18 Medicines and Healthcare Products Regulatory Agency (MHRA) Report on Blood Safety and Quality Regulation in 2015

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Introduction

The United Kingdom (UK) Blood Safety and Quality Regulations 2005 (as amended) (BSQR) require that serious adverse events (SAE) 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 Serious Adverse Blood Reactions and Events (SABRE) reporting system. All data within this report are correct as of 16/02/16.

Key messages

- The MHRA has continued to subcategorise incidents that fall into the 'other' and 'storage' event categories and the 'human error' specification category to provide greater detail and depth of analysis to SAE reports
- Human error accounts for 96.7% of all SAE
- Reporters are encouraged to investigate all possible causes, especially if at first it would seem the root cause is a slip or lapse by an individual. Further investigation may identify improvements to the overall quality system that could have long lasting preventive outcomes
- Changes to the way the MHRA and SHOT receive reports via SABRE have increased the total number of reports received and assessed by the MHRA, however, this has not resulted in a significant increase in the numbers of SAEs and reduction in the number of SARs where a confirmation report was submitted
- Reporters are encouraged always to report SAEs and SARs, not only to meet their regulatory requirements, but also to provide as much data as possible to the MHRA and SHOT haemovigilance schemes
- It has not been possible to obtain inspection data at this time. It is hoped to publish this online in due course

Summary

2015 SABRE data have been analysed by the MHRA haemovigilance team in order to identify common errors and to make recommendations for improvements to corrective and preventive action (CAPA) plans. In reviewing the data and analysis it is important to remember that even with approximately 2.7 million components issued in the UK last year, only 765 SAE confirmation reports were submitted to Europe or 283 SAEs per million components issued or 0.03%. In 2015 60/765 SAE reports were made from Blood Establishments. This is a very low error rate that likely reflects the high standards of blood transfusion procedures and techniques in place 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.

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 biomedical scientist (BMS) issued the incorrect components because they were distracted, 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.

Please be aware if comparing 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
- A report is only included in the annual figures if it has been completed/confirmed within that reporting year. This means that the same report to the MHRA and SHOT may be included in different reporting years depending on when it was completed or confirmed. (For example, confirmed on SABRE in December 2015, but not completed on the SHOT database until January 2016)
- 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 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 of 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)

If you require further guidance on this issue please contact the SABRE helpdesk on 020 3080 7336.

SABRE report data

Table 18.1 below displays the total number of SABRE confirmation reports that were submitted and satisfy the European Union reporting criteria for SARs and SAEs since 2006.

	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
SAE	507	655	790	968	889	810	931	705	764	765
SAR	237	264	436	500	549	444	343	345	346	262
Total	**744**	**919**	**1226**	**1468**	**1438**	**1254**	**1274**	**1050**	**1110**	**1027**

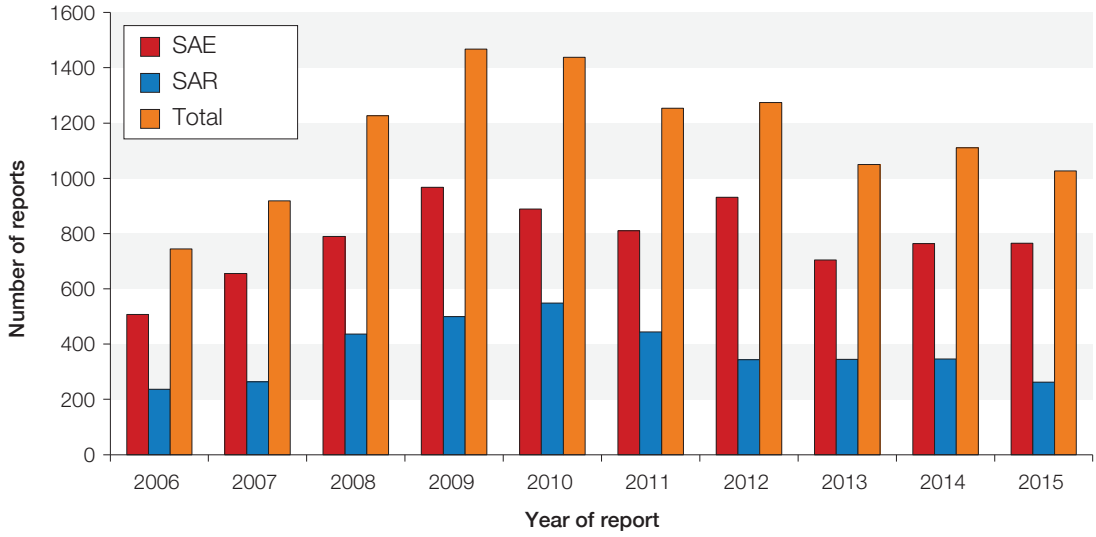
Table 18.1: Submitted SABRE confirmation reports 2006–2015

