How SHOT has informed Patient Blood Management

Paula Bolton-Maggs
Medical Director
Serious Hazards of Transfusion

Transfusion, a significant advance

- Blood transfusion is life-saving and good
- It has enabled surgery and chemotherapy
- It is of high quality and safe

- Or is it?

Lessons from haemophilia

- The importance of registries, data collection and surveillance

BRITISH MEDICAL JOURN

929

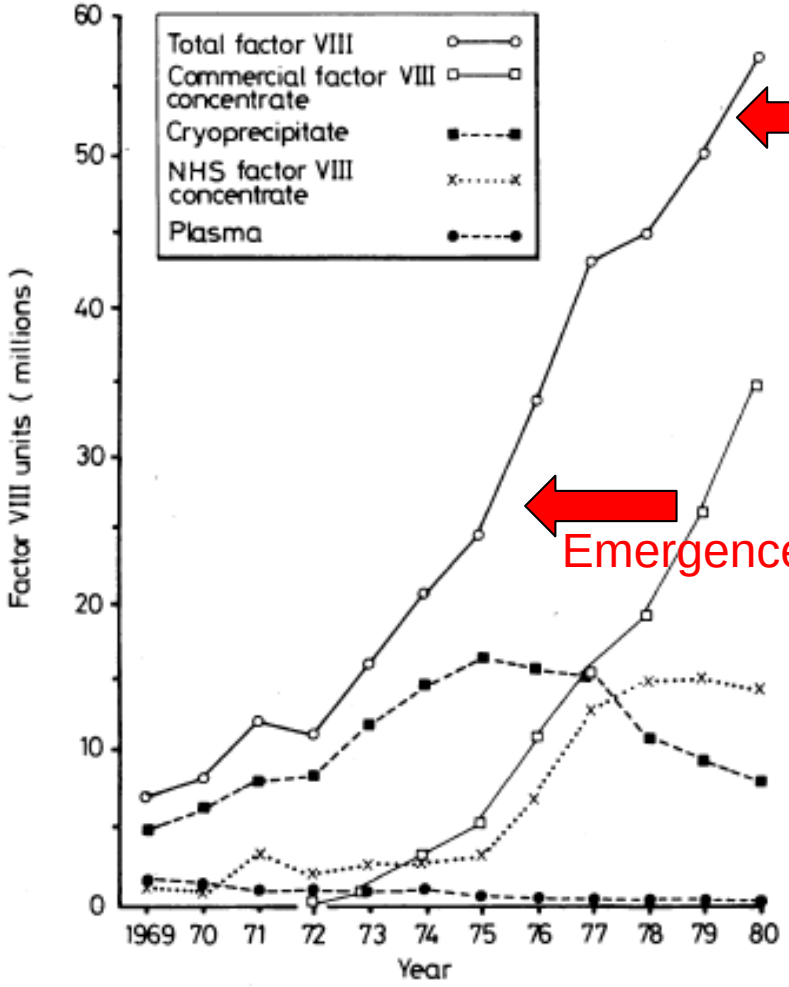
REPORTS

The UK national haemophilia database from 1968

Treatment
and North
directors o

s in Britain
behalf of the
Kingdom

C R RIZZA, ROSI



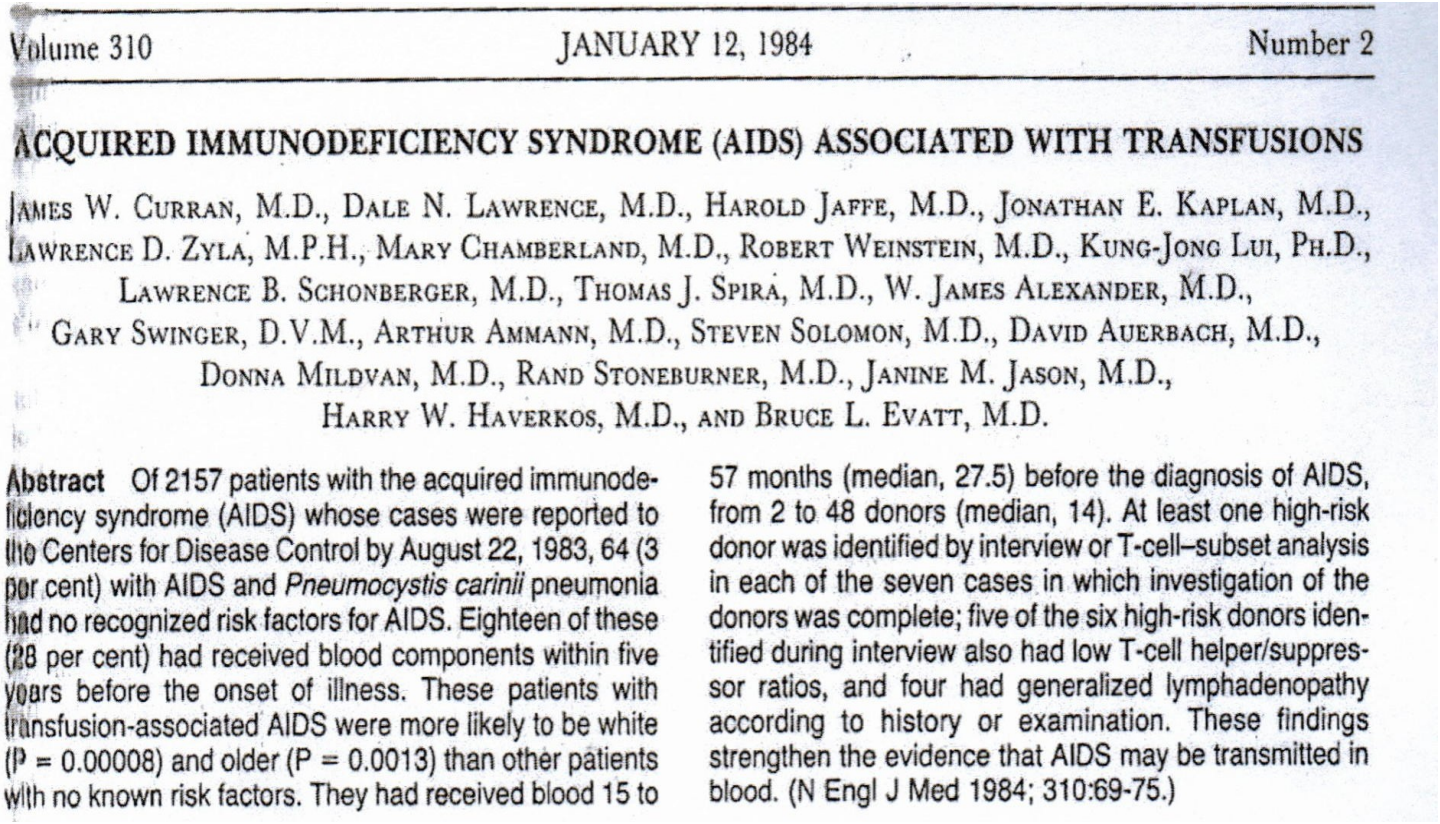
HIV seroconversions

Emergence of hepatitis

FIG 2—Amount of different types of materials containing factor VIII and total amount of factor VIII activity units used each year during 1969-80 by haemophilia centres in United Kingdom to treat patients for haemophilia A.

Confirmed link between transfusion and AIDS – 2157 patients with AIDS: There were 64 individuals with no risk factors, 18/64 (28%) had previously been transfused

NEJM



Volume 310 JANUARY 12, 1984 Number 2

ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS) ASSOCIATED WITH TRANSFUSIONS

James W. Curran, M.D., Dale N. Lawrence, M.D., Harold Jaffe, M.D., Jonathan E. Kaplan, M.D., Lawrence D. Zyla, M.P.H., Mary Chamberland, M.D., Robert Weinstein, M.D., Kung-Jong Lui, Ph.D., Lawrence B. Schonberger, M.D., Thomas J. Spira, M.D., W. James Alexander, M.D., Gary Swinger, D.V.M., Arthur Ammann, M.D., Steven Solomon, M.D., David Auerbach, M.D., Donna Mildvan, M.D., Rand Stoneburner, M.D., Janine M. Jason, M.D., Harry W. Haverkos, M.D., and Bruce L. Evatt, M.D.

Abstract Of 2157 patients with the acquired immunodeficiency syndrome (AIDS) whose cases were reported to the Centers for Disease Control by August 22, 1983, 64 (3 per cent) with AIDS and *Pneumocystis carinii* pneumonia had no recognized risk factors for AIDS. Eighteen of these (28 per cent) had received blood components within five years before the onset of illness. These patients with transfusion-associated AIDS were more likely to be white ($P = 0.00008$) and older ($P = 0.0013$) than other patients with no known risk factors. They had received blood 15 to 57 months (median, 27.5) before the diagnosis of AIDS, from 2 to 48 donors (median, 14). At least one high-risk donor was identified by interview or T-cell–subset analysis in each of the seven cases in which investigation of the donors was complete; five of the six high-risk donors identified during interview also had low T-cell helper/suppressor ratios, and four had generalized lymphadenopathy according to history or examination. These findings strengthen the evidence that AIDS may be transmitted in blood. (N Engl J Med 1984; 310:69-75.)

