

5 Laboratory Errors n=455 and MHRA Serious Adverse Events n=765

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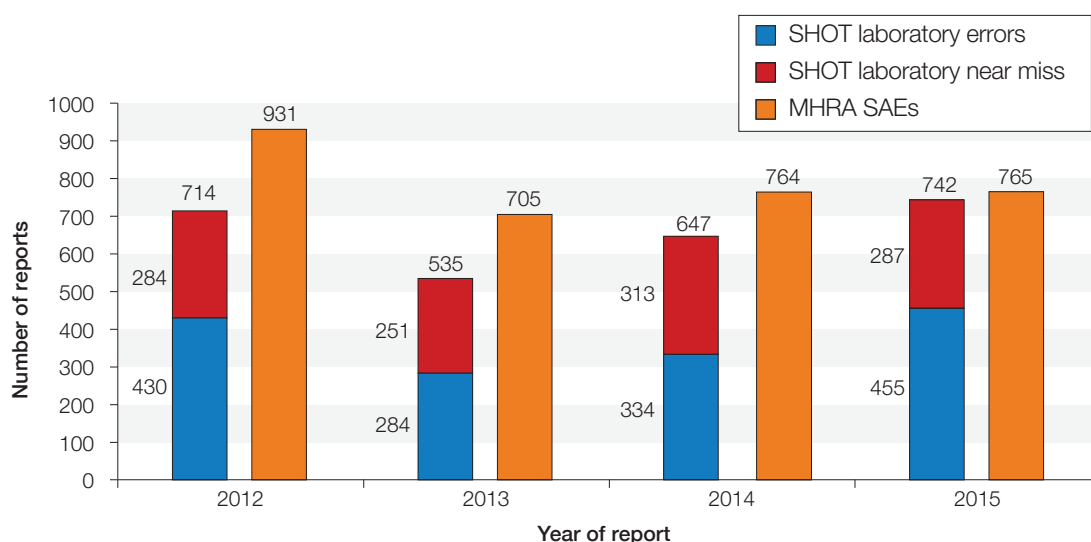
Introduction

This year the SHOT laboratory chapter has been written in conjunction with the Medicines and Healthcare Products Regulatory Agency (MHRA). The chapter highlights laboratory errors reported to SHOT and the serious adverse event (SAE) that have been reported to the MHRA as required by the Blood Safety and Quality Regulations (BSQR) (2005) (as amended). This joint chapter gives a unique opportunity for the data to be analysed independently by SHOT experts and the MHRA, but to provide a joint conclusion.

When comparing Serious Adverse Blood Reactions and Events (SABRE) and SHOT numbers there are significant, recognised differences. These differences include, but are not limited to:

- MHRA data are based on reports made strictly under the BSQR
- The same report to each organisation may be completed in a different calendar year
- MHRA data do not include errors in clinical practice and administration of blood e.g. wrong blood in tube (WBIT), inappropriate transfusions and errors in anti-D immunoglobulin (Ig) issue and administration
- SHOT does not include laboratory error cases where the component does not leave the laboratory e.g. expired components left in the refrigerator
- MHRA data do not include the issue data or reactions to blood products which are classified as medicines rather than blood components such as Octaplas® (solvent-detergent fresh frozen plasma (SD-FFP)) and immunoglobulins (both anti-D immunoglobulin and intravenous immunoglobulin)

Figure 5.1:
A comparison
of reports over
a 4 year period
2012–2015



The BSQR require that SAEs and serious adverse reactions (SAR) related to blood and blood components are reported by Blood Establishments and hospital blood banks to the MHRA, the UK Competent Authority (CA) for blood safety. This requirement is enabled by the SABRE reporting system. In 2015 60/765 SAE reports were made from Blood Establishments.

SHOT laboratory errors

The total number of laboratory incidents reported to SHOT in 2015 (n=455) has increased from 2014 (n=334) Figure 5.2, particularly component labelling, availability and in handling and storage. Errors in equipment e.g. refrigerator failures resulted in several patients receiving units that had been out of temperature control, many related to failure to notice alarms at satellite refrigerators, or inappropriate use. Miscellaneous cases have also increased. These included cases of inappropriate administration of anti-D immunoglobulin (Ig). Staff shortages are a recurring theme in several of these miscellaneous reports (see the increasing number of cases of delayed transfusion, Chapter 7, Avoidable, Delayed or Undertransfusion (ADU)).

