LABORATORY ERRORS

Stephen Bassey, RCHT

The aim of science is not to open the door to infinite wisdom, but to set a limit to infinite error

Bertolt Brecht

- To improve patient safety in blood transfusion
  - Improve standards of hospital transfusion practice
  - Educate users on transfusion hazards and their prevention
  - Aid production of clinical guidelines
  - Inform policy within the UK Blood Services
  - Inform national policy on transfusion safety within the UK
  - Inform Europe about transfusion safety in the UK

Objectives

- Collect and analyse information on transfusion reactions and adverse events from all healthcare organisations in the United Kingdom that are involved in the process of blood transfusion.
- Provide authoritative data and recommendations based on these data, which are disseminated widely.
- Investigate the contribution of deficiencies in the transfusion process to serious adverse patient outcomes.
- Identify areas where laboratory and clinical practice need to be improved and make appropriate recommendations for changes that will improve outcomes for patients.

Hep C enquiry

Mr Justice Burton

- A product is defective when it does not provide the safety which a person is entitled to expect

- The legitimate expectation of people generally was not that blood would be 100% ‘clean’ but that all legitimately expectable precautions had been taken

Berwick report

A promise to learn – a commitment to act

- The NHS should continually and forever reduce patient harm by embracing wholeheartedly an ethic of learning.

- Mastery of quality and patient safety sciences and practices should be part of initial preparation and lifelong education of all health care professionals, including managers and executives.

Berwick report

A promise to learn – a commitment to act

- The NHS should become a learning organisation.
- Transparency should be complete, timely and unequivocal.
- Fear is toxic to both safety and improvement

Commercial air travel didn’t get safer by exhorting pilots to please not crash. It got safer by designing planes and air travel systems that support pilots and others to succeed in a very, very complex environment. We can do that in healthcare, too.

Don Berwick

Pathology Quality Assurance Review

Dr Ian Barnes

- The foundation of a high quality pathology service is a well-trained, competent staff that actively seeks to ensure and improve quality through their everyday work and actions.
- Training in aspects of quality management, assurance and improvement, including developing understanding about the reporting of errors, should also become a significant component of CPD programmes.

Pathology Quality Assurance Review

Dr Ian Barnes

NHS Blood and Transplant use a Serious Hazards of Transfusion (SHOT) reporting system to identify areas where laboratory and clinical practice need to be improved and to make appropriate recommendations for changes that will improve outcomes for patients. The Review team were struck by the robustness of error definition and consistency of reporting.