Definition of Haemovigilance

- Surveillance procedures from the collection of blood and its components to the follow up of the recipients
- To collect and assess information on unexpected and undesirable effects resulting from the therapeutic use of labile blood components
- To prevent their occurrence or recurrence

SHOT

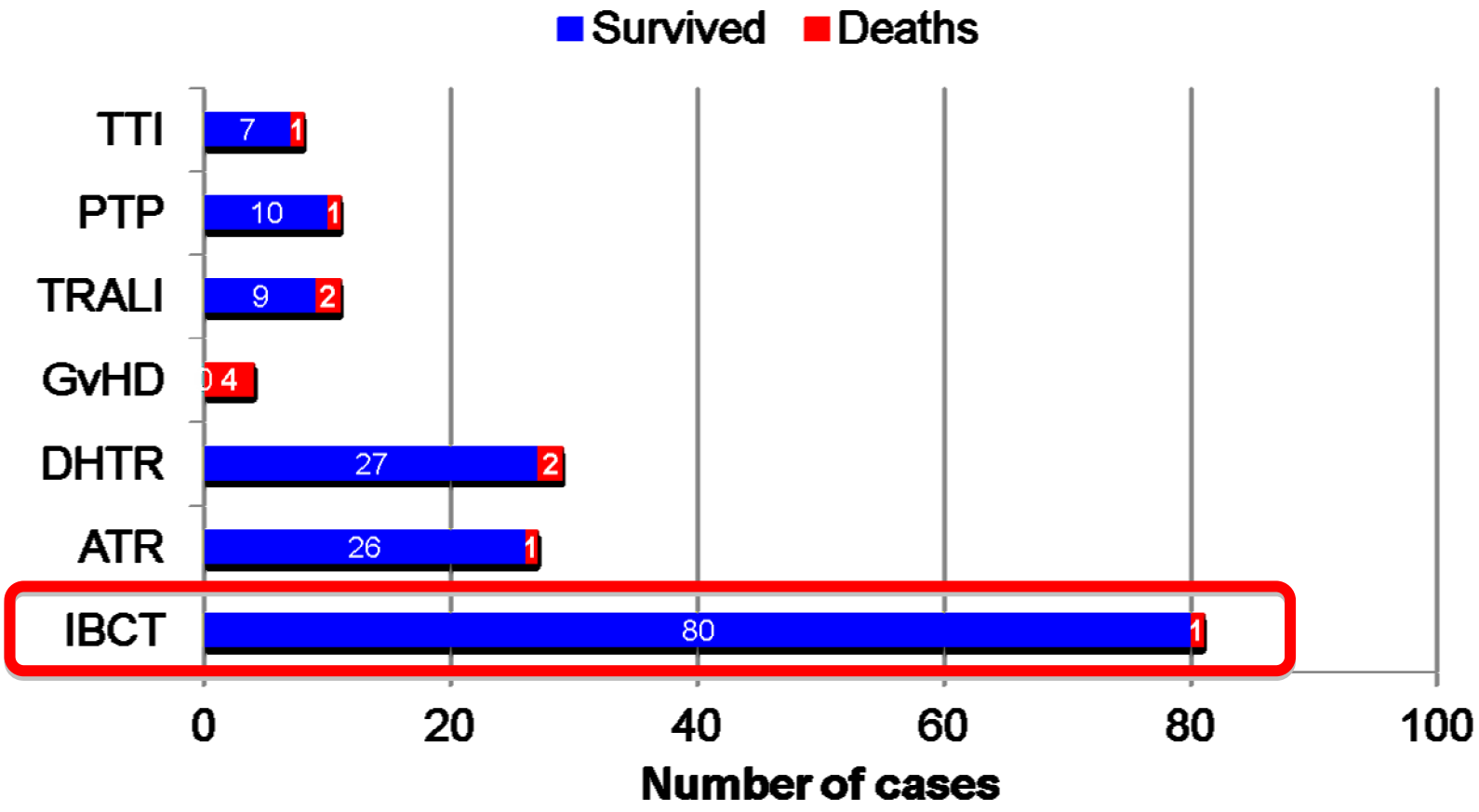
- In 1990s - growing awareness of safety issues in blood transfusion
  - especially HIV, HCV, hospital errors
    (McClelland BMJ 1994;308:1205)
  - Incidence of major complications of blood transfusion was unknown
- Working group set up in 1994 to consider haemovigilance – SHOT launched 1996
- SHOT report first published in 1998 for 1996-1997 data
  - Increasing number of reports each year
  - Evolution of new categories reflecting reports
- 18th report (2014 data) published July 2015
- Data owned by the steering group

Aims of Haemovigilance

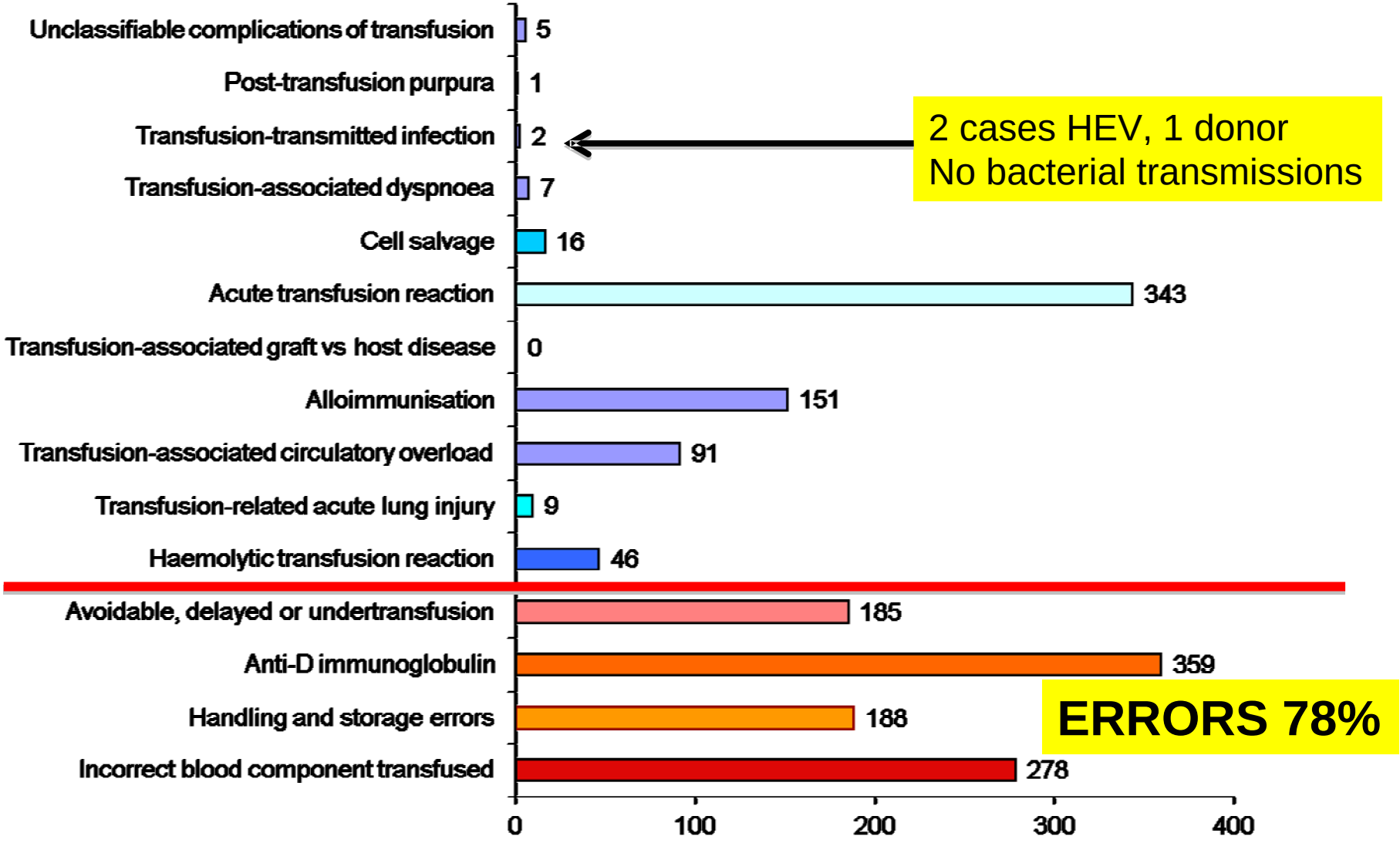
- Identify trends in adverse reactions and events
- Inform policy within transfusion services, DH, EU
- Through the Royal Colleges and professional bodies, target areas for improvement of practice
  - Aid production of clinical guidelines for use of blood components
  - Promote development of suitable education and training
  - Identify and promote standards of practice
- Stimulate research and detailed audit
- Raise awareness of transfusion hazards and their prevention
- Be an ‘early warning’ of new complications

The greatest risk from transfusion is that somebody (or several somebodies) will make a mistake (or several mistakes)

