27 MHRA Report on Blood Safety and Quality Regulations (BSQR) in 2022

Authors: Chris Robbie and Mike Dawe

Abbreviations used in this chapter

BCR	Blood compliance report
BE	Blood Establishment
BSQR	Blood Safety and Quality Regulations 2005 (as amended)
BMS	Biomedical scientist
CAPA	Corrective and preventive action
CATPD	Component available for transfusion past de-reservation
CCE	Component collection error
CLE	Component labelling error
DEE	Data entry error
ECAT	Expired component available for transfusion
EI	Electronic issue
FR	Failed recall
GPG	Good Practice Guide
HBB	Hospital blood bank
HD	Handling damage
IAG	Inspection action group
IBCA	Incorrect blood component Accepted
IBCI	Incorrect blood component issued
IBCO	Incorrect blood component ordered
LIMS	Laboratory information management system
NBTC	National blood transfusion committee
PSIRF	Patient safety incident response framework
PTTE	Pre-transfusion testing error
QMS	Quality management system
RC	Root cause
RCA	Root cause analysis
SABRE	Serious Adverse Blood Reactions and Events
SAE	Serious adverse event
SAR	Serious adverse reaction
SOP	Standard operating procedure
SPE	Sample processing error
UNSPEC	Unspecified

Key MHRA messages

- The MHRA haemovigilance team has worked hard to improve the depth of investigations and improve the identification of root causes and corrective measures with reporters.
- There has been another increase in the number of investigation reports that have identified system errors or weak processes
- There has been a 35% increase it reports which have cited staffing and workload problems as the main root cause
- Hospital transfusion teams must review their own incidents alongside the findings in this chapter to identify their most frequently occurring SAE and root causes
- Attention should be made to the SAEs and root causes highlighted in this chapter to ensure these are being reported consistently and that QMSs are reviewed for robustness and effectiveness

Summary

There has been an increase in the total number of reports received during 2022. The increase is seen to be as a result of more SAR reports being received. As we recover from the effects of the Covid-19 pandemic and struggle to get back to normal and the way SAR reports are uploaded onto SABRE following review by the SHOT experts, this increase is probably more a reflection of a backlog of reporting

and assessment rather than a reflection of an increase in the number of reactions that have occurred. In fact, there has been a slight decrease in the number of SABRE reportable events, largely driven by a reduction in the number of storage errors reported. Again, this is most likely a result of clinical areas returning to normal and therefore improving the control of the storage of components.

Despite the reduction of SAE reports received, there has been an increase in the number of errors reported to be due to system errors identified in the investigation. The majority of the increase in reported system errors appears to be a direct result of the effects of staffing and workload problems experienced.

SABRE report data

Table 27.1 and Figure 27.1 show the total numbers of reports and the numbers of reports submitted as SAEs and SARs for the previous 10 years. Although the figures remain broadly similar to previous years, the data show a decrease in the number of SAEs and an increase in SAR reports resulting an increase in the total number of reports received.

	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
SAE	705	762	764	1027	1076	1198	1197	1093	1143	1118
SAR	345	346	262	464	508	408	497	590	526	710
Total	1050	1108	1026	1491	1584	1606	1684	1683	1669	1828

Table 27.1: Submitted confirmation reports 2013–2022

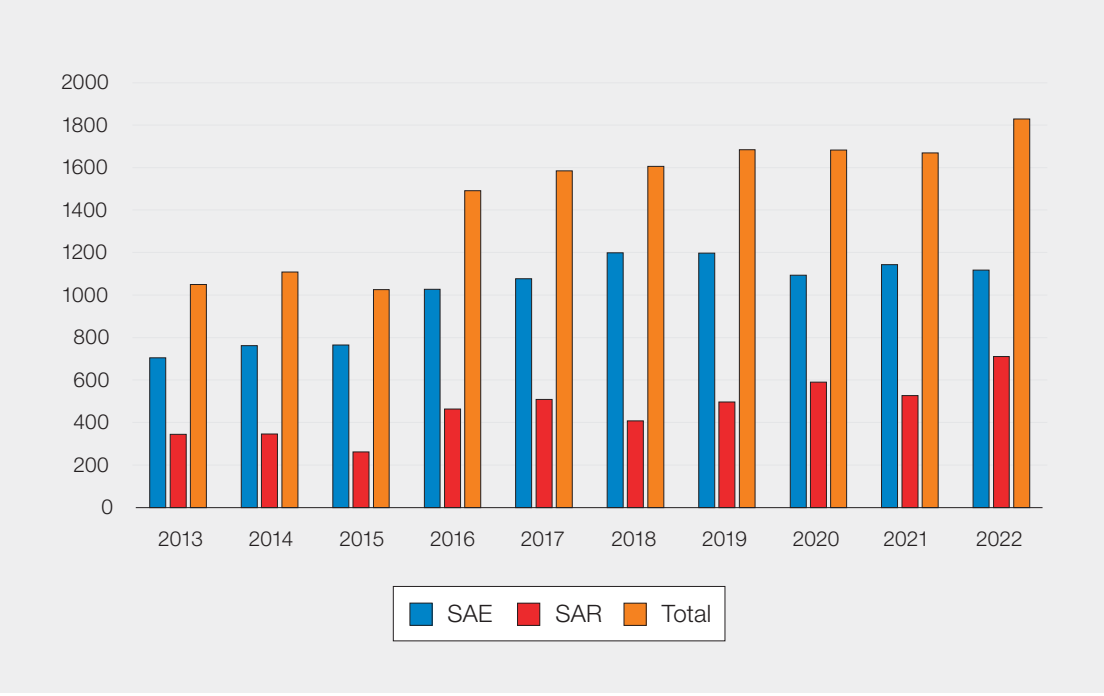


Figure 27.1: Submitted confirmation reports 2013-2022

SAE=serious adverse event; SAR=serious adverse reaction

Serious adverse events n=1118 (-25)

Definition: (BSQR 2005) 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.

Table 27.2: Total number of SAE reports by event category

Event category	Number of reports
Materials	1
Apheresis collection	2
Testing of donations	3
Processing	6
Whole blood collection	7
Distribution/HSE	22
Donor selection	70
Storage/HSE	245
Other	762
Grand total	**1118**

Table 27.2 shows the total number of SAE reports received by event category. Proportions of reports received remain similar to previous years, but there has been a slight increase in 'other' SAE and a drop in the number of storage SAE reported.

Storage data n=245 (-48)

Storage remains the second largest individual error category (after 'other') and comprises of all BSQR reportable Storage SAE in both the laboratory and clinical areas. The MHRA Senior Haemovigilance Specialist has broken this category down further to try and identify specific storage error sub-types, Table 27.3. For a description of the sub-categories used, see Appendix 1.

