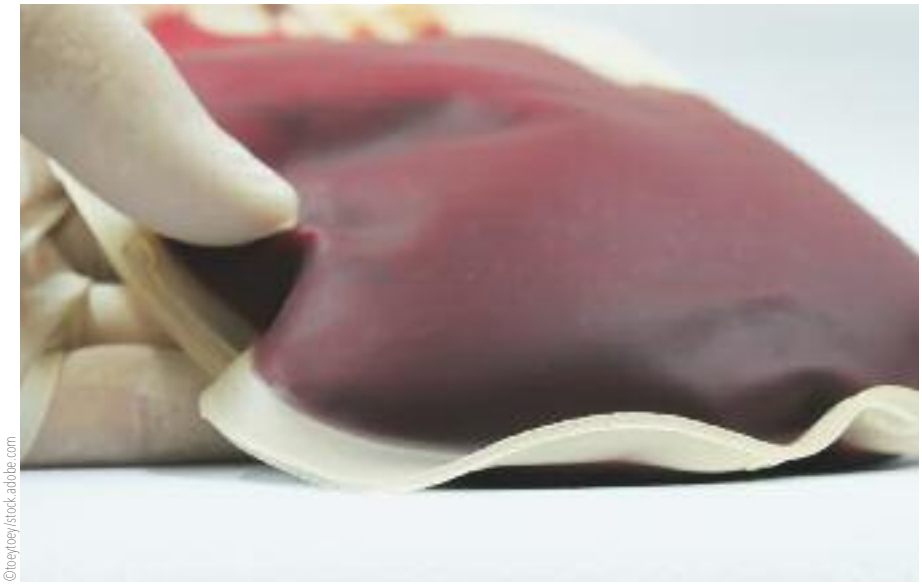
Serious Hazards of Transfusion scheme: a review of 2016 data

Laboratory Incidents Specialist Hema Mistry summarises the 2016 SHOT Annual Report and looks at why the same errors are still occurring, and why many of them could have been prevented.

The Serious Hazards of Transfusion (SHOT) scheme collects and analyses anonymised information reported in the UK about serious adverse reactions and other serious adverse events (SAE) related to blood transfusion, then makes recommendations to improve patient and transfusion safety. From 2015, SHOT reports have included data for donor vigilance provided by the four UK Blood Services demonstrating the full range of haemovigilance from donor to recipient. This year, SHOT celebrated its 20th anniversary with the release of its 2016 Annual Report (assessing a total of 3091 case reports).

Key recommendations

- A **bedside checklist** must be used at the patient's side as a final administration check prior to transfusion as standard of care. The checklist must include positive patient identification (forename, surname, date of birth, and hospital number or other unique identifier). It should also confirm that the component is correct and has any specific requirements for that patient and that it has been prescribed for transfusion to this patient at this time. Errors are made with both one-person and two-person checks. Use of a verification process (two people working together, with challenge and response) may be more effective. Whatever bedside system is in place (including electronic systems), it should be assessed and include a validation step where someone has to sign to say that all steps have been followed and completed correctly.
- Use a **TACO checklist**. Patients should be formally assessed for their risk of transfusion-associated circulatory overload (TACO) whenever possible as TACO is the most commonly reported cause of death and major morbidity.[1]



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Deaths, major morbidity and ABO-incompatible transfusions

In 2016 there were 26 deaths related to transfusion (imputability cited as possibly, probably or definitely), 16 of which were considered preventable. TACO was implicated in over half of these (14/26), double that of 2015. Delays in transfusion contributed to nine deaths in 2016, compared to six in 2015.

Cumulative data from 2010 to 2016 (seven years) show that pulmonary complications are overall the leading cause of death, accounting for 61/115

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(53%) but delayed transfusion accounted for 25/115 (21.7%). The SHOT numbers translate into a risk of death of 1 in 100,000, a risk of death from error of 1 in 250,000 and a risk of major morbidity of 1 in 20,400 blood components issued.

