Medicines and Healthcare products Regulatory Agency (MHRA) Report 28

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Abbreviations used in this chapter

BCR	Blood compliance report
BE	Blood Establishment
BMS	Biomedical Scientist
BSQR	Blood Safety and Quality Regulations 2005 (as amended)
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
EDQM	European Directorate for the Quality of Medicines & Healthcare
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 continues to work 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
- Staffing and workload issues remain a factor in the errors reported. It is the third most common ‘system error’ after inadequate processes and ineffective training
- Hospital transfusion teams should implement an effective tracking and trending system of root cause to identify emerging trends so effective CAPA can be implemented
- Attention should be made to the SAE and root causes highlighted in this chapter to ensure these are being reported consistently and that QMS are reviewed for robustness and effectiveness

Summary

There has been an increase in the total number of reports received during 2023. The increase is seen to be as a result of more SAE reports being received. While the increase in the number of reports looks sharp compared to last year, it must be remembered that the reports for the previous few years have been influenced by the effects of COVID-19. When viewed in the context of the last 10 years the increase in numbers of reports demonstrates a steadier increase. While this might demonstrate an increase in

potential risk of harm to patients, it could also be a natural increase in reporting due to greater awareness of the types of SAE reportable under the BSQR.

The proportion of SAE reported to be due to process and system deficiencies has risen to 70% and the proportion due to human error dropped to 30%. These figures should be seen as encouraging rather than discouraging as it represents a greater proportion of reporters are identifying one or more system improvements rather than holding individual staff members responsible for 'human errors'.

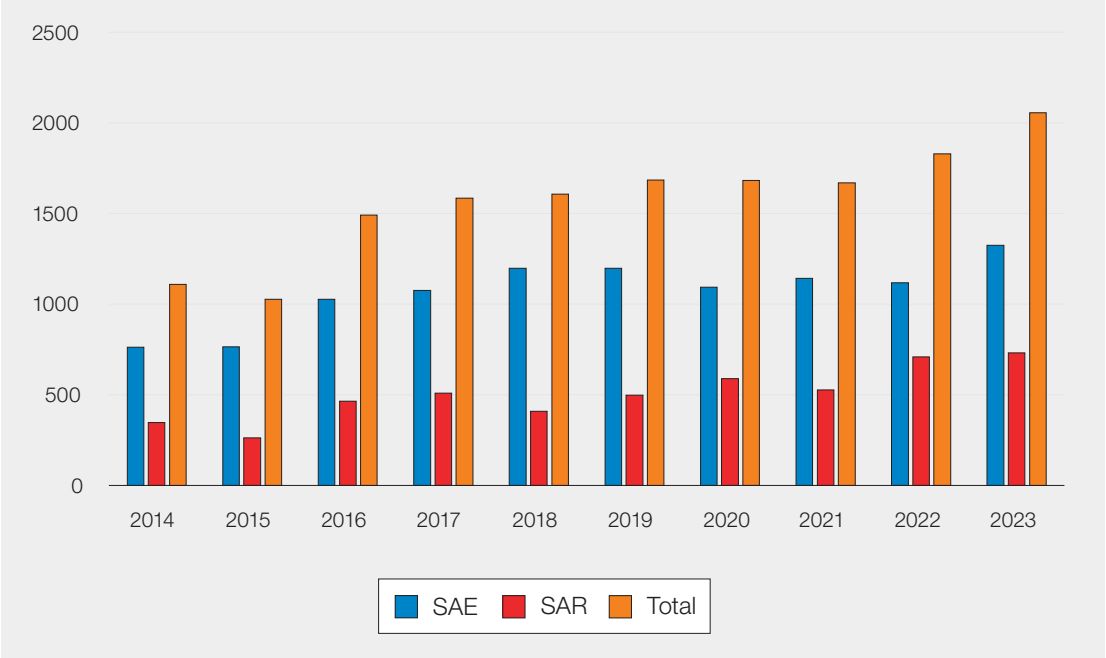
SABRE report data

Table 28.1 and Figure 28.1 show the total numbers of reports and the numbers of reports submitted as SAE and SAR for the previous 10 years. There has been a 19% increase in the total number of reports submitted in 2023. Most of these are in the SAE categories. Overall, the number of reports received show an upward trend over ten years.