Table 27.3: SAE storage error sub-classifications

Storage sub-classification	2022 (+/- 2021)	2021 position
Incorrect storage of component	118 (-19)	1
Component expiry	38 (-12)	2
Sample expiry	29 (-11)	3
Return to stock error	22 (+5)	4
Security	14 (-2)	5
Failure to action alarm	8 (-5)	6=
Miscellaneous	7 (+1)	8
Storage temperature deviation	7 (-6)	6=
30 or 60 minute rule	2 (+1)	9
Total	**245 (-48)**	**x**

There has been a 16% reduction in the number of storage SAE with fewer reports seen in most of the storage sub-categories. While it would be difficult to pinpoint exact reason for this, it is presumed as hospitals have been getting back to normal since the COVID-19 pandemic, that arrangements for storage and training are returning to pre-pandemic levels and as such the numbers of reports has decreased as a result.

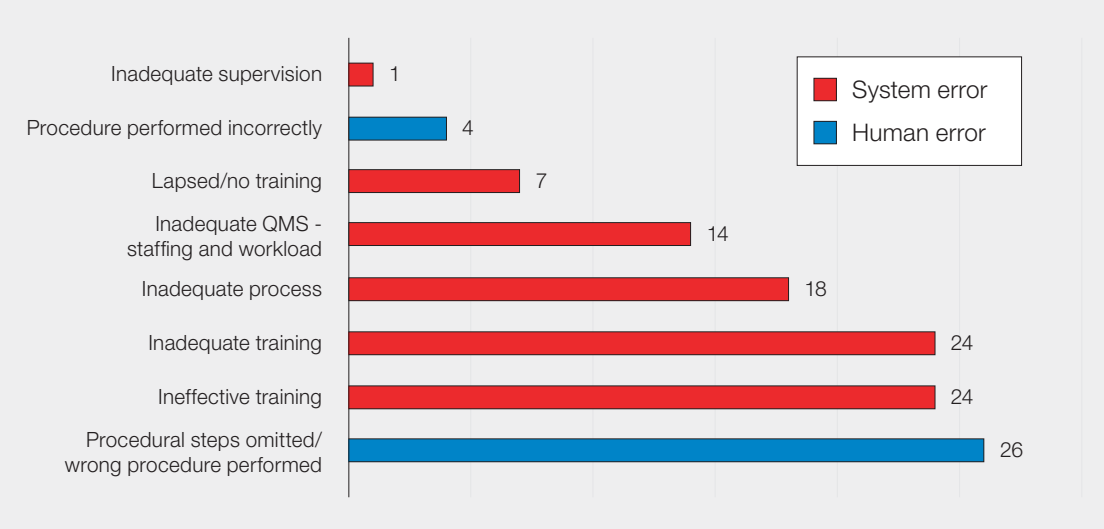


Figure 27.2: Root causes of Incorrect storage of components sub-category

QMS=quality management system

As the single largest sub-category of storage, Figure 27.2, shows the breakdown of Incorrect storage by root cause.

As last year, the majority of root causes of these types of error are System errors, especially relating to inadequate process design and the inadequate design, delivery and understanding of the training in the storage of components. In fact, only 25% of the errors are assessed as 'human error' with the remaining 75% a result of 'system errors'.

Despite a 14% reduction in the number of incorrect storage of component SAE, the root causes of these errors are similar to previous years and therefore there exists further room for improvement in this area.

Recommendation

- Review business continuity plans to ensure all changes to storage processes are adequately managed, ensuring the new processes are robust, covered with updated SOP and that re-training of staff is adequately planned and delivered

Action: Hospital transfusion teams

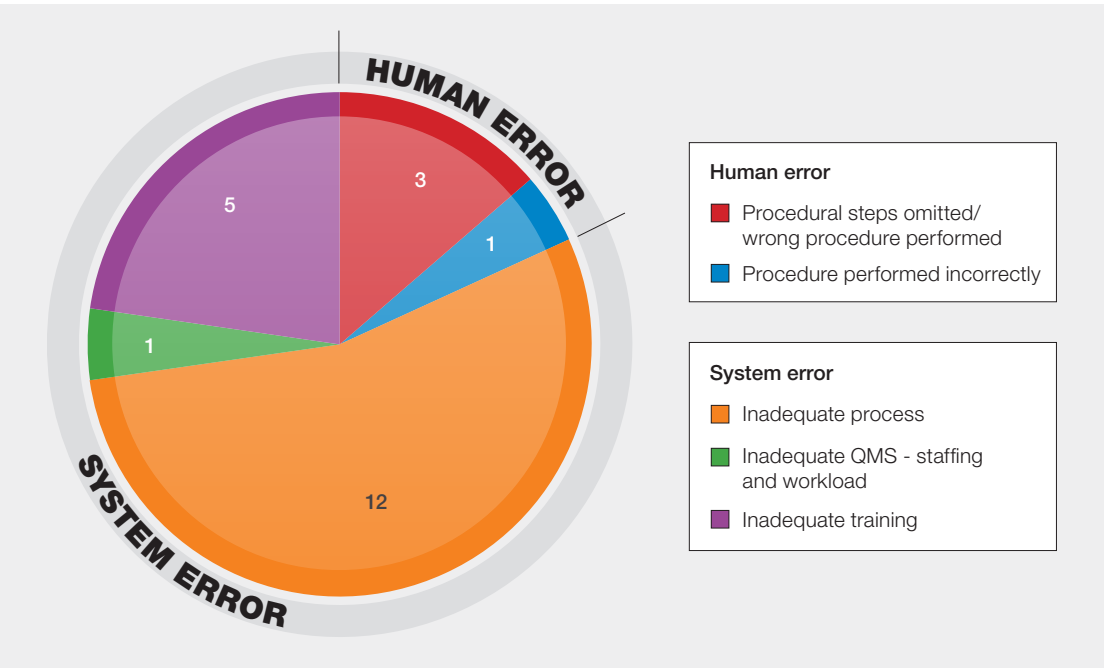


Figure 27.3: Root causes of the return to stock sub-category

QMS=quality management system

While not the second largest storage sub-category, there has been a 29% increase in return to stock errors in laboratories. The causes of error in this category demonstrate a split of 81% system errors compared to 19% human errors, with the largest proportion relating to inadequate process design.