Three ABO-incompatible red cell transfusions were reported in 2016 due to errors originating in the clinical area, two of which resulted in major morbidity, but no deaths. Two of these were caused by wrong blood in tube incidents where the two-sample policy was in place but not adhered to; the third was a combination of collection and administration errors which could have been detected had the final bedside administration check been performed properly. Almost 88% of the near-miss events reported were due to a wrong blood in tube, and 85% of them were detected during testing in the laboratory due to a discrepant group on LIMS that highlighted the error (Fig 1).

Most near-miss errors result from inadequate patient identification at two points: sample taking and blood component administration. Increasing numbers of errors are reported in patients receiving transplants, with 93 reports in 2016 compared with 70 in 2015. Nineteen of 58 haemopoietic stem cell transplant errors and four of 35 solid organ transplant errors were ABO- and/or D-related. These could have been prevented by effective communication from the clinicians to the laboratory or by the laboratory heeding the historical LIMS record. Errors in theatres and emergency departments are also increasing as a percentage of all reported errors.

Three ABO-incompatible fresh-frozen plasma infusions (now also considered 'never events') were also reported, all due to laboratory errors, in testing (1/3) and component selection (2/3) (Fig 2). In addition, there was one case where a patient received a serological crossmatch-incompatible unit, where a unit of red cells for a 21-year-old in sickle cell crisis was serologically incompatible but mistakenly labelled as compatible and transfused to the patient. No adverse reaction was reported (Fig 2).

A further 264 potential ABO-incompatible transfusions were avoided because errors were detected prior to transfusion. Review of ABO-incompatible red cell transfusions since 1996 (Fig 3) reveals a reduction perhaps as a consequence of the Blood Safety and Quality regulations and introduction of mandatory competence assessments in 2005.

