

SERIOUS HAZARDS OF TRANSFUSION

SHOT

Haemovigilance in the UK

Non-Medical Authorisation – Thur 30 Nov 2017

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(presented by Alison Watt – SHOT Operations Manager)

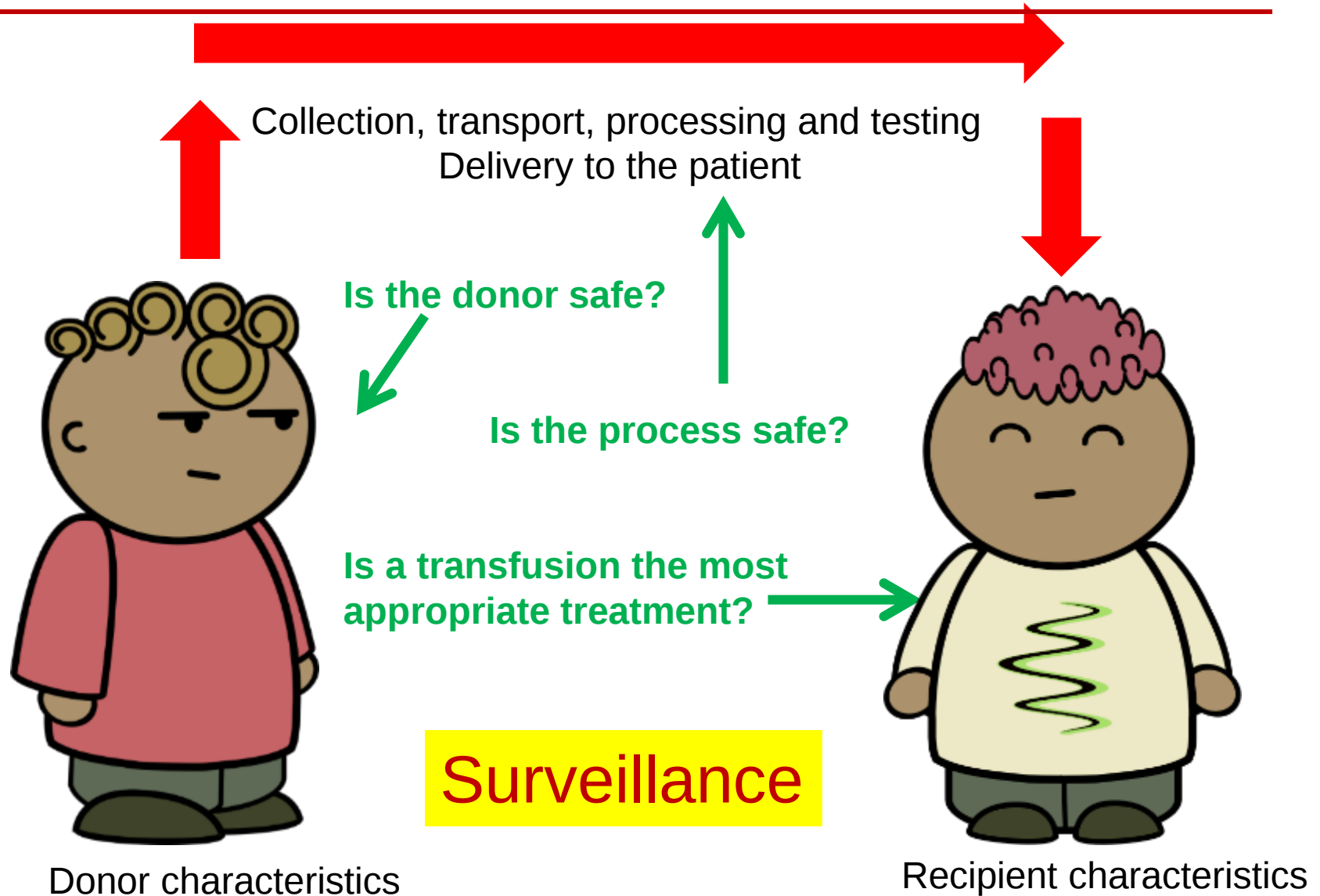
Aims

- When and where to report adverse events and reactions related to transfusion
- Learning outcomes
 - When to report externally
 - What to do about error
 - Cases as example

Are we looking from the wrong end?

- Most of the time, it goes right
- 2.5 million blood components issued 2016
- Risk of transfusion death – 1 in 100,000 components
(n=26 in 2016)
 - Death from error - 1 in 250,000 (n=8 in 2016)
 - Death from TACO - 1 in 200,000 (n=14 in 2016)
- Comparison non-transfusion risks
 - Accidental drowning - 1 in 84,000
 - Medical complications in next year - 1 in 100,000
- Risk of major morbidity - 1 in 20,400 (n=122 in 2016)

Blood is a living transplant



We are about to discuss what goes wrong.....

But transfusion is very safe:

- Total components issued 2.5 million
- Adverse events reported to SHOT 3500
- That's <10 events per thousand components issued

Development of Haemovigilance

- In 1990s - growing awareness of safety issues in blood transfusion
 - Especially HIV, HCV, hospital errors
 - Incidence of major complications of blood transfusion was unknown
- Working group set up in 1994 to consider haemovigilance – SHOT launched 1996
- SHOT report first published for 1996-1997 data
 - Increasing number of reports each year
 - Evolution of new categories reflecting reports

What does SHOT do?

- Serious Hazards of Transfusion (Est 1996)
- Collects data on serious adverse reactions and events
- Data reviewed by transfusion experts to produce Annual SHOT Report
- Participation is professionally mandated
 - a requirement of quality, inspection and accreditation organisations
- Small core team based in Manchester

The Transfusion Steps

(as used by SHOT to analyse the data)

**Critical points:
Positive patient
identification essential**

Note: once a decision to transfuse is made, the authorisation or prescription may be written at variable times during this sequence, but **must be checked at the final stage**

1 REQUEST

2* SAMPLE

3 SAMPLE RECEIPT

4 TESTING

5 COMPONENT SELECTION

6 LABELLING

7 COLLECTION

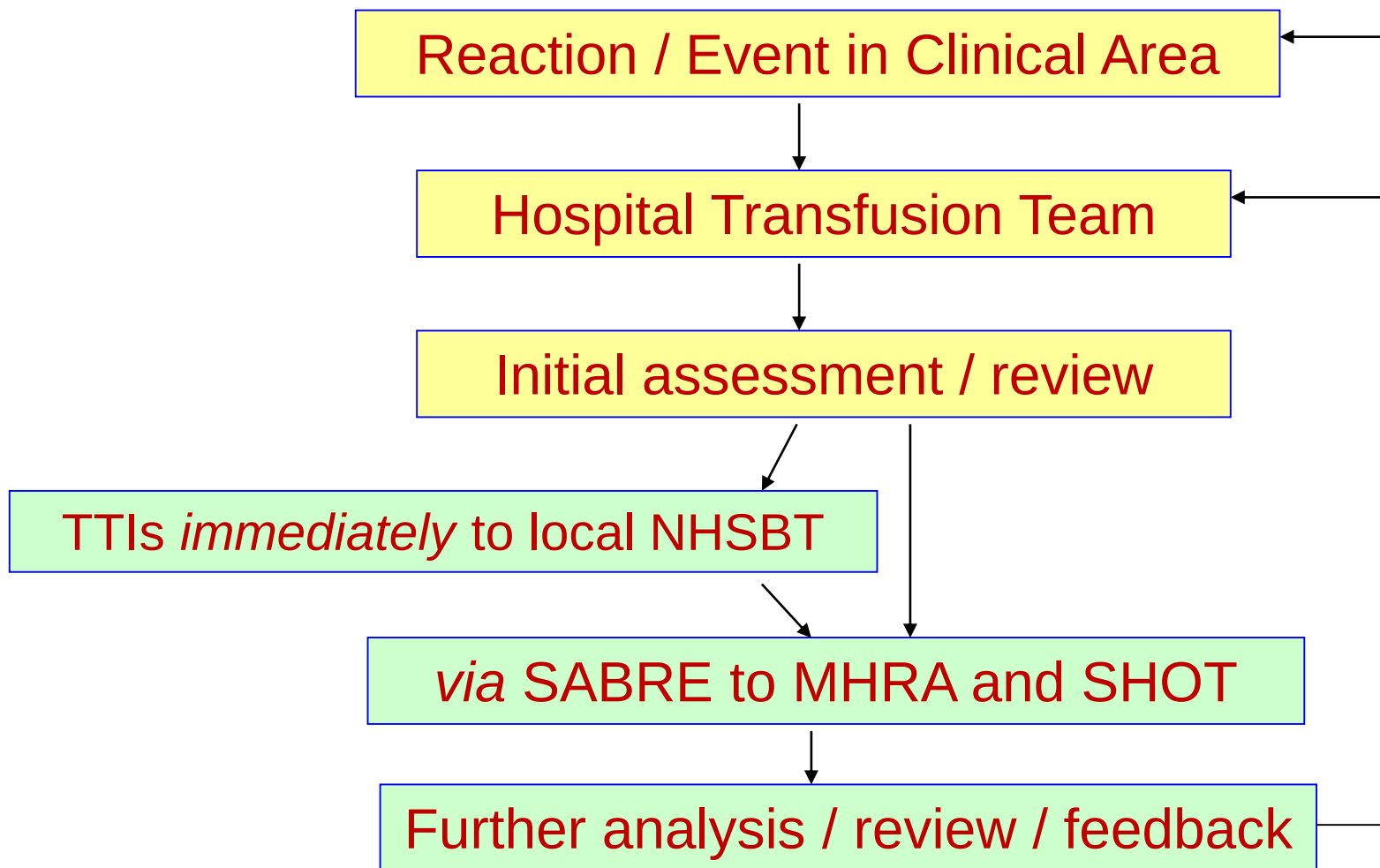
8 PRESCRIPTION

9* ADMINISTRATION

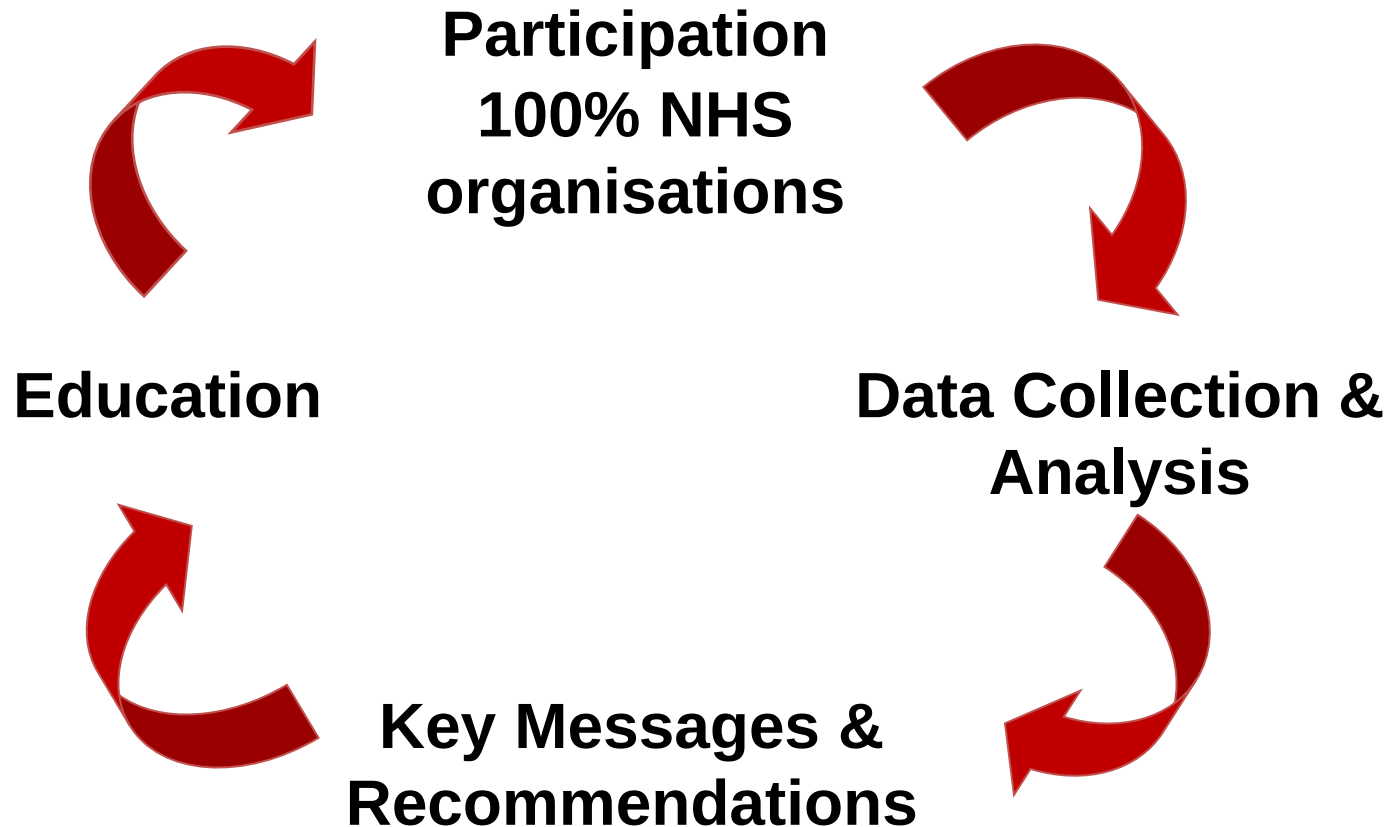
Who and how?