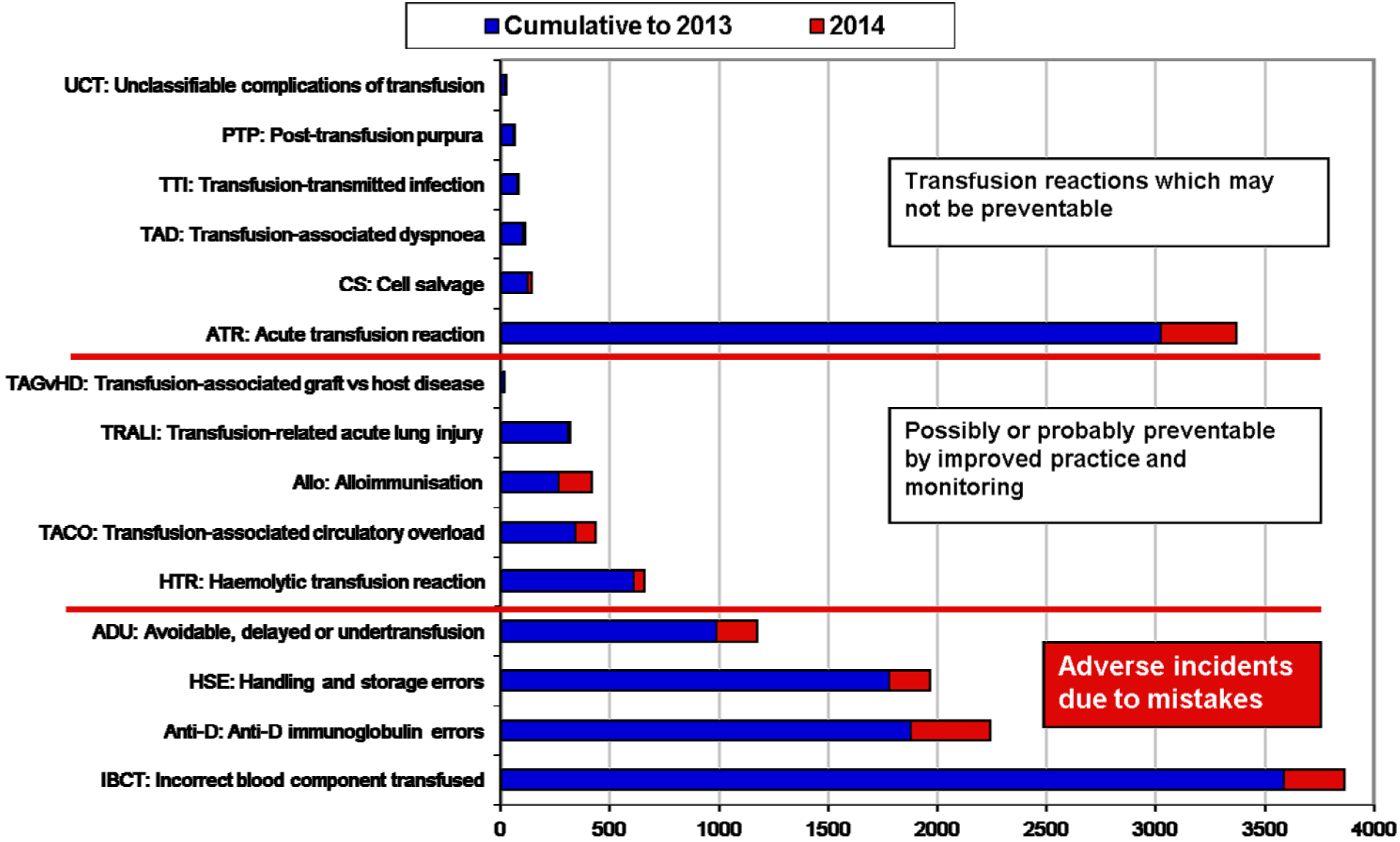
Data from 1st SHOT Report



Cases reviewed in 2014



SHOT Cumulative data: 18 years n=14822



1st SHOT Report March 1998

- 81/169 (47%): patient received component intended for another patient, 1 death and 9 cases of morbidity
- 2/3 involved a series of up to 6 errors
  - Collection errors in 30 cases
  - Failure of bedside check
  - Wrong blood in tube resulted in death from ABO mismatch
- Each hospital should have a transfusion committee

2nd SHOT Report 2000

- 144/252 (57%) wrong component transfused
- Final bedside check must be done
- ‘Information technology will prevent human error’
- Need for strategies for TRALI prevention
- There should be an overarching body to prioritise new initiatives in blood safety

‘Better Blood Transfusion’
1998, 2002 & 2007

Concerns:

- Patient safety: errors, vCJD
- Demand for blood and shortages
- Evidence of variation in practice

Health Service Circulars:

- HTC/HTTs, NBTC, RTC
- Guidelines, audits
- Support from NHSBT
- Patient involvement
- Use of technology
- Clinical research

Health Service Circular 1998

NHS Executive

Series number: HSC 1998/224
Issue date: 11 December 1998
Review date: 11 December 2001
Category: Clinical Effectiveness
Status: Action
sets out a specific action on the part of the recipients

Better Blood Transfusion

Make transfusion safer, avoi… unnecessary use and … in obstetrics

Symposium on Evidence-based Blood Transfusion UK CMOs July 1998

Transfusion practitioners

DH Department of Health

…ervice Circular

Series Number: HSC 2002/009
Issue Date: 04 July 2002
Review Date: 04 July 2005
Category: Public Health
Status: Action
sets out a specific action on the part of the recipient with a deadline where appropriate

2002

Better Blood Transfusion
Appropriate Use of Blood

DH Department of Health

Health Service Circular

Series Number: HSC 2007/001
Gateway Reference: 9058
Issue Date: November 2007

2007

Better Blood Transfusion
Safe and Appropriate Use of Blood

Much more detailed instructions including SHOT reporting, national audit
Establish hospital transfusion teams with consultant, TP and transfusion laboratory manager