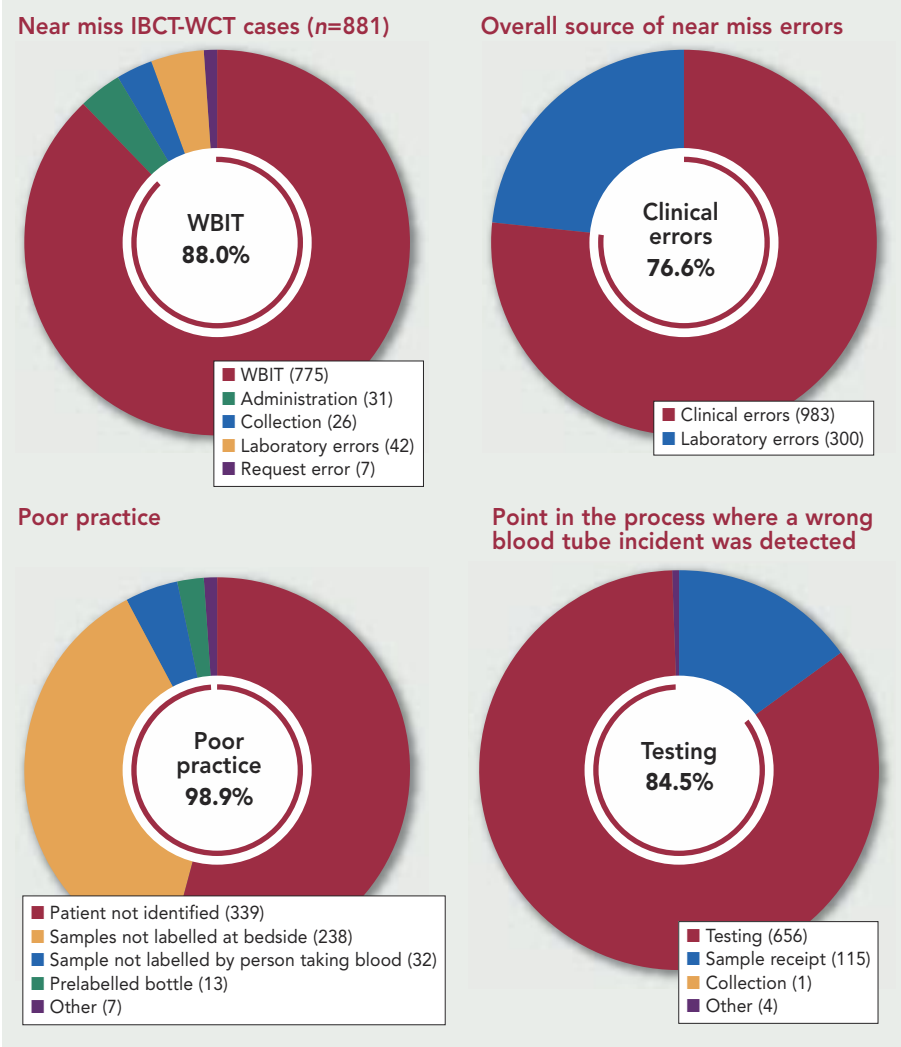

Fig 1. Near miss, wrong blood in tube.

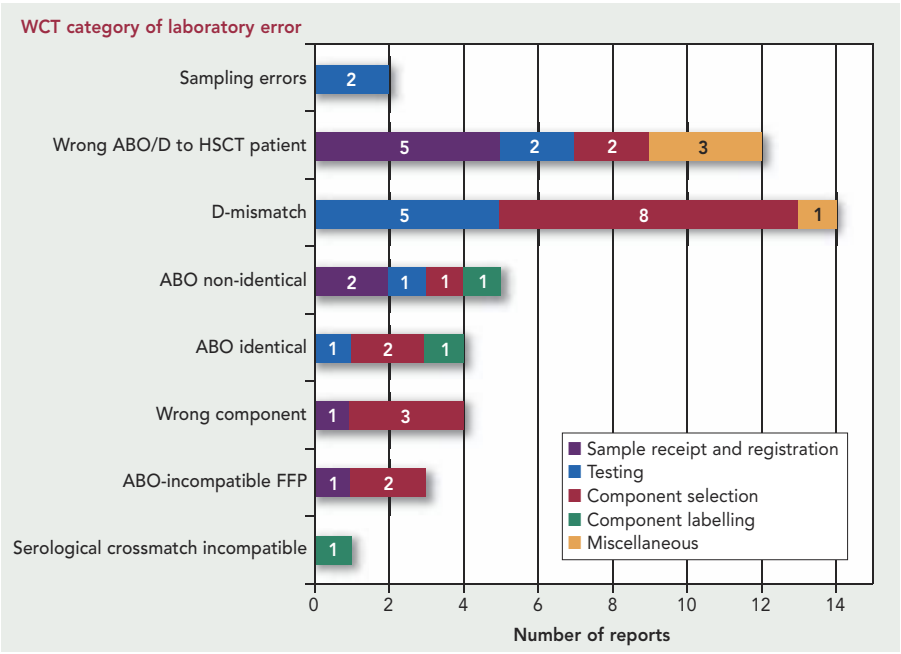

Fig 2. Wrong component transfused due to errors originating in the laboratory (*n*=45).

Information technology-related errors contributed to 20% of the serious adverse events reported jointly to SHOT and MHRA

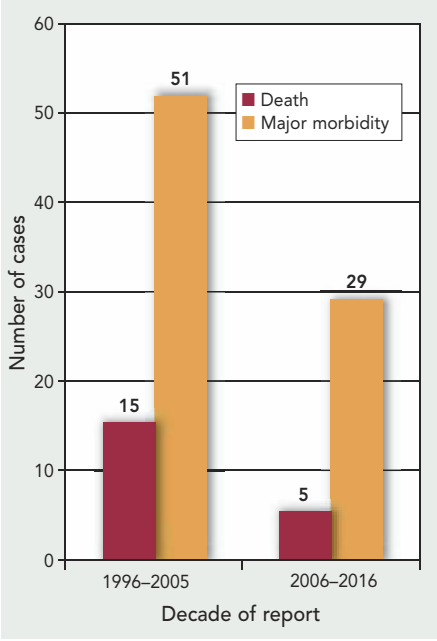

Fig 3. Reduction in ABO-incompatible transfusions in two decades of reporting.