- Hospital transfusion teams
 - Consultant haematologist
 - Laboratory manager
- Transfusion practitioner
- Make reports via on-line reporting systems
 - Select a category (SHOT and SABRE definitions)
- Follow up with incident investigation at an appropriate level
- Annual reports www.shotuk.org

How does it work ?



Serious Hazards Of Transfusion



Role of MHRA

- ‘Competent Authority’ appointed by DH to implement new legislation and as regulator
 - product quality and safety
 - compliance with requirements for QMS
- Legal requirement to send numbers of SAEs and SARs to EU annually
 - first year of mandatory reporting 2008 (June)
- May impose sanctions and demand corrective actions on individual sites
 - not analysing trends or making recommendations

MHRA reports: What is 'Serious' ?

- SAR: 'Death, life-threatening, disabling or incapacitating, or which results in or prolongs hospitalisation or morbidity'
- SAE: 'The person responsible ... shall notify... any serious adverse events related to the collection, testing, processing, storage and distribution of blood or blood components which may have an influence on their quality and safety.'

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**

What is SHOT reportable?

- Pulmonary complications
 - Transfusion-related acute lung injury (TRALI)
 - Transfusion-associated Circulatory Overload (TACO)
 - Transfusion-associated Dyspnoea (TAD)
- Acute transfusion reactions (ATR) (allergic, febrile)
- Haemolytic transfusion reactions (HTR)
- Post-transfusion purpura (PTP)
- Transfusion-associated graft-versus-host-disease (TA-GVHD)
- Transfusion-transmitted infections including bacterial contamination (TTI)

What is SHOT reportable?

- Cell salvage incidents
- Handling & Storage (HSE)
- 'Near miss' events (NM)
- Anti-D Ig errors
- New or unclassifiable complication of transfusion (UCT)
e.g. Transfusion-associated necrotising enterocolitis in infants

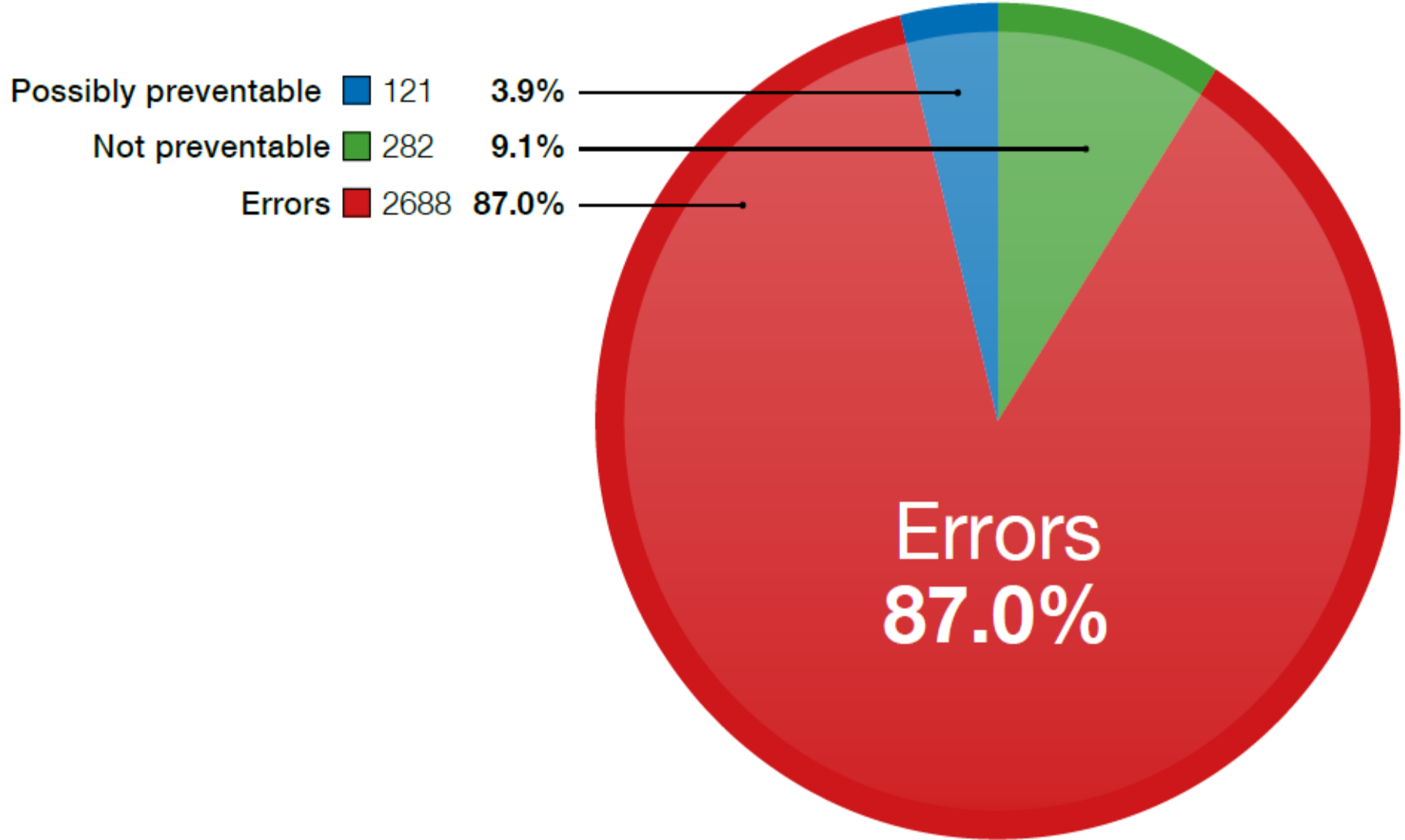
Specific Requirements Not Met (SRNM)

- Much more than just CMV or HEV-screened or irradiated
 - Need to match antigen profile (for multi-transfused haemoglobinopathy patients who develop antibodies)
 - Irradiated for haematological disorders and purine analogue drugs
 - Pathogen-inactivated non-UK plasma for patients born on or after 1.1.96 (MeBlue FFP or Solvent Detergent FFP)
- Clinicians ordering blood components unaware of the requirements - maybe unaware even of possibility of additional specification
- Failure to inform lab / update computer record
- Failure to inform when patients transferred - many cases of SRNM related to patients undergoing shared care between 2 different hospital site

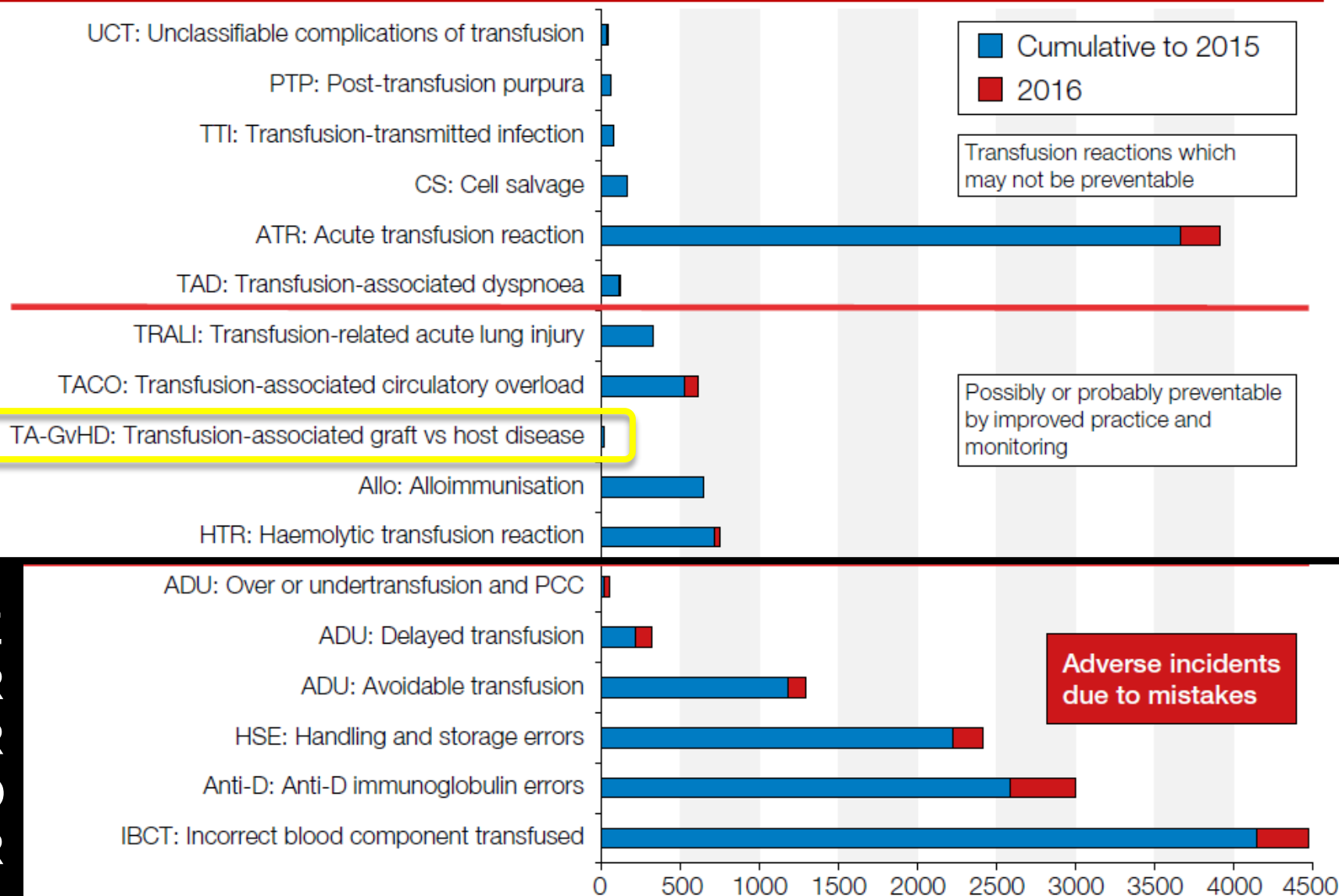
Other Errors

- **WCT – Wrong Component Transfused**
 - Component given to wrong patient
 - Given wrong component (platelets instead of red cells)
 - Incompatible units given
- **HSE – Handling & Storage Errors**
 - Gave blood out of temperature control >30 mins
 - Transfused for too long (>5 hours)
- **ADU**
 - Avoidable transfusion / avoidable use of O Neg
 - Delay in transfusion causing harm to the patient
 - Under or overtransfusion causing harm to the patient (excluding TACO)
- **RBRP - Right Blood Right Patient**
 - Component is correct for the patient, but ID or labelling errors

Reports to SHOT in 2016



SHOT Cumulative data 20 years 1996-2016 n=18258



Risks from transfusion

	Risk per components issued
Death related to transfusion (all causes)	1 in 100,000
Death related to errors	1 in 250,000
Major morbidity all causes	1 in 20,400

Estimated risk that a donation entering the UK blood supply is potentially infectious (2013-2016)

Virus	Risk estimate
Hepatitis B (HBV)	1 in 2.1 million
Human immunodeficiency virus (HIV)	1 in 15.5 million
Hepatitis C (HCV)	1 in 95.8 million

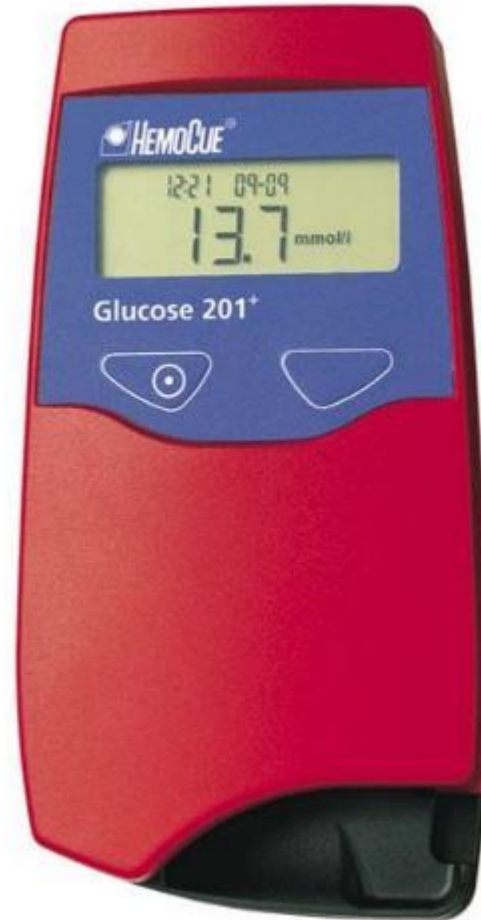
Lack of component knowledge leads to the incorrect type being transfused