Despite changes to the way the MHRA and SHOT receive data on SABRE, the number of SAE reports confirmed in 2015 has only increased by 1 report. Since October, reporters have had the opportunity to report all events they consider to be serious and all SHOT reportable clinical errors and near misses. Since the MHRA would then have full sight of all haemovigilance events, and could select SAEs that met the BSQR reporting requirements, it was expected that the number of SAE reports would increase significantly. It would be unwise to make any specific comparisons to numbers of SAEs reported this year to last but the lack of the expected rise in numbers of reports raises a number of questions.

- Have reporters have made genuine improvements to the quality management system (QMS) which resulted in fewer serious errors that meet the SAE definition in the BSQR?
- Are continuing reductions in the numbers of components produced and used resulting in fewer opportunities to make errors?
- Are laboratories suffering from reduced staffing and increased workloads, resulting in reporters not being able to make reports in a timely manner?
- Have the changes to the way reports are made on SABRE resulted in reporters feeling less confident sharing information with the MHRA/SHOT?

There is a reduction in the number of SAR reports confirmed from 346 in 2014 to 262 (24.3%). However, that is most likely down to the new process whereby SHOT update confirmation reports on behalf of reporters. These reports are updated up to a month or so in arrears, and so this year's data is effectively only accounting for 11 months. This offset is expected to balance out in the coming years.

Figure 18.1: SABRE reports 2006–2015

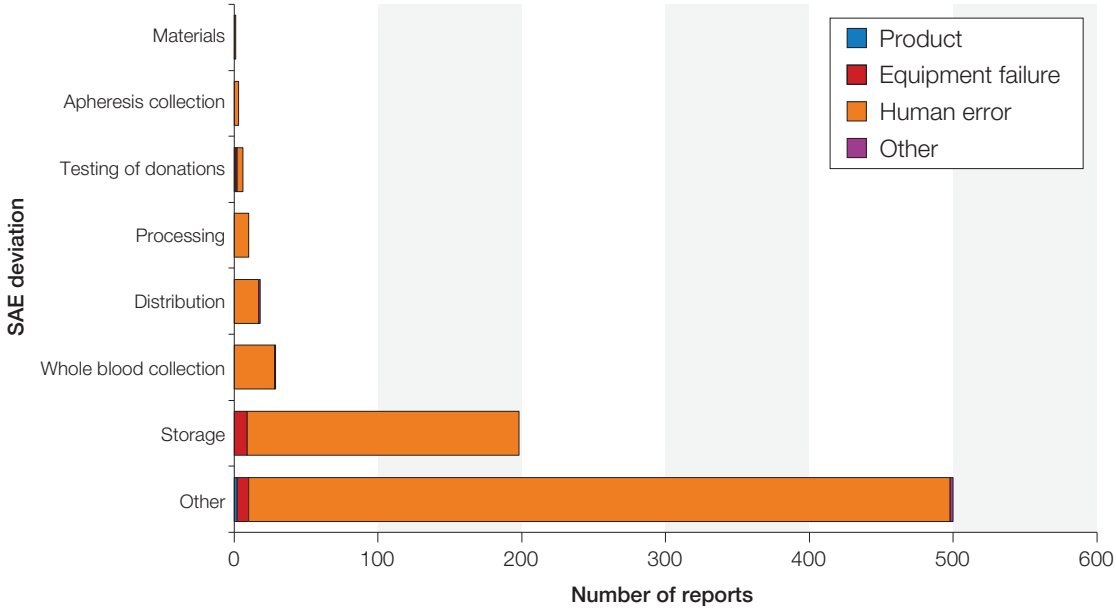


Serious adverse events (SAE)

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.