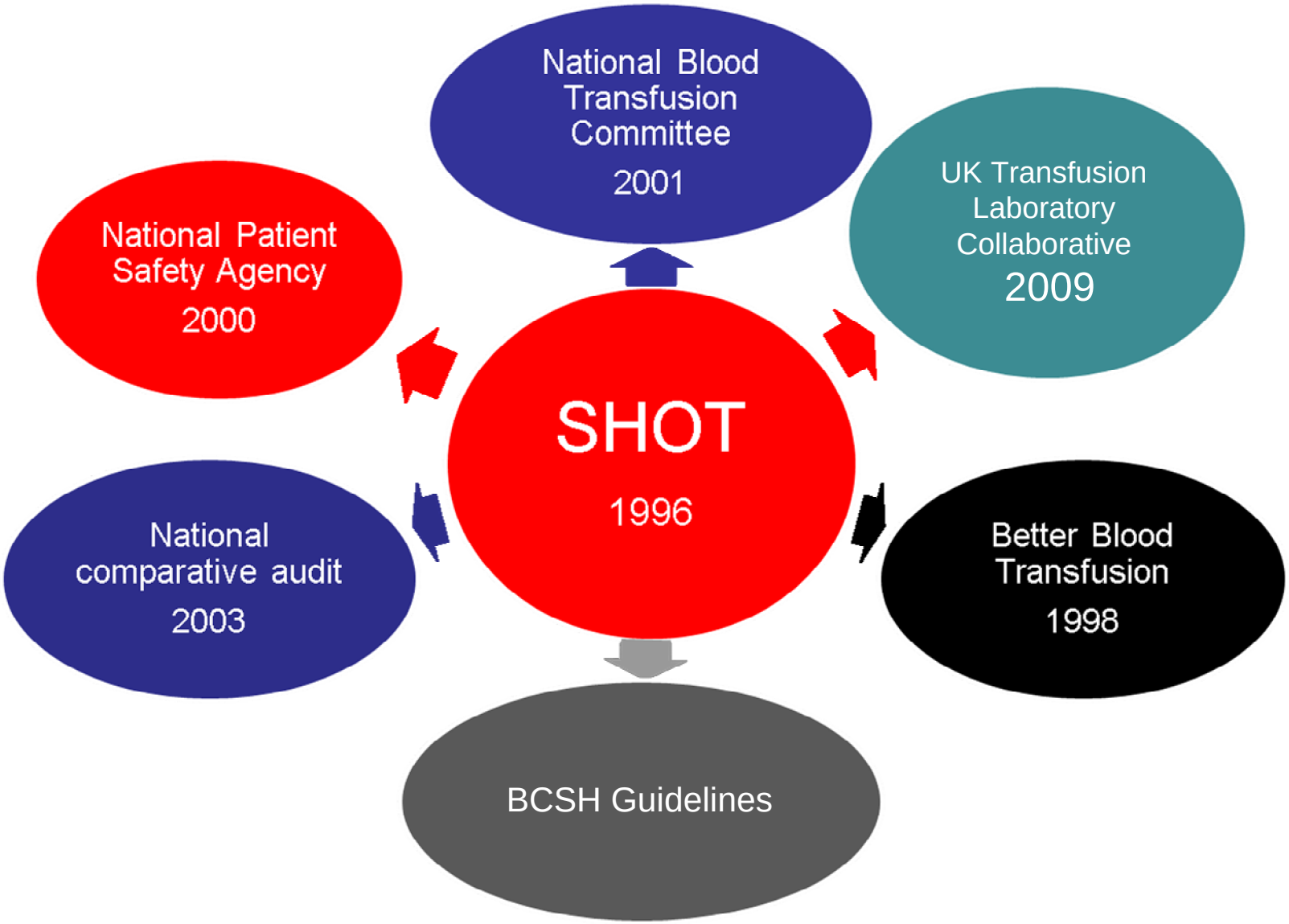
The Hospital Transfusion Team

Consultant haematologist

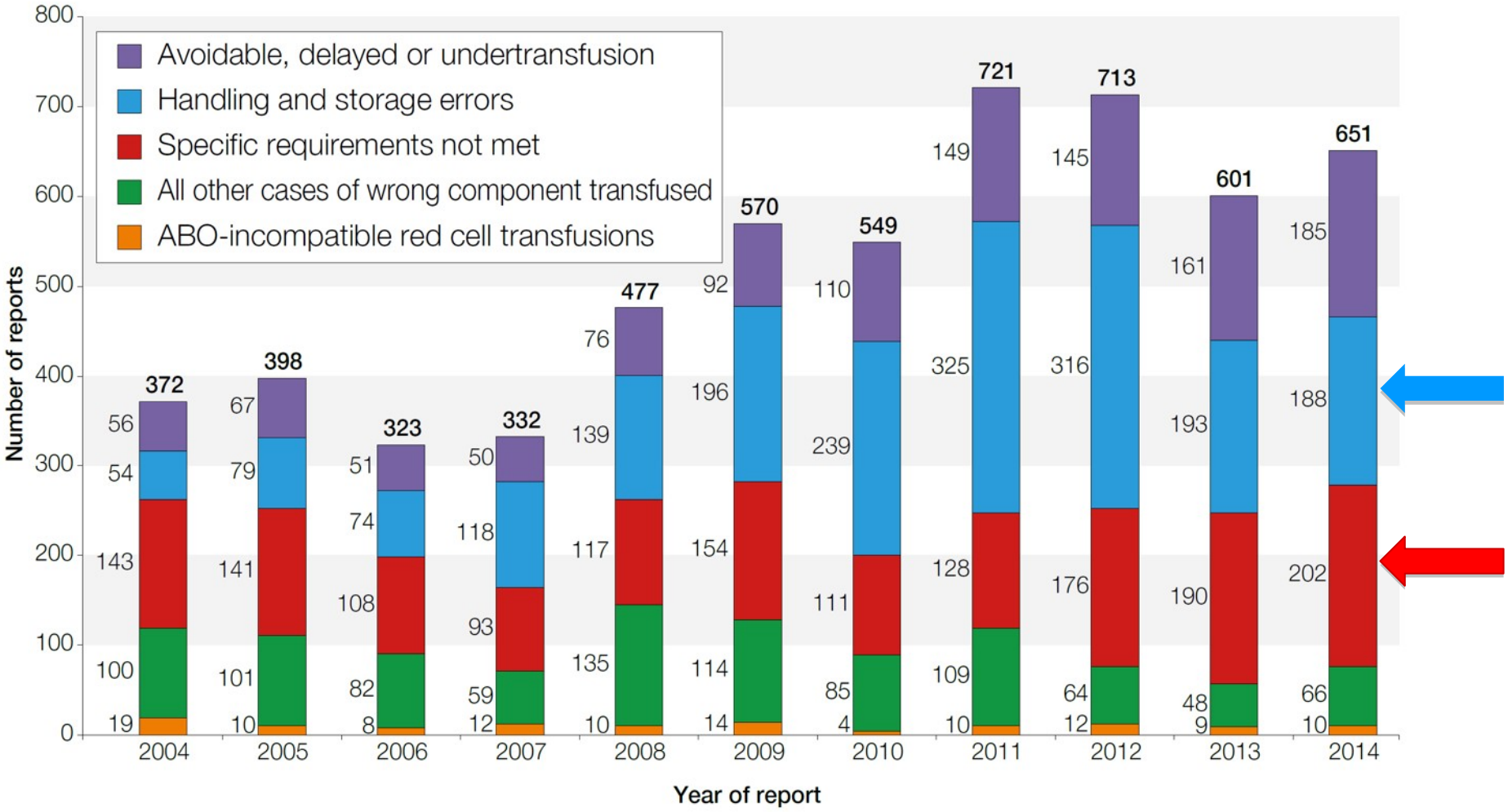
Quality manager

Transfusion laboratory manager

Transfusion practitioner


National Blood Transfusion Committee
2001
UK Transfusion Laboratory Collaborative
2009
National Patient Safety Agency
2000
SHOT
1996
National comparative audit
2003
Better Blood Transfusion
1998
BCSH Guidelines

Cumulative errors

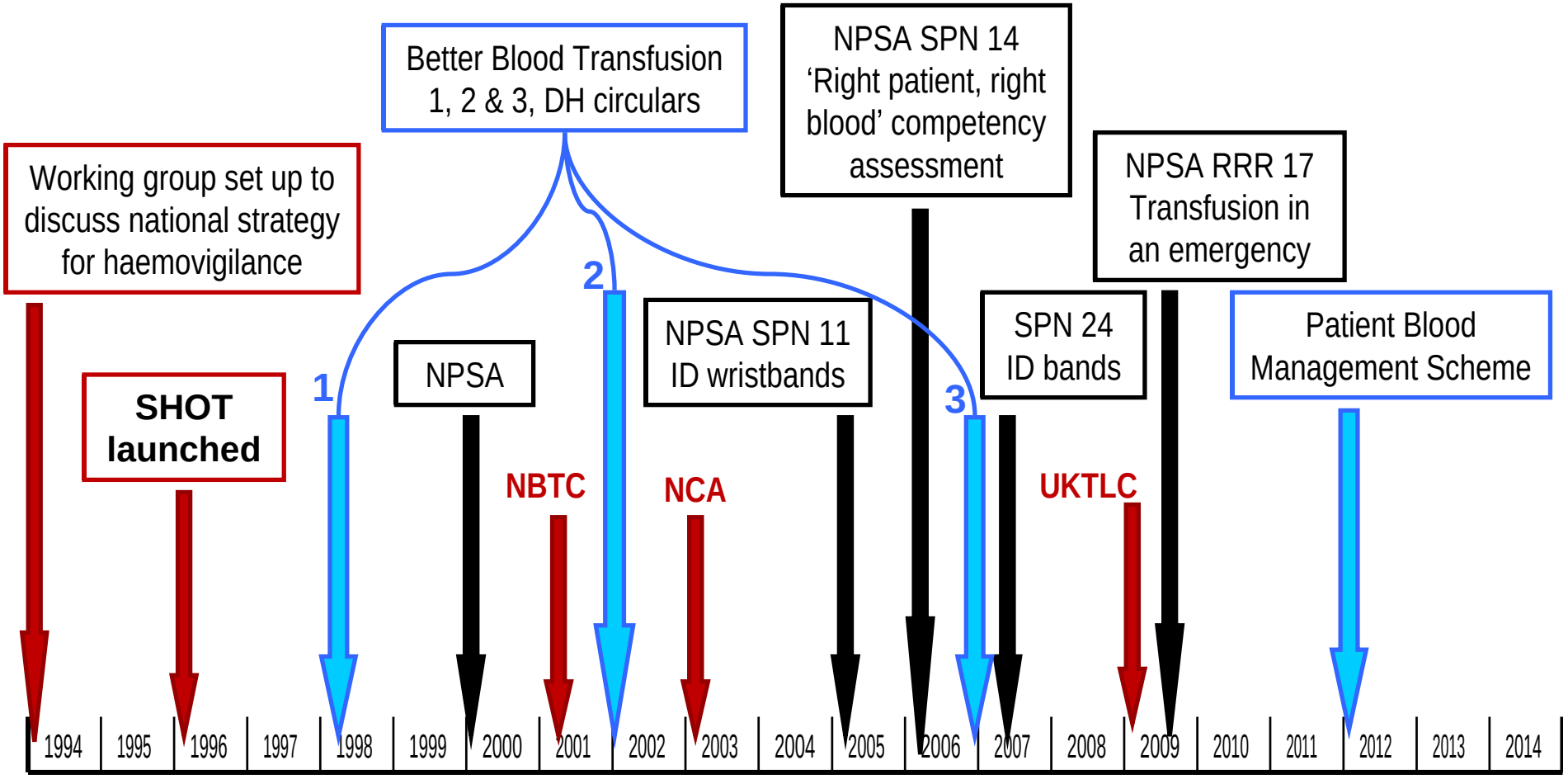


Challenges for hospital transfusion

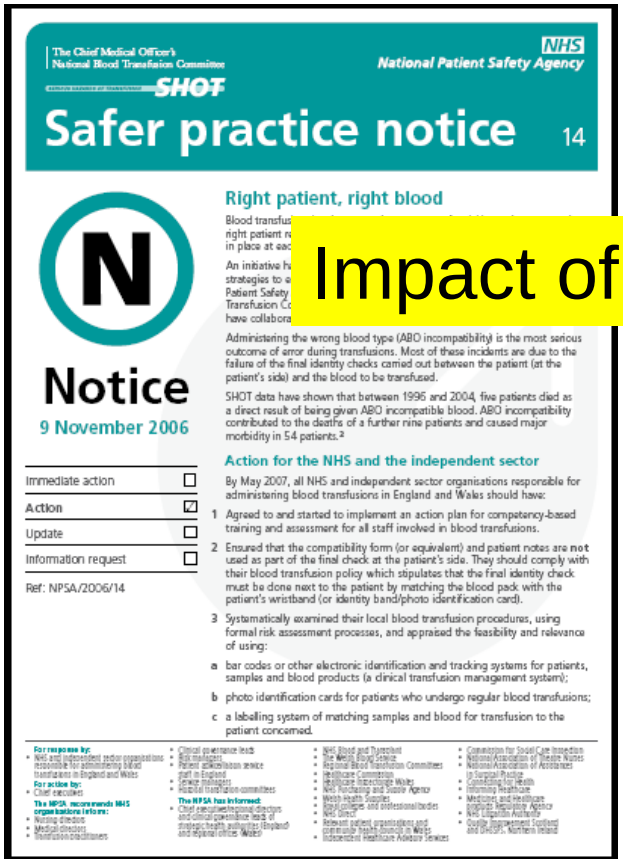
- Patient safety:
  - *few, ideally zero, errors and few complications of transfusion*
- Effective use of blood:
  - *Reduction in inappropriate use*
- Robust audit trail and documentation:
  - *100% by law BSQR 2005*
- Good blood stock management with low wastage
- Good staff training
- Rapid availability:
  - *Delayed transfusion noted by RRR 2010*

Transfusion patient safety initiatives

- NPSA = National Patient Safety Agency
- RRR = Rapid Response Report
- SPN = Safer Practice Notice
- NBTC = National Blood Transfusion Committee
- NCA = National Comparative Audit
- UKTLC = UK Transfusion Laboratory Collaborative



NPSA SPN 14 – Nov 2006
‘Right patient, right blood’



The Chief Medical Officer's National Blood Transfusion Committee

SHOT

NHS National Patient Safety Agency

Safer practice notice 14

Notice

9 November 2006

Immediate action ☐
Action ☑
Update ☐
Information request ☐

Ref: NPSA/2006/14

Right patient, right blood

Blood transfus… right patient r… in place at eac…

An initiative h… strategies to e… Patient Safety … Transfusion C… have collabora…

Administering the wrong blood type (ABO incompatibility) is the most serious outcome of error during transfusions. Most of these incidents are due to the failure of the final identity checks carried out between the patient (at the patient's side) and the blood to be transfused.

SHOT data have shown that between 1996 and 2004, five patients died as a direct result of being given ABO incompatible blood. ABO incompatibility contributed to the deaths of a further nine patients and caused major morbidity in 54 patients.[2]

Action for the NHS and the independent sector

By May 2007, all NHS and independent sector organisations responsible for administering blood transfusions in England and Wales should have:

1 Agreed to and started to implement an action plan for competency-based training and assessment for all staff involved in blood transfusions.

2 Ensured that the compatibility form (or equivalent) and patient notes are not used as part of the final check at the patient's side. They should comply with their blood transfusion policy which stipulates that the final identity check must be done next to the patient by matching the blood pack with the patient's wristband (or identity band/photo identification card).

3 Systematically examined their local blood transfusion procedures, using formal risk assessment processes, and appraised the feasibility and relevance of using:

a bar codes or other electronic identification and tracking systems for patients, samples and blood products (a clinical transfusion management system);

b photo identification cards for patients who undergo regular blood transfusions;

c a labelling system of matching samples and blood for transfusion to the patient concerned.