- The patient was prescribed two units of platelets before surgery. Red cells were also reserved, because he had irregular red cell antibodies
- The staff gave two units of red cells thinking that the 'optimal additive solution' meant the bag contained platelets
- They tried to give each bag of red cells over 30 minutes as this is the time stated on the prescription for transfusion of platelets
- The error was detected by a doctor when taking a blood sample to measure the platelet increment

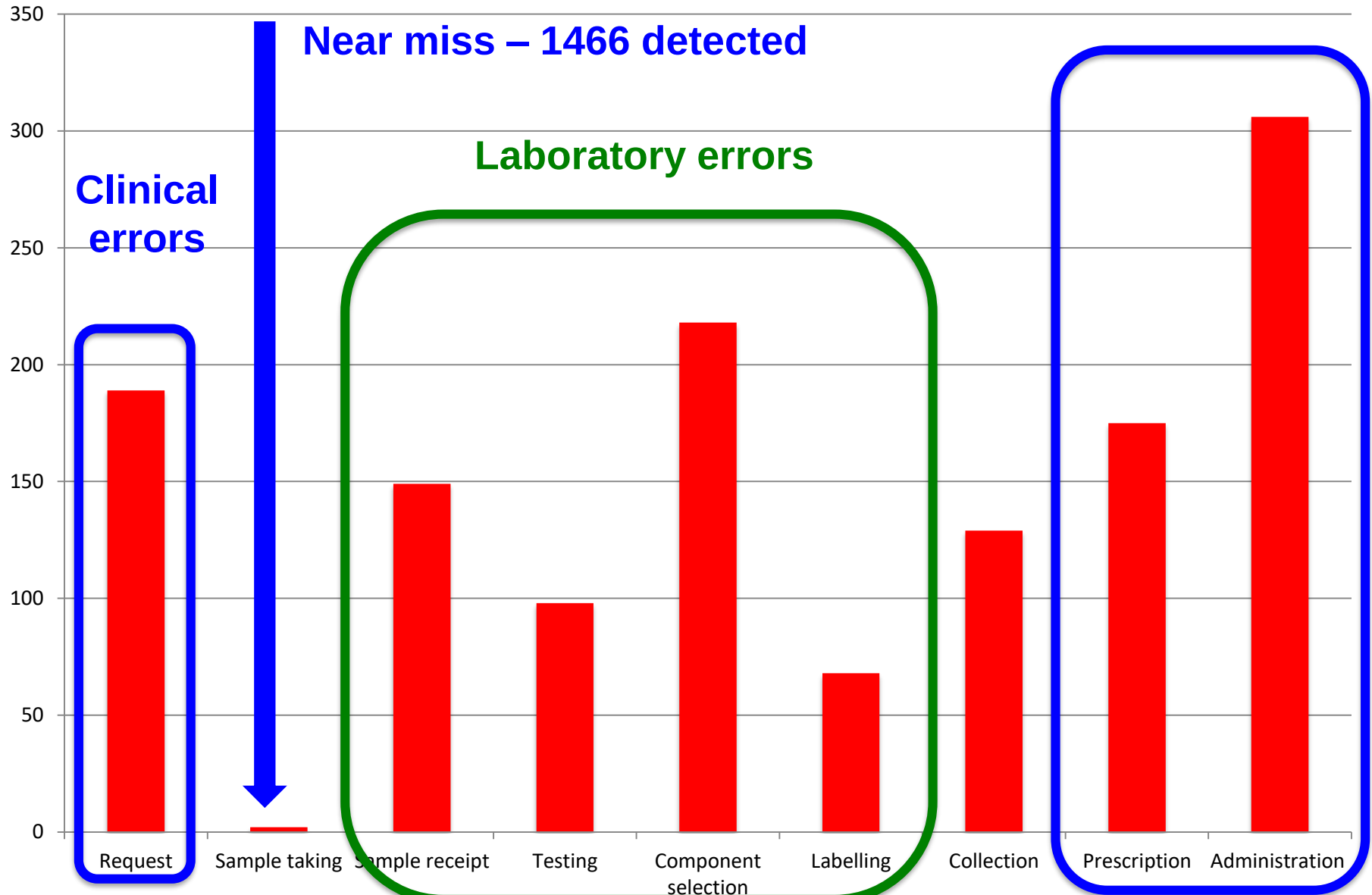
Being set up to fail...

...an accident waiting to happen

Errors have been made in theatre with point-of-care testing



Wrong transfusions 2014 and 2015



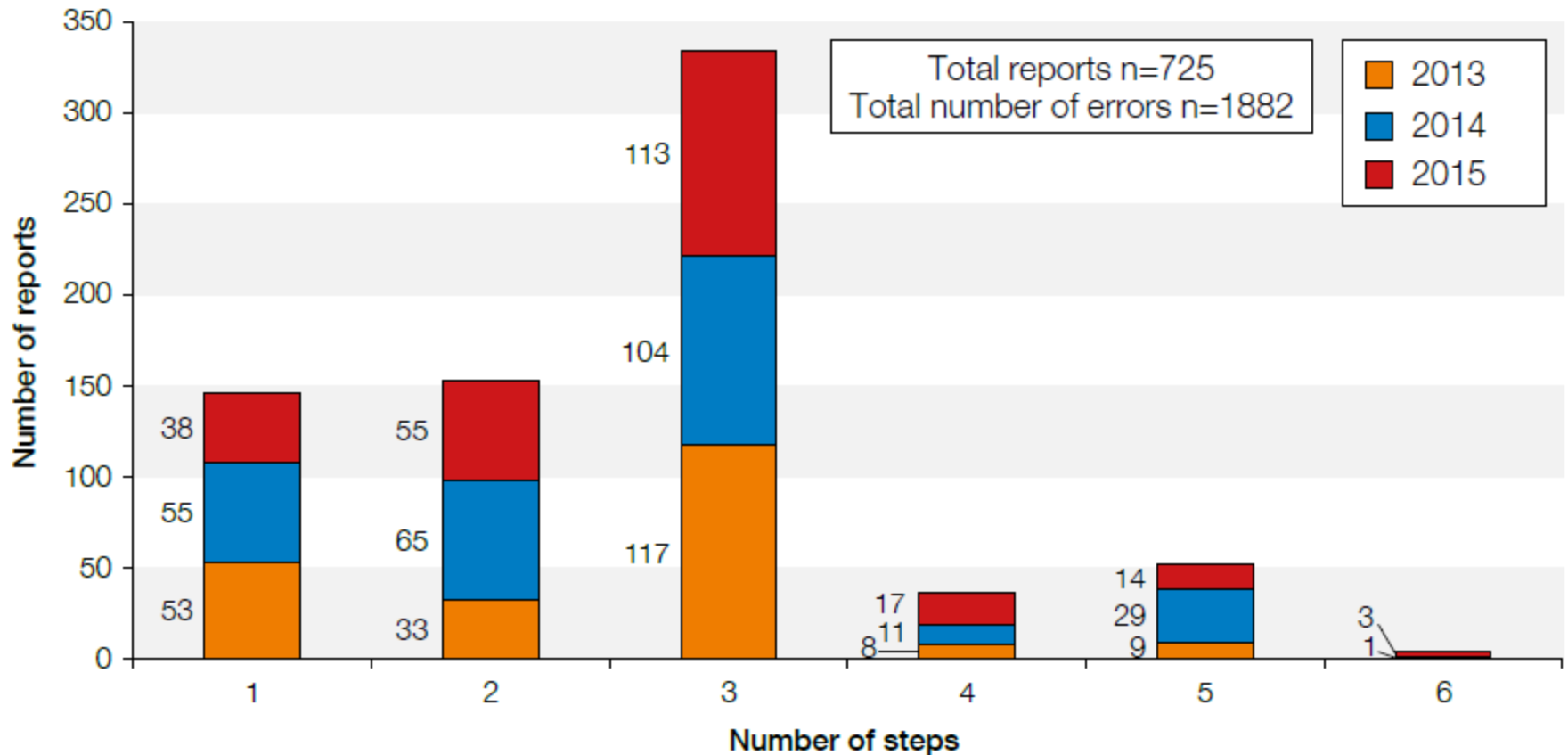
Combinations of errors

- The median number of errors made is 3
- The commonest combination is 3 clinical errors

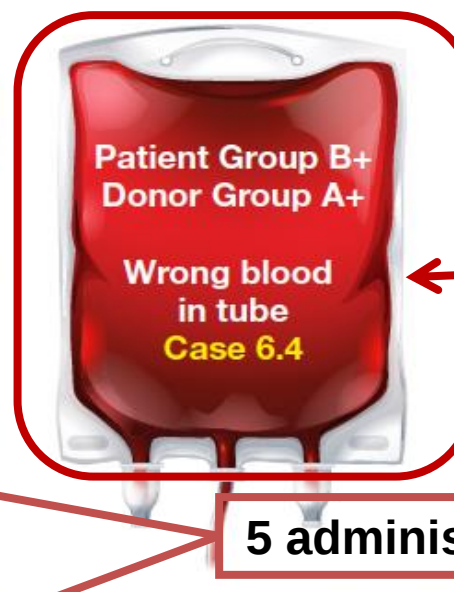
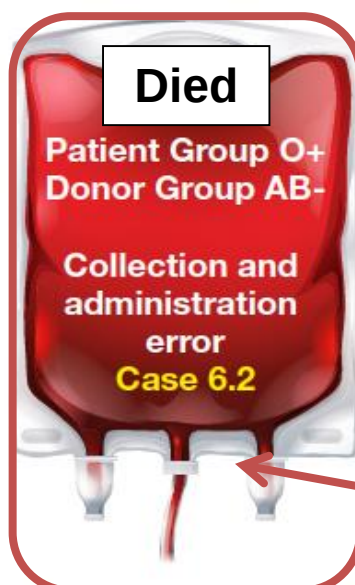
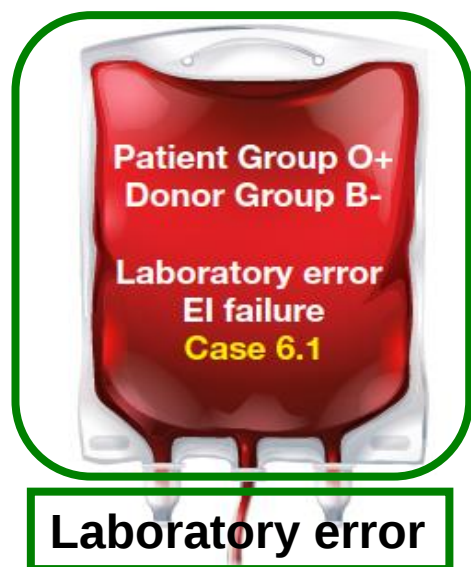
Request, prescription and administration

- Laboratories or clinical teams may have several opportunities to detect an earlier error

Multiple errors are common – incorrect blood components transfused 2013-2015



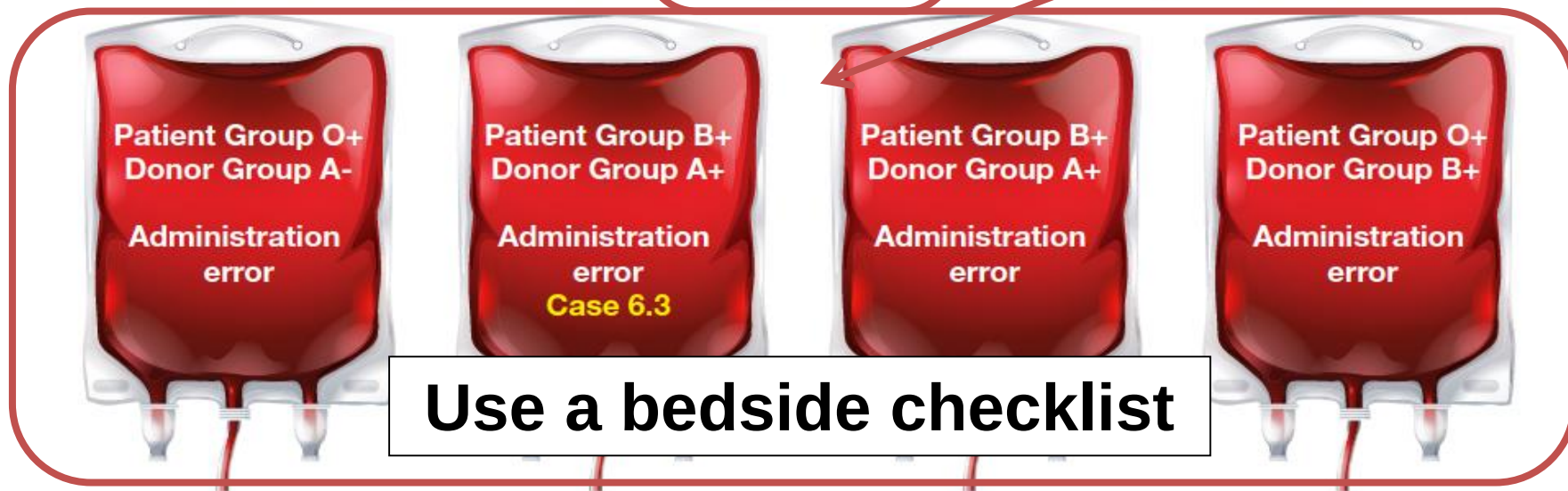
ABO-incompatible red cell transfusions (2015) n=7



in 2016
n=3

1 WBIT

5 administration errors



Death in 2014 from ABO-incompatible transfusion

Filipina nurse who killed a pensioner when she mixed up his name with another patient and gave him the wrong blood during a transfusion is facing jail