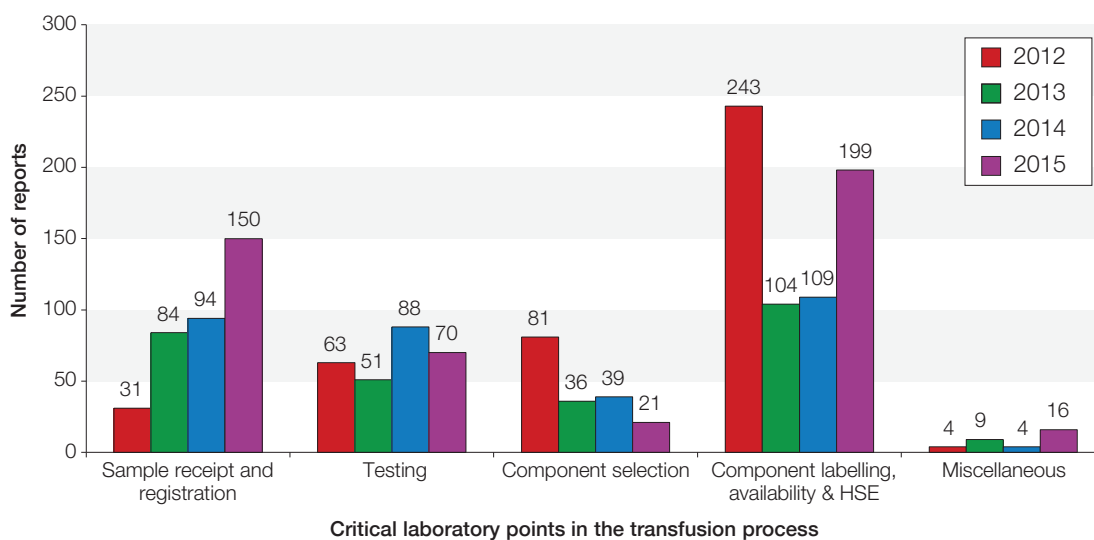


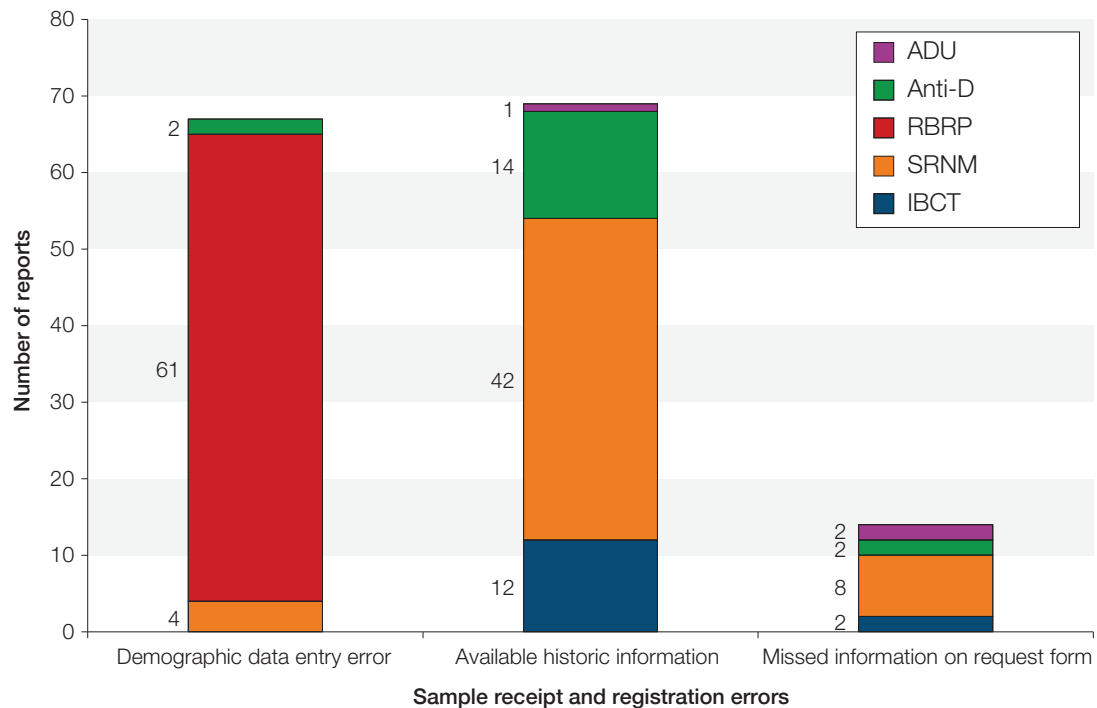
Figure 5.2:
SHOT data
2012–2015
showing 4 year
trends indicating
the critical points
in the laboratory
processes where
errors occur

SHOT data have been categorised into critical points that are undertaken in the laboratory and these are described below:

Sample receipt and registration n=150

Sample receipt and registration errors are increased compared to 2014 (n=94)

Figure 5.3:
Sample receipt and
registration errors
n=150



Key: ADU: avoidable, delayed and undertransfusion; RBRP: right blood right patient; SRNM: specific requirements not met; IBCT: incorrect blood component transfused

In 67/150 cases the wrong information or details had been transcribed onto patients' records. It is important that a robust procedure is in place to ensure that patient records are maintained and information updated accurately. In 69/150 cases laboratory staff could have prevented the error had they taken note of the patients' records thoroughly where correct information was available prior to issuing blood components.

Case 5.1: D-mismatched red cells transfused to a haemopoietic stem cell transplant (HSCT) patient on 3 occasions

A 59 year old female group O D-positive was transplanted with group A D-negative haemopoietic stem cells and as a result should have received O D-negative red cells. There were clear notes in the laboratory information management system (LIMS), however on 3 separate occasions, 3 different biomedical scientists (BMS) issued group O D-positive red cells which were transfused. The first BMS made the error by issuing the patient's group rather than the group indicated in the LIMS. The subsequent BMS staff referred back to the original error and selected red cells of the same incorrect group.

Good practice points

- The corrective action would be to state in the individual patient HSCT protocols the ABO and D type of red cells required for transfusion including the date(s) from which changes need to be made
- BMS staff should be vigilant and check LIMS information carefully, particularly in transplant patients (now also including hepatitis E (HEV)-screened blood components for allogeneic HSCT)
- Nursing staff should be reminded to check discrepant blood groups with the transfusion laboratory
- Preventative action would be to issue patient information 'warning cards' to transplant patients similar to those issued to patients requiring irradiated blood components

Testing errors n=70

Testing errors have decreased in 2015 (n=70) compared to 2014 (n=88)

