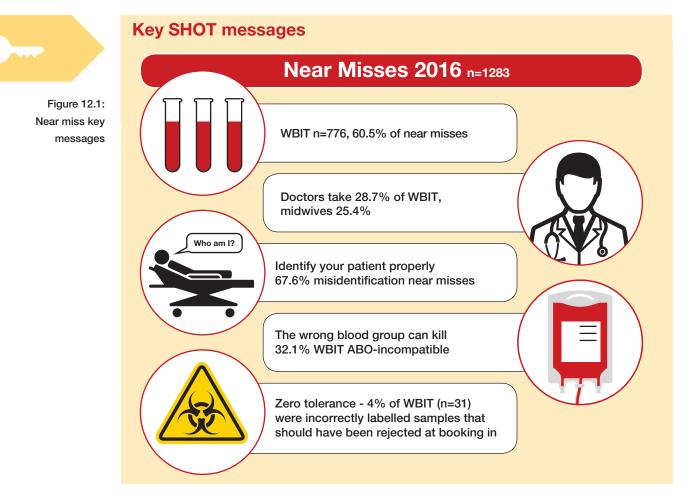
12 Near Miss Reporting (NM) n=1283

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Definition:

A 'near miss' event refers to any error which if undetected, could result in the determination of a wrong blood group or transfusion of an incorrect component, but was recognised before the transfusion took place.

The number of reports of near misses continues to increase, n=1283 from n=1243 in 2015. It is important to learn from near miss cases and SHOT strongly encourages reporting of these incidents.



WBIT=wrong blood in tube

Discussion of near miss errors in other categories

Full discussion of these cases can be found in each relevant chapter. Table 12.1 details the subcategorisation of near miss events according to SHOT definitions.

Category of outcome had near miss incident not bee		Discussed in chapter	Number of cases	%
Incorrect blood component	Wrong component transfused (WCT)	Chapter 10	881	68.7
transfused (IBCT)	Specific requirements not met (SRNM)	Chapter 10	121	9.4
Handling and storage errors (HSE)		Chapter 9	124	9.7
Right blood right patient (RBI	t blood right patient (RBRP) Chapter 8		121	9.4
Adverse events related to an	related to anti-D immunoglobulin (Anti-D Ig) Chapter 14		29	2.3
Avoidable, delayed or undertransfusion (ADU)		Chapter 11	7	0.5
Total			1283	100

Table 12.1: Possible outcomes from near miss incidents if not detected

Near miss wrong blood in tube samples (WBIT), caution with testing rejected samples

The largest number of near misses in a single category continues to be WBIT incidents 776/1283 (60.5%).

Some reporters are submitting cases where they have detected a WBIT when there is evidence that the sample should have been rejected at the booking-in stage, 31/776 (4.0%) of all WBIT. These incidents have been accepted as SHOT-reportable, because the laboratory staff have tested and confirmed the sample as WBIT, not simply a labelling error, but this practice of testing inadequately or poorly labelled samples should be discouraged. Zero tolerance (i.e. some error in the labelling) requires that such samples should be rejected immediately at booking-in. Laboratory staff would need to be very careful if testing a sample that should have been rejected, because of the risk of those tests becoming accidentally validated and used inappropriately as historical results for the wrong patient.

Learning point

• Full implementation of zero tolerance requires that all incorrectly or incompletely labelled samples should be discarded without testing and this applies to all pathology samples, not only those in transfusion

ABO incompatibility prevented by detection of near miss incidents n=264

Near miss incidents could have resulted in ABO-incompatible red cell transfusions. In a total of 881 near miss potential incorrect blood component transfused (IBCT) cases, 264/881 (30.0%) would have resulted in an ABO-incompatible transfusion. The highest risk error is one that results in group A red cells being given to a group O recipient, because anti-A titres tend to be higher than anti-B titres and the anti-A titre tends to be higher in group O subjects than group B (Klein and Anstee 2014). Half the ABO-incompatible near misses could have resulted in group A red cells being given to a group O patient (130/264, 49.2%). This is discussed in more detail in Chapter 3, Headline Data: Deaths, Major Morbidity and ABO-Incompatible Transfusions.