- Lea Ledesma was working at London Heart Hospital as a nurse
- She injected Ali Huseyin, 76, with blood meant for Irfan Hussain
- Her blunder caused Mr Huseyin to have a heart attack and die
- She was today found guilty of manslaughter and cried at verdict

By ANTHONY JOSEPH FOR MAILONLINE [Twitter](#)

PUBLISHED: 21:53, 14 December 2016 | UPDATED: 07:42, 15 December 2016

She was respected and experienced and known as 'the mother' of the intensive care unit. She received a suspended sentence



(On a building site in Cardiff)

ABO-incompatible red cell transfusions

3

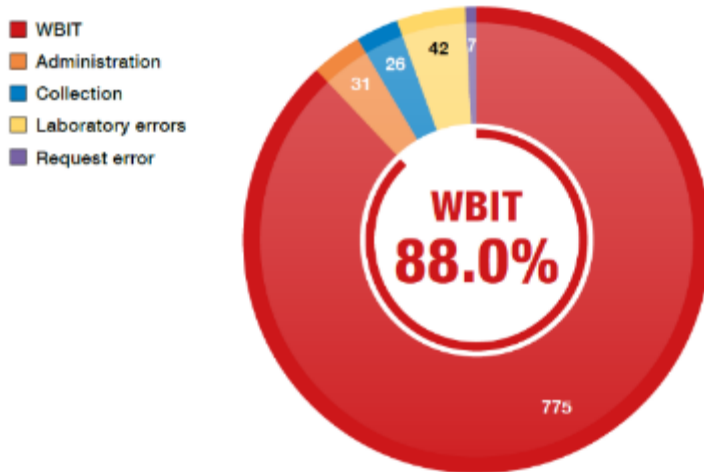
The seriousness of the error is not determined by the patient outcome

Near miss ABO-incompatible transfusions

264

Near miss (n=1283) and wrong blood in tube (n=776*)

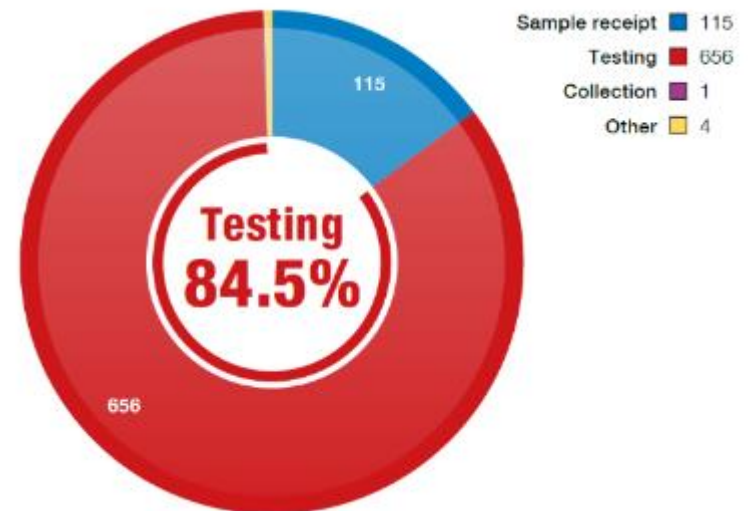
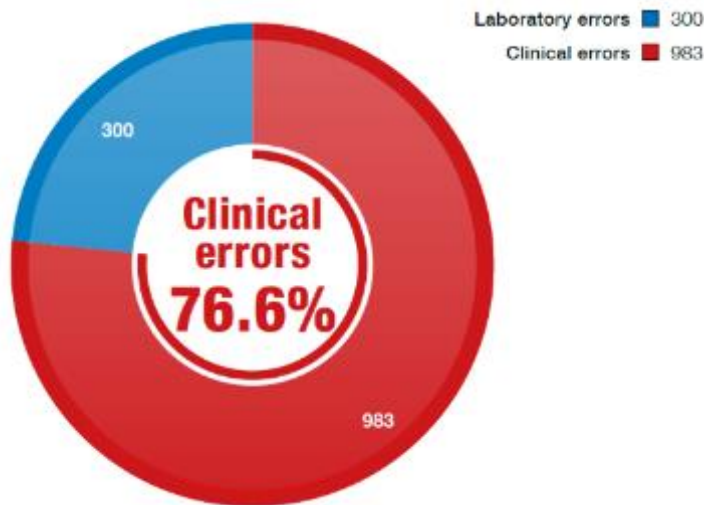
Near miss IBCT-WCT cases n=881



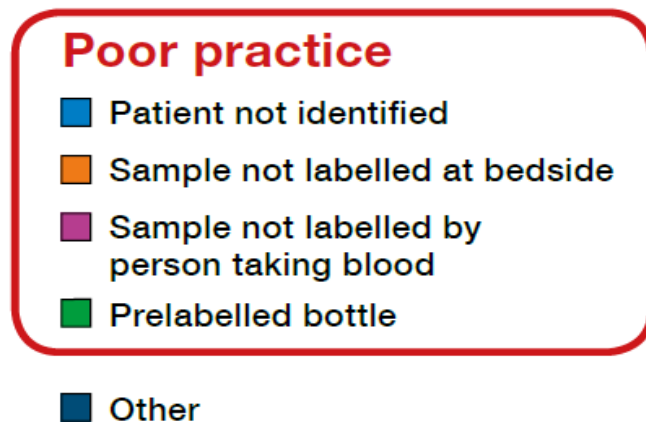
*includes 1 full blood count WBIT

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

Overall source of near miss errors



Practices leading to near miss WBIT incidents n=629/776



Transposed patient ID during phlebotomy leads to ABO incompatible transfusion

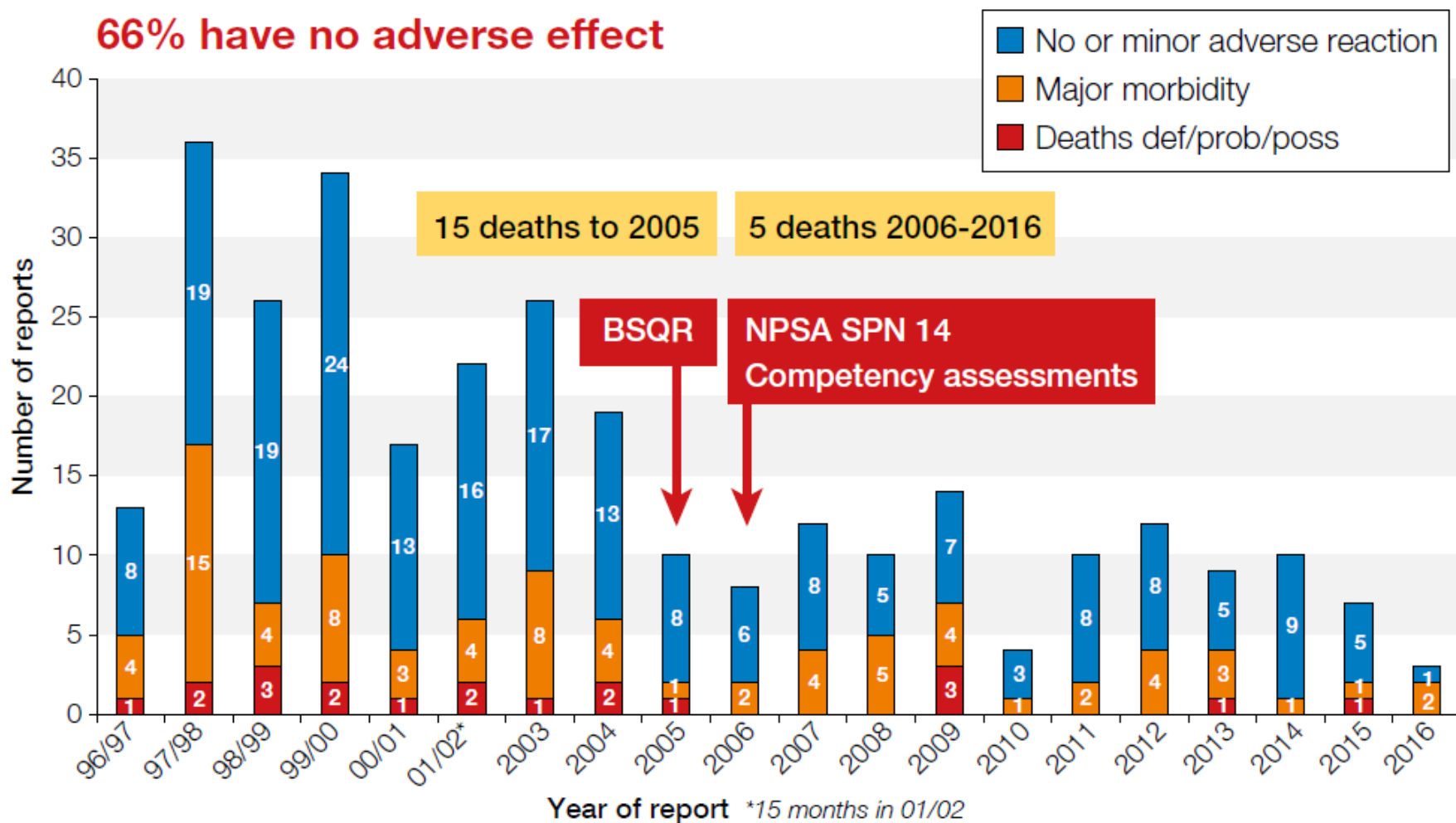
- Patient A, blood group O RhD negative, was transfused 2 units of A RhD positive blood during cardiac surgery
- On arrival in ICU he received two more group A units without apparent adverse events
- Following transfusion, the patient showed evidence of haemolysis, with a fall in Hb requiring further transfusions, and rise in bilirubin to 241mmol/L within 6 days
- He had an extended stay in ITU

One error results in one near miss and one potentially lethal event

- Patient A and patient B were sampled at the same time in a preoperative clinic. The nurse was distracted while bleeding patient A, did not complete the process at the bedside, and so patient details were transposed when labelling the samples
- **Near Miss:** Patient B's mislabelled sample was detected in the laboratory, because a historical group was available
- **Adverse event:** Patient A had no historical group and the error was not detected

Outcome of ABO-incompatible transfusions

66% have no adverse effect



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

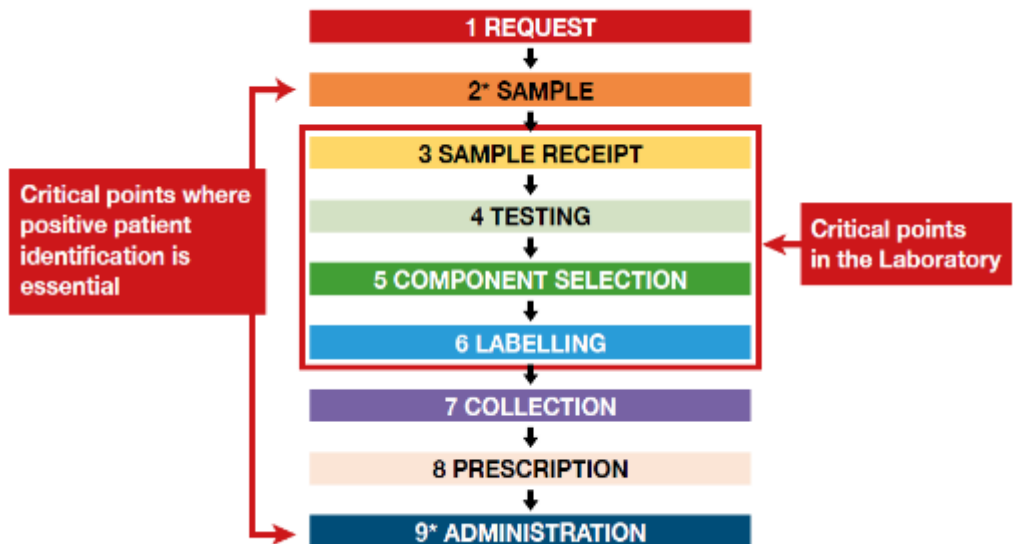
No amount of experience or years of practice will remove the risk of misidentification if you are interrupted or distracted

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)



Recommendation 2014, 2016 and 2017

These **must** be checked at the bedside:

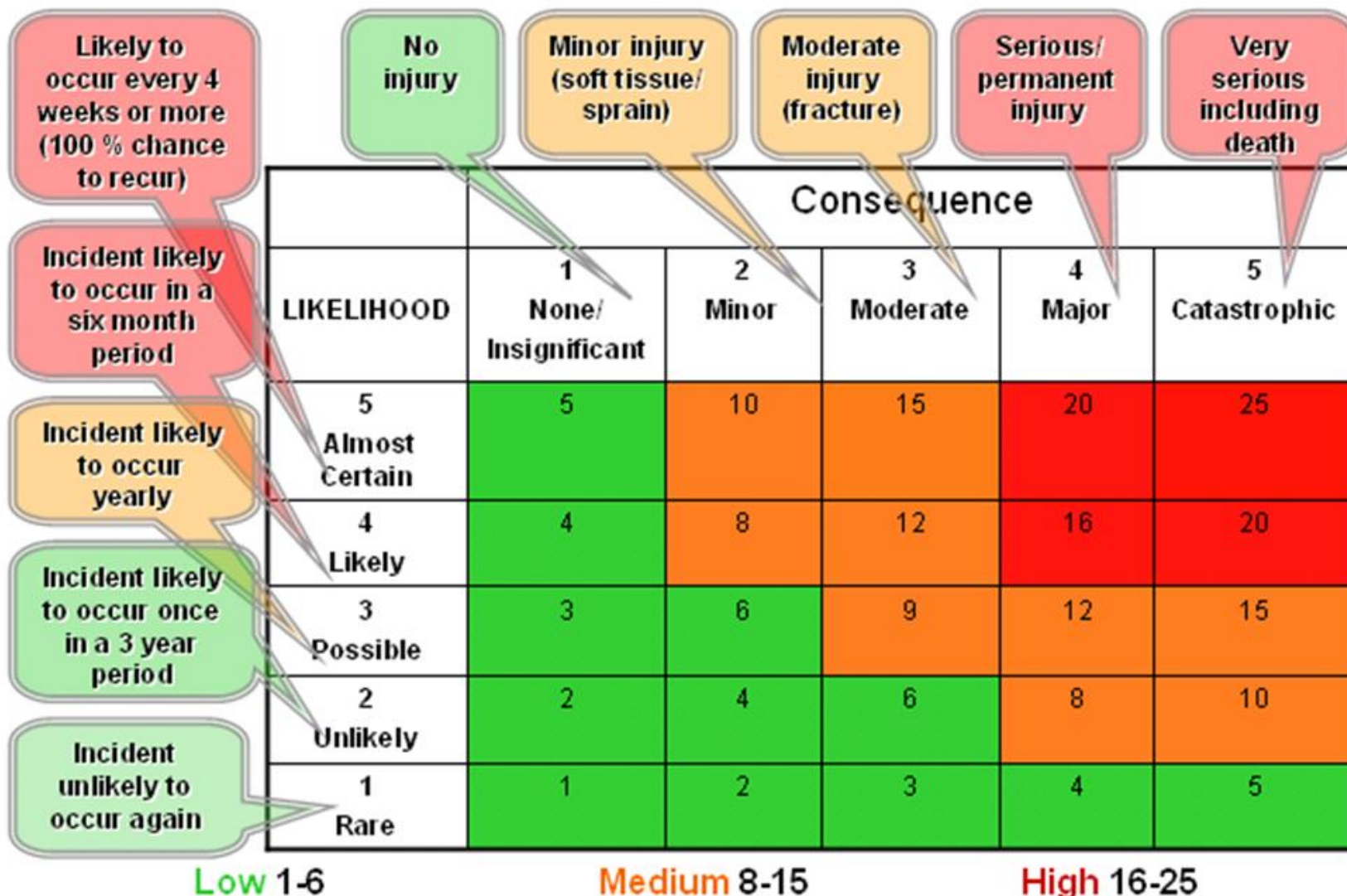
- 1 Positive patient identification
- 2 Check identification of component against patient wristband
- 3 Check the prescription: has this component been prescribed?
- 4 Check the prescription: is this the correct component?
- 5 Check for specific requirements – does the patient need irradiated components or other specially selected units?

Incident investigation and feedback is very important

- Why did it happen?
- What can be learned from it?
- Corrective and preventive actions to reduce likelihood of recurrence

Error reporting – example

- A child with beta thalassaemia major, blood group O, receives 3 mL of an incompatible unit of blood group A
- Recognised early, stopped, no harm done, but kept in hospital overnight for observation
- **Blame culture** – dreadful deed, sack the nurse
- **Just culture** - understand the circumstances which led to this and take action to prevent recurrence



She did not intend to make this mistake but it could have resulted in death, and was very likely to happen again, so was treated as a very serious incident with a high risk score

Investigation – several issues

- The nurse was working alone in the day unit
- Three people needed transfusions – she collected all three units at the same time
- She borrowed a nurse from the next ward to check all three, putting each down on a table beside the patient
- She was using aseptic technique to access the portacath, and the second nurse handed her the wrong unit which was not checked again at the bedside
- Incident recognised when next unit put up with bedside check

Investigation – several issues

Key Root Cause: Collection of three units at the same time, and later failure to do the final bedside check immediately prior to transfusion

- The nurse was working alone in the day unit
- Three people needed transfusions – she collected all three units at the same time
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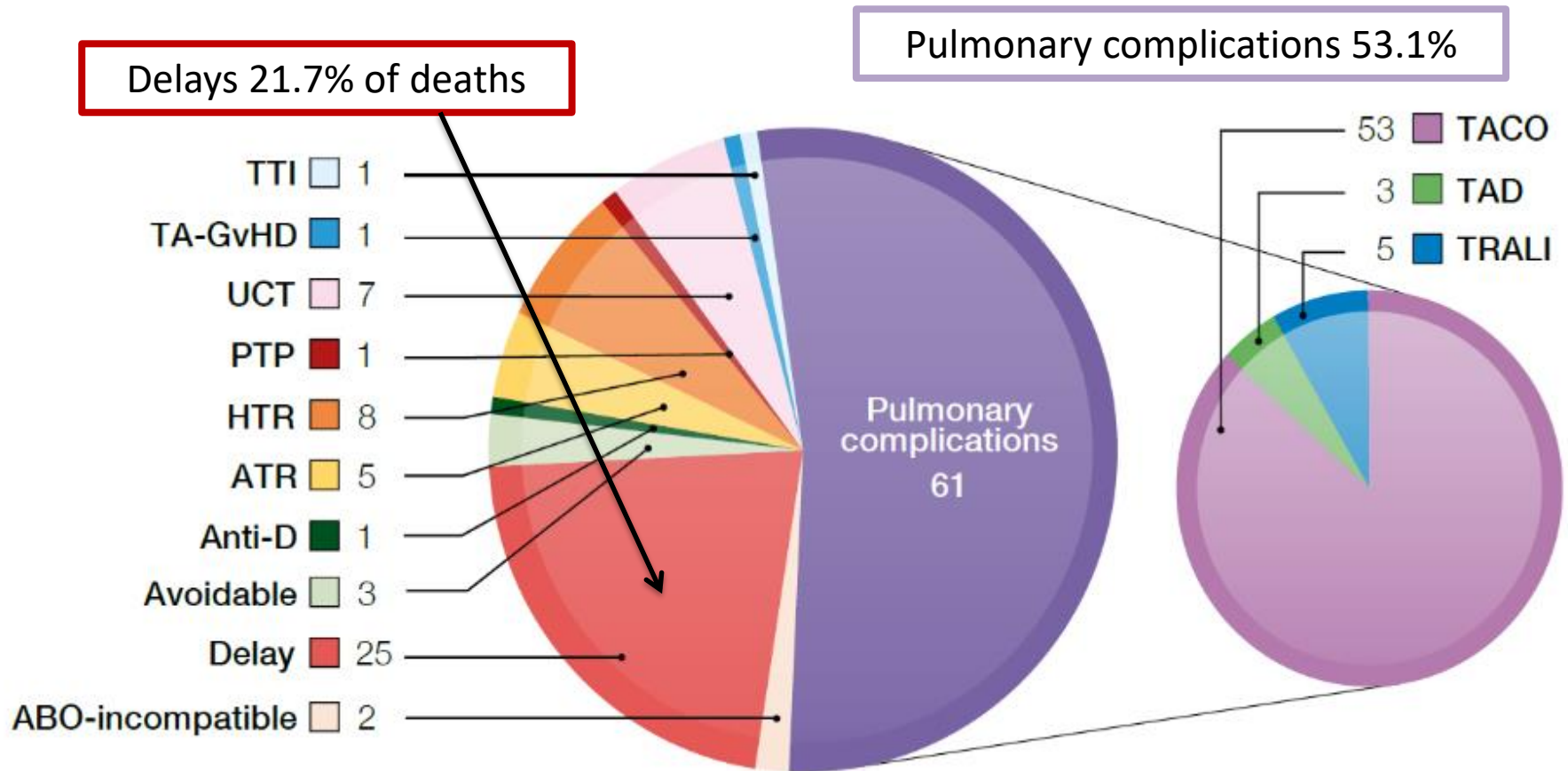
The layout of the day unit was reviewed and changed

The staff were accepting a culture of chronic understaffing – audit showed solo working 75% of the time. Lone working was also associated with a poor record (42%) of correct observations during transfusion. **As a result of this investigation, an additional member of staff was employed**

The transfusion training of both nurses was out of date, and she forgot that collection of more than one unit at a time was against policy but also it was difficult to get away from the ward on three separate occasions while working alone

So, the RCA resulted in several SOLUTIONS to improve the system

Transfusion-related deaths 2010 to 2016 n=115



Acute transfusion reactions (ATR)

- Allergic or anaphylactic reactions are unpredictable and usually occur early
- This is why all patients having blood components must be monitored
- Adrenaline (IM) is the treatment of choice for anaphylaxis and should be available in all areas where transfusions take place

TRALI

- Acute dyspnoea with hypoxia and bilateral pulmonary infiltrates during or within 6h of transfusion, not due to circulatory overload or any other likely causes
- Most suspected cases are complex
- Need expert panel assessment
- Serology: find anti-leucocyte antibodies in donor which react with recipient neutrophil antigens

TRALI

- Can lead to transfusion-related mortality and major morbidity
- Caused by HLA/HNA antibodies, main source is donor plasma:
 - A donor with a history of transfusion
 - A female donor with a history of pregnancy – antibodies in 10-15%

TACO (unsatisfactory definition)

- Any 4 of the following occurring within 6h of transfusion
 - Acute respiratory distress
 - Tachycardia
 - Increased blood pressure
 - Acute or worsening pulmonary oedema
 - Evidence of positive fluid balance

Fatal TACO as a result of transfusion following spurious result

- Female in her 90s was 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”

What would you do next?

- 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 observations or the findings on endoscopy, but patient 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 (TACO) and died shortly afterwards

Life threatening management of iron deficiency

- A woman in her 80s with chronic iron deficiency, Hb 45 g/L
- Transfused 4 units, each over 2.5h
- Developed TACO with tachycardia, hypertension, short of breath etc.
- Intubation, ventilation 2d
- Full recovery

Day case transfusion – what are the risks?

- A woman in her 70s with myeloma, wt 56 kg, was transfused 3 units of red cells as a day case

What are the risk factors for TACO?

- Renal impairment, hypoalbuminaemia, age ≥ 70 years, low bodyweight
- She developed fluid overload and pulmonary oedema with hypertension and hypoxia before the end of the third unit. She initially responded to diuretic and was sent home by a junior doctor
- She was unable to lie flat all night because of shortness of breath
- She was readmitted, to the HDU, within 24 hours with pulmonary oedema and myocardial infarction