Recommendation

- Review processes that involve the returning components to the supply chain ensure they are thoroughly robust ensuring that units are returned to stock prior to their expiry date being exceeded

Action: Transfusion laboratories

Other n=762 (+19)

Table 27.4: 'Other'

Other sub-category	2022 (+/- 2021)	2021 position
Sample processing error (SPE)	147 (+15)	3
Incorrect blood component issued (IBCI)	141 (-31)	1
Component collection error (CCE)	136 (-16)	2
Pre-transfusion testing error (PTTE)	124 (+40)	5
Component labelling error (CLE)	115 (+15)	4
Data entry error (DEE)	62 (+2)	6
Failed recall (FR)	15 (-5)	7
Incorrect blood component ordered (IBCO)	9 (+6)	10=
Unspecified (UNSPEC)	4 (-6)	8
Component available for transfusion past de-reservation (CATPD)	4 (NC)	9
Expired component available for transfusion (ECAT)	3 (+1)	12
Incorrect blood component accepted (IBCA)	1 (NC)	13
LIMS Failure	1 (+1)	14
Handling damage (HD)	0 (-3)	10=
Total	**762 (+19)**	**x**

Table 27.4 shows the number of reports in the 'other' category of SAE. There has been a slight increase (2.5%) in events that fall into this category and some quite marked changes in numbers of reports for the top 5 categories which have been explored in greater detail below.

Last year's report noted a significant drop in the number of pre-transfusion testing error SAE received which was considered to be unexpected. The numbers of reports in this category have now returned to previous levels and therefore the reduction of PTTE SAE in 2021 would appear to be unexplained. Please see Appendix 2 for a description of the sub-categories.

Human and system error categories and human factors

The BSQR (2005) requires that 'preventable causes' of SAE are investigated and reported. The GPG (2018) also states 'Where human error is suspected or identified as the cause of the deviation, this should be formally justified and care should be exercised so as to ensure that process, procedural or system-based errors or problems are not overlooked, if present.'

What this means is that for all SAE reported on SABRE, the root-cause investigation must first identify any system-based causes, or 'human factors'. It must be stressed that the term 'human factors' is not a fancy term now used to describe 'human error'. Human factors are all the factors which influence an individual's behaviour. These can be factors associated with an organisation itself, the task or the process being undertaken, including the environment and equipment used as well as factors associated with an individual's personality and actions. Therefore, human factors, or ergonomics, are exactly the system-based factors reporters are required to investigate according to the requirements of the BSQR and the GPG.

The MHRA assign a category on review of an SAE report to reflect the most prominent causative factor. Assessment of these reports can distinguish between events caused by system errors and human errors (slips/lapses/omissions). For a description of the categories used, see Appendix 3.

Table 27.5 shows the breakdown of reports in the human/ system error sub-categories.

Human error sub-category	Total 2022 (+/- 2021)	2021 position
System error/ Inadequate process	275 (+2)	2
Human error/ Procedure performed incorrectly	227 (-66)	1
Human error/ Procedural steps omitted/wrong procedure performed	176 (-4)	3
System error/ Inadequate QMS – staffing and workload	140 (+52)	5
System error/ Ineffective training	125 (-3)	4
System error/ Inadequate training	80 (-7)	6
System error/ Incorrect procedure	43 (+6)	7
System error/ Lapsed/no training	22 (-2)	8
System error/ Inadequate supervision	10 (-2)	9
Total	**1098 (-24)**	**x**

Table 27.5: Human/system error sub-categories, 2022

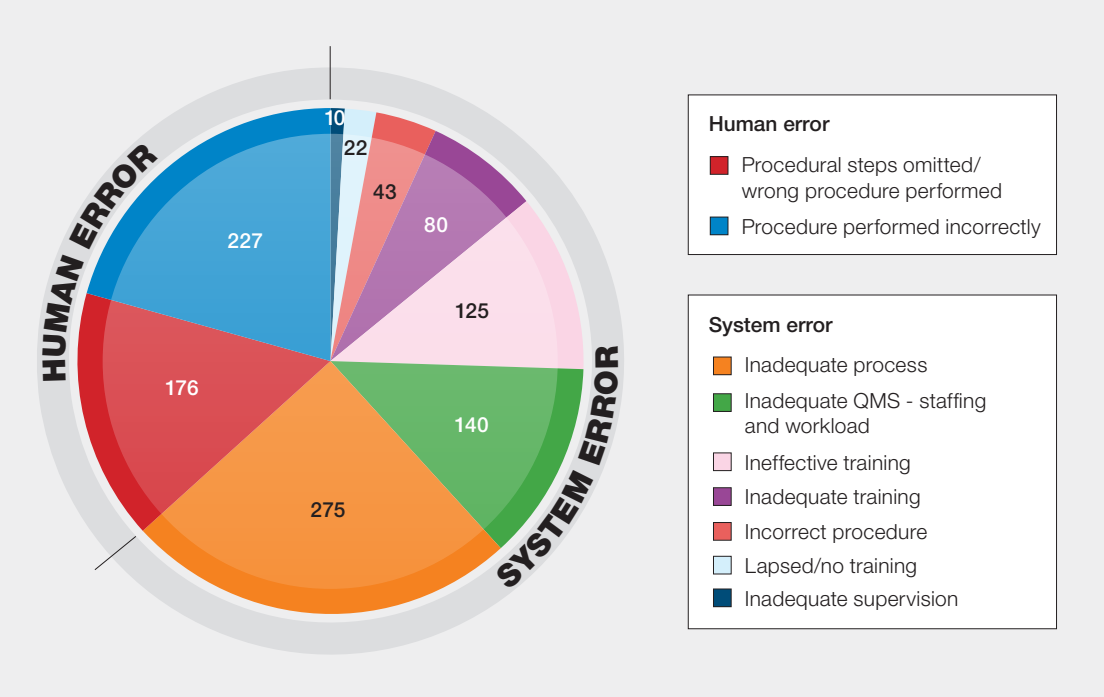


Figure 27.4: Human/system error sub-categories

QMS=quality management system

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

- The RC of incidents are usually the result of many contributory factors. The sub-category chosen reflects the most likely reason for the main SAE category. If multiple factors are involved relating to the QMS, then 'Inadequate process' has been chosen as the sub-category rather than choosing a category that best fits the main SAE reported
- The sub-category chosen is based on the information in the report. A limited investigation or a report which does not provide MHRA with enough information may not be sub-categorised appropriately

The MHRA haemovigilance team has done much work in trying to improve the quality of SAE investigations undertaking several site visits and training presentations specifically dealing with investigations and RC and CAPA. The team has been much stricter in terms of accepting Confirmation reports and many have

been returned to encourage reporters to investigate and report to a much greater depth to encourage them to identify the system-based problems and improve the quality of the CAPA.

Table 27.5 shows that due to fewer SAE reports being reported, there has been a slight decrease in the number of SAE human error reports. While the proportions of reports remain largely the same to previous years, there has been a marked reduction in the number of reports attributed to slips, lapses or omissions by individuals. In fact, there has been a 17% reduction in 'human error' reports.