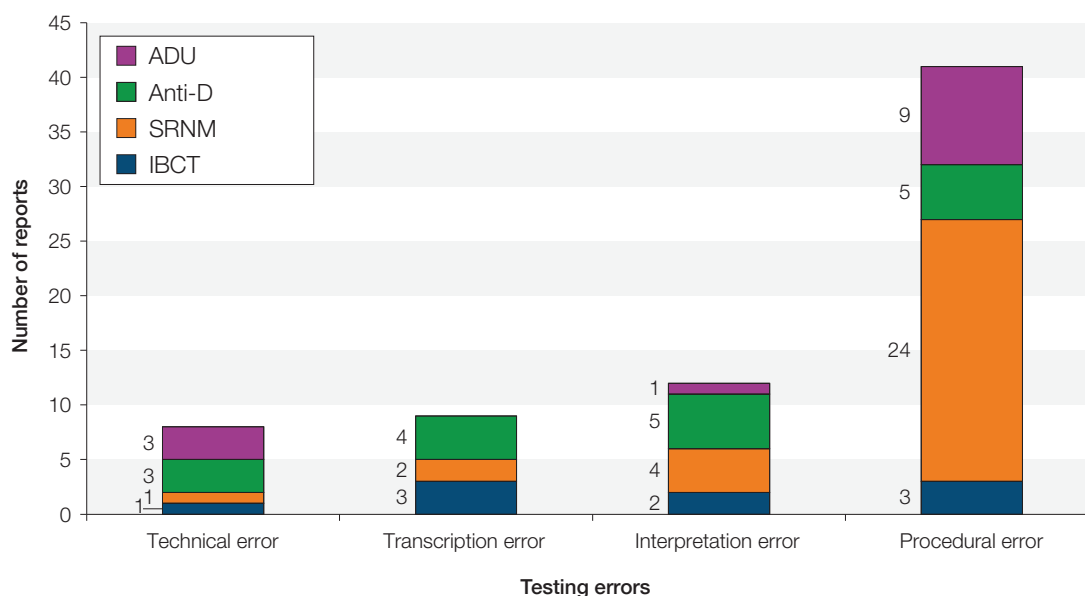


Figure 5.4:
Testing errors with
their outcome n=70

Case 5.2: Testing error leads to transfusion of incompatible red cells

Two units of red cells were requested for a 70 year old female patient. The crossmatch was incompatible and so the result was rejected on the blood grouping analyser and 2 further red cell units were crossmatched. Instead of returning the incompatible units to stock, the BMS (X) left these in the 'under test' refrigerator. This was verbally communicated to BMS (Y) who was taking over the shift. Due to staff shortages and having to deal with other emergency crossmatches, the incompatible units were overlooked and on completion of the testing, a third BMS (Z) issued the 2 incompatible units to the patient. The root causes were a breakdown in communication and failure to adhere to procedures. No symptoms or signs of a transfusion reaction were reported.

Good practice points

- Timely communication between staff is essential
- Components no longer required for a patient should be moved back to general stock
- Staff involved should complete reflective practice statements
- The learning outcomes need to be clearly identified (ask for help when under pressure, prioritisation of non-urgent work)

Component selection errors n=20

A variety of component selection errors were reported resulting in:

- 10 incorrect blood components transfused
- 6 inappropriate/late administrations of anti-D Ig
- 3 specific requirements not met
- 1 expired unit given to a patient

These cases could have been prevented if laboratory staff had adequate knowledge especially about the differences between certain components i.e. cryoprecipitate and FFP. An increasing number of SHOT reports note difficult laboratory conditions and the United Kingdom Transfusion Laboratory Collaborative (UKTLC) survey has confirmed this (UKTLC 2015). These issues include:

- Increasing workloads
- Working under pressure

- Inadequate staffing levels
- Staff competencies

Component labelling, availability and handling and storage errors (HSE) n=199

This category includes labelling issues, availability of blood components and HSE. HSE are subdivided as shown below:

- Expired components transfused
- Cold chain errors i.e. equipment failures and documentation errors

Miscellaneous n=16

Five of sixteen are summarised below:

- One delay in transfusion was due to lack of staff available to answer the telephone. A robust procedure must be in place to ensure that adequate staffing levels are maintained at all times, especially during periods where staff are more likely to have holidays i.e. during school holidays, public holidays, weekends and also during lunch times (UKTLC Bark et al. 2016)
- In 4 cases anti-D Ig was given inappropriately to D-positive women:
 - 2 cases where the anti-D Ig was given to a woman who had immune anti-D
 - 2 cases where anti D Ig was given outside the 72 hours time limit postnatally

MHRA data (see also full MHRA Chapter 18 in the 2015 Annual SHOT Report: Web Edition)

2015 SABRE data have been analysed by the MHRA haemovigilance team in order to identify common errors and to make recommendations for improvements in corrective and preventive action (CAPA) plans.

Human error accounts for 96.7% (740/765) of SAE reports received. SABRE confirmation reports mostly record that individuals are aware of their local standard operating procedures (SOPs) and that those SOPs are complete and up to date. Human factors play an important part in any total quality system and as such it is key that the appropriate root cause is identified so the appropriate CAPA can be implemented. For example, where a BMS issued the incorrect components because of distraction, although the distraction is relevant it is not the root cause. It is important to identify what caused the distraction and the CAPA should reflect that. The failure to address the appropriate root cause is a recurring problem in some SABRE confirmation reports.

Serious adverse events (SAE)

Definition: Any untoward occurrence associated with the collection, testing, processing, storage and distribution, of blood or blood components that might lead to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity.