The majority of potential ABO-incompatible transfusions result from WBIT samples, 249/264 (94.3%). The 249 ABO-incompatible WBIT out of a total of 776 WBIT, means 32.1% of all WBIT incidents could have resulted in an ABO-incompatible transfusion. All but 4 of the total 264 ABO-incompatible near misses resulted from clinical errors.

Table 12.2: Cause of potential ABO-incompatible transfusions n=264

Cause of potential ABO-incompatible transfusions	Number of cases	%		
WBIT	249	94.3		
Component collection/administration error	9	3.4	Clinical error	
Sample error	2	0.8	11-200	
Wrong group component selected	2	0.8	Laboratory error	
Grouping/testing error	2	0.8	n=4	
Total	264	100		

The seriousness of the error is not determined by the patient outcome. A nurse was convicted of manslaughter in December 2016 after transfusing an ABO-incompatible red cell unit to a patient (Thelawpages.com, 2017). Any of the 264 near miss cases that were potential ABO-incompatible transfusions could have resulted in the same outcomes. Although criminal charges are seldom warranted, this case showed that such a result is possible. According to the concept of 'Just Culture' (Dekker 2012) staff members should not be punished unless there has been wilful violation or gross negligence. Full investigation of all contributory factors in each incident may be more beneficial that placing blame on individuals. Further information can be found in Chapter 6, Human Factors in SHOT Error Incidents where there is additional discussion of whether it is appropriate in some cases to score 10 for individual error and nothing for other contributory human factors such as environment, organisation or high level government factors (Case 6.1).

In 2016 SHOT included a question in the near miss reporting questionnaire to assess whether the introduction of a group-check policy as recommended in the British Society for Haematology (BSH) guidelines for pre-transfusion compatibility (BSH Milkins et al. 2013) is helping to detect WBIT. In 529/776 (68.2%) WBIT reports the hospital laboratory had a group-check policy in place, but 213/776 (27.4%) indicated there was no policy in place and 34/776 (4.4%) did not answer the question.

Case 12.1: Group-check policy detects original sample was of transfused blood, not patient's

The first sample from an emergency department (ED) patient grouped as O D-negative and the second sample 30 minutes later showed mixed field O D-positive. The patient had been brought in by air ambulance and was given two units of O D-negative emergency blood in transit. Unfortunately there was no pre-transfusion sample taken by the helicopter emergency medical service (HEMS) staff. Subsequent samples taken in the intensive therapy unit (ITU) grouped as O D-positive (mixed field). The most probable cause of the discrepant blood group is that most of the original sample consisted of the emergency O D-negative unit that was being transfused instead of an uncontaminated sample of patient blood.

Learning point

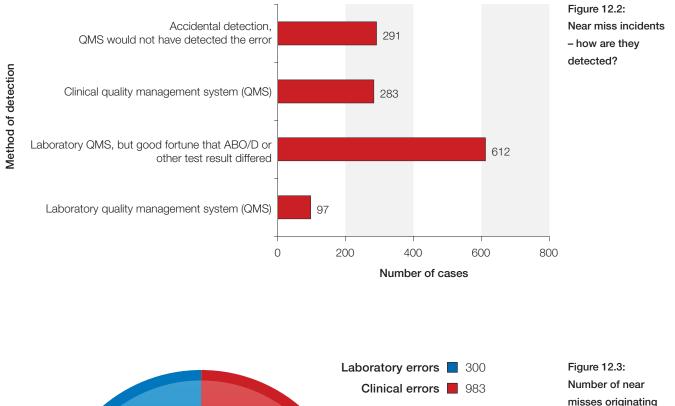
• It is important to obtain a pre-transfusion sample before giving an emergency blood transfusion, but if this is not possible, and a sample is obtained during the transfusion, it should be taken distant from the transfusion site and the laboratory should be informed