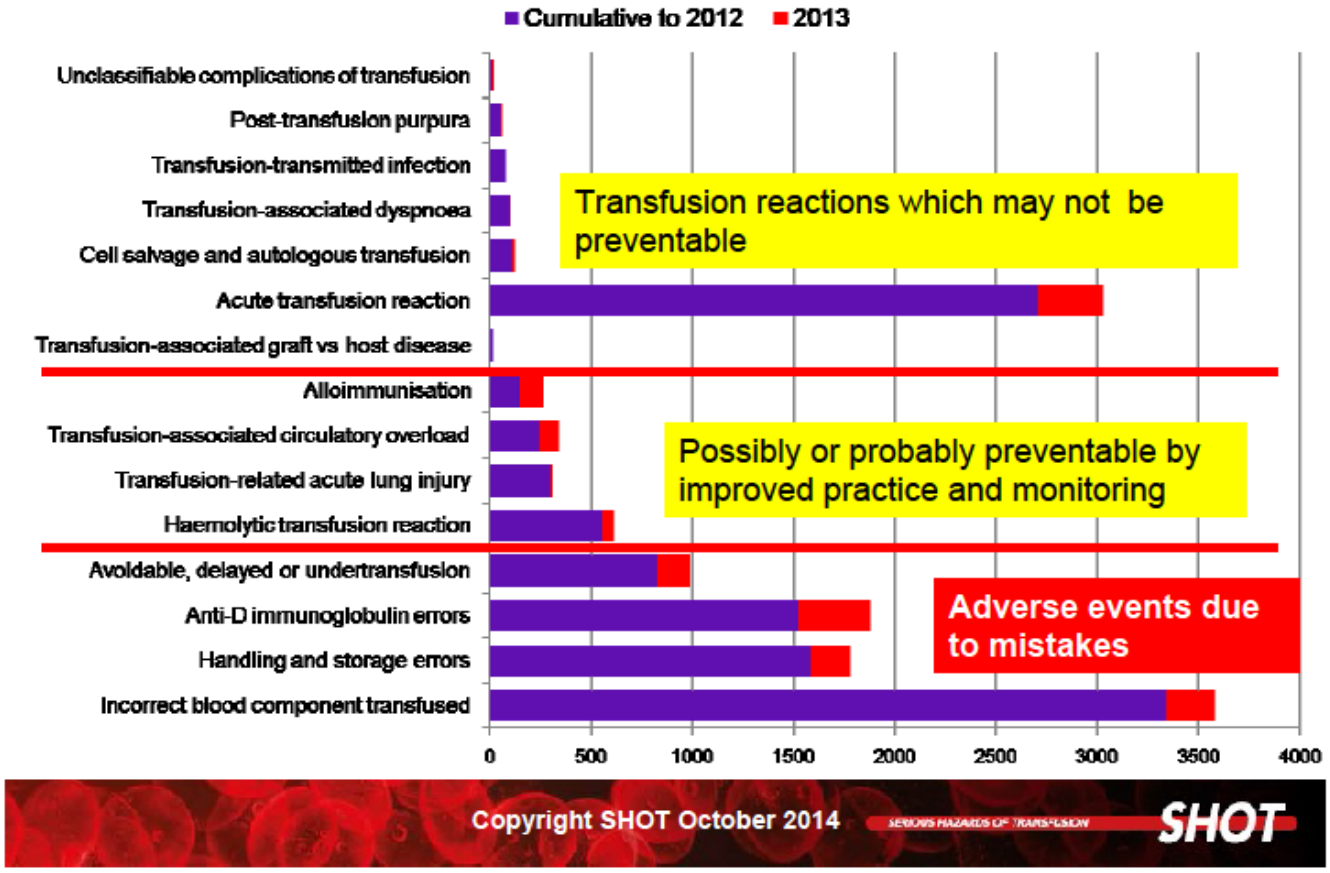
Incident investigation

- Information gathering
- Assessment of system faults
- Statements
  - Reflective practice
  - Impact on patient care

CAPA

- Systems failures
- Education and training
- Competency

SHOT Cumulative data: 17 years n=13141



Failure to consult historical records

- A patient had a positive antibody screen in 2002 which was fully investigated and flagged under the patient's A&E number
- The patient received further red cell transfusions on two later occasions (2007 and 2013)
- These units were not of the correct phenotype due to a failure to consult historical records

Failure to consult historical records...

- On the second two occasions the samples were booked in using the NHS/Hospital number
- The antibody screens were negative
- The patient was transfused red cells that had been electronically issued on both occasions

Failure to consult historical records...

- When a further request was received by the laboratory the patient s historical record under the A&E number was found and it was noted the patient had previously detectable anti-K, anti-Jka and anti-Kpa in 2002

Failure to consult current request

Information provided on request form but missed by laboratory staff	Number of reports
Request for irradiated components	7
Request for RhD/K matched and HbS negative for sickle cell patient	2
Request for irradiated and cytomegalovirus (CMV) negative	1
Total	**10**

Procedural errors

Procedural errors	Number of reports
Omission or late administration of anti-D Ig because Kleihauer test was: a) not performed within 72 hours post delivery b) performed within 72 hours but anti-D Ig was not administered within 72 hours (Case 2)	6
Erroneous low platelet counts that were reported for patients whose platelets were known to 'clump' in ethylene diamine tetraacetic acid (EDTA)	4
Antibody identification not performed following a positive antibody screen	4
Red cells issued and transfused before crossmatch results had been confirmed	3
Group and antibody screen not performed prior to issue of crossmatched red cells	2
Antibody screen not performed	1
Red cells transfused to neonate not crossmatched against the maternal sample which contained multiple alloantibodies	1
Non–human leucocyte antigen (HLA)-matched platelets transfused due to failure to enter available HLA results into the computer system	1
Erroneous full blood count due to clotted sample	1
Total	**23**

Anti-D error

- A standard dose of 500IU anti-D Ig was given to a woman after delivery, but there was an estimated 9 mL bleed by Kleihauer testing.
- The sample was referred to the RCI laboratory to confirm the result by flow cytometry.
- Further anti-D Ig was required to cover the fetomaternal haemorrhage (FMH) and was not administered within 72 hours, because the flow cytometry result was reported 60h after delivery leaving only 12 hours (overnight) to achieve administration of anti-D Ig which was to be given in the community.

Special requirements not met

- Compatibility testing was performed against a neonatal sample and not the maternal sample as required. The mother had multiple antibodies including anti-D, anti-Fya, anti-Jkb, anti-M and anti-S and subsequent testing showed that the unit issued to the neonate was incompatible with the mother.

Special requirements not met

- A biomedical scientist (BMS) inadvertently removed a specific requirements flag indicating the patient required C negative red cells, therefore the BMS who issued the blood was not aware of this requirement.

- The patient was consequently transfused two red cell units that were C positive.

IBCT

- An ABO incompatible red cell unit was transfused resulting in an acute haemolytic transfusion reaction (this was not an emergency case)
- The computer warning flag indicated that the units were incompatible but was overridden by the BMS
- The incompatibility (O Pt, A RBC) was not picked up at the bedside by the Nurse

Conclusions

- Laboratory errors are still common
- Use full automation 24/7
- Test & validate all IT systems (GMP annexe 11)
- Skills, knowledge & competency require regular assessing
- Remain open & honest
- Learn from mistakes (not just your own)

Insanity: doing the same thing over and over again and expecting a different outcome

Albert Einstein