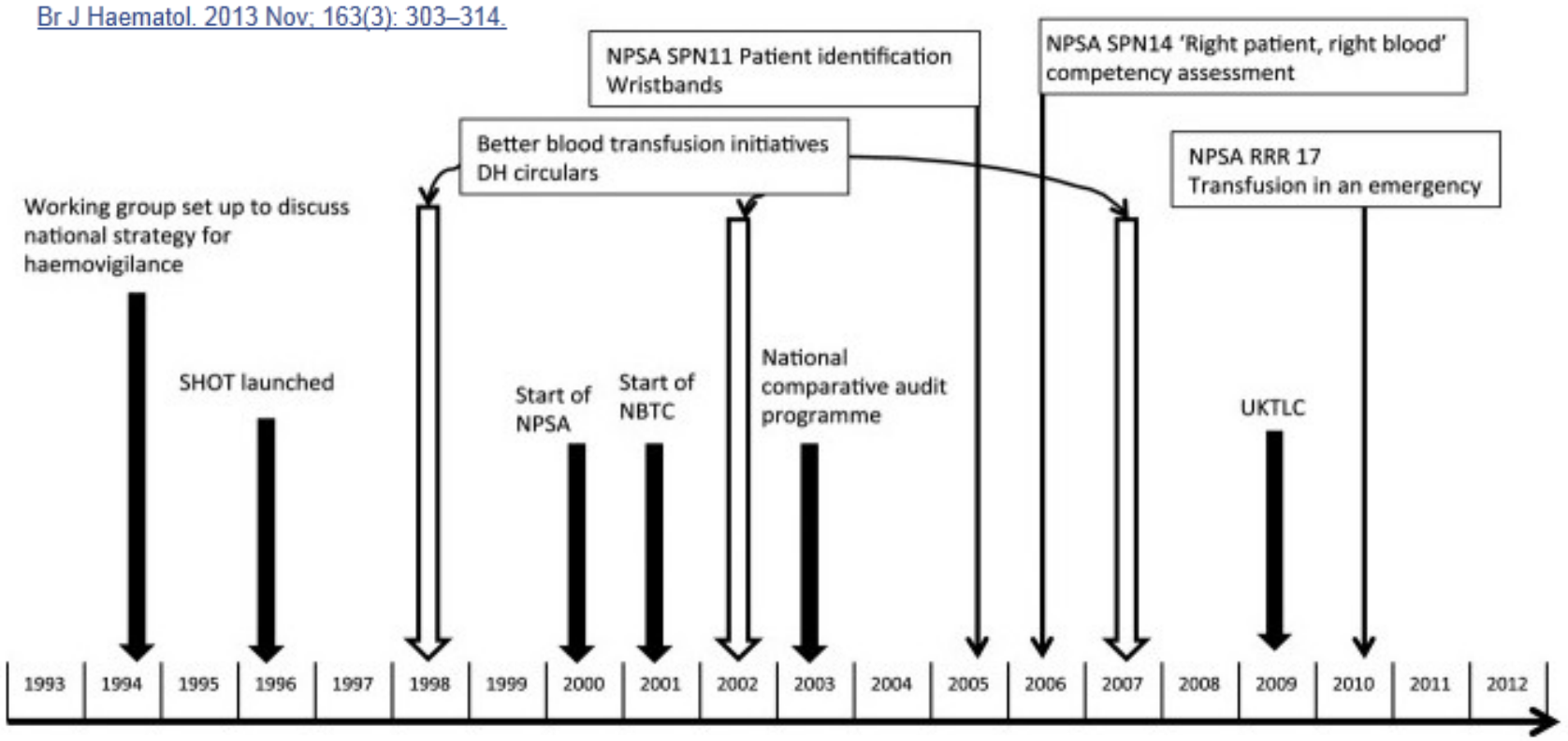
- inform policy within the UK blood services

- aid production of clinical guidelines

- inform Europe about transfusion safety within the UK

- collaborate with other bodies responsible for transfusion safety

Br J Haematol. 2013 Nov; 163(3): 303–314.



Timeline for SHOT development showing organizations that SHOT reporting has triggered or supported.