Other serious adverse incidents and reactions

Transmission of infection is very rare. There was a single viral transmission (hepatitis E virus) reported in 2016 (in nearly 2.5 million components issued). There were no cases of transfusion-related lung injury, transfusion-associated graft versus host disease or post-transfusion purpura. Adverse reactions were reported in a total of 385 cases (12.5% of all reports), with allergic, hypotensive and severe febrile reactions continuing to be the most common.

Thirty-five cases of acute haemolytic transfusion reactions (AHTR) and five delayed haemolytic transfusion reactions were reported this year. One patient with sickle cell disease (SCD) died, related to hyperhaemolysis. There were seven cases of major morbidity, five with hyperhaemolysis in patients with SCD. Four of 17 cases of AHTR involved the presence of antibodies to low-frequency antigens (LFAs) on red cells electronically issued. One was attributable to anti-Wr^a; in the other cases no antibody was identified or was not fully investigated. HTRs due to antibodies directed against LFAs are an acknowledged, but small, risk of omitting the indirect antiglobulin test (IAT) crossmatch, estimated at 1 in 500,000 to 1 in one million transfusions.[2] The possibility of this event should always be considered when a patient has an acute HTR episode following transfusion, and a retrospective crossmatch should be undertaken to confirm the presence of a red cell antibody, so that the patient can be flagged as being unsuitable for electronic issue, thereby preventing future incompatible transfusions.

Laboratory errors

More testing and component selection errors in the laboratory have been reported since 2015 (Fig 4). Understaffing, poor knowledge and skills, and high workloads feature in many of the reports, consistent with findings from the 2017 UK Transfusion Laboratory Collaborative (UKTLC).[3]

Key laboratory messages

- Laboratories should always have adequate staffing at the appropriate grade to support those who 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 any deficiencies.

The UKTLC published recommended minimum standards for hospital transfusion laboratories in October 2014.[4] These standards focus on staffing, knowledge and skills, and technology and are intended to encourage appropriate use of technology and staff in hospital transfusion laboratories within the framework of current legislation. They are designed to promote best practice and to reduce the number of errors leading to transfusion-related patient safety incidents as monitored by SHOT and the Medicines and Healthcare products Regulatory Agency (MHRA) through their respective haemovigilance systems. The standards are mapped against the BSQR and are supported by the United Kingdom Accreditation Service (UKAS) and MHRA during their inspections.

> Most near-miss errors result from inadequate patient identification at the two points of sample taking and blood component administration

Pathology continues to experience major process changes. The UKTLC standards have been considered by many laboratories, especially in relation to staffing levels. However, staffing shortages have still not been addressed. This, together with increased workload, likely contributes to lower morale and reduced job satisfaction, with many leaving for posts in other organisations, or taking early retirement. This is resulting in a wealth of experience and knowledge being lost to the organisation.[3]

Information technology (IT)-related errors contributed to 20% of the SAE reported jointly to SHOT and MHRA. These include transcription errors resulting in incorrect patient demographic