For response by:
- NHS and independent sector organisations responsible for administering blood transfusions in England and Wales

For action by:
- Chief executives

The NPSA recommends NHS organisations inform:
- Nursing directors
- Medical directors
- Transfusion practitioners
- Clinical governance leads
- Risk managers
- Patient administration service staff in England
- Service managers
- Hospital transfusion committees

The NPSA has informed:
- Chief executives/executive directors and clinical governance leads of strategic health authorities (England) and regional offices (Wales)
- NHS Blood and Transplant
- The Welsh Blood Service
- Regional Blood Transfusion Committees
- Healthcare Commission
- Healthcare Inspectorate Wales
- NHS Purchasing and Supply Agency
- Welsh Health Supplies
- Royal College and professional bodies
- NHS Direct
- Relevant patient organisations and community health councils in Wales
- Independent Healthcare Advisory Services
- Commission for Social Care Inspection
- National Association of Theatre Nurses
- National Association of Assistants in Surgical Practice
- Counselling for Health
- Informing Healthcare
- Medicines and Healthcare products Regulatory Agency
- NHS Litigation Authority
- Quality Improvement Scotland and Direct+, Northern Ireland

Impact of BBT teams and TPs

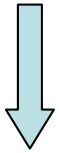
1 Training and competency assessment for all staff involved in blood transfusions

2 …ient notes **not** to be used as part of the final identity check – match blood pack with the patient’s wristband (or identity band/photo identification card)

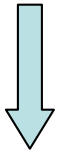
3 Appraise the feasibility and relevance of using electronic identification and tracking systems

Evolution of the PBM Team

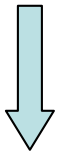
Transfusion Liaison Nurse Team



Transfusion Liaison Team



Better Blood Transfusion Team

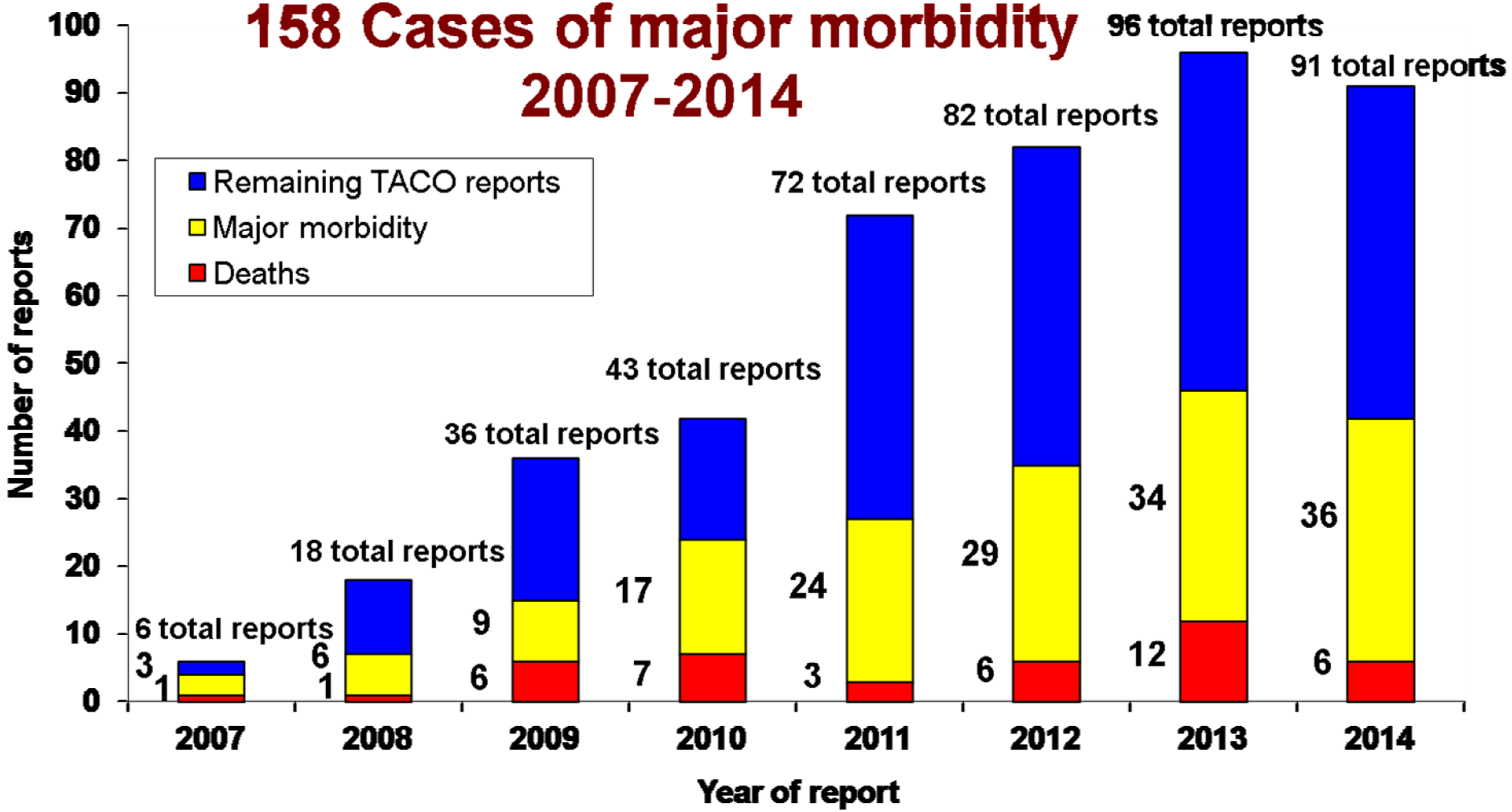


Patient Blood Management Team

Haemovigilance feedback loop

TACO as an example

42 TACO-related deaths and 158 Cases of major morbidity 2007-2014



*Includes 4 deaths and 5 cases of major morbidity from ADU

Major morbidity from over-transfusion 2000-2011

Year	Number	Error	Outcome	Underlying diagnosis
2003	2	XS red cells – low BW	Polycythaemia	Haematuria
		Unsuitable sample	Unnecessary surgery	Acute abdomen
2005	2	XS red cells	TACO	GI bleed
		XS red cells	Polycythaemia	Surgery
2007	4	Inadequate handover	TACO	CRF
		Incorrect prescription	TACO	Unknown
		XS red cells	Polycythaemia	Regular transfusion for iron deficiency
		XS FFP	TACO	Warfarin reversal
2008	1	Incorrect prescription	Polycythaemia	Unknown (infant 1 year)
2009	1	Incorrect prescription	Polycythaemia	Unknown (infant 1 year)
2010	4	XS red cells	TACO	GI bleed
		WBIT	TACO	Carcinoma
		XS red cells – low BW	Polycythaemia	Unknown
		XS red cells	Polycythaemia	Premature infant
Total	**14**			

Data compiled by Sue Knowles

Mortality from over-transfusion 2000-2011

Year	Number	Error	Outcome	Underlying diagnosis
2000/1	2	Unsuitable sample	Cardiac arrest	IHD
		Unsuitable sample	TACO	GI Bleed
2001/2	2	Unsuitable sample	TACO	GI Bleed
		Unsuitable sample	TACO	GI Bleed
2004	1	WBIT	TACO	Unknown
2005	1	Misdiagnosis haemorrhage	TACO	Acute abdomen
2006	2	Paediatric prescription	Cardiac arrest	Premature infant
		Unsuitable sample	TACO	Fractured femur
2008	1	XS red cells	Polycythaemia	GI bleed
2009	2	WBIT	TACO	Carcinoma
		Unsuitable sample	TACO	Fractured femur
2010	1	XS red cells	TACO	GI bleed
2011	1	XS red cells	TACO	GI bleed
Total	**13**			

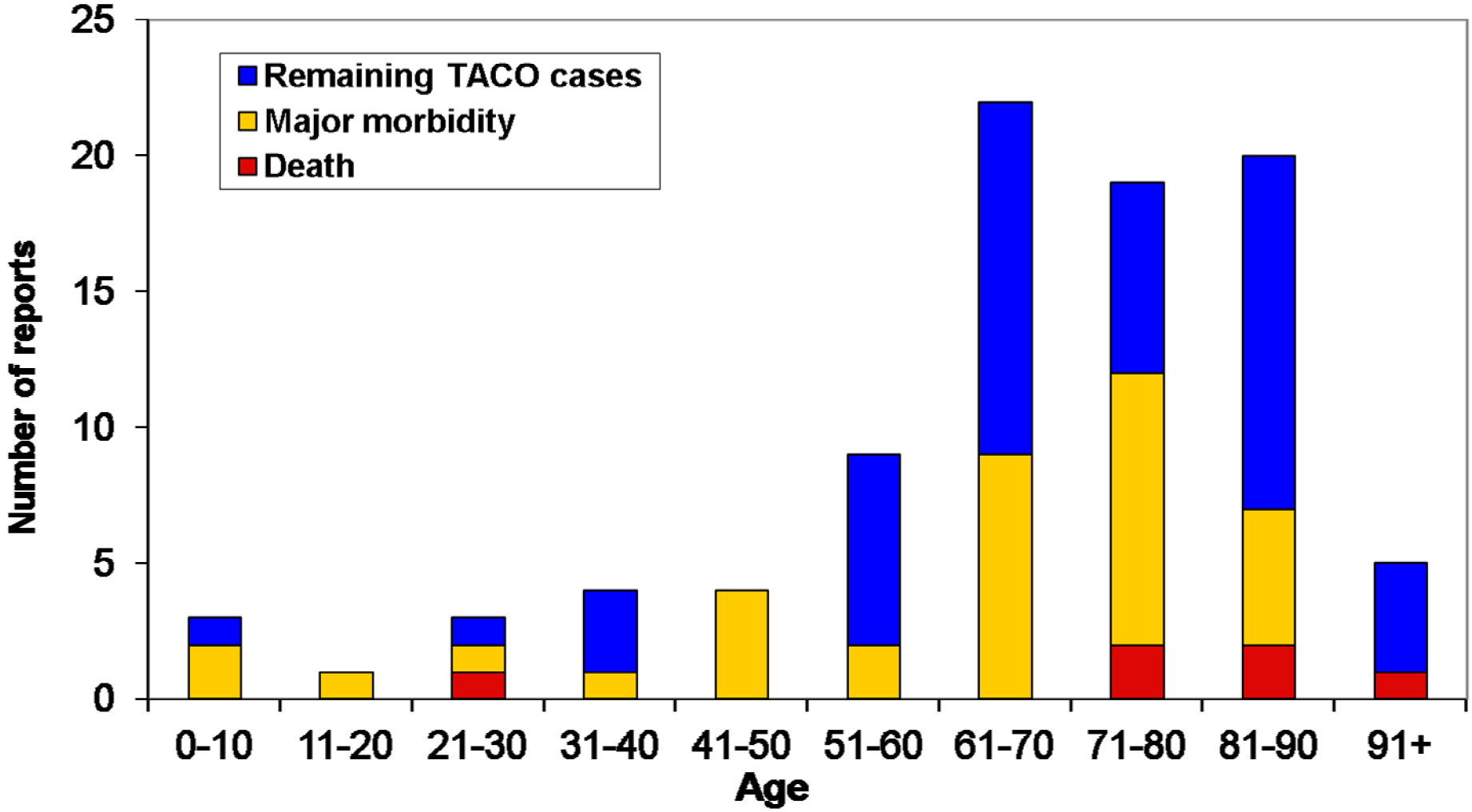
Fatal TACO as a result of transfusion following spurious result