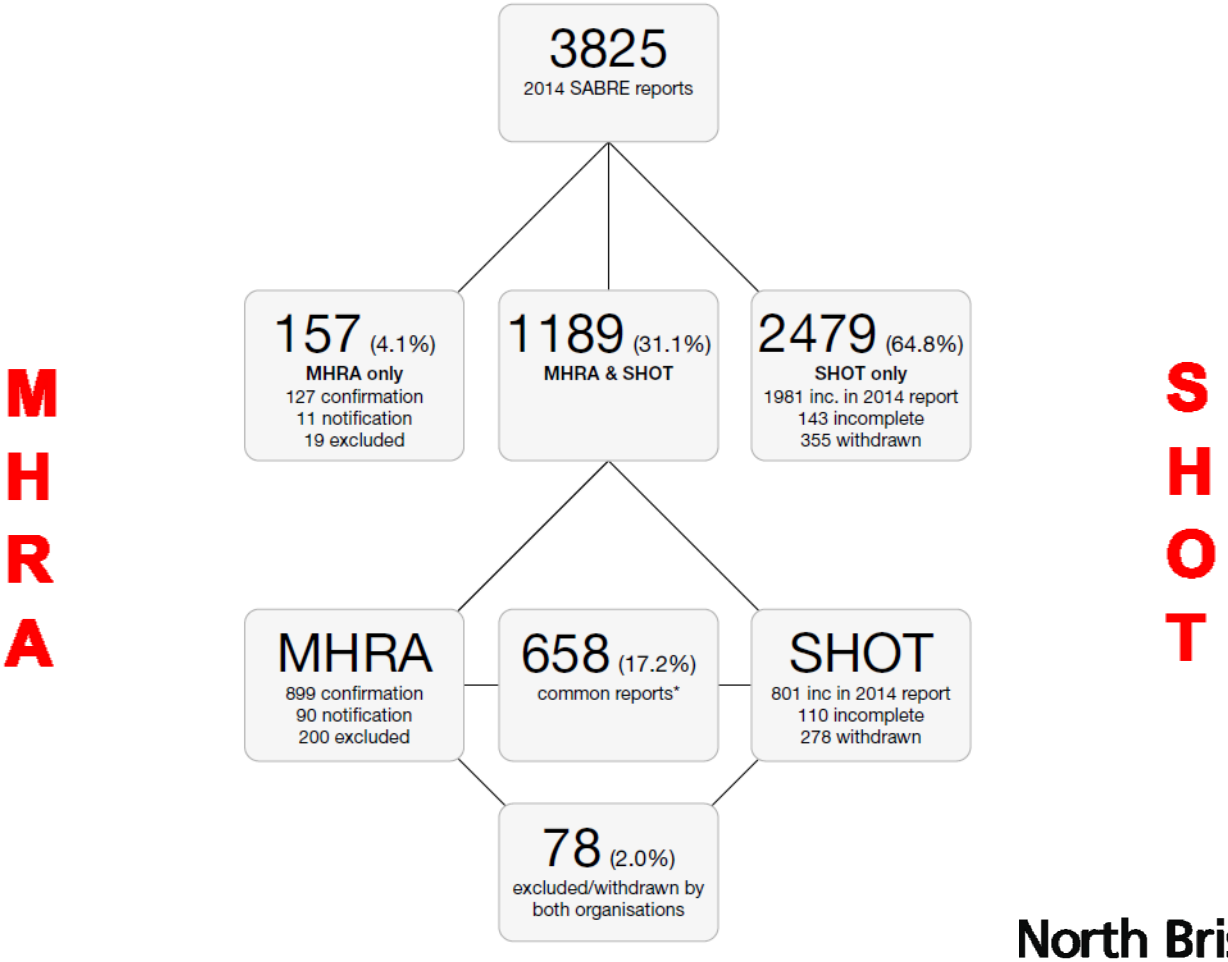
Haemovigilance in the UK

MHRA	SHOT
Medicines & Healthcare Products Regulatory Agency	**Serious Hazards of Transfusion**
• Competent Authority for the BSQR 2005 - QMS in blood establishments and hospital blood banks. • Competent Authority for the Medicines Act 1968 • Competent Authority for the Medical Devices Regulations 2008 • **STATUTORY** reporting	• Confidential enquiry • Serious adverse reactions/events AND near misses all of which occur in BOTH a laboratory and CLINICAL environment. • **PROFESSIONALLY MANDATED** reporting

Overlap of critical points in the process between SHOT and MHRA

- Decision to transfuse
- Prescription/request
- Sampling for pre-transfusion testing
- **Laboratory testing**
- **Collection of blood from issue fridge**
- Bedside administration
- **Monitoring the patient**