Unrecognised delayed haemolytic transfusion reaction (DHTR) at home

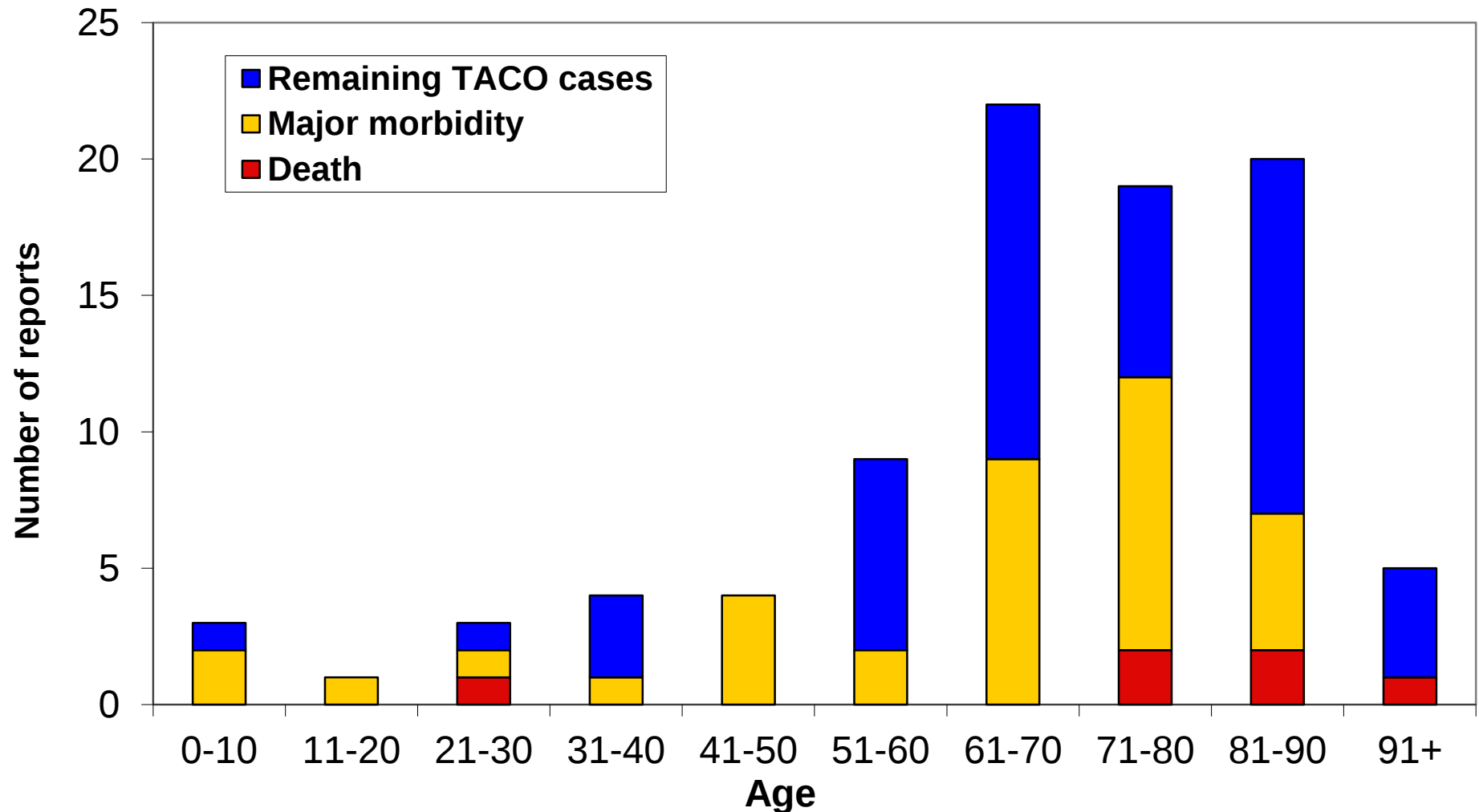
- An elderly woman with myelodysplastic syndrome received two units of red cells on the haematology day unit with no ill effect
- Eight days later she experienced loin pain and passed black urine, which continued for 5 days
- The primary care team prescribed antibiotics, but did not take a urine sample or report this to the haematologist
- It was not until 3 weeks later, when the patient returned to the day unit for an appointment that a DHTR (due to anti-c) was diagnosed

Recommendation 2015

Patients transfused as day cases or outpatients must be given printed advice and a 24-hour contact telephone number and warned to report any adverse symptoms or complications

(BSH guidelines 2009)

TACO can occur at any age



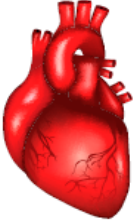
Learning points

- TACO is much more common than TRALI and it can be difficult to confirm the cause of acute respiratory symptoms
- Elderly patients are particularly at risk of TACO
- Even small transfusions may be enough
- All patients need careful monitoring and appropriate investigation

Recommendation 2016

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

Key recommendation 2 – Updated

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.

Transfusion-associated graft vs host disease (TA-GvHD)

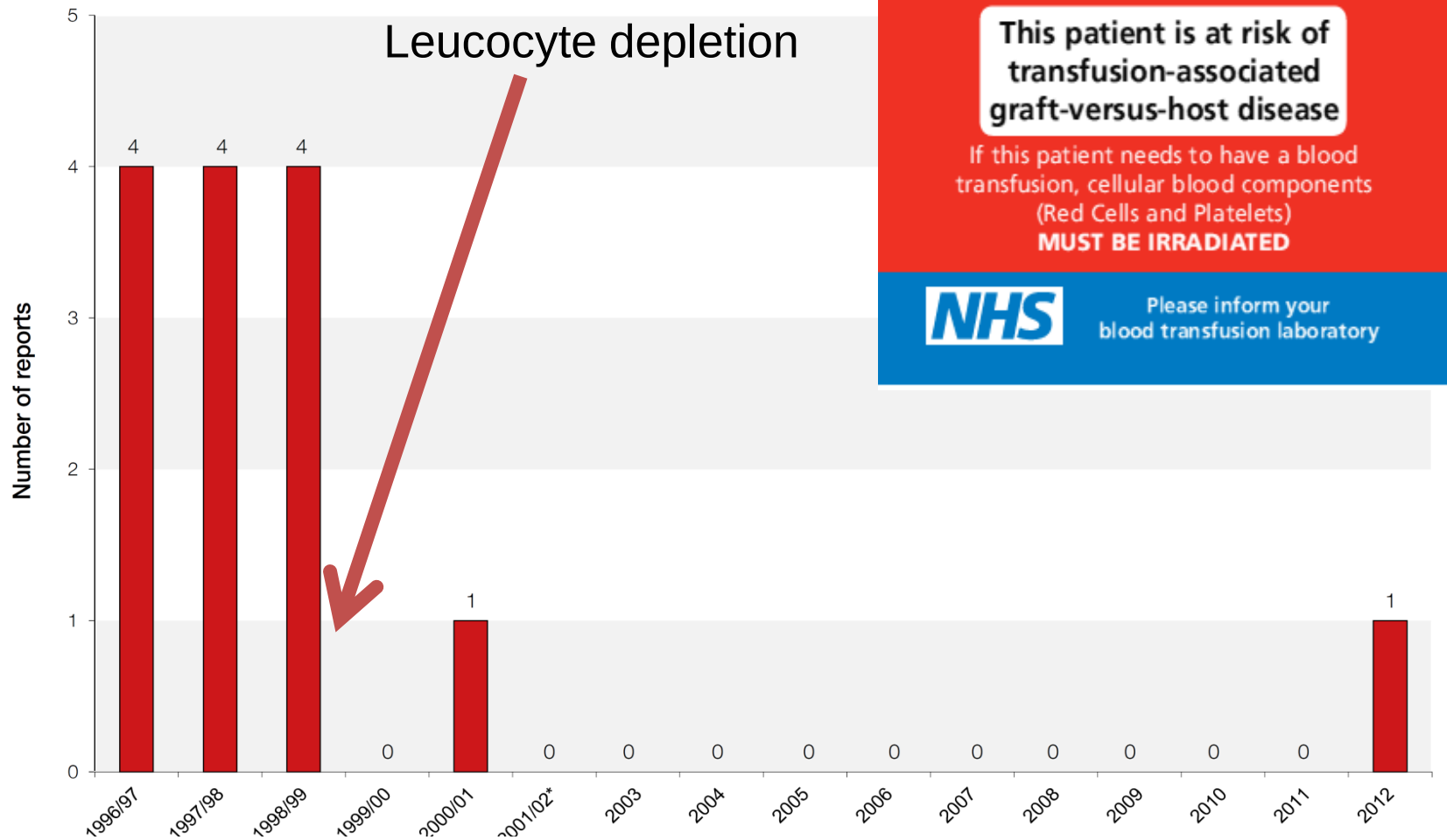
- A lethal condition caused by lymphocytes in transfused blood taking root in an immune compromised recipient
- TA-GvHD cases reported in 1993, 1994, 1996
- Also associated with fresh blood and HLA-relationship
- Guidelines for irradiated blood components 1996 (latest update 2010)

Indications for irradiation

- Immune deficiency
 - Congenital (SCID, CVID, DiGeorge)
 - Acquired
 - IUT and exchange (and any other Tx up to 6mo)
 - Stem cell transplants
 - Solid organ transplants
 - People with Hodgkin lymphoma (lifelong)
 - During and after some types of chemotherapy – purine analogues (fludarabine etc)
- Make sure the patient knows!