SABRE report data

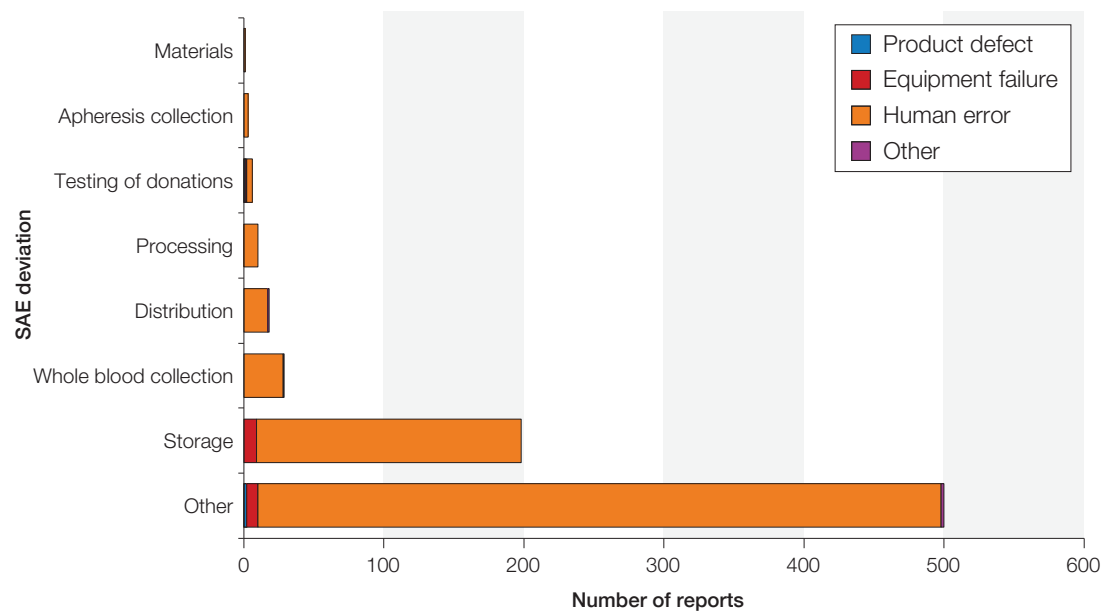


Figure 5.5:
2015 SAE
confirmation
reports by
deviation (what part
of the process) and
specification (type
of report)

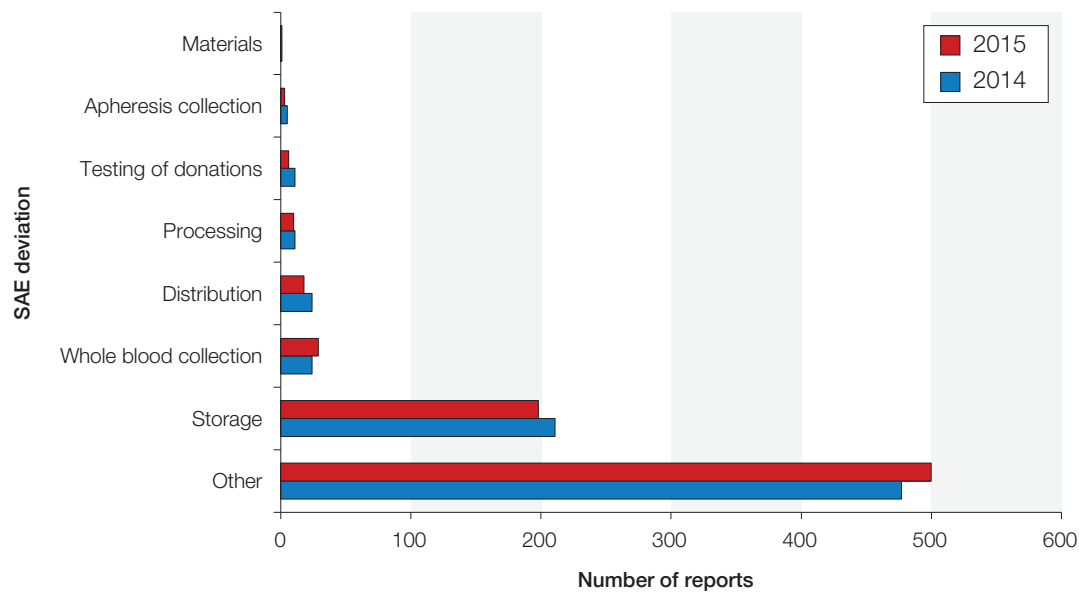


Figure 5.6:
SAE confirmation
reports by
deviation and
specification
2014–2015

Although the numbers in most categories of report are broadly similar to the 2014 data there is a noticeable increase (+23 or 4.8%) in the number of SAEs that fall into the ‘other’ category and also a noticeable decrease in the number of ‘storage’ SAEs (-13 or 6.2%).

Storage errors n=198

Storage remains the second largest individual error category. Specific storage error subtypes are shown below.

Table 5.1:
SAE storage error
subclassifications
2013–2015

Storage subclassification	2013	2014	2015	Change
30 minute rule	9	13	9	-4
Component expiry	56	77	58	-19
Failure to action alarm*	18	14	21	+7
Incorrect storage of component	73	42	45	+3
Miscellaneous	0	4	3	-1
Return to stock error	13	15	17	+2
Sample expiry	18	18	19	+1
Security	7	7	13	+6
Storage temperature deviation	17	21	13	-8
Total	211	211	198	-13