Haemovigilance Reporting

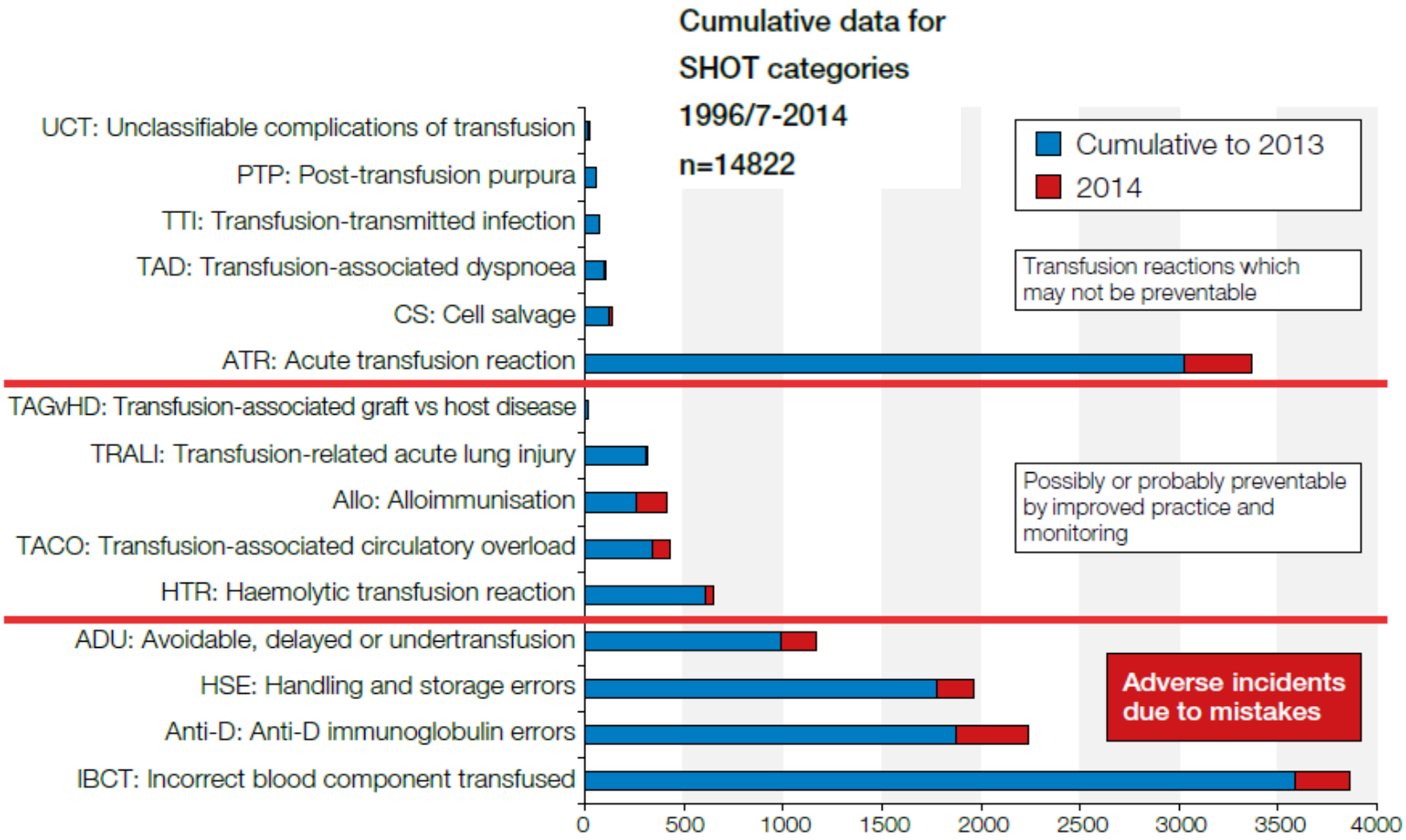


M H R A

S H O T

Cold Chain & Traceability *(NOT the same thing!)*

- Issues around cold chain and traceability are dealt with by the MHRA unless 'inappropriate' units are actually transfused, then it should be reported to SHOT.
- If blood that is expired / OTCOL / past dereservation date is *available* in an issue / satellite fridge / cold box then that is MHRA reportable as an SAE, but not reportable to SHOT
- If blood is *collected for transfusion*, but the error is spotted at the bedside, then that is a SHOT near miss
- If blood is *transfused* then that becomes a full-blown HSE / IBCT / SRNM SHOT report