In line with evidence from inspections and anecdotally, there has been a marked increase in the number of reports attributed to the effects of staffing, workload, and skill-mix with a 35% increase in reports in this sub-category.

Overall, data shows that currently SAE are 37% due to 'human error' and 63% a result of failures in the QMS. It is anticipated that further efforts to improve the depth and coverage of investigations will further help to improve the identification of system improvements.

Recommendations

- All reporters must continue to thoroughly investigate all SAEs, even those with no actual harm to patients. It is through thorough investigation that improvements can be identified to reduce risks to the quality and safety of blood and blood components and reduce the risk of harm to patients
- Ensure that training regimes adequately cover the process or task being trained
- Ensure that any changes to processes are adequately planned, including the planning and delivery of training programmes
- When investigating an incident, reporters must have taken care to ensure that process, procedural or system-based errors or problems have not been overlooked. For example, if distractions have been identified then these distractions must be addressed in the CAPA to avoid reoccurrence
- Trusts are advised to ensure that they have an effective capacity plan, or similar document in place
- Occasions where the capacity plan cannot be met should be raised as a quality incident and addressed with suitable RC and CAPA

Action: Hospital transfusion teams

MHRA/SHOT and NHS England

There have been several confirmation reports that were submitted to MHRA that appeared to lack adequate investigation of root cause. Additionally, many confirmation reports are submitted late or delayed without adequate justification. On further discussion with the reporters, it has become clear that this is often due to NHS Trusts in England implementing the recommendations of NHS England's Patient safety incident response framework. While MHRA and SHOT support the aims of PSIRF, the investigation and reporting requirements of the BSQR and the GPG are a legal responsibility and should not be adversely affected.

For information on PSIRF and the impact on haemovigilance reporting and investigation of transfusion incidents in England see https://www.shotuk.org/reporting/.

Top 5 SAE

The 'top 5' SAE have been presented slightly differently to previous year's reports. This year we have decided to pick the top 5 SAE other subcategory and then give a breakdown of all the root causes for that category.

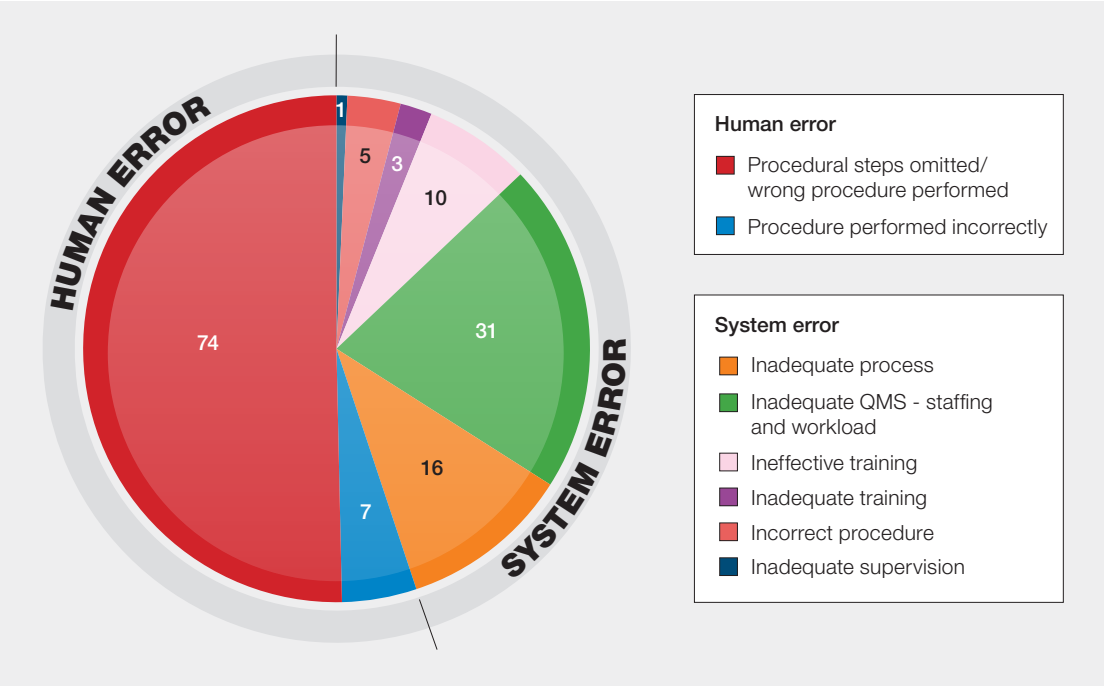


Figure 27.5: Sample processing error (SPE)

QMS=quality management system

For the first time, sample processing errors are the most commonly reported SAE sub-category, overtaking Incorrect blood component issued. The process is largely manual and relies on many checks prone to slips and lapses of concentration. It is therefore no surprise that 55% of these reports are reported to be due to human error. However, 21% are recorded to be due to staffing and workload issues. Investigations into SPE, including the regular trending and monitoring of these errors should therefore try to go further to attempt to determine if these errors are genuinely due to slips or lapses only or whether further system improvements such as the elimination and reduction of distractions to assist staff conducting these tasks.