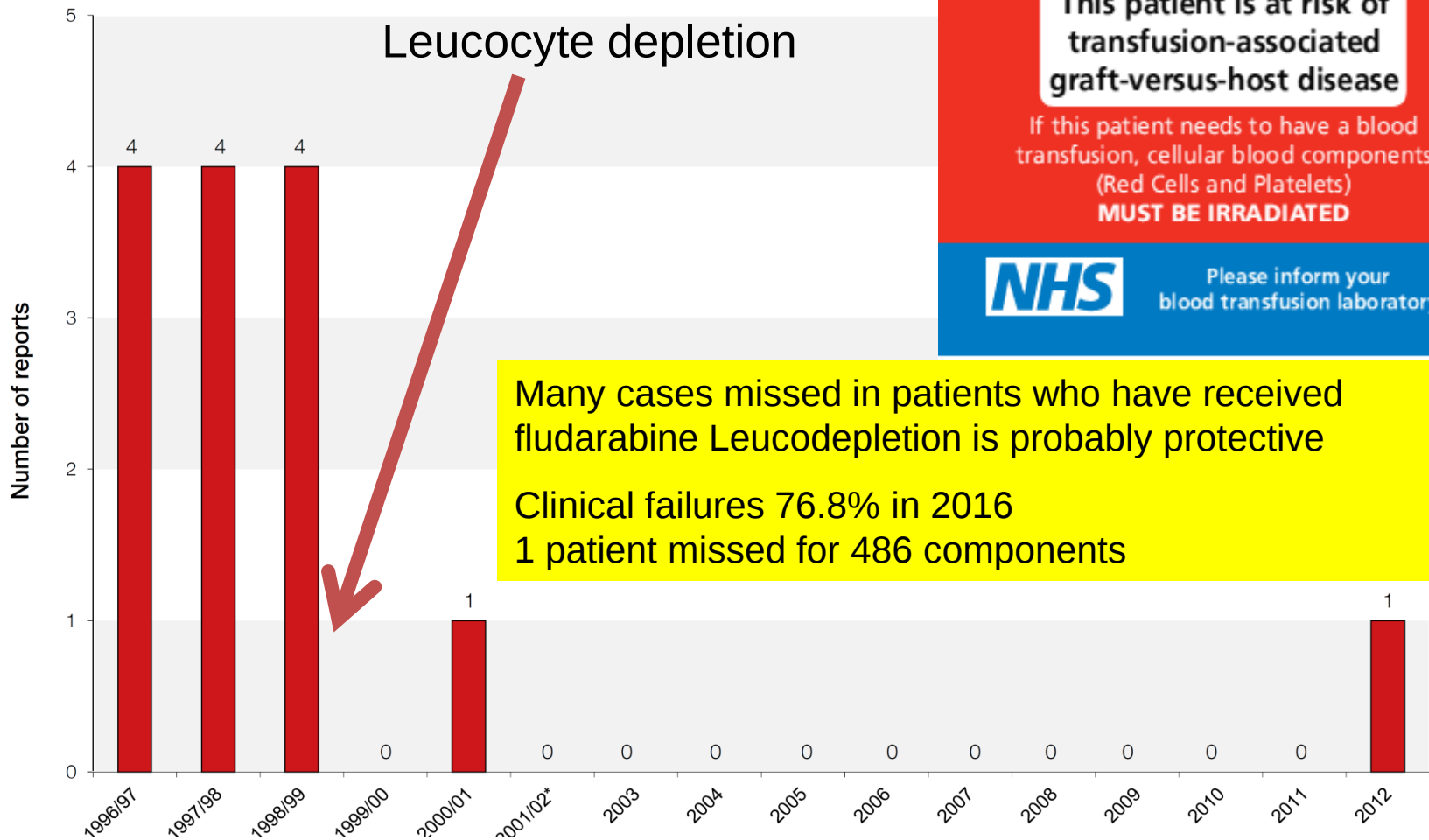
TA-GvHD 1996 – 2016

Omission of irradiation in 1310 patients at risk



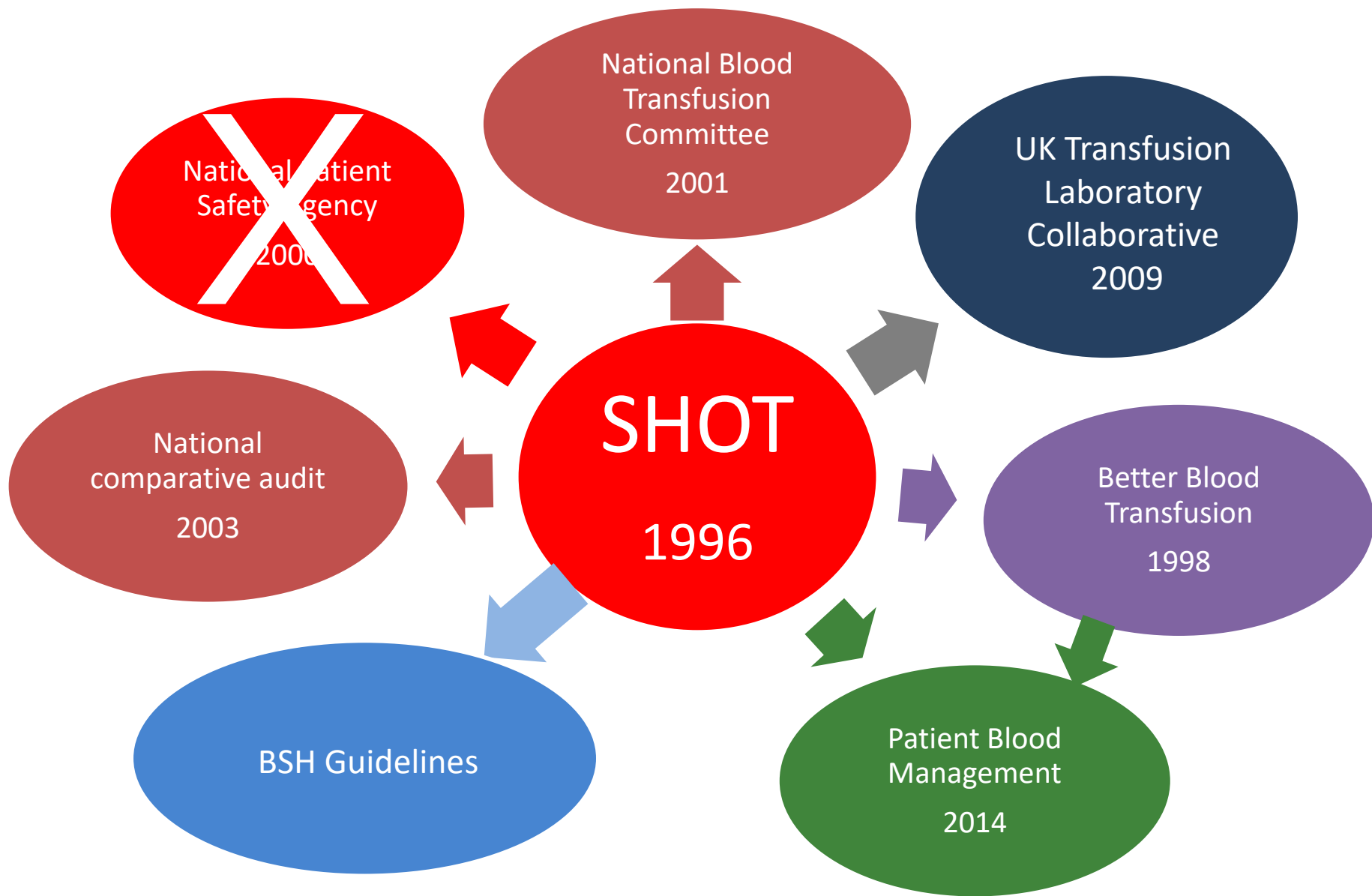
TA-GvHD 1996 – 2016

Omission of irradiation in 1310 patients at risk



Reasons for failure to provide irradiated components

- Haematology clinical staff forget/fail to inform the transfusion laboratory
- Need for irradiation overlooked when patient is admitted to a different specialty or hospital
- Need for irradiation is forgotten when historical (e.g. HD, fludarabine many years before)
- Immune deficiency not recognised (CVID, Di George syndrome)
- Overlooked in infants needing later top-up transfusion after intrauterine or exchange transfusion



National comparative audit of blood transfusion

- A programme of clinical audits looking at use and administration of blood and blood components in England and N Wales
- Funded by NHSBT
- Started 2003, in collaboration with the clinical standards unit of the RCP

http://hospital.blood.co.uk/safe_use/clinical_audit/national_comparative/index.asp

Transfusion safety – 3 critical factors in patient safety

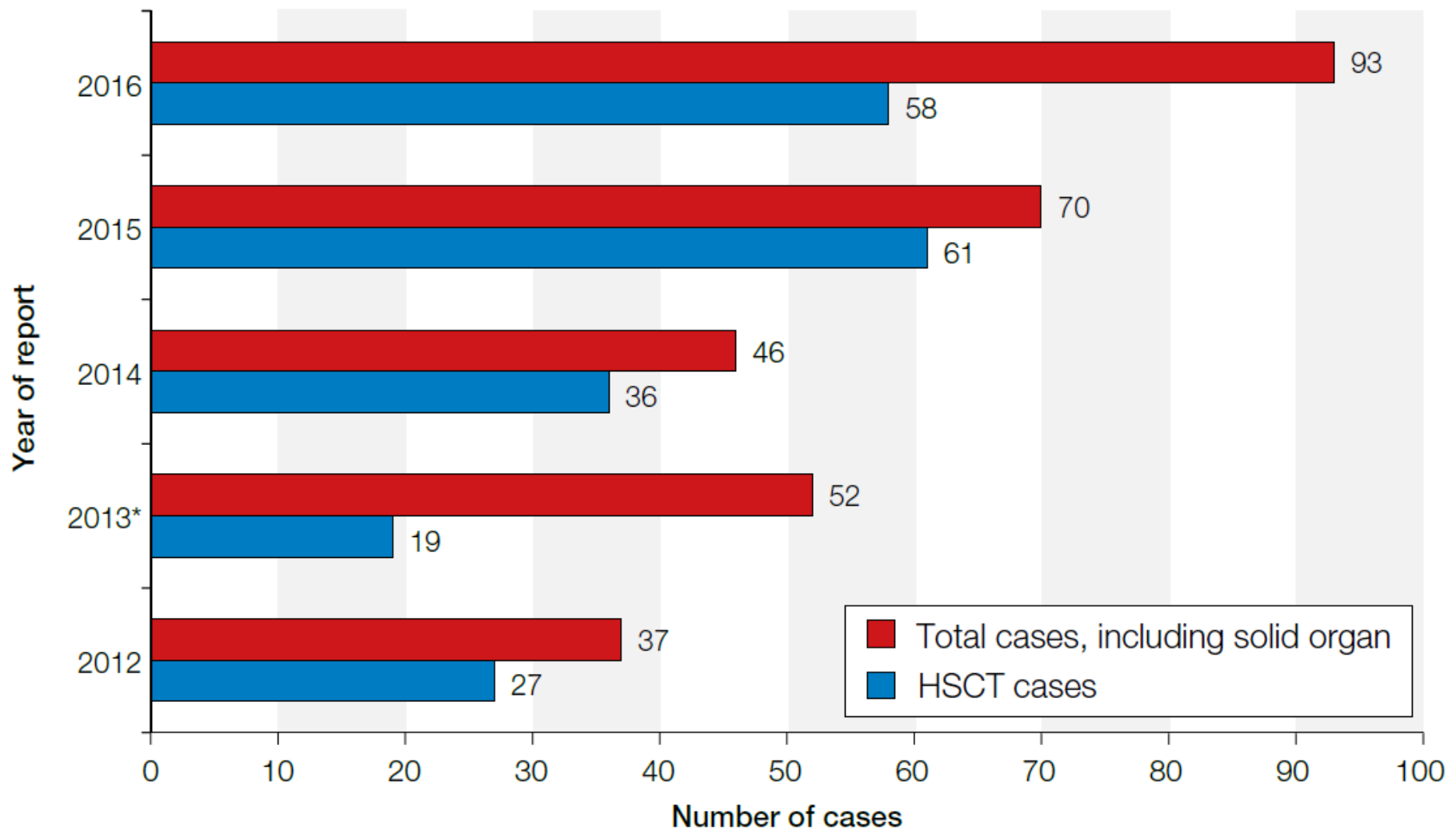
- Identification
- Documentation
- Communication

But these apply in all
areas of medical
practice

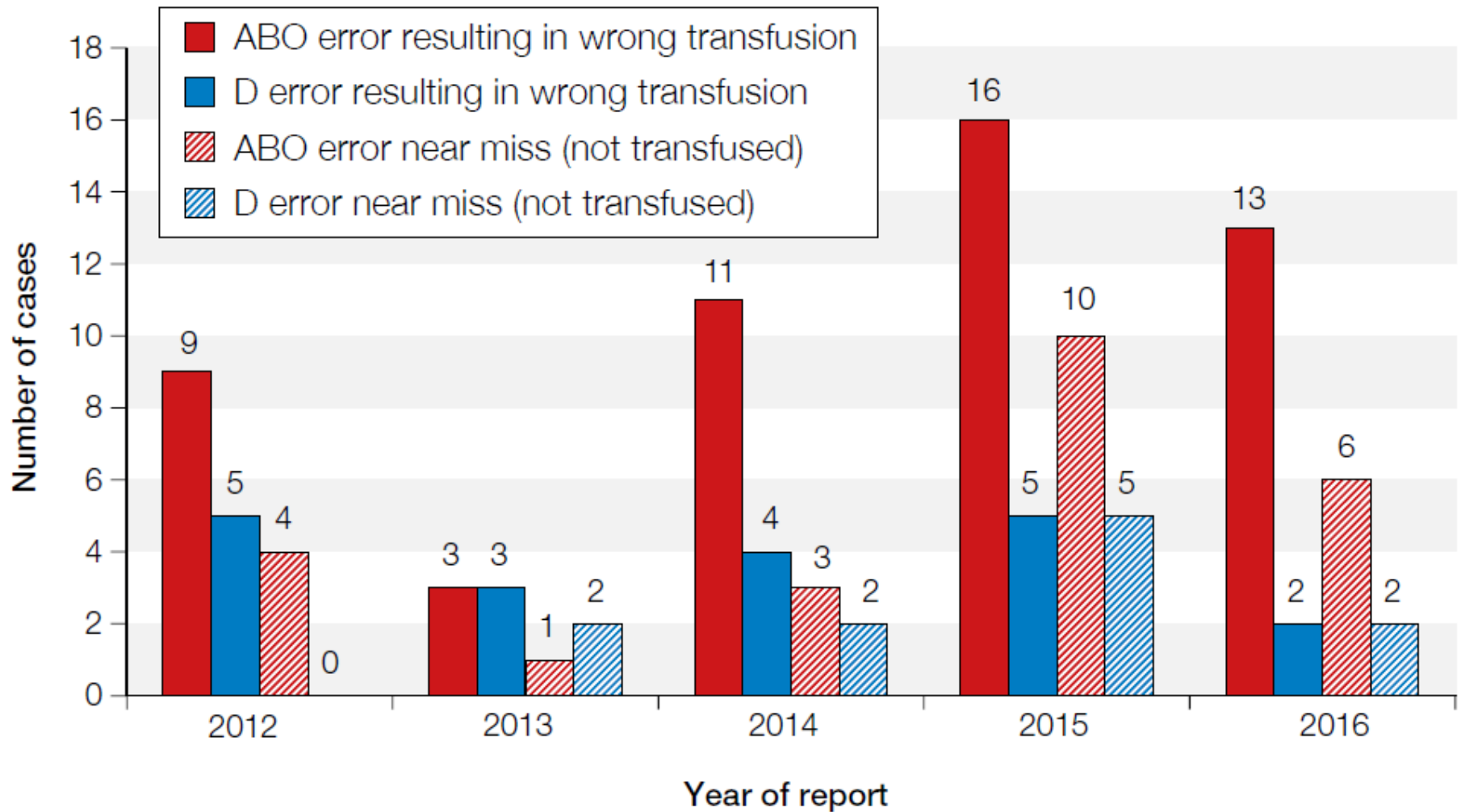
Incorrect ABO group transfused due to lack of communication

- A staff nurse noticed a patient was being transfused with group A red cells, but knew that the patient had received HSCT from his sister, group O, 7 days before
- The nurse contacted the transfusion laboratory who had no record of the transplant
- The transfusion was stopped during the second unit

Transplant-related errors continue to increase



Transplant-related ABO and D errors n=106



Human factors

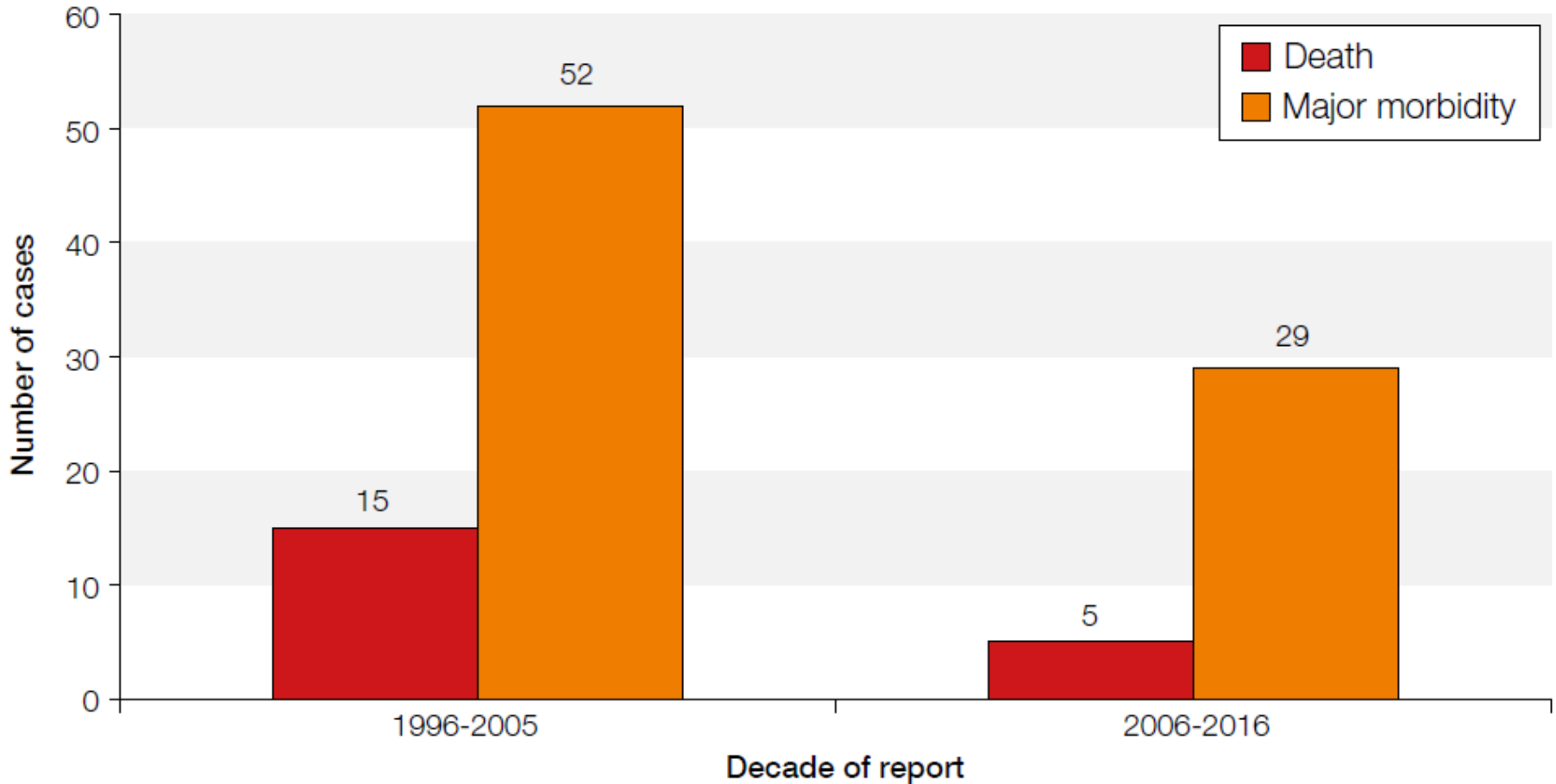
- We all make mistakes and cannot be made perfect by punishment
- Change the working conditions so that ‘the possibility of making errors is reduced and if an error happens, things fail to safety not danger’
- ‘Sign up to Safety’ – a new national patient safety campaign introduced in June 2014
 - Reduce avoidable harm over the next 3 years