Table 28.1: Submitted confirmation reports 2014–2023

	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
SAE	762	764	1027	1076	1198	1197	1093	1143	1118	1325
SAR	346	262	464	508	408	497	590	526	710	731
Total	1108	1026	1491	1584	1606	1694	1683	1669	1828	2056

Figure 28.1: Submitted confirmation reports 2014-2023



Serious adverse events n=1325 (+207)

Definition: (Department of Health, 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

Event category	Number of reports
Materials	0
Apheresis collection	2
Whole blood collection	6
Testing of donations	8
Processing	10
Distribution	16
Donor selection	83
Storage	326
Other	874
Grand total	**1325**

Table 28.2: Total number of SAE reports by event category

Table 28.2 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 15% increase in 'other' SAE and a 33% increase in the number of storage SAE following a reduction last year.

Storage data n=326 (+81)

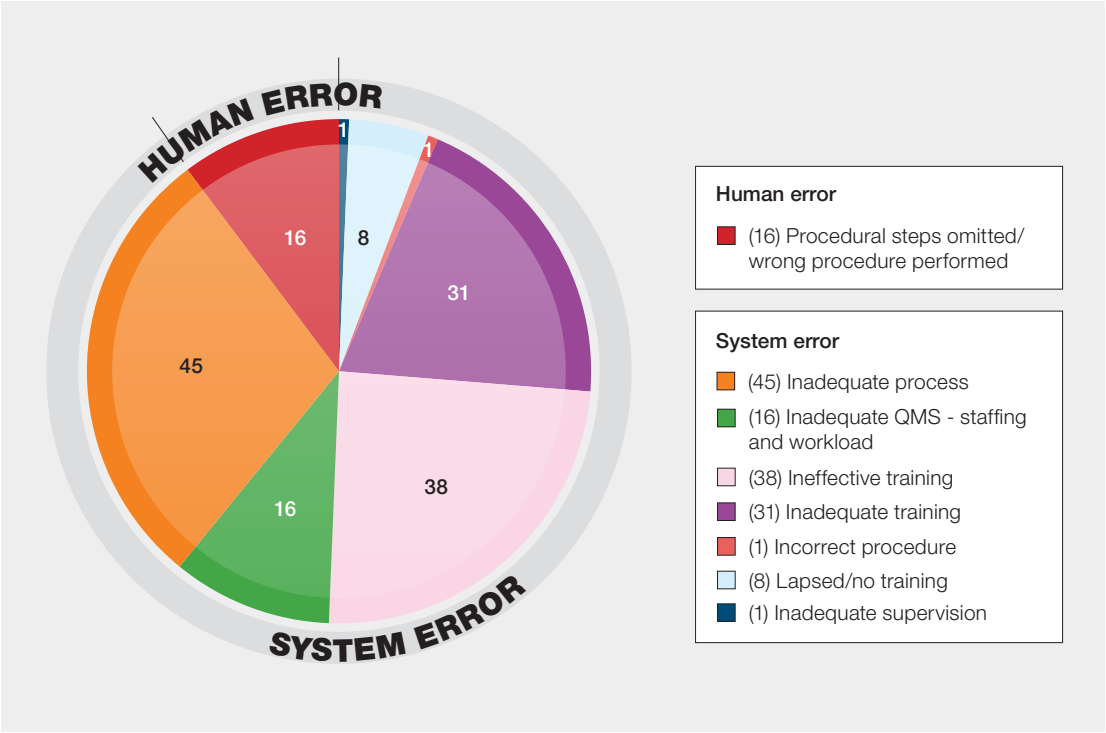
Storage remains the second largest individual error category (after 'other') and comprises of all BSQR reportable storage SAE in both the laboratory and clinical areas. The MHRA Haemovigilance Team lead has broken this category down further to try and identify specific storage error sub-types, Table 28.3. For a description of the sub-categories used, see Appendix 1.

Storage sub-classification	2023 (+/- 2022)	2022 position
Incorrect storage of component	156 (+38)	1
Component expiry	58 (+20)	2
Return to stock error	37 (+15)	4
Sample expiry	36 (+7)	3
Security	13 (-1)	5
Storage temperature deviation	9 (+2)	7=
Failure to action alarm	9 (+1)	6
Miscellaneous	7 (NC)	7
30- or 60-minute rule	1 (-1)	9
Total	**326 (+81)**	**X**

Table 28.3: SAE storage error sub-classifications

Following a decrease in the number of storage errors last year, there has been a 33% increase in total in 2023. The top 4 storage sub-categories have all shown an increase with the largest increase in incorrect storage of component.