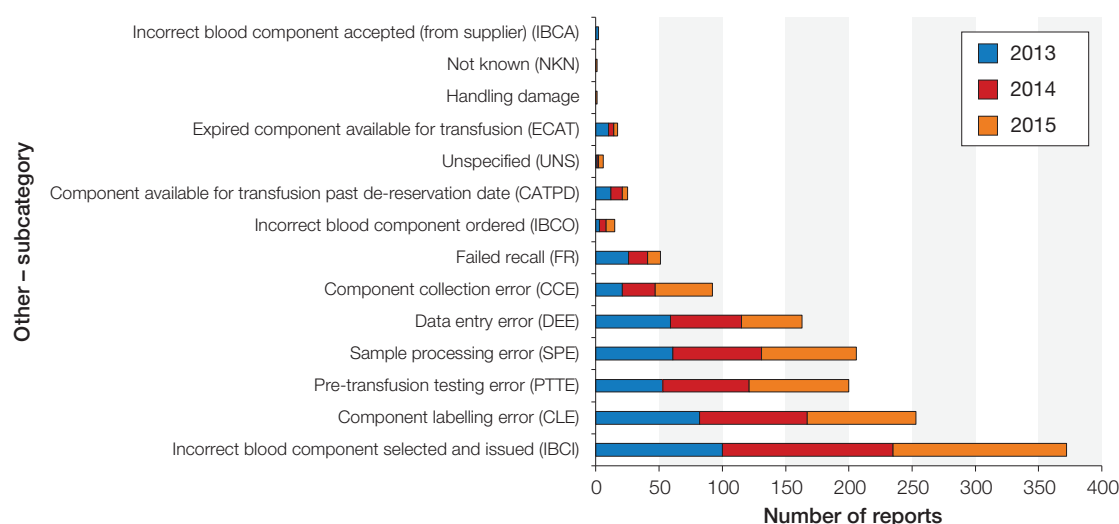
*An increase of 7 SAEs related to failure to action alarm generally refers to inadequate procedures for dealing with alarms or in some cases situations where staff were not able to effectively deal with an alarm as well as carrying out their normal laboratory duties

Laboratory staff should also ensure that procedures related to storage equipment, temperature monitoring and removing unsuitable units from storage locations are robust and clear and that staff are trained and able to activate those procedures effectively, even when lone working or during emergency situations.

Other n=500

As 'other' is the largest category of SAE reports, the MHRA haemovigilance team has created subcategories to further analyse this type of error.

Figure 5.7:
SABRE reports,
subcategory
'other'/ human
error, 2013–2015



Incorrect blood component issued (IBCI) errors remain the largest group and are mainly laboratory errors where specific requirements are not met. A common theme emerging from review of a selection of narratives in IBCI reports is that these errors occur when the BMS has been busy during a lone working period. Furthermore, many have occurred following HSCT or solid organ transplant where the appropriate ABO and D group for transfusion has changed from the patient's original group.

Component collection errors (CCE) may be either the wrong type of component for the right patient, or more worryingly, a component for a different patient. These errors should be detected at the bedside, but some are not, (see sections on wrong component transfused and inappropriate transfusions) fortunately without harm to a patient. Three key reasons are demonstrated for CCEs occurring:

- The correct selection and checking procedures are not performed
- Staffing or workload issues had resulted in the checks being rushed and performed incorrectly
- Although trained, the member of staff had forgotten the correct procedure

All staff must complete all steps in a procedure and at a pace that minimises risk of error. If staff have a workload that is not suitable for their ability, they are more likely to make mistakes. It is important that re-training is delivered at an appropriate frequency. Staff who perform a task less often may require more frequent training than someone that performs the same task regularly. These issues and discussion about **component labelling errors (CLE)**, **pre-transfusion testing errors (PTTE)** and **sample processing errors (SPE)** are expanded in the full MHRA chapter in the 2015 Annual SHOT Report: Web Edition.

Human error n=740

Human errors can be divided into the following categories:

- Procedural steps not performed correctly – failure to carry out a step(s) correctly
- Procedural steps omitted – missing a key step or not following the procedure
- Inadequate process – inadequate design of a process or fundamental quality management system (QMS) failure
- Incorrect procedure – process not properly described in the SOP
- Ineffective training – training not understood by operator
- Inadequate training – training process not fit for purpose
- Lapsed or no training – carrying out a procedure without any formal training

Human error subcategory	Total
Inadequate process	263
Procedure steps not performed correctly	159
Procedural steps omitted/wrong procedure performed	141
Ineffective training	75
Inadequate training	43
Incorrect procedure	39
Lapsed/no training	20
Total	740

Table 5.2:
SABRE reports
by human error
subcategory 2015

NOTE: These numbers should be used as guidance only. The quality of these data is limited by a number of factors:

- The root causes of incidents are usually the result of many contributory factors. The subcategory chosen reflects the most likely reason
- The subcategory chosen is based on the information in the report which may be limited

The most common reason for SAEs occurring is **inadequate process**. This category covers poorly designed tasks which have not been properly planned and allow errors and mistakes to go unnoticed. It also includes those SAEs where there is a fundamental flaw in the overall QMS such as a high workload and inappropriate levels of staffing at the time of the error.

Procedural step errors: These may be a result of being busy, multi-tasking, being distracted or interrupted during the task.

Procedural steps not performed correctly. These incidents are likely to result from slips and lapses by individual members of staff. The individual has carried out the correct procedure, but they have made a mistake in calculation, interpretation or accuracy. These errors may be rare or infrequent for the individual, but are unlikely to be related to a poorly designed process, competency, training and education. A common error that falls into this category is **component labelling error** (CLE), where compatibility labels are transposed.