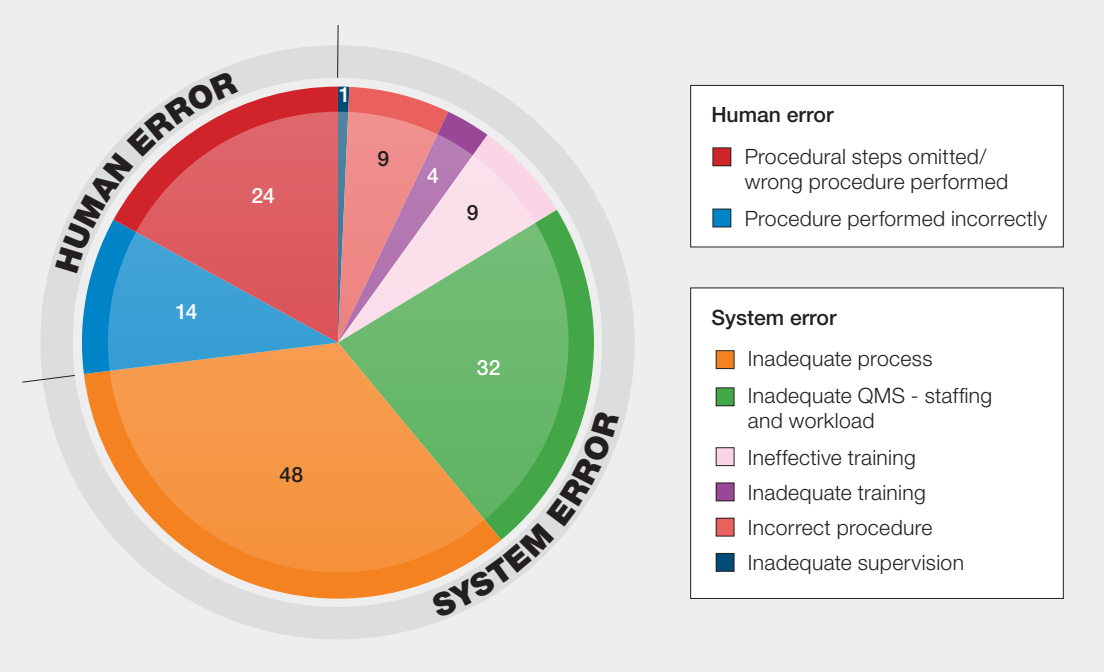
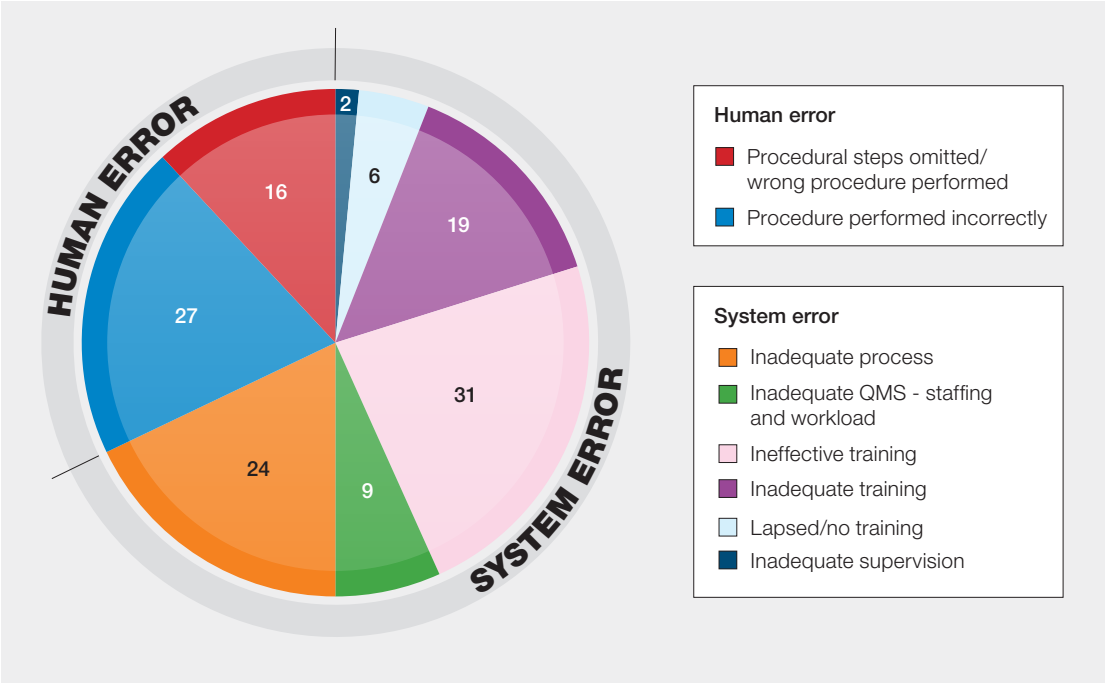


Figure 27.6: Incorrect blood component issued (IBCI)

QMS=quality management system

Nearly three quarters of Incorrect blood components issued (73%) are related to system errors and the rest (27%) are due to slips lapses and omissions. The largest proportion are due to inadequately designed processes or a combination of system errors. Nearly a quarter (23%) are a direct result of staffing and workload issues which affect the selection of the correct requirements for patients.

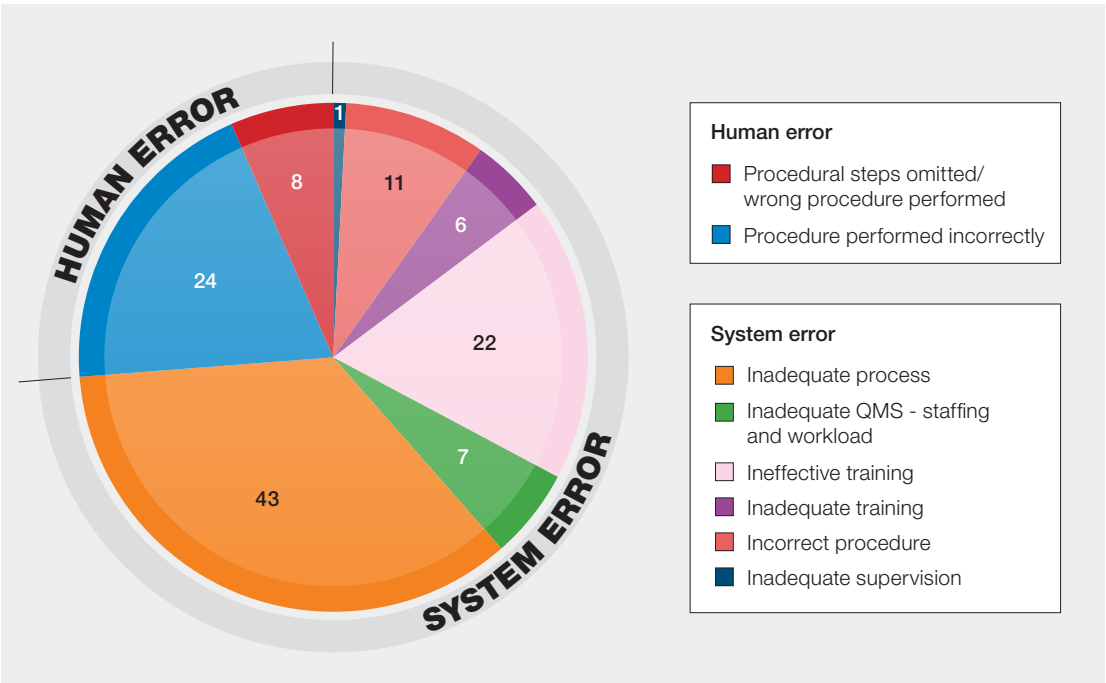
Figure 27.7: Component collection error (CCE)



QMS=quality management system. 2 equipment failures are not included in the figure

As a largely manual process that relies on visual checks around 32% of component collection errors are reported to be a result of human errors. However, where investigations have been conducted to an acceptable level of depth 68% of reports have been concluded to be a result of some form of system error. Training issues account for 41% whether that is because people haven't been trained at all or because training has been poorly delivered or not clearly understood.