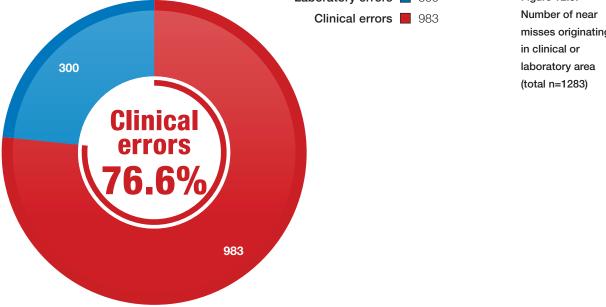
Value of historical samples

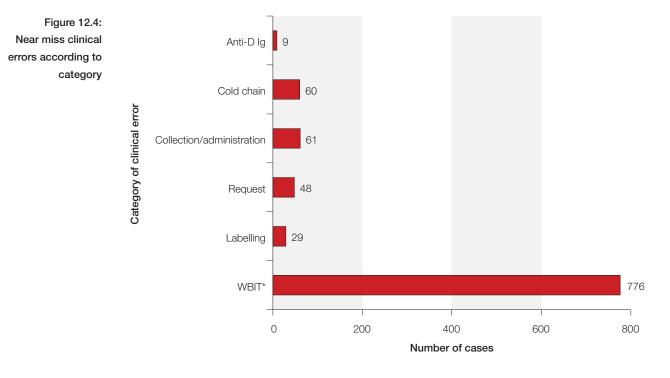
SHOT data from WBIT reports in 2016 show that 49/776 (6.3%) WBIT were historical samples. Although many of these historically incorrect samples were taken in the same patient episode or close to the repeat sample that demonstrated the error, the dates of historical WBIT errors were recorded as far back as 1995. Local group-check policies should consider the criteria for a valid historical record in that institution. An addendum to the BSH guidelines (BSH addendum 2015) for pre-transfusion compatibility procedures in blood transfusion laboratories includes a set of scenarios of possible combinations of historical and current samples that can be used to inform local policy in hospital transfusion departments and reference laboratories.

Quality management systems

Quality management systems (QMS) and checking procedures can detect errors and prevent incorrect transfusions, but not all near miss incidents can be detected by the QMS. There was good fortune in the accidental detection of 291/1283 (22.7%) of near miss cases and 612/1283 (47.7%) were found as a result of testing anomalies, where detection is only possible if current results differ from a historical sample.







Near miss clinical errors n=983

*Includes 1 full blood count (FBC) WBIT error where transfusion could have taken place based on an incorrect result

Case 12.2: WBIT error for full blood count (FBC) sample fortunately results in no harm

A transfusion sample was labelled with the correct patient details and handwritten at the bedside, but the haematology and biochemistry samples were mislabelled with details from another baby who had the same surname and date of birth, but a different hospital number. The haematology and biochemistry sample labels were printed away from the patient using an electronic system and the doctor used the patient name rather than hospital number to search for details on the electronic system. The incorrectly labelled sample for FBC was found to have a haemoglobin (Hb) of 54g/L. Fortunately the correct baby was transfused.

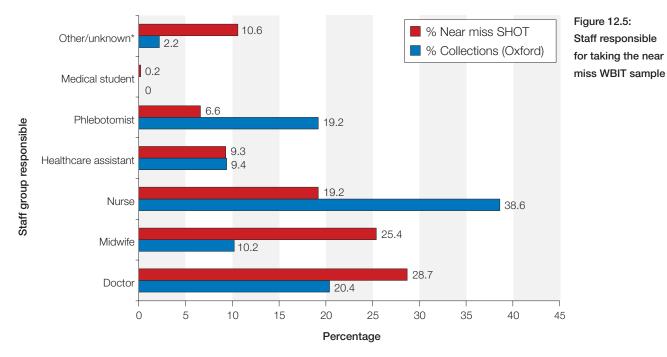
Wrong blood in tube (WBIT) n=776

Definition of wrong blood in tube incidents:

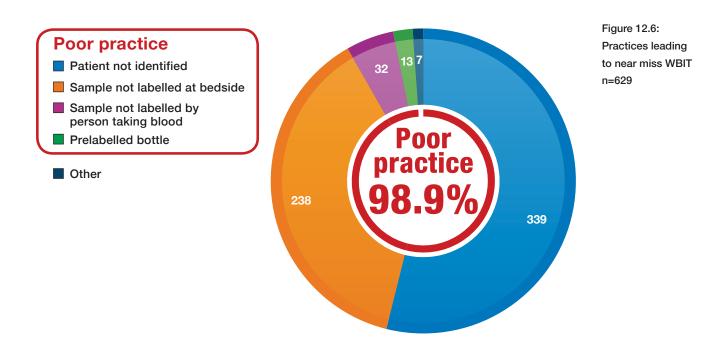
- · Blood is taken from the wrong patient and is labelled with the intended patient's details
- Blood is taken from the intended patient, but labelled with another patient's details