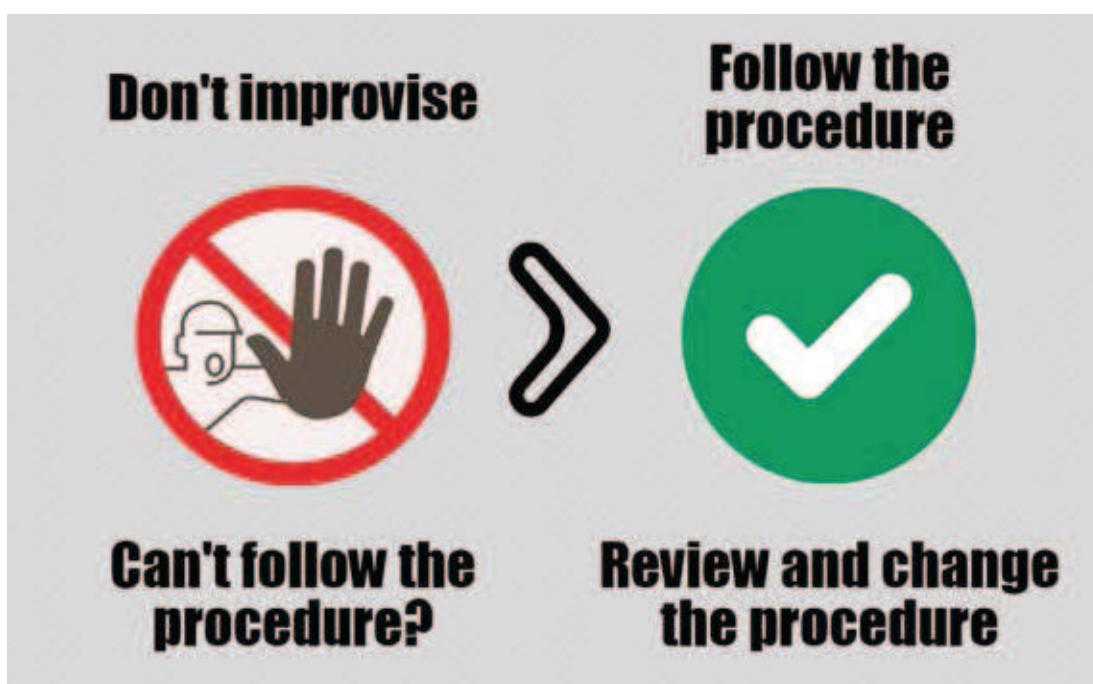
Procedural steps omitted or wrong procedure performed. These errors are characterised by omission of a vital step in a procedure, or the wrong procedure carried out. Common errors include **incorrect blood component issued** (IBCI), where a patient's transfusion history is not checked.

These errors are best addressed by:

- Reviewing and redesigning processes, focusing on the human factors involved, such as the causes of distractions
- Assessing laboratory ergonomics to ensure lean processes and effective laboratory lay-outs
- Completing or reviewing capacity plans which can be used as evidence for addressing long-term staffing issues
- Addressing workload and workflow issues to avoid peaks and troughs in activity
- Addressing short-term staffing levels with policies for annual leave, appropriate break times and cover for acute staffing shortages

It is important **always** to follow the correct procedure – never cut corners or take short cuts.
If you cannot follow the procedure as written, then review it, improve it and re-write it.

Figure 5.8:
Don't improvise,
follow the procedure



One-off or infrequent procedural errors can be dealt with as above. However, should there be a trend that develops indicating these same errors affect multiple members of staff, or at the same time of day, or day of the week, a more thorough investigation may be required to uncover CAPA that can address flaws or weaknesses in the overall QMS.

Top 5 SAEs with good laboratory practice points

SAE what happened	Why did it happen?
1. Incorrect blood component selected and issued (IBCI)	Inadequate process
2. Component labelling error (CLE)	Procedure performed incorrectly
3. Pre-transfusion testing error (PTTE)	Inadequate process
4. Sample processing error (SPE)	Procedure performed incorrectly
5. Storage (component expiry)	Inadequate process

Table 5.3:
Top 5 SAEs with the
type of human error

The following examples illustrate what might be considered as CAPA to address the root causes. These are representative of many of the reports received, and are designed to focus on improvements to systems, practice and transfusion laboratories. The examples show the categorisation for MHRA SAEs and the SHOT equivalent in brackets.

1. IBCI (incorrect blood component transfused IBCT): Inadequate process

Neonatal FFP was ordered, but neonatal cryoprecipitate was selected, issued and transfused.

- Two similar looking components were stored on the same shelf
- The BMS should have taken time to properly read the labels and select the correct component
- Laboratory staff also need to address additional knowledge and training and understanding of the blood components and be able to differentiate between them

A simple change to the process addressed the human factors involved. The root cause was addressed by separating the two types of component, placing them on different shelves and labelling the shelves with the expected contents.

2. CLE (right blood right patient RBRP): Procedure performed incorrectly

Two red cell components were being issued and had similar donation numbers.

- The labels were transposed
- The porter collecting the units did not notice the error, but it was discovered during the bedside check
- The BMS admitted to being fatigued
- The BMS was undertaking the activity in the designated 'quiet zone' and was listening to the conversation of two other members of staff
- This distraction led to a failure to properly check that the donation numbers on the label and the bag matched before attaching them
- The porter collecting the units did not carry out the proper checks before taking them to the clinical area

This example demonstrates how a relatively simple process can be affected by a number of contributory factors and it also demonstrates the 'Swiss cheese' effect when a number of barriers within the process fail. Distractions, such as conversation, in a busy laboratory are not always avoidable. This is why it is important that staff concentrate on the task at hand, following the procedures they have been trained in, to the letter. Although it is typical to see 'second checks' or scanners used to detect labelling errors, these do not address the human factors which have already led to the error.