Figure 18.2: 2015 SAE confirmation reports by deviation (what part of the process) and specification (type of report)



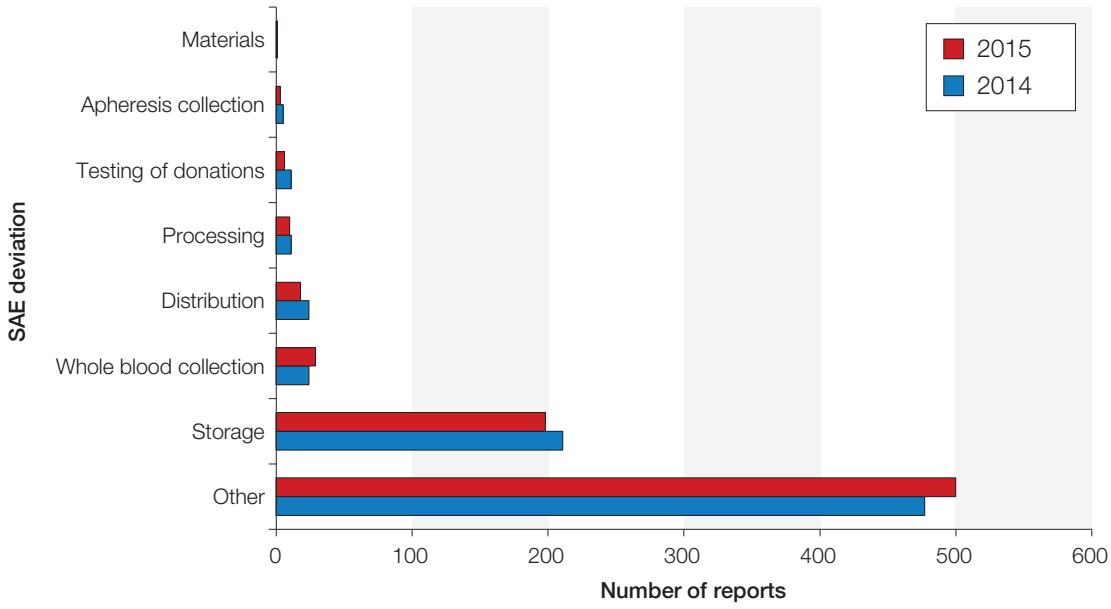


Figure 18.3: SAE confirmation reports by deviation and specification 2014–2015

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 data n=198

Storage remains the second largest individual error category. The MHRA has broken this category down further to try and identify specific storage error subtypes, Table 18.2.

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**

Table 18.2: SAE storage error subclassifications 2013–2015

The most obvious change in 2015 compared to 2014 is a reduction of **component expiry** SAEs from 77 to 58. In these incidents expired components are found in a storage location after they should have been identified and removed by the de-reservation/re-stocking process. This had been highlighted as a notable increase in reports from the previous year but analysis of individual reports in 2015 has shown laboratories making great efforts to improve the processes involved.