Staff responsible for wrong blood in tube incidents

Denominator data have been supplied by the Oxford University Hospitals NHS Foundation Trust. Total Oxford samples n=14,678, in a 3-month period December 2016 to February 2017, population 670,000 in 2015. Doctors remain the staff group most likely to be responsible for wrong blood in tube errors, accounting for 28.7% (223/776) but this has fallen from 35.0% (273/780) in 2015. Midwives and doctors are over-represented when compared against the percentage of samples taken by those staff groups in the Oxford region.



*Includes historical WBIT incidents reported to SHOT where details are unknown With thanks to Professor Mike Murphy and colleagues for supplying the Oxford data



The majority of WBIT samples result from failure to identify the patient correctly and labelling the sample away from the bedside, together 577/629, 91.7% (in 147 the procedures were not stated; these are not included in Figure 12.6). One way of reminding staff to complete the process correctly is the use of posters on the wards with the 'sample circle' promoted by Joy Murphy, a transfusion nurse practitioner, noting that unlabelled samples must not leave the sample circle.



All samples <u>must be labelled at the bedside</u> from the wristband details. Unlabelled blood samples MUST NOT leave the SAMPLE CIRCLE. Unlabelled blood samples outside the circle should be disposed of.

The majority of WBIT are detected during laboratory testing, Figure 12.8.

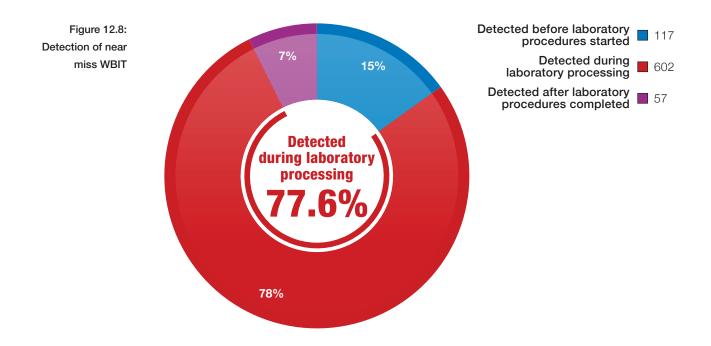


Figure 12.7: The sample circle

Near miss laboratory errors n=300

Please see Chapter 7, Laboratory Errors for further information on category of error.

Near miss information technology (IT) errors

Case 12.3 was initially reported and included in the numbers for the 2015 Annual SHOT Report. The case is reported in full here as there are important learning points which have emerged after detailed analysis. This is a reminder that IT systems are not always as safe as users might expect, and that there may be a time delay in implementing the correction which was made in early 2017.

Case 12.3: Auto-validation by laboratory information management system (LIMS) assigns incorrect ABO group to the patient record

A blood sample on a patient previously unknown to the transfusion laboratory was tested on the Galileo Echo analyser and, having required no manual editing, the test result was suitable for autovalidation so was exported to the CliniSys WinPath v5 LIMS. The result assigned to the patient record was B D-positive but the result produced and interpreted by the analyser was O D-positive. No blood transfusion was required so the patient came to no harm. This was extensively investigated by the LIMS provider and a notification issued to all users of the same software highlighting the potential, albeit very unlikely, whereby a patient's blood group could be transposed with the results of another patient, under a very specific set of circumstances and that there will shortly be a point upgrade to the software to resolve the issue and mitigate the risk.

CliniSys state that 'The approved methodology to auto-validate a batch of blood group results from BT Analyser is to click the auto-validate button and wait until the queue is fully processed and the checking has completed'. They have discovered that 'should a user scroll down the queue, minimise the screen, or cause the validate grid to refresh in any way while the auto-validate process is still running, a patient's blood group *may* be written against the wrong patient record.' However they also noted 'that this has *only* been seen and recreated when a degradation in network connectivity and/or performance is experienced, hence the rarity of the occurrence'.

Due to the action taken by CliniSys, all transfusion laboratories using a specific version of their software have now been informed to take appropriate action to prevent any patient harm. However there are some learning points for all transfusion laboratories and the SHOT recommendation for software providers to work together with transfusion professionals to learn from errors and provide fit for purpose software is relevant to this case.