3. PTTE (IBCT): Inadequate process

Incorrect electronic issue of blood

- A sample result showed a dual population in the anti-B test of the blood group performed on the analyser. This was due to recent transfusion of emergency group O blood

- One unit was requested urgently by the ward and issued by electronic issue (EI) but the sample was not suitable for EI because the blood group had to be interpreted manually
- The BMS did not notice the dual population result when checking during the process where the LIMS asks if the results are automated and to confirm that it has not been amended. The wrong entry was selected
- The error occurred at the weekend when the BMS was working alone. Due to the high volume of work, the BMS had not had any kind of break for over 5 hours

A long-term solution to the problem was stated to be a new LIMS system which does not ask the BMS to enter whether the sample is automated or manual. This is an improvement to the way the process itself runs, but does not address the actual root cause of this incident.

Human factors such as workload, staffing, break times and urgency of the task can affect the behaviour of the member of staff in terms of their concentration, accuracy, judgement and the pace at which they work. Laboratory managers should not expect staff to work in environments that do not allow staff to work safely.

4. SPE (IBCT or RBRP): Procedure performed incorrectly

Minor discrepancy in patient demographic

- A sample was received into the laboratory and booked in
- Two units of red cells were issued and one unit had already been transfused before it was noticed that there was a slight discrepancy in the spelling of the patient's name
- The sample was checked and it was discovered that the name on the sample was incorrect by a single letter. Note that in another similar instance with a single wrong letter, a patient died as a result of delayed transfusion (Case 7.1 in Chapter 7, Avoidable, Delayed or Undertransfusion (ADU))

The SHOT category depends on whether the sample with the incorrect spelling of the patient name resulted in a transfusion to the patient it was intended for (RBRP) or to another patient (IBCT) or as above ADU if delayed.

This case study demonstrates how very small errors or discrepancies are extremely hard to spot in the laboratory. CAPA in this case may simply be to make the member of staff aware of the error and provide a reminder of the procedure. However, when processes and workflow are being designed, managers should pay attention to the human factors related to tasks that involve a high level of concentration and may be repetitive and monotonous.

5. Component expiry (not SHOT-reportable): Inadequate process

Expired red cells in blood refrigerator

- Seven units of blood expired at midnight on Friday 4th. They were discovered, still in the stock refrigerator, on Monday 7th

If the expired component had been transfused then it would become SHOT-reportable as a handling and storage error (HSE).

The reporter identified a number of factors which failed or were not robust demonstrating an overall weakness in the QMS:

- There was a procedure to clear the refrigerator at midnight, but it can only work if people know about it. The BMS was not aware of the correct procedure which indicates problems with training and communication
- The training processes need to be reviewed to ensure that changes to procedures are communicated and adequately trained in a timely fashion. A daily task sheet is not fit for purpose if it does not include all the key tasks that are expected to be completed

Effective CAPA

From these top five categories of SAEs (Table 5.3), a number of different approaches and actions can be applied when identifying suitable, targeted CAPA. Effective CAPA that addresses weaknesses and flaws in the QMS can prevent errors occurring in other areas of the laboratory, and not just with the actual task that failed. The focus should not necessarily be on retraining, re-competency assessment or adding extra steps in a process, unless it is absolutely necessary. There are certain key principles to consider when improving QMS and when investigating incidents. This list is not exhaustive and is meant for guidance only.

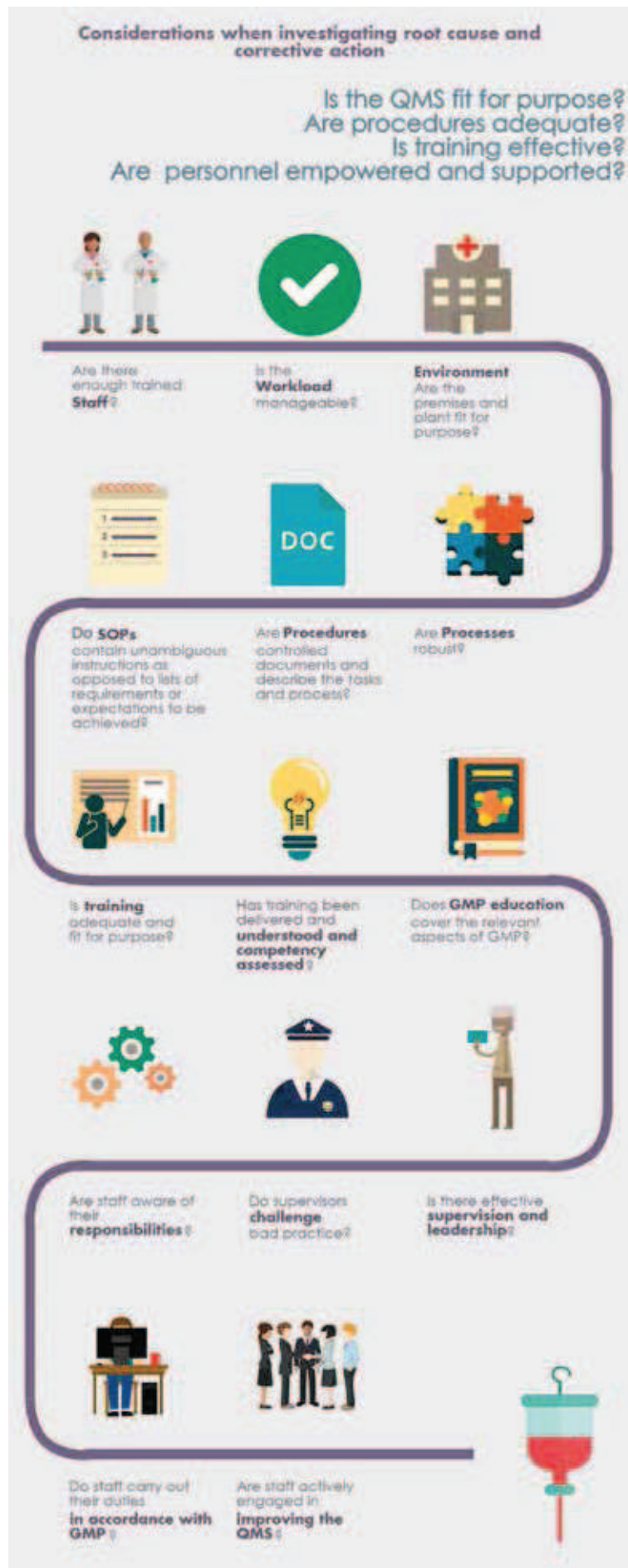
- QMS
 - Is staffing appropriate?
 - Is workload manageable?
 - Is the environment (premises and plant) fit for purpose?
 - Are tasks and processes designed to be robust?
- Procedures
 - Are there SOPs to describe the tasks and processes?
 - Are they document-controlled?
 - Do they contain unambiguous instructions as opposed to a set of requirements or expectations that need to be achieved?
- Training
 - Is there a training plan?
 - Is the training material adequate and fit for purpose?
 - Has training been delivered?
 - Has training been understood and understanding assessed?
 - Does good manufacturing practice (GMP) education cover the relevant aspects of GMP?
- Personnel
 - Is there effective supervision and leadership?
 - Do supervisors watch out for and challenge bad practice?
 - Are staff aware of their responsibilities?
 - Do staff carry out their duties in accordance to GMP?
 - Are staff actively engaged in improving the QMS?