Figure 28.2
Root causes of incorrect storage of components sub-category (n=156)



QMS=quality management system

As the single largest sub-category of storage, Figure 28.2, shows the breakdown of incorrect storage of component by root cause.

90% of all Incorrect storage of component errors are related to one or more deficiencies in the quality system. Only 10% were related to human error where staff have knowingly followed the wrong procedure or skipped steps in a process.

29% demonstrate either inadequate design of processes designed to maintain the quality and safety of blood and blood components or involved multiple errors within the system in use.

49% are in some way related to training;

- 24% show the training to be ineffective
- 20% show the training to be inadequate
- 5% show staff have either not received training or their previous training has lapsed

Common themes from the narratives of incorrect storage of component reports shows;

- Processes and procedures are not clear on how blood should be stored safely and correctly
- Errors are made when staff do not handle blood regularly and have forgotten their training
- Training of staff in blood and blood component storage is not given a high enough priority during staff induction training and continuous training thereafter
- Training material does not always cover all aspects of storage e.g., how to distinguish between components and their different storage requirements
- Errors often occur because shifts are not staffed with adequate numbers of trained staff
- Agency/bank staff training is inadequate
- Agency/bank staff are expected to handle components without having been trained in the local procedures

All storage errors are covered by the requirements of the BSQR. Most of these storage errors occur in clinical areas. It is still a widely held belief that storage errors in clinical areas are clinical errors and that investigation and reporting of these errors is not covered by the BSQR. This is incorrect. All storage

errors that affect the quality and safety of blood and blood components must be fully investigated as per the requirements of the BSQR and GPG.

Recommendation

- Hospital Trusts/Health Boards must improve all areas relating to the quality and safety of blood and blood component storage and the investigation of such storage errors

Action: Hospital transfusion teams

Other n=874 (+118)

Table 28.4: 'Other'

Other sub-category	2023 (+/- 2022)	2022 position
Incorrect blood component issued (IBCI)	194 (+58)	2
Pre-transfusion testing error (PTTE)	148 (+24)	4
Sample processing error (SPE)	146 (-1)	1
Component collection error (CCE)	127 (-9)	3
Component labelling error (CLE)	115 (NC)	5
Data entry error (DEE)	89 (+27)	6
Failed recall (FR)	24 (+9)	7
Component available for transfusion past de-reservation (CATPD)	10 (+6)	9=
Incorrect blood component ordered (IBCO)	7 (-2)	8
Expired component available for transfusion (ECAT)	6 (+3)	11
Incorrect blood component accepted (IBCA)	4 (+3)	12=
Handling damage (HD)	3 (+3)	14
Unspecified (UNSPEC)	1 (-3)	9=
Total	**874 (+118)**	**X**

Table 28.4 shows the number of reports in the 'other' category of SAE. There has been a 15% increase in events that fall into this category. The majority of the increases have been in the sub-categories;

- Incorrect blood component issued
- Data entry error
- Pre-transfusion testing error

Please see Appendix 2 for a description of the sub-categories.

Human and system error categories and human factors

The BSQR requires that 'preventable causes' of SAE are investigated and reported (Department of Health, 2005). The GPG 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.' (EDQM, 2023).

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.