Learning points

- Implementation of the group check provides additional safety to prevent issue of wrong blood. The principle of the group check is to ensure correct patient identification but group check also detects discrepancy if the wrong sample is tested and, in this situation, the allocation of the wrong result to the patient record
- Previous blood grouping errors have been reported where the interface between the analyser and the LIMS transmits the wrong result and validation protocols can be used to test the integrity of interfaces. It is important to note this error is not due to the interface but due to interrupting an auto-validation programme which is much more difficult to validate unless there is an inbuilt check to read and compare the group with a historical group already assigned to that patient. The software upgrade provided in response to this error will include such a check but is not going to be effective in first-time patients

Case 12.4: Analyser error that could not be detected by quality management system

A crossmatch was processed on the analyser, which gave the result as negative, i.e. compatible. Another biomedical scientist (BMS) put the same sample on the analyser a couple of hours later not realising the crossmatch had already been performed. The re-run of the crossmatch gave results as positive i.e. incompatible. On review of both crossmatch results it was noted that on both occasions the unit was incompatible with the patient's plasma, but the analyser had incorrectly called the initial crossmatch compatible. This anomaly has been investigated further by the analyser manufacturer. They identified that the picture from the rear of the cassette gave a query (?) result, but the picture from the front had a value below the level to trigger a ? result. As a front-and-back average feature is used, and this average was below the threshold, the result was given as negative. A correction should follow in one of the next software versions and in the meantime results are being reviewed by a BMS prior to transmission from the analyser to the LIMS.

Further analysis of total near miss errors n=1283

Tables showing the subcategorisation of near miss errors consistent with those in previous Annual SHOT Reports (2010-2015) can be found in the supplementary information on the SHOT website www.shotuk.org.

Commentary

The key messages are the same as previous years, with failure of correct patient identification as a common root cause of near miss cases 867/1283 (67.6%). WBIT incidents remain the most commonly reported near miss error and accounted for 776/1283 (60.5%) of all near misses in 2016. Many near miss incidents, particularly WBIT, are potential ABO-incompatible transfusions. In 2016 264/881 near miss IBCT could have been ABO incompatible (30.0%).

The practice of testing poorly labelled samples to confirm if they are WBIT is questionable and SHOT has previously recommended full zero tolerance for all pathology samples. There is a risk that test results on unacceptably labelled samples could be accidentally validated and used inappropriately as a historical result when the sample was from the wrong patient.

References

BSH Milkins C, Berryman J et al. (2013) Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories. Transfus Med 23, 3-35

http://onlinelibrary.wiley.com/doi/10.1111/j.1365-3148.2012.01199.x/pdf [accessed 8 March 2017]

BSH (2015) Addendum to guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories.

http://www.b-s-h.org.uk/media/5149/pre-transfusion-historical-samples-scenarios-version-_-final290115.doc [accessed 8 March 2017]

Bolton-Maggs PHB, Poles D et al. (2013) on behalf of the Serious Hazards of Transfusion (SHOT) Steering Group. **The 2012 Annual SHOT Report.** https://www.shotuk.org/wp-content/uploads/SHOT-Annual-Report-20121.pdf [accessed 19 March 2017]

Bolton-Maggs PHB, Poles D et al. (2014) on behalf of the Serious Hazards of Transfusion (SHOT) Steering Group. **The 2013 Annual SHOT Report.** http://www.shotuk.org/wp-content/uploads/2013.pdf [accessed 08 March 2017]

Dekker S (2012) Just culture: Balancing safety and accountability. Ashgate Publishing, Ltd.

Dzik WH, Murphy MF et al. (2003) **An international study of the performance of sample collection from patients.** Vox Sang 85(1), 40-47

Klein HG and Anstee DJ (2014) 12th edition. **Mollison's blood transfusion in clinical medicine.** John Wiley & Sons, 122-124

Murphy MF, Stearn BE, and Dzik WH (2004) Current performance of patient sample collection in the UK. Transfus Med 14(2), 113-121

Thelawpages.com (2017) http://www.thelawpages.com/court-cases/Lea-Ledesma-19287-1.law [Accessed 08 March 2017]