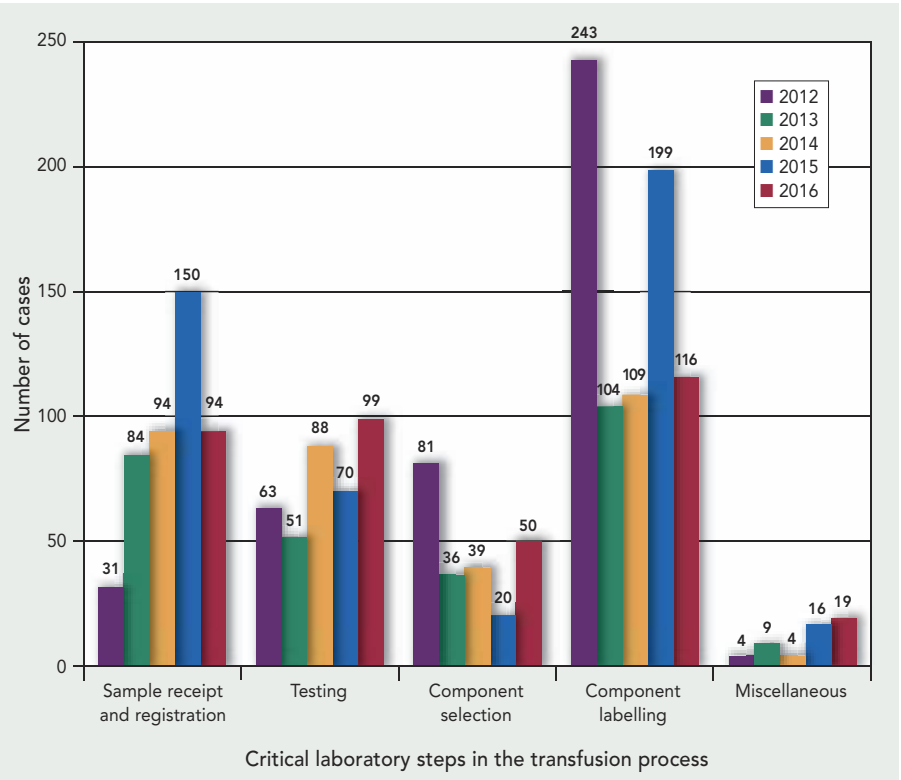

Fig 4. Laboratory data – five-year trend.

details and incorrect results entered onto the LIMS, failure to heed warning flags, and poor LIMS control of component selection and suitability for electronic issue; 20 cases were reported this year where blood was issued electronically when the patient was not eligible.

IT reflection

- *Knowledge and skills*: IT does make transfusion safer by controlling and supporting the task, but does not replace knowledge of the task itself.
- *Personal responsibility*: It is the responsibility of the laboratory managers and supervisory staff to ensure that their staff are trained and deemed competent to carry out the duties that are expected of them
- *Fit for purpose*: Need to ensure that IT systems are fit for purpose and tested against a broad range of scenarios. The IT systems need to be flexible and take into consideration the changes in transfusion safety. SHOT errors continue to show weaknesses in IT systems, and these need to be taken into account when upgrading existing IT systems and developing new ones.
- *Sharing information*: This is key to good transfusion care, but the lack of connectivity and interoperability fails to show the potential benefit of secure electronic data transfer between IT systems.

Human factors

A human factors investigation tool (HFIT) was added to the SHOT (Dendrite) database in January 2016, asking the reporter to review the extent to which four sources of human factors were implicated in each incident (where a score 0 = no contribution, and 10 = fully responsible), as follows:

- Unsafe practice by individuals.
- Unsafe conditions associated with the local environment or workspace.
- Unsafe conditions associated with organisational or management.
- Conditions associated with the government, Department of Health or high-level regulatory issues.

Data collected since 2016 (*n*=2677), where the HFIT questions were available, with the percentages of each score attributed to each of the four groups, are shown in Figure 5.