Figure 27.8: Pre-transfusion testing error (PTTE)



QMS=quality management system. 2 equipment failures are not included in the figure

The most commonly reported cause of pre-transfusion testing errors are inadequate processes (35%). While most of these would suggest that processes are not as robust as they could be, there is significant evidence to suggest that other system factors are involved such as incorrect procedures (9%) and training issues (18%). The data would therefore suggest that testing processes would be improved by;

- reviewing processes and training to ensure they are robust
- making full use of equipment capabilities

- producing effective documentation that directs staff to follow procedures correctly
- ensuring that training is thoroughly understood

Many reports that fell into the Ineffective training sub-category indicated that staff involved lacked experience so support should be given to staff even after training to ensure that they fully understand the process correctly.

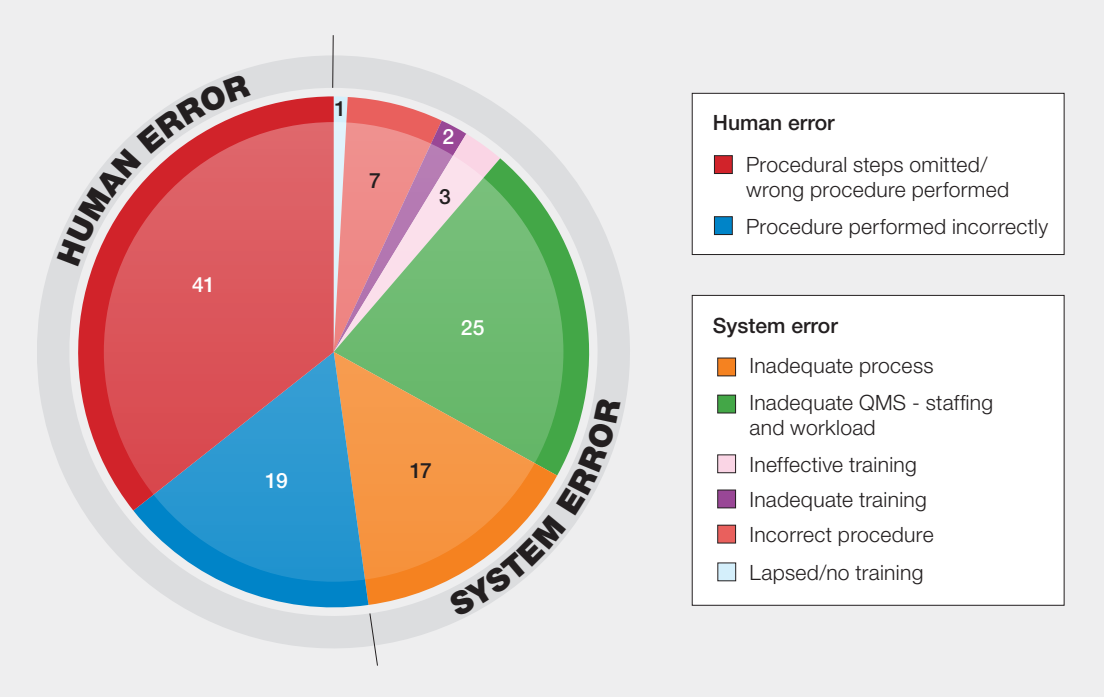


Figure 27.9: Component labelling error (CLE)

QMS=quality management system

As a largely manual process, over half (53%) of component labelling errors are reported to be due to human error where labels are not thoroughly verified at the point of attachment. Reports that have been investigated to a greater depth, however, do demonstrate system weaknesses where these checks are rushed due to high workload or lack of staff at the time of the error (22%). Inadequate processes were also described to be the cause of 15% of reports. Either these were a combination of system factors, or because the process for printing, checking and labelling components had not been thoroughly defined leaving staff to improvise their own procedures for labelling which were later found not to be robust.

Recommendations

Review QMS to ensure the processes involved in the most frequently occurring SAE are robust. Ensure that

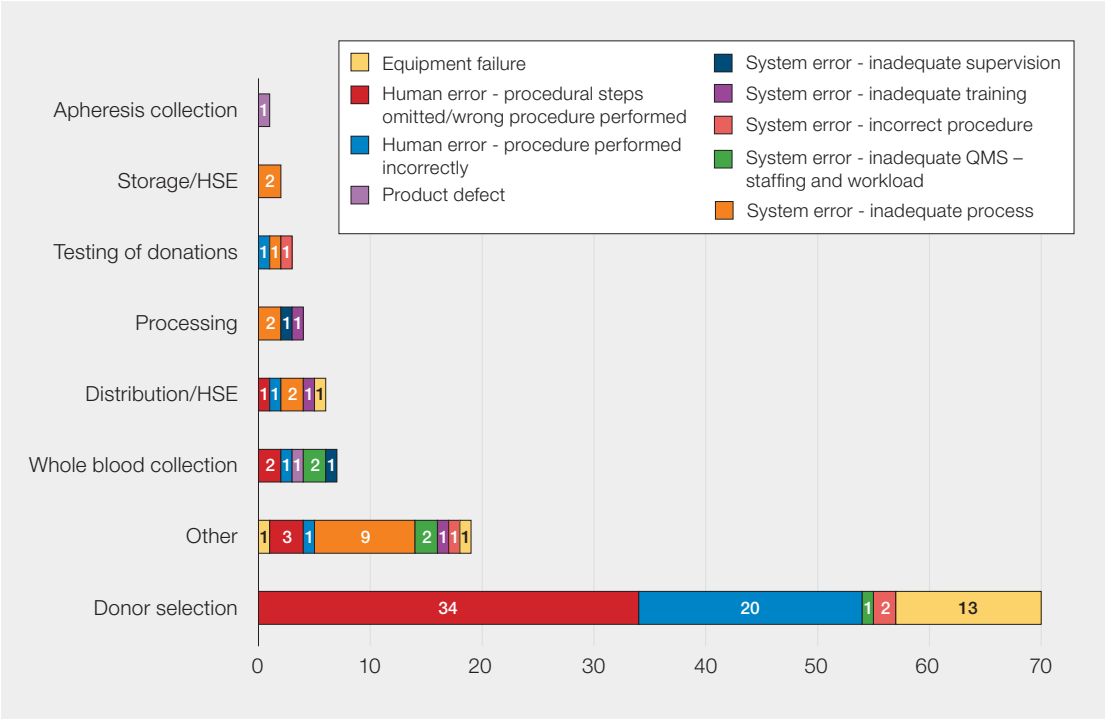
- The process is thoroughly defined
- That procedures are written giving full and clear instructions how to perform the task
- That training is planned, adequate, delivered and understood

Action: Hospital transfusion teams

Blood establishment reporting n=112 (+5)

Although reports from BE are included in the main analysis, the specific nature of the SAE reports from BE are lost in the greater numbers of reported hospital transfusion laboratory SAE. Figure 27.10 displays the reported BE SAE in 2022.