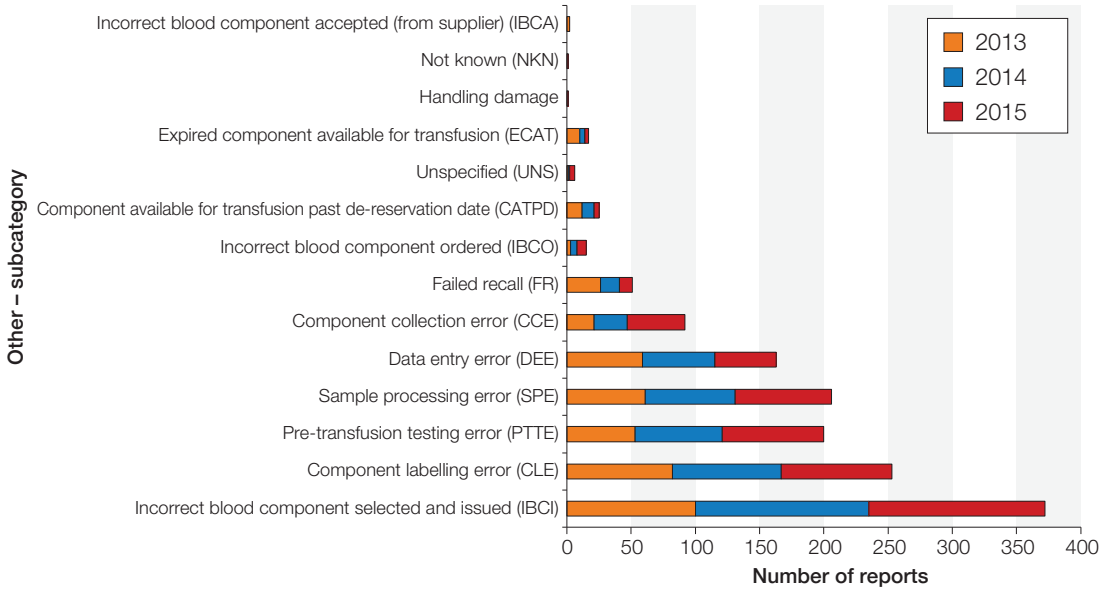
The next most significant change is a reduction in **storage temperature deviation** SAEs from 21 to 13. Events in this category are where the correct storage temperature deviates above or below the required specification. Typically the alarm system also fails and the laboratory is not notified in adequate time to maintain the correct storage temperature of the implicated components. The implication is that laboratories have improved temperature monitoring and storage equipment which either works better than before, or alerts the laboratory to a problem with storage equipment that can be dealt with. However, 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.

Although it is encouraging to see a reduction overall related to storage of about 5%, laboratories are encouraged to continue to improve storage and monitoring equipment. However, laboratories should also ensure that processes and procedures related to storage equipment, temperature monitoring and removing unsuitable units from storage locations are robust and clear and that staff are trained in them 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 18.4.

Figure 18.4: SABRE reports, subcategory 'other', 2013–2015



Incorrect blood component issued (IBCI) errors remain the largest group and these are mainly laboratory errors where specific requirements are not met. Although SABRE does not have the facility for reporters to enter the exact time that the error occurred, in reviewing a selection of IBCI reports the narratives suggest a common theme appears to be that these errors occur when the BMS has been busy during a lone working period. This hypothesis is based on comments in the report narrative such as 'BMS A was working on their own, either over a break time, late shift and/or out-of-hours.' Furthermore, it is apparent that many of these reports have occurred following haemopoietic stem cell transplant (HSCT) or solid organ transplant where the appropriate ABO and D group for transfusion has changed from the patient's original group.

The number of **component collection errors (CCE)** reported has increased from 26 to 45. These reports arise when any member of staff (medical staff included) collect the wrong component from storage, 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 may have been transfused 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 perform these 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 below.

Human error category

In order to understand human error the SABRE team has developed subcategories which can be applied to the report narratives to help understand the human factors involved. The categories are:

- 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 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

The following table shows the breakdown of reports received and categorised into the human error subcategories.

Human error subcategory	Total
Inadequate process	263
Procedural 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 18.3: SABRE reports, human error subcategory 2015

NOTE: These figures should be used as guidance only. The quality of this 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 for the main SAE category
- The subcategory chosen is based on the information in the report. A limited investigation or a report which does not provide the MHRA with enough information may not be subcategorised correctly

The largest subcategory and 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. For this reason, the MHRA will add further subcategories in 2016 to differentiate process and QMS errors such as staffing and workload.

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

By reporting and investigating incidents thoroughly, it is hoped then that over time reporters will be able to gain enough evidence where necessary to help ensure they have sufficient resources to address long term problems with appropriate preventive action.

Procedural steps:

Procedural steps not performed correctly reflects those incidents 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. They may be a result of being busy, multi-tasking, being distracted or interrupted during the task. A common error that falls into this category is **component labelling error (CLE),** where compatibility labels are transposed.

Procedural steps omitted/wrong procedure performed errors are characterised by omission of a vital step in a procedure, or the wrong procedure carried out. These errors often occur as a result of multi-tasking, being distracted or being interrupted rather than being related to training or flaws in the QMS. Common errors include **incorrect blood component issued (IBCI)**, where a patient's transfusion history is not checked.

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.