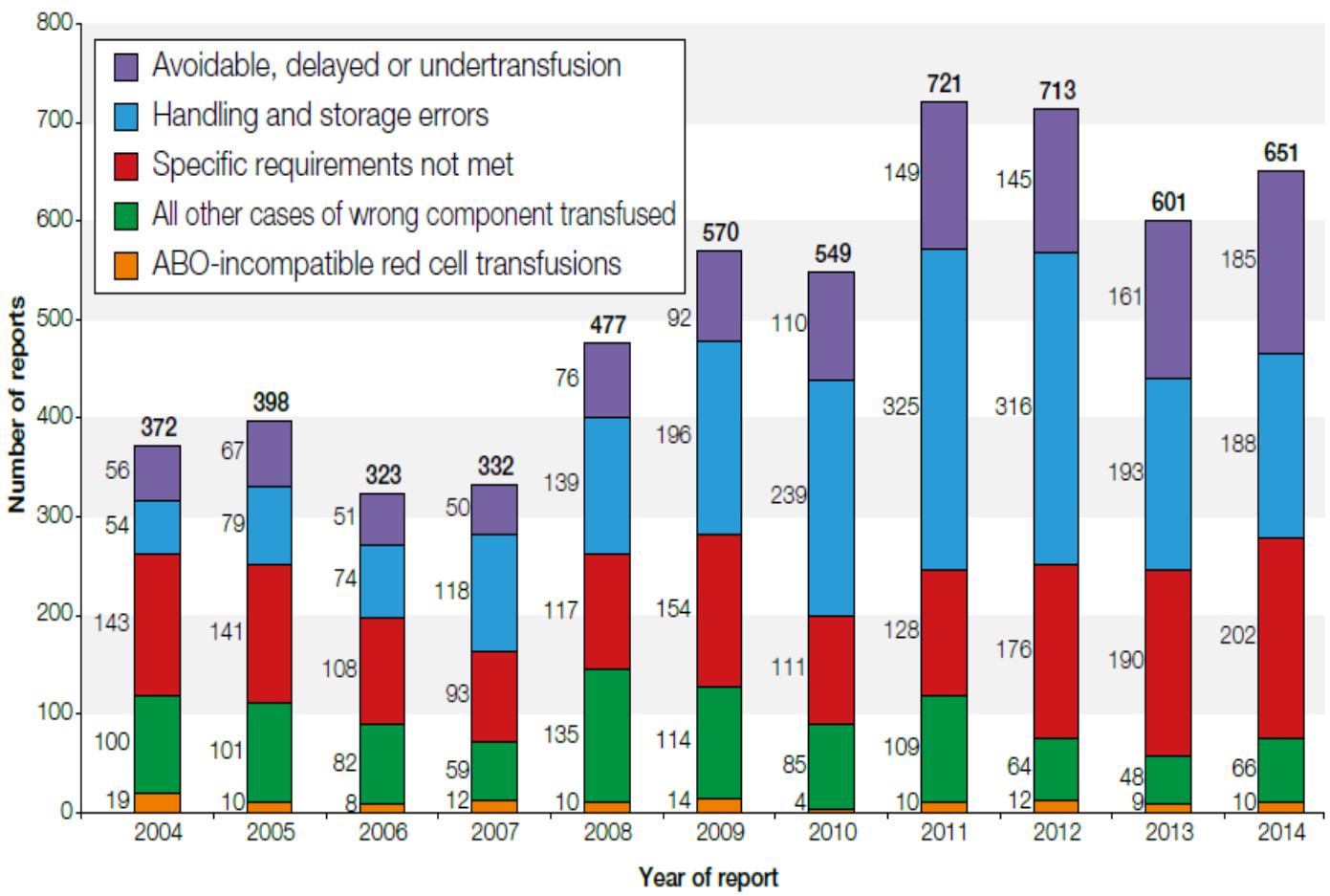

Cumulative data for
SHOT categories
1996/7-2014
n=14822
Cumulative to 2013
2014
Transfusion reactions which may not be preventable
Possibly or probably preventable by improved practice and monitoring
Adverse incidents due to mistakes
UCT: Unclassifiable complications of transfusion
PTP: Post-transfusion purpura
TTI: Transfusion-transmitted infection
TAD: Transfusion-associated dyspnoea
CS: Cell salvage
ATR: Acute transfusion reaction
TAGvHD: Transfusion-associated graft vs host disease
TRALI: Transfusion-related acute lung injury
Allo: Alloimmunisation
TACO: Transfusion-associated circulatory overload
HTR: Haemolytic transfusion reaction
ADU: Avoidable, delayed or undertransfusion
HSE: Handling and storage errors
Anti-D: Anti-D immunoglobulin errors
IBCT: Incorrect blood component transfused
0
500
1000
1500
2000
2500
3000
3500
4000

Blood Safety v Transfusion Safety

Transfusion transmitted infections	Risk of infected donation entering blood supply
HBV	1 in 1.3 million
HCV	1 in 28.6 million
HIV	1 in 7.1 million

SHOT REPORTS	Risk per component issued
Total risk of death	1 in 125,000
Total risk of major morbidity	1 in 19,157
Risk of ABO incompatible red cells	1 in 263,157
Risk of wrong component	1 in 48,309
Risk of specific requirements not met	1 in 14,514

Cumulative numbers for blood component error-related reports (excluding anti-D Ig)



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Never Events List 2015/16

12. Transfusion or transplantation of ABO-incompatible blood components or organs
Unintentional transfusion of ABO-incompatible blood components. • Excludes where ABO-incompatible blood components are deliberately transfused with appropriate management.