Have we made a difference?

- Participation in SHOT increased
 - 22% in 1996 to 100% in 2014
- Reduction in transfusion transmitted bacterial infection
 - better arm cleansing/bacterial screening of platelets
- Reduction in ABO incompatible transfusions; 15 deaths in first decade, 5 in second decade
- Reduction in rates of TRALI by using male donors as far as possible for apheresis platelets and for making pooled platelets

Good news...

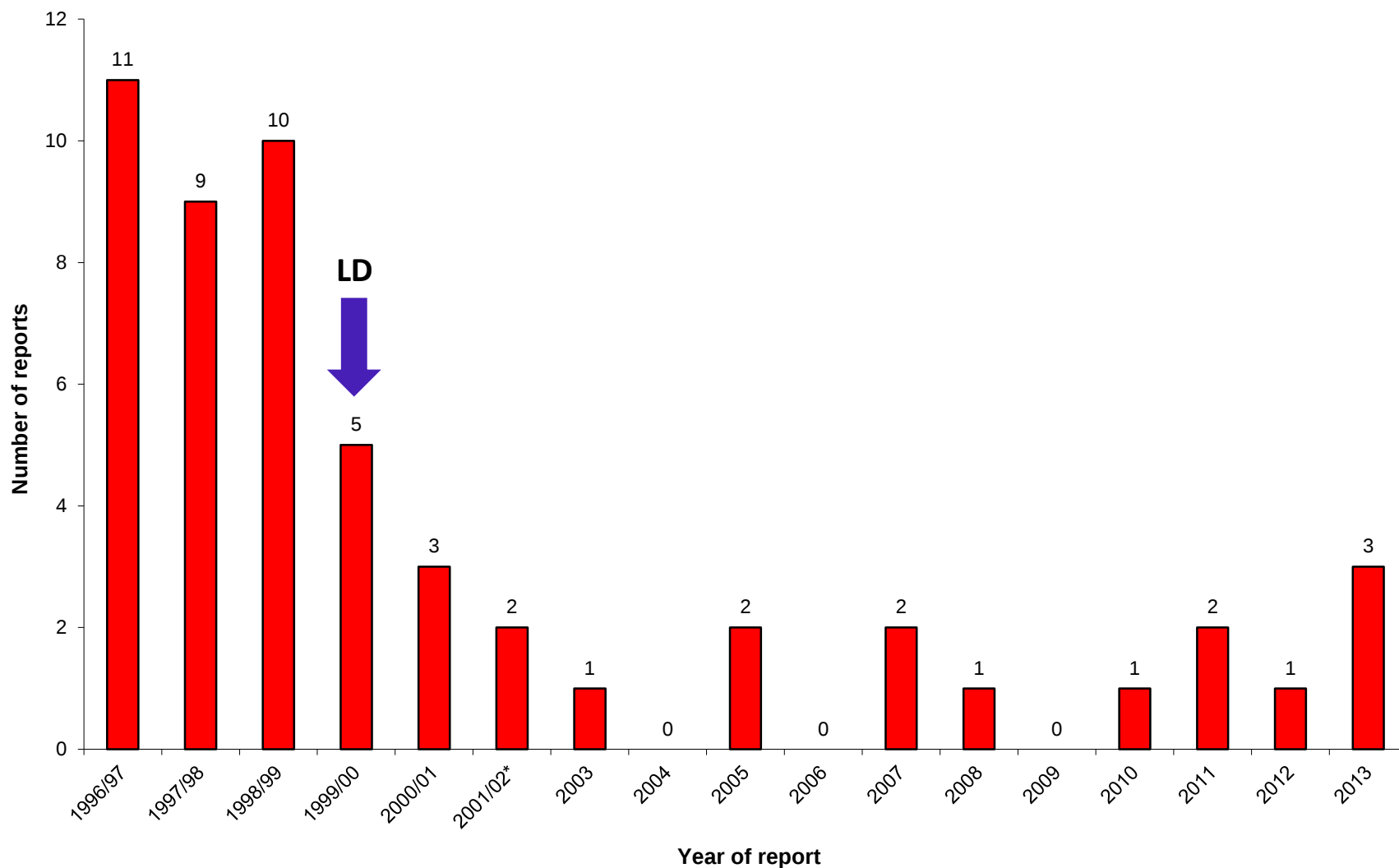
Reduction in ABO-incompatible transfusions



Post-transfusion purpura

- Definition: sudden onset of thrombocytopenia occurring 5-12 d following red cell transfusion associated with antibodies in the patient directed against human platelet antigen systems. More common in women, but rare (1-2 pa)
- Management: IVIg
- Women are at risk of neonatal alloimmune thrombocytopenia in future pregnancies

Post Transfusion Purpura 1996 - 2013



Additional Information

Following documents available on website www.shotuk.org

- Teaching slide set
- SHOT Bites
- SHOT Cases
- Figures from SHOT Report
- SHOT reporting definitions

Also available:

- Previous SHOT reports
- SHOT summaries
- Supplementary information



Acknowledgements

- **SHOT Team in Manchester**
- **SHOT Working and Writing Expert Group**
- **SHOT Steering Group**
- **UK NHS Organisations for reporting**

SHOT Symposium 2018
The Lowry Centre, Salford Quays
Thursday 12th July 2018

Cases and examples

Report to SHOT or not? 1

- A porter collected a unit of blood for a patient but did not complete the necessary paperwork at the transfusion laboratory issue fridge
- The blood was taken to the ward and administered to the correct patient following independent checking by two nurses

SHOT or not? 1

- A porter collected a unit of blood for a patient but did not complete the necessary paperwork at the transfusion laboratory issue fridge
- The blood was taken to the ward and administered to the correct patient following independent checking by two nurses

Report to MHRA as a serious adverse event, because collection from the fridge is covered by the BSQR and staff collecting blood must be competent

Not reportable to SHOT

SHOT or not? 2

- A unit of blood for patient A was collected from the issue fridge by a staff nurse but was taken to the bedside of patient B
- No formal identity checks were performed, the giving set was inserted into the bag. It was connected to the patient but a second staff nurse noticed the error before any blood was transfused

SHOT or not? 2

- A unit of blood for patient A was collected from the issue fridge by a staff nurse but was taken to the bedside of patient B
- No formal identity checks were performed, the giving set was inserted into the bag. It was connected to the patient but a second staff nurse noticed the error before any blood was transfused

Not reportable to the MHRA – clinical error not covered by BSQR
Reportable to SHOT as a near miss

SHOT or not? 3

- A middle aged woman with known ALD presented with haematemesis, Hb 113 g/L
- Transfused 7 units without assessment
- Post transfusion Hb 164 g/L, venesected 2 units and admitted to HDU for ventilation for pulmonary oedema
- Died of multi-organ failure, death related to transfusion

SHOT or not? 3

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Reportable to both MHRA and SHOT (TACO) as a serious adverse reaction but also inappropriate transfusion

SHOT or not? 4

- The wrong sample was selected for testing so that a patient was grouped as AB RhD pos and transfused 3 units
- The correct group was A RhD pos, and this was identified when a second sample was sent a week later
- The patient suffered no ill effects

SHOT or not? 4

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- The patient suffered no ill effects

This is reportable to both MHRA as a laboratory quality incident:
Serious Adverse Event, SAE

and also to SHOT as an IBCT, Incorrect Blood Component Transfusion

If the patient had reacted to the transfusion this would be SAR

Case 1

- WBIT incident detected
- Occurred 3 days before implementation of “Group check” sample
Emergency department sample was A Pos
- Anaesthetist sample sent pre-op was B Pos

NEAR MISS

(Unexpected repeat sample prevents selection of ABO-incompatible blood)

Case 2

AVOIDABLE TRANSFUSION

(inappropriate transfusion of patient with iron deficiency)

- 57 year old woman pre op hip replacement.
- Hb 62 g/L
- Tx prescribed by orthopaedic trainee
- Attended day case unit and no medical review prior to transfusion
- Results review retrospectively showed clear evidence of iron deficiency
- Two months later G&S sample identified anti-S, anti-E and anti-Lua

Case 4

ANTI-D (Laboratory assumption regarding maternal sample)

- Mother and cord samples sent to lab
- Maternal sample rejected due to incomplete labelling
- Cord sample D negative
- Repeat maternal sample arrived
- BMS assumed was for PSE and issued 500IU anti-D Ig

Case 5

RIGHT BLOOD RIGHT PATIENT (RBRP)
(Duplicate records merged on hospital computer system causing patient's hospital number to change)

- Baby admitted to SCBU, registered with 2 Hospital numbers
- Blood components issued using HN1
- Further request 2 days later, BMS noted HN2 was being used, wristband had been changed. Sample requested by BMS
- Investigation revealed all components issued after the change had different hospital number on component to that on wristband

Scenario 1

- 00:20 – patient transfused wrong unit of red cells
 - donor unit AB RhD Neg, recipient O RhD Pos
- 03:45 – observations changed, patient deteriorated
- 16:10 - patient died
 - Who would you report this to?
 - What would you report as?
 - What further information would you need to define the root cause and CAPA?

Scenario 1

- 00:20 – patient transfused wrong unit of red cells
 - donor unit AB RhD Neg, recipient O RhD Pos
- 03:45 – observations changed, patient deteriorated
- 16:10 - patient died
 - Who would you report this to? **Both**
 - What would you report as? **SAR/IBCT**
 - What further information would you need to define the root cause and CAPA? **Full details to understand WHY**

Scenario 2

- 47 year old male patient – no prev Tx history
- 2 units of 'standard' blood XM and dispatched to local community hospital and transfused
- Request form indicated that irradiated units were required
- Special requirements were not entered onto computer as per SOP
 - Who would you report this to?
 - What would you report as?
 - a) Incorrect blood component issued
 - b) Component collection error
 - c) Data entry error
 - What further information would you need to define the root cause and CAPA
 - What is the most likely root cause of this incident?
 - Based on your answer to this what do you think the most appropriate corrective action might be?

Scenario 2

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- 2 units of 'standard' blood XM and dispatched to local community hospital and transfused
- Request form indicated that irradiated units were required
- Special requirements were not entered onto computer as per SOP
 - Who would you report this to? **MHRA as SAE and SHOT as SRNM**
 - What would you report as?
 - a) Incorrect blood component issued
 - b) Component collection error
 - c) Data entry error
 - What further information would you need to define the root cause and CAPA
 - What is the most likely root cause of this incident?
 - Based on your answer to this what do you think the most appropriate corrective action might be?

Scenario 3

- 3 units of red cells were packed correctly in a transport box and taken to Theatre
- Transport box validated for 6 hours
- Box was discovered 24hrs later, red cells unused.
 - Who would you report this to?
 - What would you report as?
 - What further information would you need to define the root cause?
 - What corrective and preventive measures would you suggest?

Scenario 3

- 3 units of red cells were packed correctly in a transport box and taken to Theatre
- Transport box validated for 6 hours **Max 4h**
- Box was discovered 24hrs later, red cells unused.
 - Who would you report this to? **MHRA as SAE**
 - What would you report as?
 - What further information would you need to define the root cause?
 - What corrective and preventive measures would you suggest?