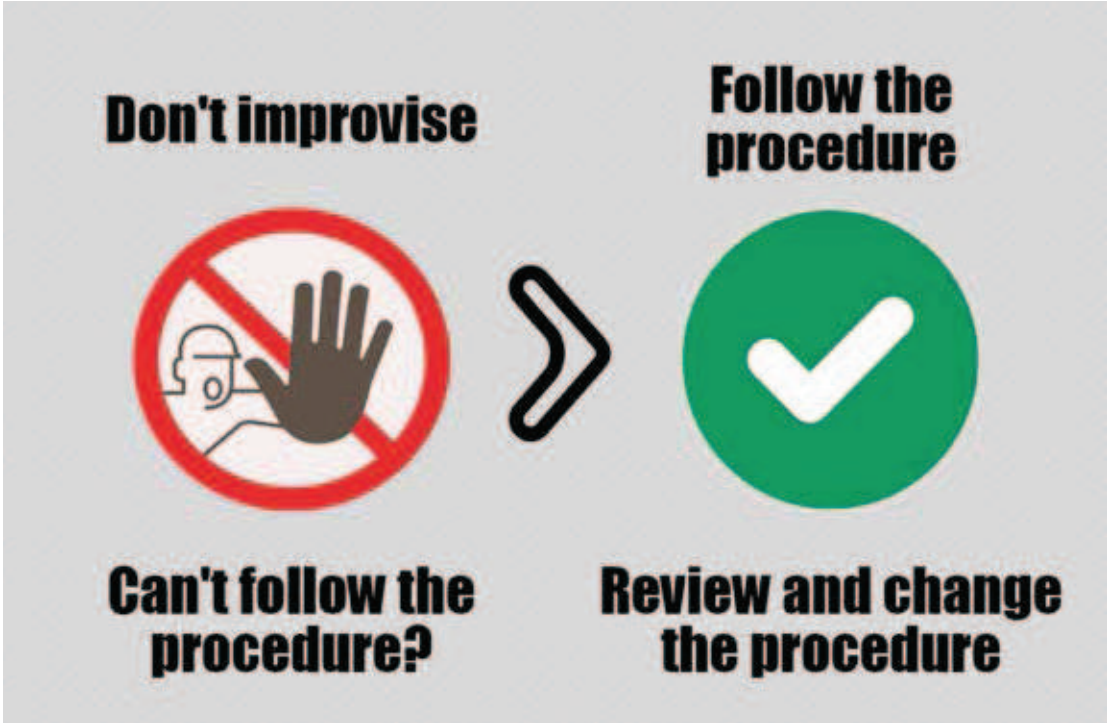


Figure 18.5: Don't improvise, follow the procedure

These errors can often be addressed by simply reminding the member of staff of the correct procedure, and situational awareness training to cope with high workloads and distractions. Staff should be made aware that they should work at a pace that is suitable for them to reduce errors of inaccuracy and omission, and should ask for help for periods of acute and short-term low staffing and heavy workloads.

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 five SAEs

SAE deviation subcategory	Specification subcategory
Incorrect blood component selected and issued (IBCI)	Inadequate process
Component labelling error (CLE)	Procedure performed incorrectly
Pre-transfusion testing error (PTTE)	Inadequate process
Sample processing error (SPE)	Procedure performed incorrectly
Storage (component expiry)	Inadequate process

Table 18.4: Top five SAEs with human error subcategory

Table 18.4 shows the top five SAE deviation subcategories and the subcategory of human error. The following real examples are shown to illustrate what might be considered as CAPA to address the root causes. They are not meant to represent actual investigation processes and CAPA for all similarly categorised incidents, but are representative of many of the reports received, and are clearly designed to focus on improvements to systems, practice and transfusion laboratories. The examples show the categorisation for the MHRA SAEs and the SHOT equivalent is 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 about 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 both had similar donation numbers.

- The labels were transposed
- The porter collecting the units did not spot 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 them not properly checking 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 must concentrate adequately 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 being made.

3. PTTE (IBCT): Inadequate process

Incorrect electronic issue of blood

- A sample result showed a dual population when the cells were tested with anti-B 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 laboratory information management system (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 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 as 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 management 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 went to the patient it was intended for (RBRP) or to another patient (IBCT).