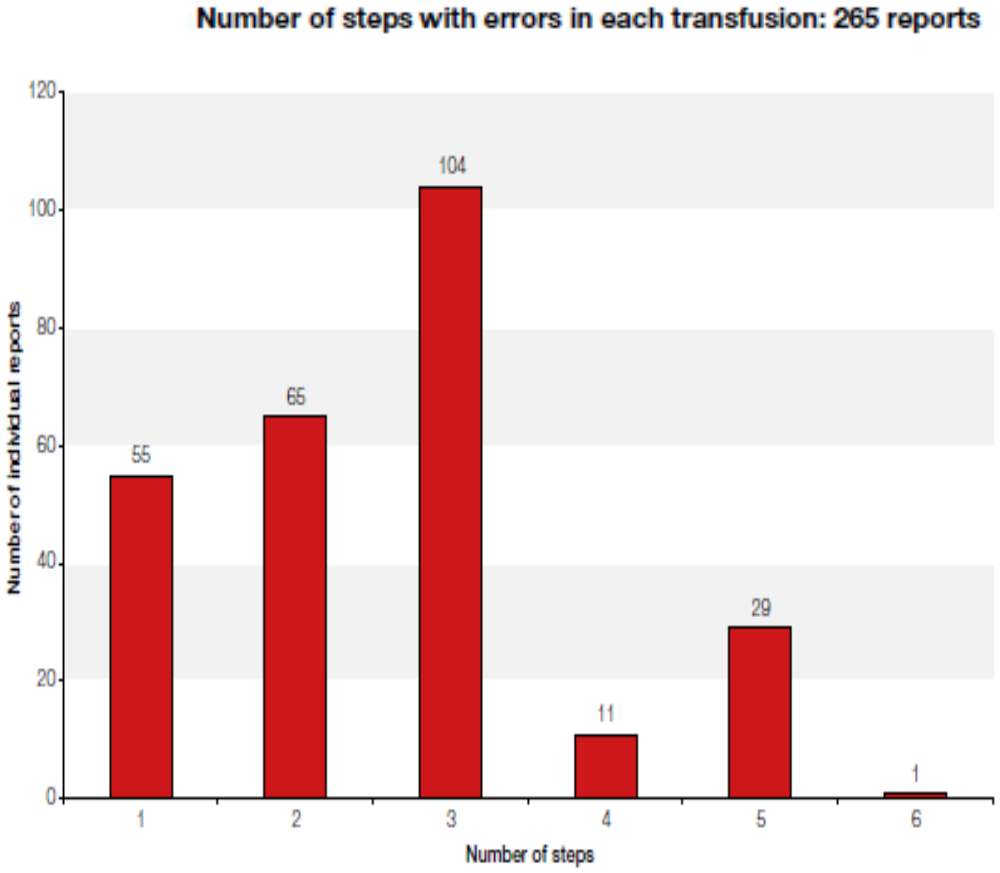
Key Recommendations:

- All ABO incompatible red cell transfusions to be included as 'never events': ABO incompatible transfusions may be fatal and are absolutely preventable. The two thirds that do not result in harm should be included as reportable 'never events'

Action: NHS England, patient safety domain

ANNUAL SHOT REPORT 2013

Incorrect Blood Component Transfused 2014



1 REQUEST

2* SAMPLE

3 SAMPLE RECEIPT

4 TESTING

5 COMPONENT SELECTION

6 LABELLING

7 COLLECTION

8 PRESCRIPTION

9* ADMINISTRATION

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A request for 4 units of solvent-detergent fresh frozen plasma (SD-FFP) was received for a patient with a bleeding disorder. The initial request for FFP was made by telephone and the BMS started thawing standard FFP. The request form arrived and the BMS failed to notice that SD-FFP had been requested and continued to issue and label the thawed FFP.

1. **Primary error: Request**: The initial telephone request failed to identify the correct component required
2. **Component selection**: The component was not selected based upon the request form which clearly indicated the component required
3. **Component labelling**: A final check during component labelling failed to cross-check the request form
4. **Collection**: the collector did not check that they had collected the right component
5. **Prescription**: The requirement for SD-FFP was not specified on the prescription chart to prompt the person performing the bedside check
6. **Administration**: The final bedside check failed to identify the right component was to be transfused