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

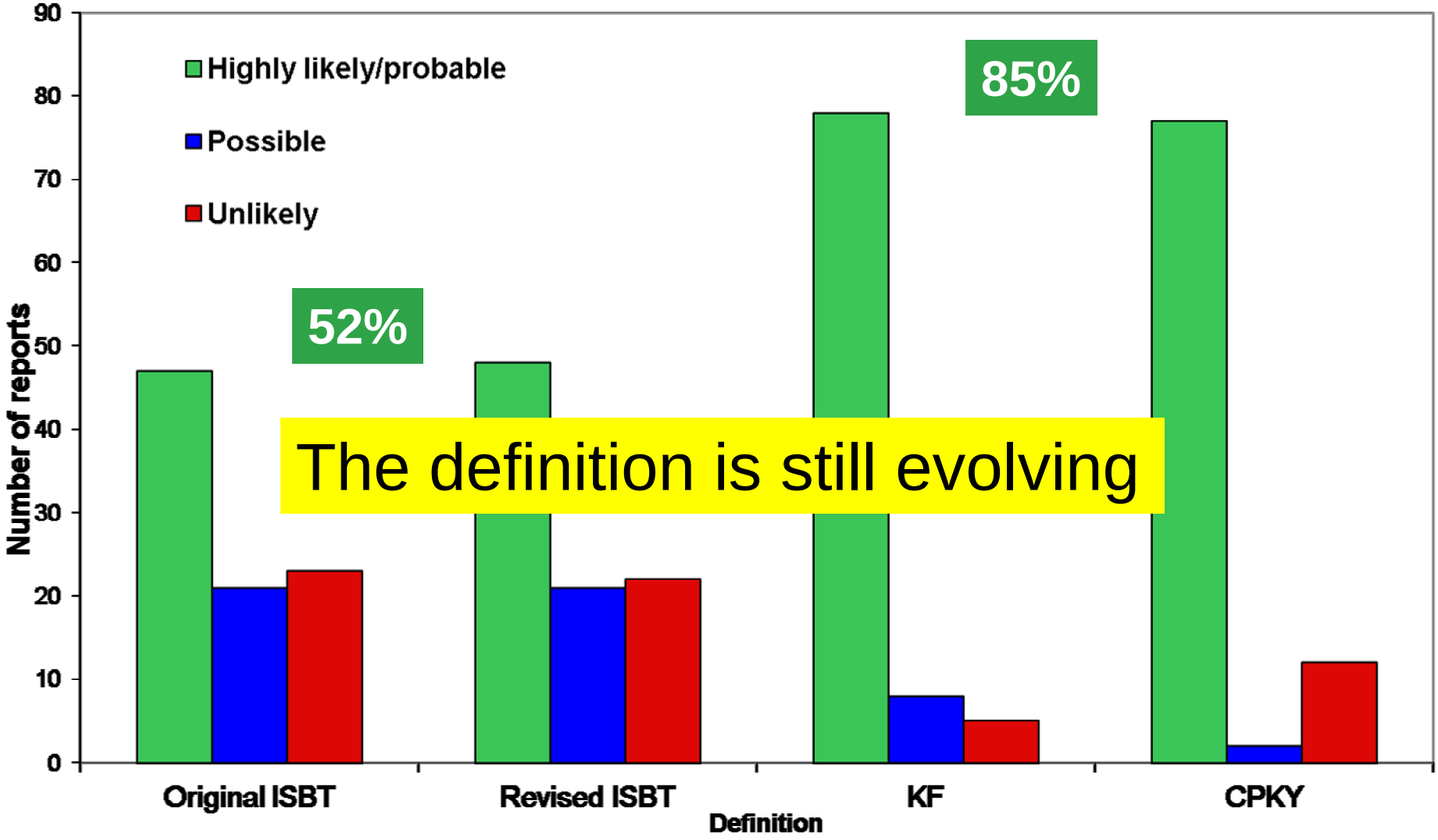
Over-transfusion due to lack of monitoring

- Elderly patient admitted to 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