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 remind them of the procedure. However, when management are designing processes and workflow, they 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 of 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 had failed or were not robust which shows an overall weakness in the QMS:

- There was a procedure to clear the refrigerators at midnight, but it can only work if people know about it. The BMS was not aware of the 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, it can be demonstrated how 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 re-training, re-competency-assessment or adding extra steps in a process, unless it is absolutely necessary. There are certain key principles to consider when improving your 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?

Figure 18.6: What to consider when investigating an event

Training

Although not the most commonly reported factor related to the root causes of SAEs, training, and frequency of training is a common discussion point between reporters and the SABRE team. Without adequate and effective training, any member of staff is more likely to make mistakes. Quite simply, unless a member of staff is adequately trained they should not be performing a task. 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. Many SAE reports received relate to locum staff and often it is because they are somehow expected to know what to do in a laboratory that is unfamiliar. While they are being trained, a member of staff should be adequately supervised with their work thoroughly checked for errors.

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 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 management need to assess the effectiveness of training over a period of time. A member of staff that 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.

Assessing competency of staff following training for each stage/element of the transfusion process will provide assurance that an individual can demonstrate the correct procedure to be followed.

Serious adverse reactions (SAR)

Definition:

An unintended response in a donor or in a patient that is associated with the collection, or transfusion of blood or blood components that is fatal, life-threatening, disabling or incapacitating, or which results in or prolongs hospitalisation or morbidity…Blood Establishments and the person responsible for the management of a hospital blood bank shall notify the Secretary of State (Competent Authority) of any serious adverse reactions observed during or after transfusion which may be attributable to the quality or safety of blood or blood components:

(i) Collected, tested, processed, stored or distributed by the Blood Establishment, or

(ii) Issued for transfusion by the hospital blood bank

This definition (BSQR 2005) is pertinent to both SHOT and SABRE reports, therefore if the SAR conforms to this definition it must be reported to both SHOT and SABRE.

Blood products

Adverse reactions involving blood products which are licensed medicines such as anti-D Ig, Octaplas® (SD-FFP), or coagulation factor concentrates should not be reported to the MHRA via SABRE although some are reportable to SHOT. Complications from these medicines are reportable to the MHRA through the Yellow Card scheme (http://yellowcard.mhra.gov.uk).

Summary of SAR report data

Changes to the way SARs are reported in SABRE have been in effect since October 2015. As well as being the first step towards a single, integrated reporting process, reducing duplication of effort for a reporter, these changes were also implemented to address a perception that some reporters were not meeting their regulatory requirements in reporting all SARs to the MHRA, but were reporting some reactions as ‘SHOT only’ incidents. This change in process has also allowed SHOT experts to assess reaction reports to ensure that SARs are categorised consistently with SHOT data. SHOT will then upload the confirmation report on behalf of the original reporter.

It is too early to tell how this change will affect the collection of SAR reports in SABRE. Analysis of this year's data has shown a significant reduction in the number of SAR reports included in the annual summary. Data received on SABRE up to the date of the change was equivalent to previous years' reporting patterns. Since the change, the MHRA has not received as many confirmation reports as previously. However, this is explained by the extra time it takes for the reports to be received at SHOT, and then analysed by the experts and fed back to SABRE.

The regulatory requirement is that the CA must be informed by a notification report 'as soon as known' and this still occurs. There is no requirement for confirmation reports to be received by any deadline, so there is no failure or flaw in the new system. The expectation is that the difference in numbers of SAR reports received will find a new equilibrium for next year's SHOT report.

To avoid any confusion the MHRA will only supply, in this Annual SHOT Report, total SAR figures reported to Europe.

Table 18.5: SAR reports, by imputability, reported to SABRE only in 2015 n=262

	Imputability score				
	NA	0	1	2	3
SAR reports by imputability score	1	28	98	105	30

In previous years SAR data between the two organisations have differed and caused confusion for reporters, the EU and at parliamentary level. It is hoped that the new SAR reporting arrangements will avoid this confusion and produce more accurate SAR data for the UK and Europe. For SAR type please see the relevant clinical reactions chapters in this report for more detail.

References

BSQR (2005) **Blood Safety and Quality Regulations**. (SI 2005/50, as amended) http://www.legislation.gov.uk/uksi/2005/50/contents/made [accessed 30 April 2016]

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