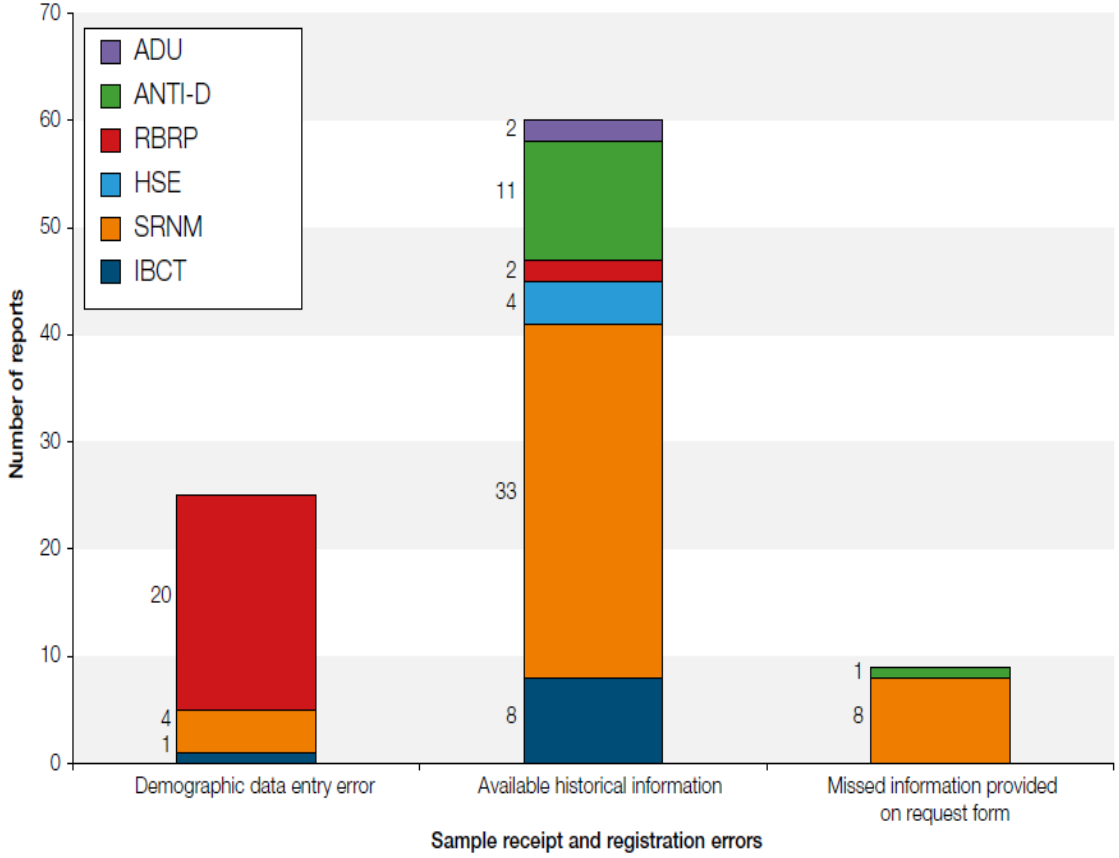
Laboratory Based Errors - 2014

Laboratory categories	Total	Percentage	Chapter					
			IBCT	SRNM	HSE	RBRP	ANTI-D	ADU
Sample receipt and registration	94	28.1%	9	45	4	22	12	2
Testing	88	26.3%	11	32	9	0	23	13
Component selection	39	11.7%	13	8	6	1	11	0
Component labelling, availability, handling and storage	109	32.6%	3	0	44	50	2	10
Miscellaneous	4	1.2%	0	1	0	0	3	0
Total	**334**	**100%**	**36**	**86**	**63**	**73**	**51**	**25**

Key: IBCT – incorrect blood component transfused; SRNM – specific requirements not met; HSE – handling and storage errors; RBRP – right blood right patient; ADU – avoidable, delayed and undertransfusion.

In addition – 313 near miss reports

Sample Receipt and Registration (N=94)