TACO can occur at any age

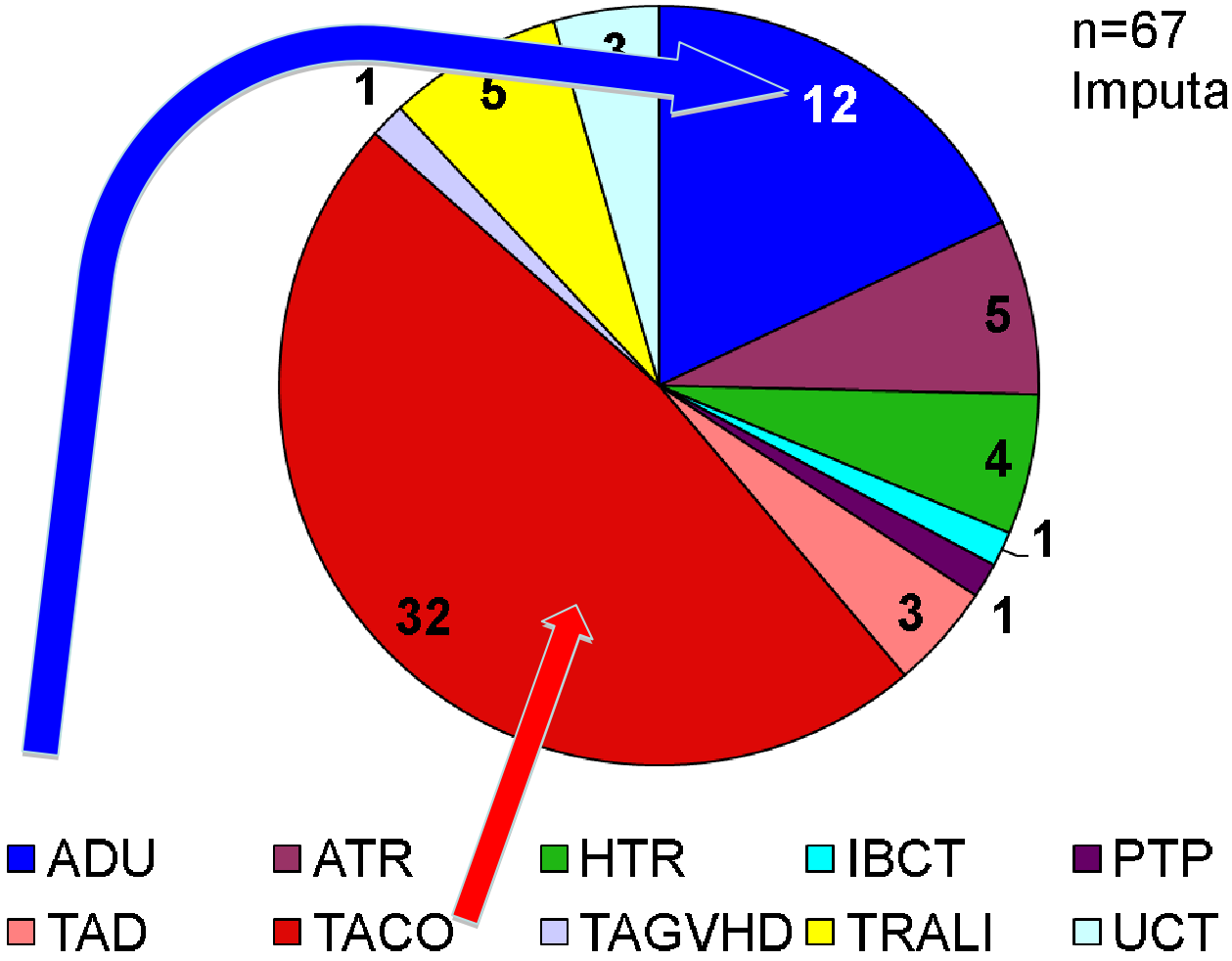


Number of TACO cases (2014) by 4 different definitions



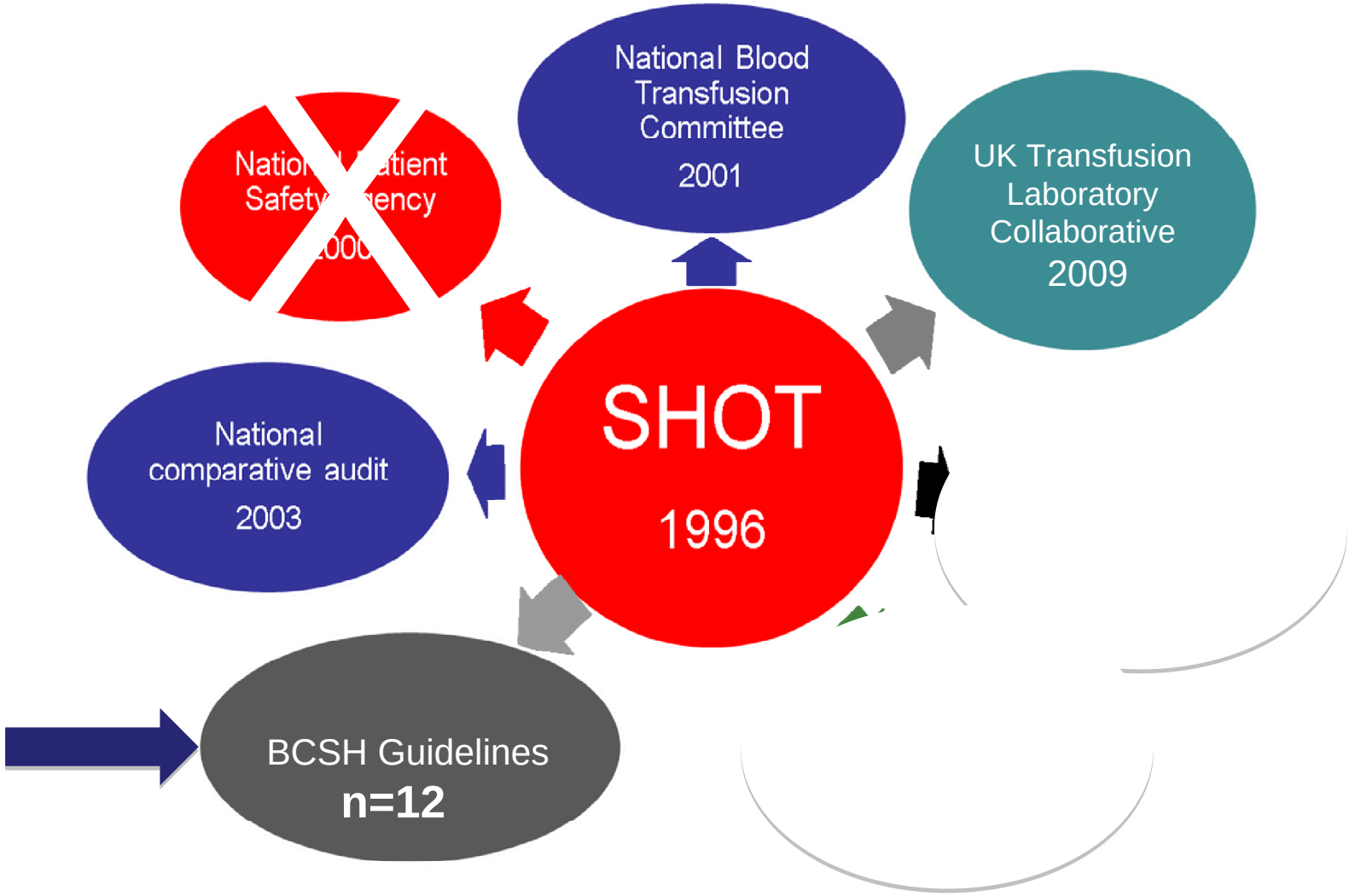
Total deaths by category
5 years - 2010-2014

n=67
Imputability 1-3



Where are we now?

- National, regional and local audits consistently show inappropriate use of 15-20% red cells and 20-30% platelets/plasma
- Low uptake of methods to avoid use of blood
- Safety of hospital transfusion still an issue
- Poor education and training
- Lack of patient involvement
- Evidence base getting stronger but more research needed
- Poor IT for blood safety and for providing data on blood usage


National Blood Transfusion Committee
2001
UK Transfusion Laboratory Collaborative
2009
SHOT
1996
National comparative audit
2003
BCSH Guidelines
n=12

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 the 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

National audit programme

Audit	n Invited	n Participated	% Participated	Reported
2003 Bedside Audit	289	217	75%	2003
2005 Bedside Re-audit	355	278	78%	2005
Use of Platelets	357	187	52%	March 2007
Blood use in Hip Replacement	373	254	68%	July 2007
Use of blood in UGI Bleeding	257	217	84%	December 2007
Overnight Transfusion	229	204	89%	January 2008
Use of Fresh Frozen Plasma – NHS	248	186	75%	March 2009
2008 Bedside Re-audit – NHS	217	208	96%	April 2009
2009 Blood Collection Audit - NHS	175	140	80%	October 2009
Audit of use of Blood in Neonates & Children – NHS	165	155	94%	October 2010
2010 Re-audit of Group O RhD red cells	245	214	87%	April 2011
2010 Re-audit of the use of Platelets in Haematology*	245	172	70%	May 2011
2011 Re-audit of Bedside Transfusion practice	219	211	96.4	October 2011
2011 Audit of the Medical Use of Red Cells	156	135	86.5	Summer 2012

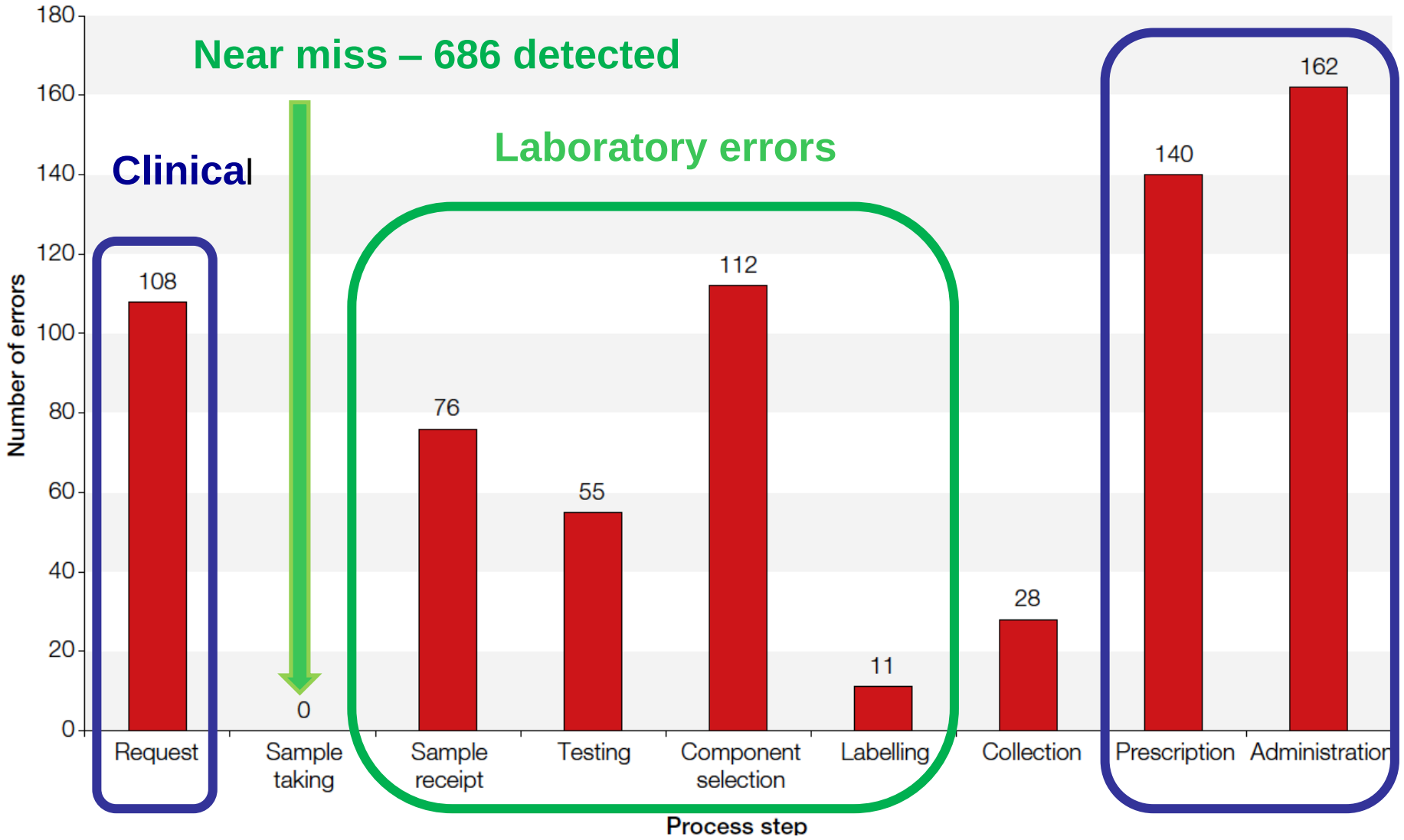
Not all sites were able to send data because they do not treat haematology patients