In most reports, individual staff members were felt to be primarily responsible; however, other research into human culpability suggests that this score may have been overestimated by more than 50%, which means an underestimate of the impact of other non-individual factors. The 2017 UKTLC survey reported

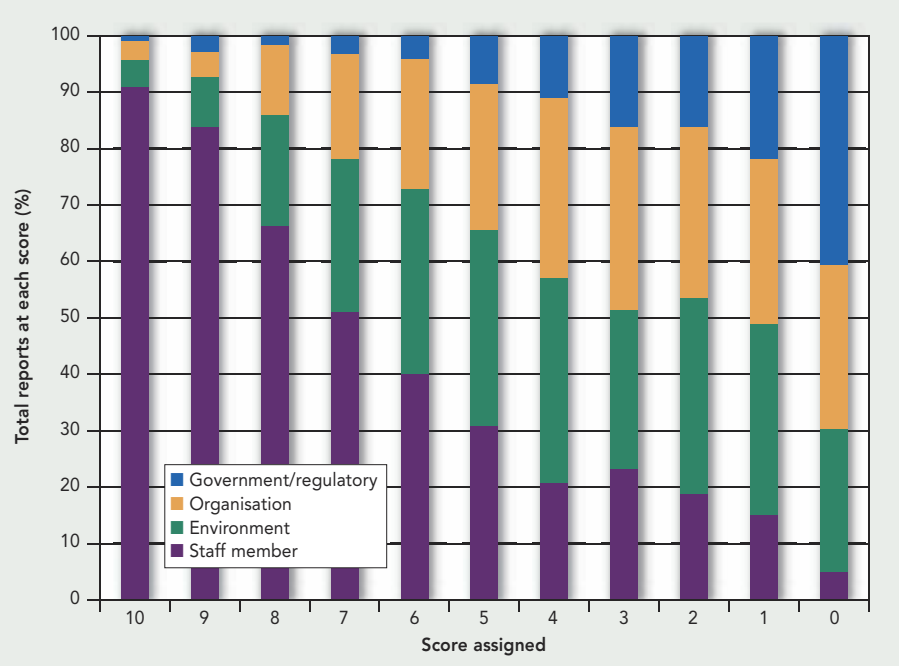

Fig 5. Estimation of different human factors contributing to errors (score out of 10).

Many errors originating within the laboratory are reportable to haemovigilance organisations, and reporting is a key requirement of any quality management system

that 117/187 (63%) laboratories that answered the question had vacant posts, 73 of these employed agency staff. 124/171 (73%) said that staffing levels had remained the same or decreased, with very few reporting an increase (23/171); however, 88/191 (46%) stated that workload had increased, with 85/88 (97%) saying this increase was over 50% compared to the previous year. It is often easier to blame the individual than to consider the organisational circumstances that contributed to the error. A self-learning package is available on the SHOT website to help reporters score and categorise the human factors of adverse incidents.[5]

Many errors originating within the laboratory are reportable to both haemovigilance organisations, and reporting is a key requirement of any quality management system. Addressing errors and understanding the human factors involved will provide benefits in the long term by preventing errors and ensuring safe laboratory practices with provision of components of the correct quality and service. Blood components are very safe but we must continue to learn from errors and improve our practice.

All figures are published with permission from SHOT and can be found with additional material in the SHOT report (www.shotuk.org/wp-content/uploads/SHOT-Report-2016_web_11th-July.pdf).

References

1 Serious Hazards of Transfusion Report 2016 (www.shotuk.org/wp-content/uploads/SHOT-Report-2016_web_11th-July.pdf [TACO chapter]).
2 Garratty G. Screening for RBC antibodies-what should we expect from antibody detection RBCs. *Immunohematology* 2002; **18** (3): 71–7.
3 UK Transfusion Laboratory Collaborative (www.shotuk.org/wp-content/uploads/2017-UK-Transfusion-Laboratory-Collaborative-Survey.pdf).
4 UK Transfusion Laboratory Collaborative (www.shotuk.org/wp-content/uploads/UKTLC-standards-2014.pdf).
5 Serious Hazards of Transfusion self-learning package (www.shotuk.org/reporting/human-factors-tuition-package).

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