Figure 27.10: Blood establishment SAE event category by specification

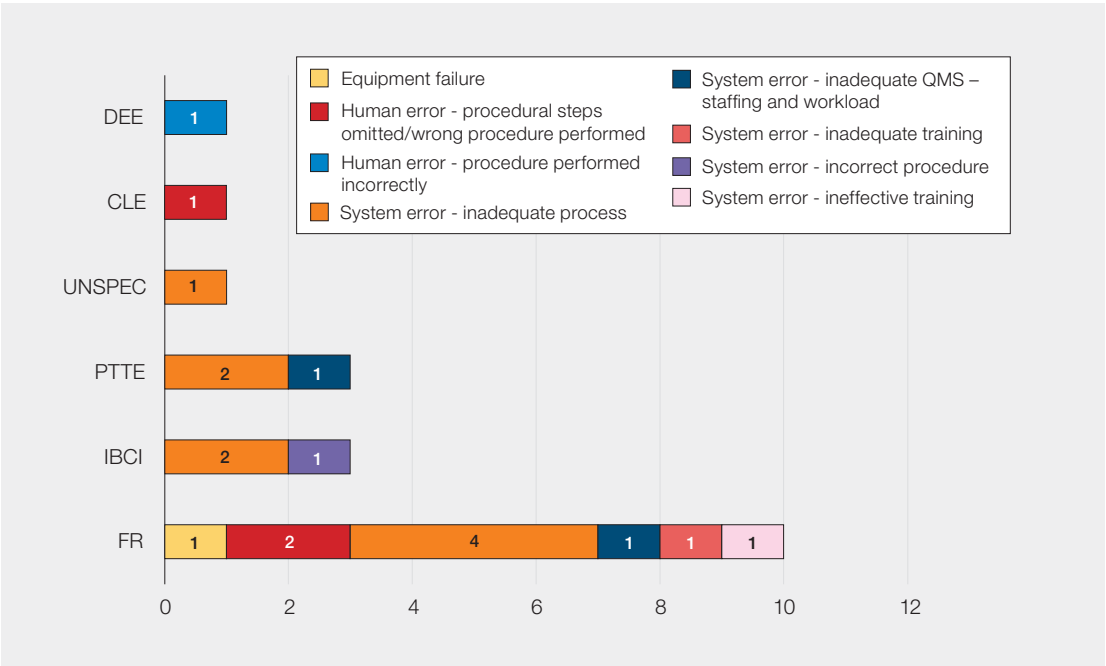


QMS=quality management system; HSE=handling and storage errors

The majority of the reports fall into the donor selection category and typically involve errors where a donor is accepted despite requiring deferral for travel, medical or life-style reasons. Although the diagram indicates that most of these reports are due to 'human' error, i.e., slips, lapses and omissions, this is usually because the error is not spotted until after the donor's next donation. This makes it difficult to assess if the error is a 'system' error. However, all BE when reporting donor selection errors perform recalls and assess the current donation for the deferral reason. Also, processes, procedures and training are regularly reviewed so the risk to the patient is classed as low.

Figure 27.11 shows a breakdown of the 19 reports which fall into the 'other' category.

Figure 27.11: BE reports in 'other' category



See Appendix 2 for key to category abbreviations; QMS=quality management system

Comment from Julie Staves, Chair of the NBTC Laboratory Managers' Working Group

I always look forward to reading the Annual SHOT Report, and the information provided by the MHRA is always especially interesting. It is pleasing to see a reduction in the number of component storage errors in 2022. As we know these are usually preventable errors, and as such, are either primarily a system or human factors issue. If you haven't already done so I'd like to ask you to review your systems for component storage to pick up on any system errors and look for a simple solution to prevent these happening. Errors associated with returning units to stock remain a concern, and again I would urge you to review these.

The other laboratory-associated errors remain a mix of types. Of concern to me is an increase in sample processing and pre-transfusion testing errors. These are tasks which are part of the routine of a transfusion laboratory and as such should be the ones we pride ourselves at doing well. It is not possible from this data to determine the root cause of this increase, but it does indicate that we should not become complacent with routine things.

Serious adverse reactions (SAR)

Definition: (Ref 2) 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

Blood products

Adverse reactions involving blood products (i.e., licensed medicines such as anti-D Ig, Octaplas® (Solvent-Detergent fresh frozen plasma), or coagulation factor concentrates should be reported to the MHRA via the Yellow Card scheme (http://yellowcard.mhra.gov.uk).

Summary of SAR report data

To avoid any confusion the MHRA will only supply, in this Annual SHOT Report, total SAR figures that qualify for reporting to MHRA under the BSQR, see Figure 27.12.

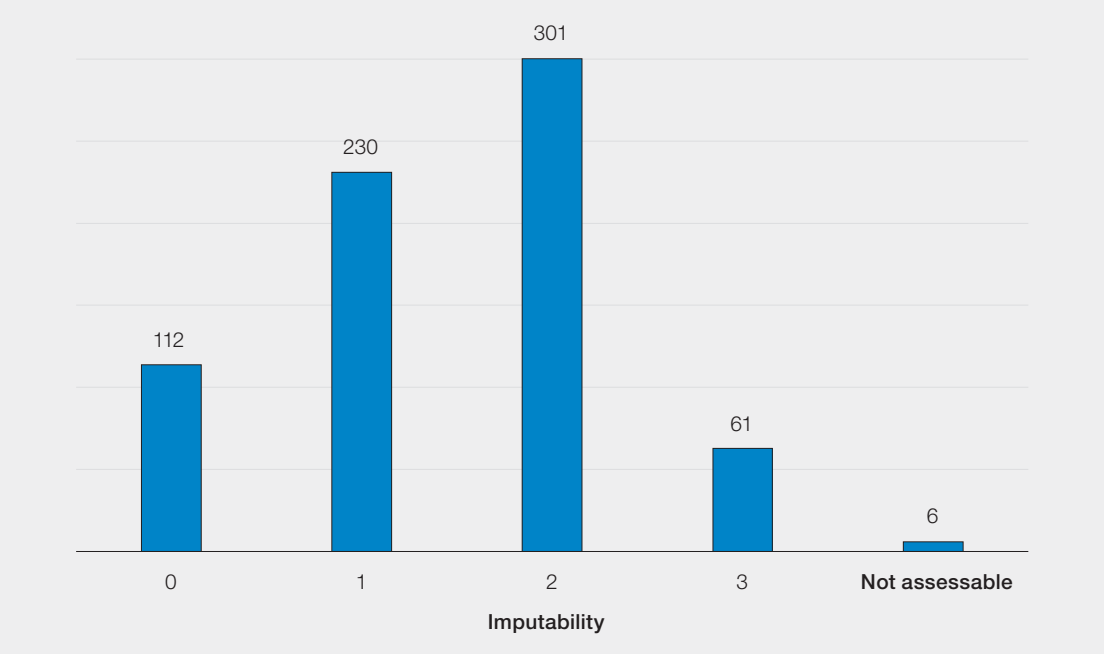


Figure 27.12: SAR reports, by imputability, reported to SABRE in 2021

MHRA Inspection activity on hospital blood banks

Author: Mike Dawe

The MHRA inspectorate have continued to verify blood compliance reports and have conducted 27 inspections since April 2022. A total of 295 BCR were submitted for review for the reporting period 01 April 2021 to 31 March 2022.