Training

Adequate and effective training is essential. No member of staff should perform a task unless adequately trained. This also applies to any locum or bank staff. Simply because a member of staff has the required level of education and experience on paper, it cannot be assumed that they are familiar with local processes and procedures. A recurring theme in SAE reports relates to locum staff who may be unfamiliar with the laboratory.

Frequency of training is also a factor when errors are made when members of staff appear to forget what the correct procedure is. Although the National Blood Transfusion Committee (England) recommendation for training is 3 yearly, the BSQR does not stipulate any time-frames for training. The MHRA recommendation for activity within the BSQR is at least yearly. If a risk-based approach is taken to training, then that period can be extended to 2 yearly training. What this means is that senior laboratory managers need to assess the effectiveness of training over a period of time. A member of staff who performs a task, for example re-stocking a satellite refrigerator, on a daily basis may have their training period extended to 2 yearly if they continue to perform the task accurately. A member of staff who only performs the same task once or twice a week will require training more frequently to ensure they perform the task correctly.

Figure 5.9:
What to consider
when investigating
an event



Joint MHRA and SHOT conclusions

It is important to note that, even with approximately 2.7 million components issued in the United Kingdom (UK) last year, only 765 SAE confirmation reports were submitted to Europe which equates to 283 SAEs per million components issued or 0.03%. SHOT laboratory incidents were 455 and there were also 287 near miss laboratory errors so the total is 742, a comparable number to the MHRA SAEs. The number of components issued in 2015 was 2,577,276 (Chapter 2, Table 2.2), so the error rate for SHOT-reportable laboratory incidents was 0.029%. (The number of issues recorded by MHRA and SHOT are sourced differently, the MHRA from hospitals and SHOT from the Blood Services and Octapharma). These are very low error rates that likely reflect the high standards of blood transfusion throughout the UK. The UK remains one of the safest countries in the world to receive a blood transfusion, but further efforts can be made to continue to improve the quality and safety of blood and blood components and the safety of the transfusion process.

Pathology services within the National Health Service (NHS) are undergoing fundamental changes. The pressures of such changes are a recurring theme in many cases. These incidents raise concerns in relation to laboratory staff shortages and pressures associated with heavy workload and distractions (Chaffe et al. 2014).

The majority of reports highlight that the LIMS or the clinical area supply all relevant information to the laboratory, but the BMS fail to heed this due to:

- Lack of knowledge and understanding
- Communication
- Staffing and work pressures
- Inadequate processes

Several other reports have highlighted the inadequacy of some information technology (IT) systems to meet the required standards to support safe transfusion practice (BCSH Jones et al. 2014).

UKTLC survey results

In 2015 the UK Transfusion Laboratory Collaborative undertook a further national survey which was distributed to 327 transfusion laboratories to be answered on Wednesday 25th March 2015 in order to give a snapshot of one day in a hospital transfusion laboratory. The survey consisted of 90 questions. The questions were designed to enable comparison with data collected by UKTLC surveys in 2011 and 2013, but included additional questions identified by the National Blood Transfusion Committee (NBTC) (England), emerging through the Regional Transfusion Committees and of interest particularly to the laboratory managers' group. The total number of responses was 204/327 (62.4%) in 2015.

Reorganisation of pathology services was reflected by 100/178 (56.2%) laboratories who had been, were currently or were to be reorganised in future. Managing staff through change is challenging. Staff shortages were reported with dependence on locum and agency staff. Vacancies were present in some laboratories for significant periods of time, for example 14 laboratories reported Band 7 BMS vacancies for over a year. It has become more difficult to train and mentor staff (69.1%, 123/178, who answered this question), and financial resources for training have reduced. Attendance at educational events, other than those which are mandatory, was not facilitated by meeting the agreed staffing level in 50/146 (34.2%) respondents. Fifty-six laboratories had one or more members of staff over the age of 60 years and 144 have staff aged 50-59 years. As these members of staff retire much specialist knowledge will be lost. Blood Service specialist laboratory staff have noted an increase in requests for tests or advice which in the past they expected hospital transfusion laboratory staff to know. Comments about changes in training with the advent of Modernising Scientific Careers (MSC) suggest that knowledge and competency at the time of qualification are reducing. It is not surprising that morale is low (UKTLC Bark et al. 2016).

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