Back to the future

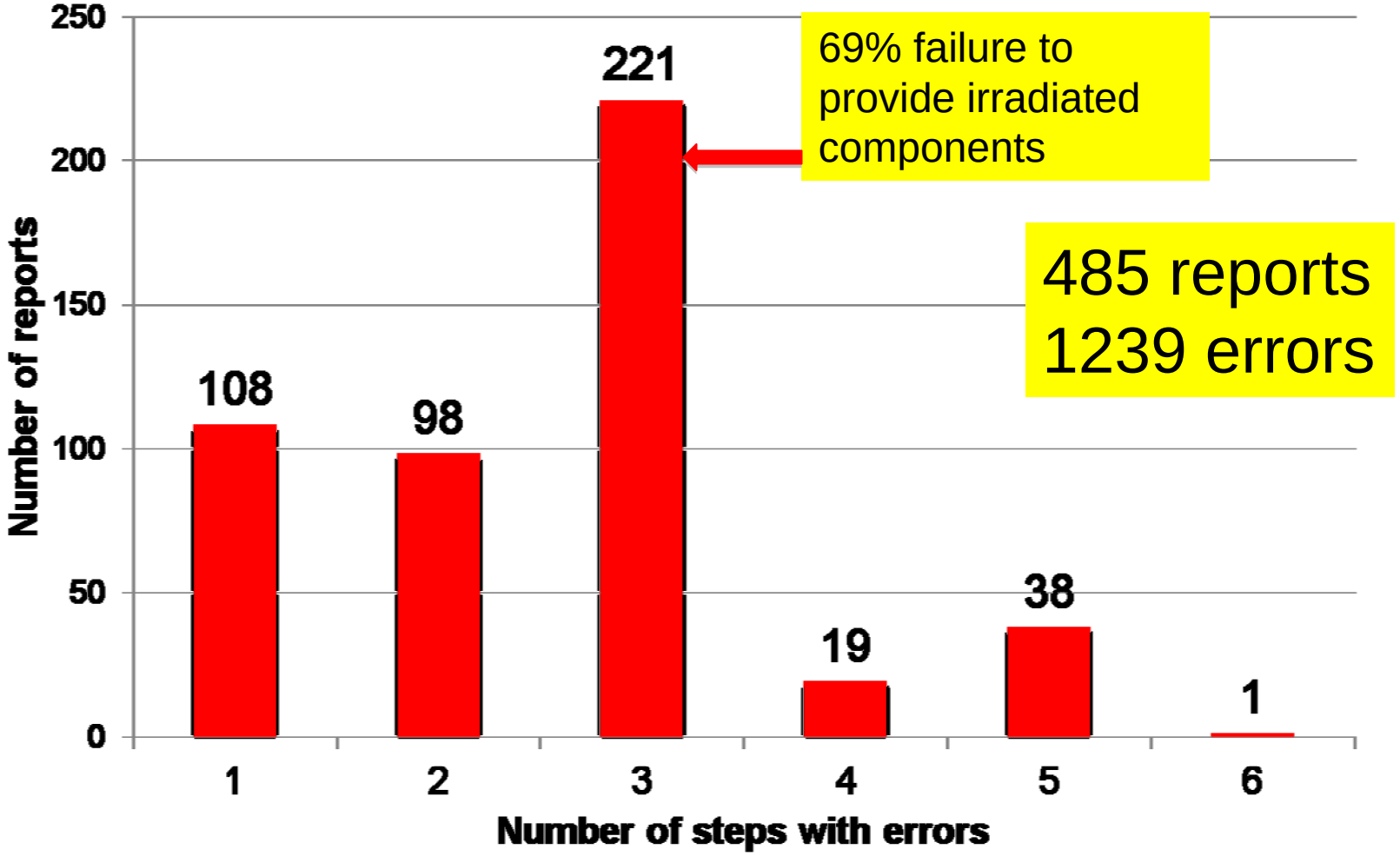
Multidisciplinary process

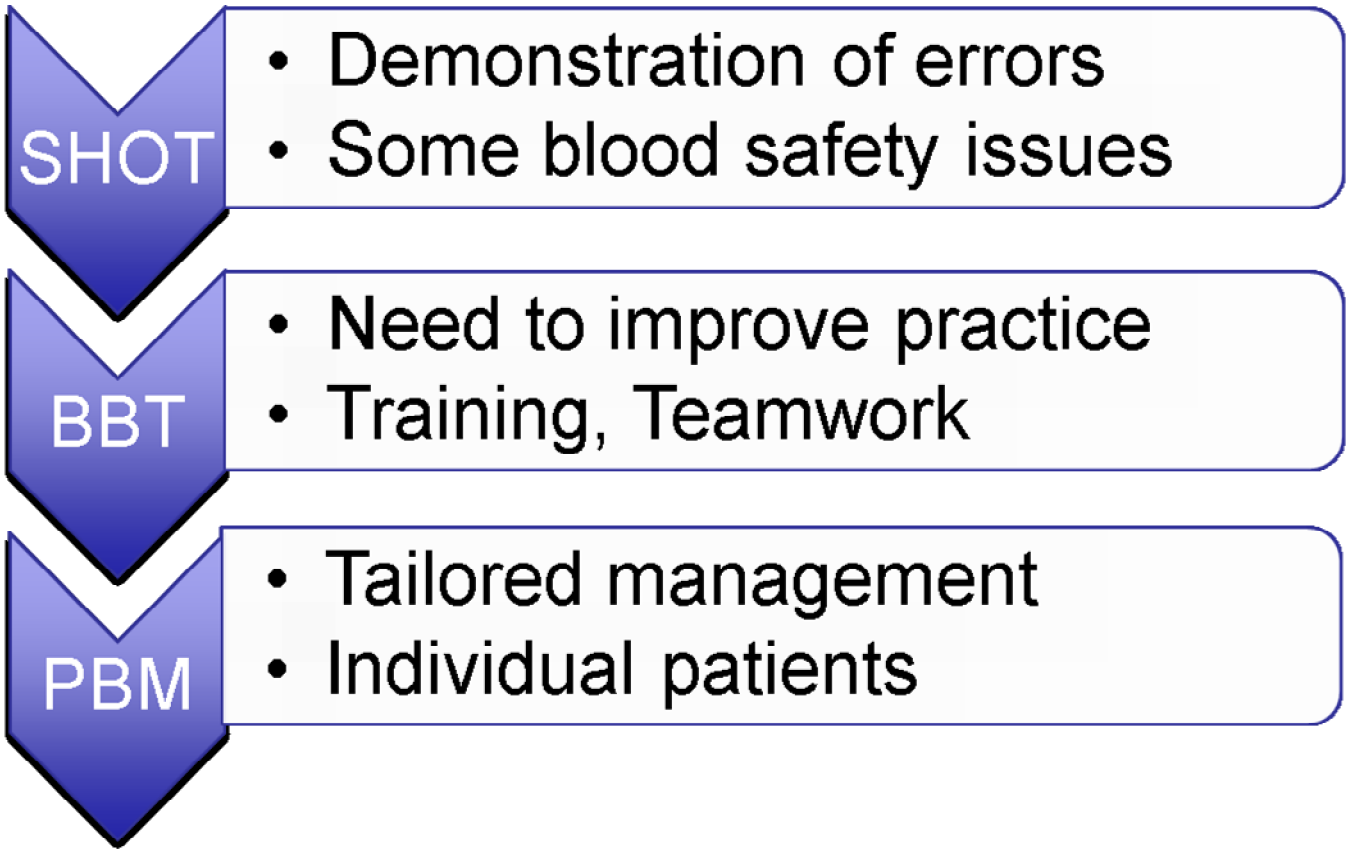
Human factors

Wrong transfusions, where are the mistakes made?

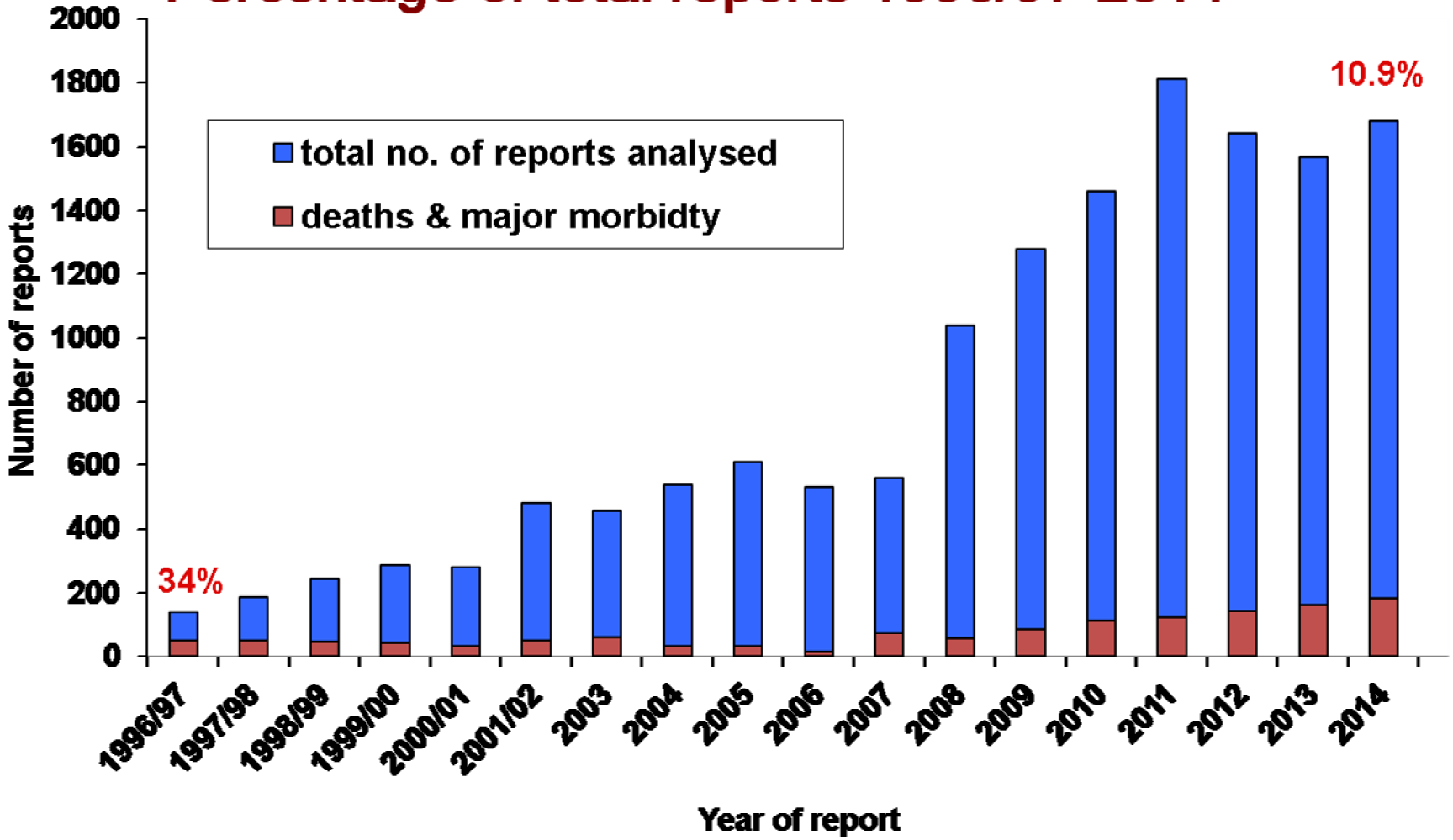


Multiple errors are common – incorrect blood components transfused 2013 and 2014




SHOT
• Demonstration of errors
• Some blood safety issues
BBT
• Need to improve practice
• Training, Teamwork
PBM
• Tailored management
• Individual patients

Deaths and major morbidity: Percentage of total reports 1996/97-2014



Feedback to individual laboratories

Putting the patient at the centre of everything we do

MHRA

1110 reports

From blood safety

to transfusion safety

3668

eports

Patient Blood Management

Detailed analysis
Trending
Clinical feedback

Acknowledgements

- The SHOT team
- Our working expert group
- The Steering Group
- MHRA haemovigilance team
- The vigilant reporters and hospital staff who share their incidents with us
- The UK Forum for funding

Many resources on website

www.shotuk.org