The BCR were scored and discussed at a meeting of the BCR Assessment Team (BAT) in August 2022.

An overview of the compliance management escalation processes used by the GMP inspectorate, including information on the IAG and CMT referral processes, is available from the MHRA inspectorate blog: https://mhrainspectorate.blog.gov.uk/2017/02/06/overview-of-compliance-management-escalation-processes-used-by-the-gmp-inspectorate/

There have been 2 referrals to IAG or CMT so far from this cycle of inspections. Summary of significant issues identified at inspected sites include:

Management of change

The control of change continues to be a deficiency that is commonly raised at blood inspections. The deficiencies raised include:

- The absence of a user requirement specification
- inadequate risk assessment and actions to mitigate risks
- The lack of evidence of sign off of stages of the change control prior to implementation
- The lack of validation evidence to show that the system was fit for task before implementation
- Failure to carry out a post implementation effectiveness check

Management of non-conformances

The management of non-conformances is regularly raised as a deficiency due to the following:

- The absence of a root cause
- Failure to consider the potential for harm as well as actual harm
- The lack of an adequate justification for human error being identified as a root cause
- Tracking and trending systems not effectively employed to identify recurring problems

The availability of trained and competent staff

Initial training and ongoing competency are generally appropriately managed. However, issues with adequate capacity within the laboratory is an ongoing problem and is often raised as highlighted by;

- The absence of an effective capacity management plan or similar document to ensure adequate management of blood transfusion operations and the quality management system.

Recall

Although there was evidence that external and internal recalls had been regularly performed, the systems in place lacked sufficient detail regarding that actions were to be taken within pre-defined periods of time.

For further information on MHRA and the Regulation of Blood please refer to the MHRA website: www.gov.uk/topic/medicines-medical-devices-blood/blood-regulation-safety

The MHRA Blood forum was launched in June 2016 as a tool to help those involved in blood component collection, processing, testing and distribution to comply with the EU Blood Directives, UK Statutory Instruments and good practice requirements. It provides the ideal opportunity for extended communication between peers and allows users to put forward their comments and get 'real-life' examples of ways in which they can manage robust quality procedures that ensure compliance and which dovetail with their own business needs and resources. https://forums.mhra.gov.uk/forumdisplay.php?60-Blood-Forum

HAEMOVIGILANCE TEAM UPDATE 2022

Whilst Mike is seconded to the Inspectorate team and unable to conduct site visits and training in person, the Haemovigilance team continues to provide an education service. During 2022 there has been one face to face education session and 11 online education events. The team also supports SHOT, UKTLC, NBTC and Regional HTT meetings on request.

If you are interested in finding out more about how the Hemovigilance Team could support you, contact

E Mail: Mike.Dawe@mhra.gov.uk,
Chris.Robbie@mhra.gov.uk

Other useful contacts

gmpinspectorate@mhra.gov.uk – For matters regarding inspections and inspector advice
BCRBF@mhra.gov.uk – Any advice regarding Blood Facilities
bcr@mhra.gov.uk – For advice regarding the Blood Compliance Report

References

BSQR. The Blood Safety and Quality Regulations ISBN 0110990412 (2005). http://www.legislation.gov.uk/uksi/2005/50/contents/made [accessed 04 May 2022].

GPG (2018). Good Practice Guidelines for Blood Establishment Required to Comply with Directive 2005/62/EC

For information on PSIRF and the impact on haemovigilance reporting and investigation of transfusion incidents in England click below

https://www.shotuk.org/reporting/

Appendices

Appendix 1: Storage subcategories

Component expiry	A component has time expired and not been removed from the storage location according to laboratory procedures
Incorrect storage of component	A component has not been stored in the correct location
Sample expiry	A sample has expired and the component has not been removed from the supply chain for the original patient
Return to stock error	A component has been returned to the supply chain in error instead of being quarantined or discarded
Failure to action alarm	A storage location alarm has been activated but not actioned according to the procedure
Storage temperature deviation	The storage temperature has gone out of specification without an alarm being activated
Security	A storage location is accessible to staff or public who are not authorised to do so
30 or 60 minute rule	Red cells are returned to a refrigerator after 30 or 60 minutes have elapsed contrary to local procedures for return of unused red cells
Miscellaneous	Any other storage event affecting the quality and safety of blood or blood components

Appendix 2: Other subcategories

Incorrect blood component issued (IBCI)	Blood issued which does not meet the patient's specific requirements
Sample processing error (SPE)	Sample incorrectly receipted into the laboratory that should have been rejected
Component labelling error (CLE)	Typically transposition of labels
Pre-transfusion testing error (PTTE)	Any error in the process of testing patient samples and the interpretation of results
Component collection error (CCE)	Any error in the collection of components from storage locations, or the handover of components on collection from the laboratory
Data entry error (DEE)	Transcription errors of data, including both electronic and hand-written data
Failed recall (FR)	Failure to recall components in a timely manner
Unspecified (UNSPEC)	Any error affecting the quality and safety of components not specified elsewhere
Component available for transfusion past de-reservation (CATPD)	Expired components which were incorrectly collected, prior to their scheduled re-stock by the laboratory
Expired component available for transfusion (ECAT)	Any component issued for a patient, where the component expires prior to the planned transfusion
Incorrect blood component ordered (IBCO)	Components ordered from a blood establishment that do not meet the patient's specific requirements
Handling damage (HD)	Damage to a component affecting its quality and safety
Incorrect blood component accepted (IBCA)	Blood accepted into a laboratory for a specific patient where the special requirements have not been matched

Appendix 3: Human error subcategories

Procedure performed incorrectly	Failure to carry out a step(s) correctly
Procedural steps omitted/wrong procedure performed	Missing a key step or not following the procedure
Inadequate process	Inadequate design of a process. Also includes multiple causative factors
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
Inadequate QMS – staffing and workload	Staffing levels below the minimum level, or unacceptably high workload has resulted in staff making errors. It is also important to consider an appropriate skill-mix when deciding on minimum staffing levels
Inadequate supervision	Errors have been made by trainees or inexperienced members of staff and should have been noticed by adequate supervision