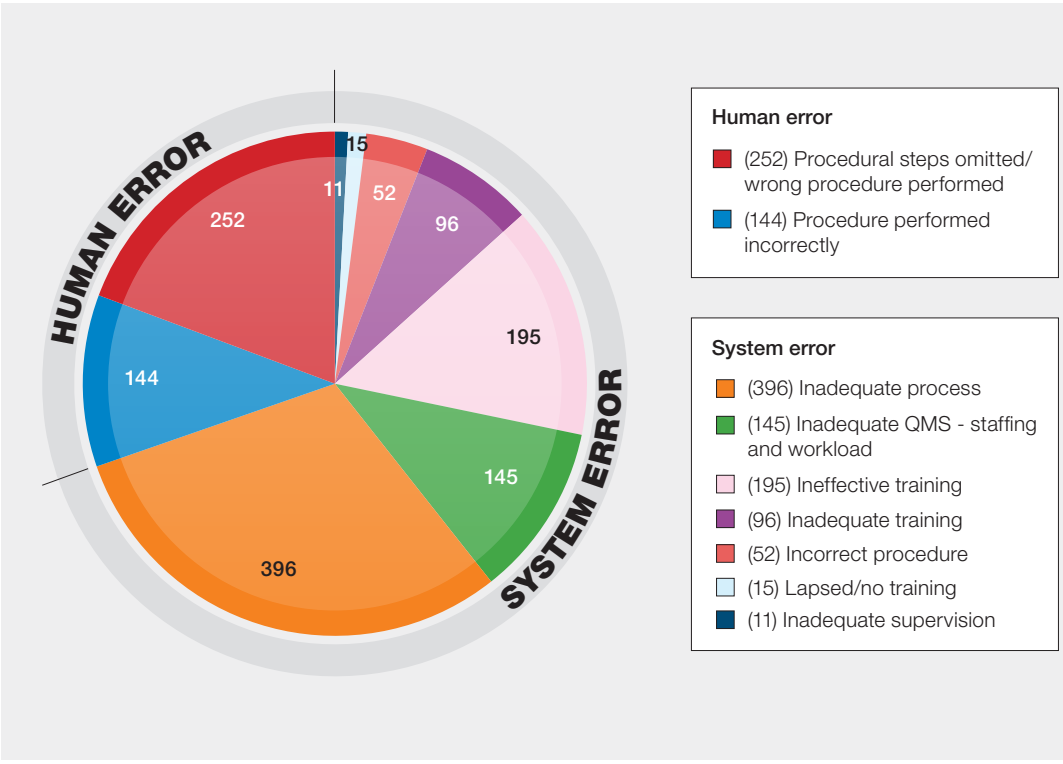
MHRA assign a category on review of an SAE report to reflect the most prominent causative factor. Assessment of these reports can distinguish between events caused by system errors and human errors (slips/ lapses/ omissions). For a description of the categories used, see Appendix 3.

Table 28.5 shows the breakdown of reports in the human/system error sub-categories.

Table 28.5: Human/ system error sub-categories, 2023

Human error sub-category	Total 2023 (+/- 2022)	2022 position
System error/ Inadequate process	396 (+121)	1
Human error/ Procedure performed incorrectly	252 (+25)	2
Human error/ Procedural steps omitted/wrong procedure performed	195 (+70)	5
System error/ Inadequate QMS – staffing and workload	145 (+5)	4
System error/ Ineffective training	144 (-32)	3
System error/ Inadequate training	96 (+16)	6
System error/ Incorrect procedure	52 (+9)	7
System error/ Lapsed/no training	15 (-7)	8
System error/ Inadequate supervision	11 (+1)	9
Total	**1306 (+208)**	**X**

Figure 28.3: Human/system error sub-categories (n=1306)



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 continues to work with reporters to improve the quality of SAE investigations. 14 training sessions were undertaken either with individual hospital trusts or regional

groups. These training sessions in investigation of events, RC and CAPA are available free of charge on request. The team continues to be strict 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 28.5 shows a 19% increase in the number of reports due to human factors. However, 70% of these reports have identified one or more system improvements as a result of their investigations. This demonstrates a continued improvement in the quality and depth of investigations, either initially or after a request for more detail by the MHRA haemovigilance team. The remaining 30% are either genuine slips or lapses by individuals, or examples of reports that may have benefitted from a more in-depth investigation.

Common themes from the narrative of these investigation reports show;

- 30% of these reports either demonstrate a weak process or system design or involve multiple system deficiencies
- Inadequate process errors may involve the poor identification and mitigation of distractions
- 11% of these reports are directly related to staffing, workload, or skill-mix issues and is the third largest 'system error' sub-category. However, it must be noted that some of the 30% Inadequate process reports, may also include some aspects of staffing and workload issues, since this category may reflect multiple system or process deficiencies
- Many reports note errors are made when staff are 'busy'. It may not always be possible to directly link these to staffing and workload since improved prioritisation of workloads may have prevented the error from occurring
- Many reports do not reflect the seriousness of the event as they only reflect actual harm and not potential harm
- Many confirmation reports initially assign a RC as Human error without fully identifying process or system deficiencies
- Many CAPA are initially proposed to be reminding staff to 'be more vigilant' and to 'follow procedures'. This is not an appropriate CAPA as it demonstrates a failure to identify genuine causes and the implementation of effective CAPA
- RC are often identified as a failure to perform an adequate second check. Failure to perform second checks are not RC as the error has already occurred by the time the second check was performed
- Many reports continue not to be reported 'as soon as known'
- Many confirmation reports are delayed due lack of engagement from clinical areas or by reviews of investigation reports