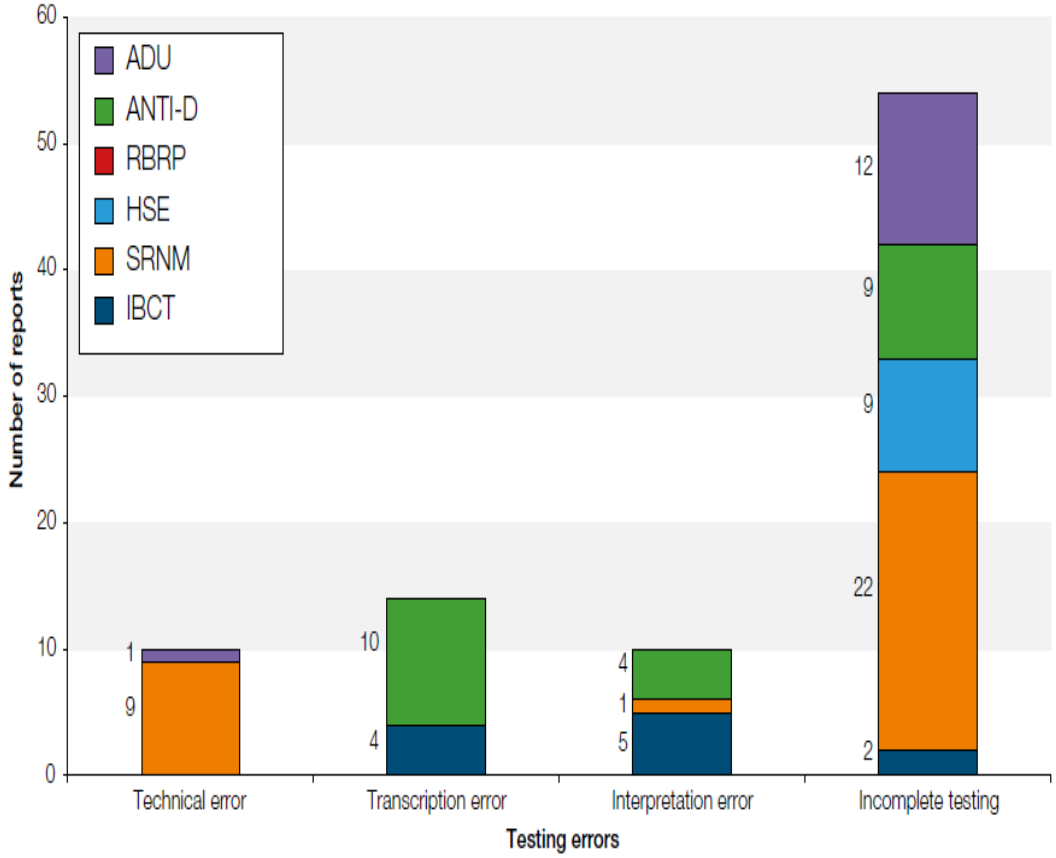


Demographic Data Entry:
Name, ID number, DoB,
previous history not being entered

Available Historical Information:
Requirements missed / not heeded
Incorrect ABO/D group to HSCT patients
Anti-D to women with known immune anti-D
Samples exceeding BCSH guidelines
Anti-D Ig to Mums of RhD negative infants
Wrong blood group ordered – delay
Anti-D to a RhD positive woman

Missed Information on Request:
Irradiated components
SD-FFP
CMV negative
Group and Kleihauer

Testing Errors (n=88)



Technical Error:
Inappropriate use of electronic issue
IT error – no results for authorisation

Transcription Error:
Cord samples incorrectly reported as RhD-
(omission of anti-D to D neg women)
Cord samples incorrectly reported as RhD+
(inappropriate administration of anti-D Ig)
ABO/D group incorrectly entered onto LIMS
Mum (RhD-) entered at RhD+ (no anti-D)
Inaccurate LIMS comments / codes used

Interpretation Error:
ABO/RhD, Ab ID, FMH result,
anti-D algorithm interpretation

Incomplete testing (breach of SOP):
Samples exceeding BCSH guidelines
Clinically significant Ab not excluded/identified
Erroneous results (e.g. Hb, fibrinogen etc)
Ab ID not performed following pos Ab screen
Components issued on single sample
Kleihauer test not performed <72 hours

Component Selection (n=39):

33% - Wrong component selection i.e. FFP instead of cryo

28% - Late / omitted / insufficient anti-D Ig to women

21% - Not correct specification i.e. irradiated / phenotype

15% - Selection of expired units

3% - Selection of wrong pack (RBRP)

Issue of inappropriate group ABO FFP in an emergency

Following admission of a trauma patient with haemorrhagic shock the massive haemorrhage protocol was activated. Three units of group O FFP thawed for a previous patient were available. These 3 units were allocated and transfused to the trauma patient. The patient's correct group was A. This error was noticed during fating of the units. This work was performed out-of-hours by a BMS who did not normally work in the transfusion laboratory. The laboratory SOP was also not clear concerning the ABO compatibility requirements of FFP.

Learning point

- All members of staff working in a blood transfusion laboratory must actively and regularly participate in a programme of practical and knowledge-based competency. Staff who are not permanently established in blood transfusion should complete at least 10 days of supervised working with the transfusion laboratory (Chaffe et al. 2014)

Component labelling, availability, HSE (n=109):

46% - Transposed labels (for same patient)

40% - Expired units not discarded but re-issued, cold chain errors – OTC prior to transfusion

11% - Availability of components

3% - Transposed labels (for different patient)

Key SHOT messages

- Errors with sample receipt and registration, and testing all highlight key areas for improvement, particularly lack of effective communication together with poor serological knowledge and understanding in laboratory staff. During the 'booking in' process it is essential to take into account any historic patient laboratory information and to ensure that all previous results and any specific requirements have been taken into consideration

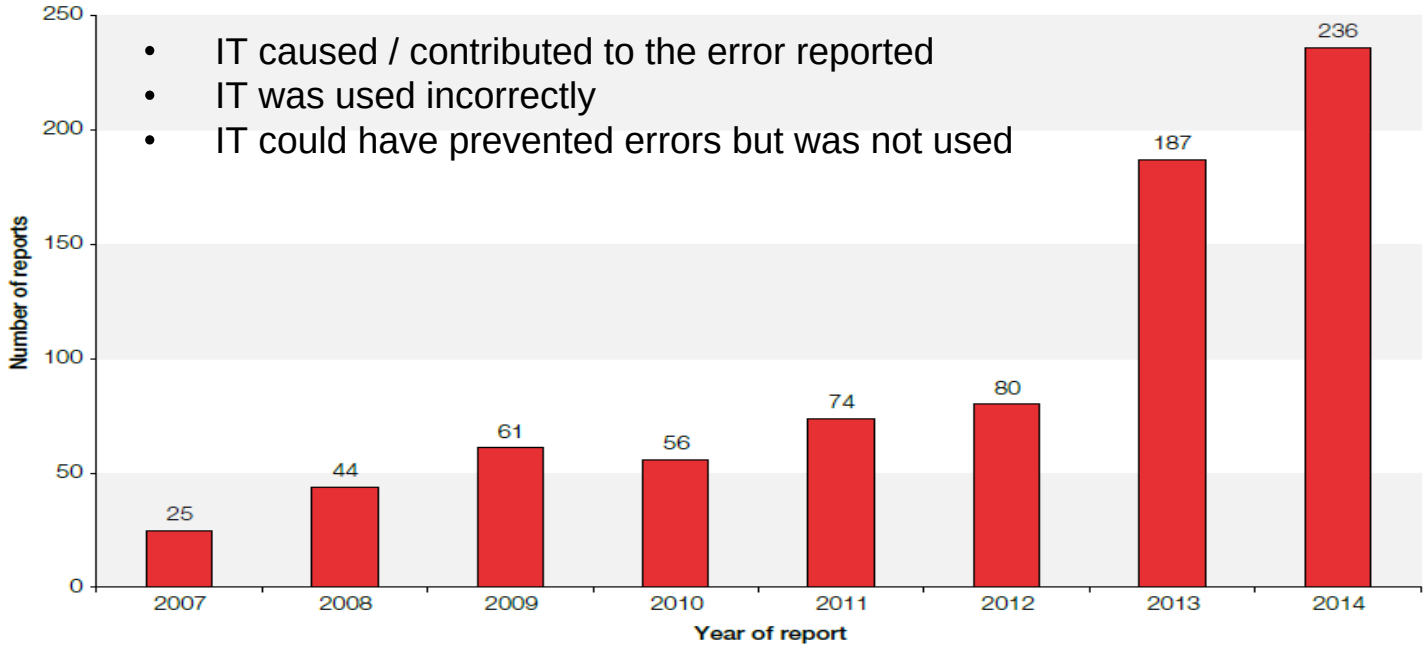
Learning point

- Regular participation or assessment within a continuing professional development (CPD) scheme is essential for all transfusion laboratory staff

Learning points and suggested actions

- Standardisation of laboratory reports so they cannot be misinterpreted
- Standardisation of patient records with electronic transfer of D-grouping results where possible

Errors relating to Information Technology (IT)



In 2014:

44% lab IT
56% clinical IT

Mostly caused by human factors

- inappropriate set-up / work-arounds
- Not setting up flags / over-riding flags

An 83 year old man required an urgent red cell transfusion. He had a past medical history of chronic lymphocytic leukaemia and had been admitted to the emergency department with possible neutropenic sepsis. Irradiated blood components had not been requested and the transfusion laboratory staff did not check patient details on the old laboratory information management system (LIMS). The new LIMS had not been updated to indicate that irradiated components were required. Three units of non-irradiated red cells were issued and transfused.

1. **Primary error: Request**: The need for irradiated components was not documented on the request form
2. **Sample receipt and registration**: The need for irradiated components was recorded on the old LIMS but had not been transferred to the new LIMS – this was missed by the BMS
3. **Component selection**: The specific requirement was not considered when the units of red cells were selected
4. **Prescription**: The need for irradiated components was not recorded on the prescription chart to prompt the person administering the blood that the patient had specific requirements
5. **Administration**: The need for irradiated components was not detected prior to administration and non-irradiated components were transfused

Errors relating to Information Technology (IT)

Key SHOT messages

- The modern transfusion laboratory is critically dependent on IT and automation. Worryingly, there has been a number of cases in 2014 where the error in relation to the use of IT may have been an error in the actual software or function of the IT system
- The BCSH guidelines on IT in blood transfusion (BCSH Jones et al. 2015) and the UKTLC standards (Chaffe et al. 2014) have both been published recently, and laboratory staff are strongly encouraged to perform a gap analysis and ensure their laboratories comply with them

Learning point

- Laboratories should ensure all automated processes are fully validated and constantly monitored for accuracy. IT systems should be audited on a regular basis against the BCSH guidelines for the specification, implementation and management of IT systems in hospital transfusion laboratories (BCSH Jones et al. 2014)

Conclusions

- Effective communication, good serological knowledge and understanding is key
- Historical patient information, previous results and special requirements must be taken into consideration
- In clinical emergencies, clear timelines for blood component provision must be clearly communicated
- If a patient has known antibodies, potential delays in blood provision need to be discussed and agreed
- Be open and honest
- Learn from mistakes (yours and those of others)