Recommendations

- All reporters must continue to thoroughly investigate all SAE, even those with no actual harm to patients. It is through thorough investigations 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
- 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
- CAPA must correct the error made and not just rely of making error checking more robust

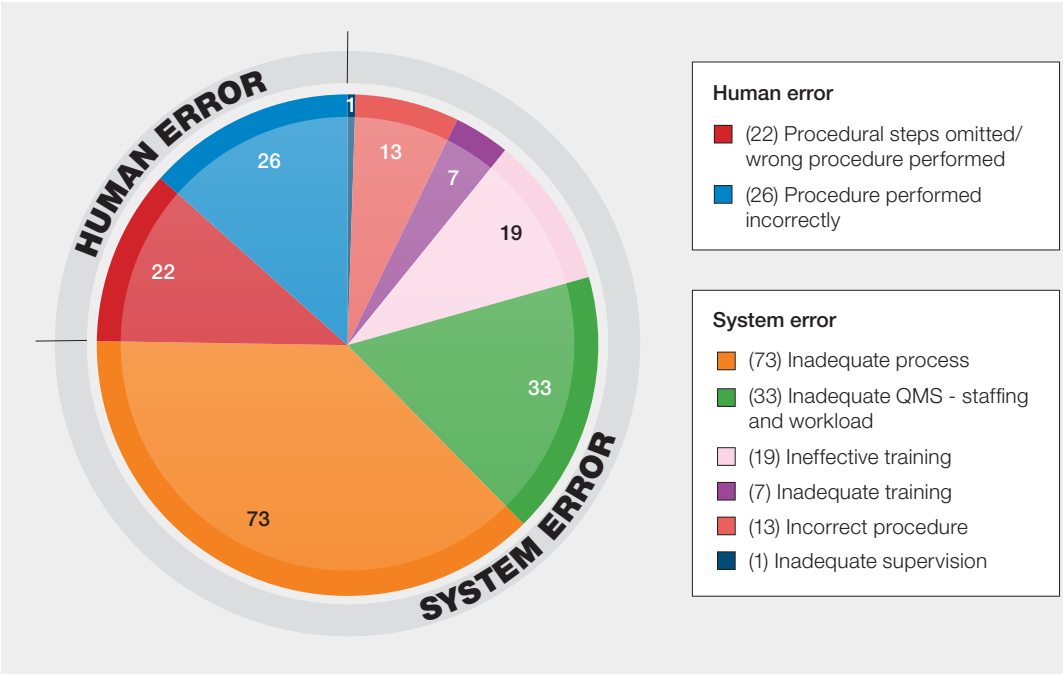
- Engagement from staff in clinical areas must be improved. It is the responsibility of the Trust or Health Board to ensure all SAE are investigated and reported in a timely manner as per the requirements of the BSQR
- Reporters are reminded to report 'as soon as known'. You are required only to submit a Confirmation report with RC and 'Proposed' CAPA. Changes to CAPA following review can be added to SABRE reports as Footnotes

Action: Hospital transfusion teams

Top 5 SAE

Presented below are the top 5 SAE that originate from the 'other' category. These have been broken down into their specification or 'human factors' sub-categories.

Figure 28.4: Incorrect blood component issued - IBCI (n=194)



QMS=quality management system

Nearly three quarters of Incorrect blood components issued (76%) are related to system errors and the rest (24%) are due to slips lapses and omissions. The largest proportion are due to inadequately designed processes or a combination of system errors. 17% are a direct result of staffing and workload issues which affect the selection of the correct requirements for patients.

As the single most common SAE sub-category and following a 43% increase in the number of IBCI reports it is imperative that reporters thoroughly investigate and address the RC and identify effective CAPA. Reporters are reminded that CAPA must ensure that the correct component is selected in the first place and not rely on ensuring that checks later in the process identify errors already made.

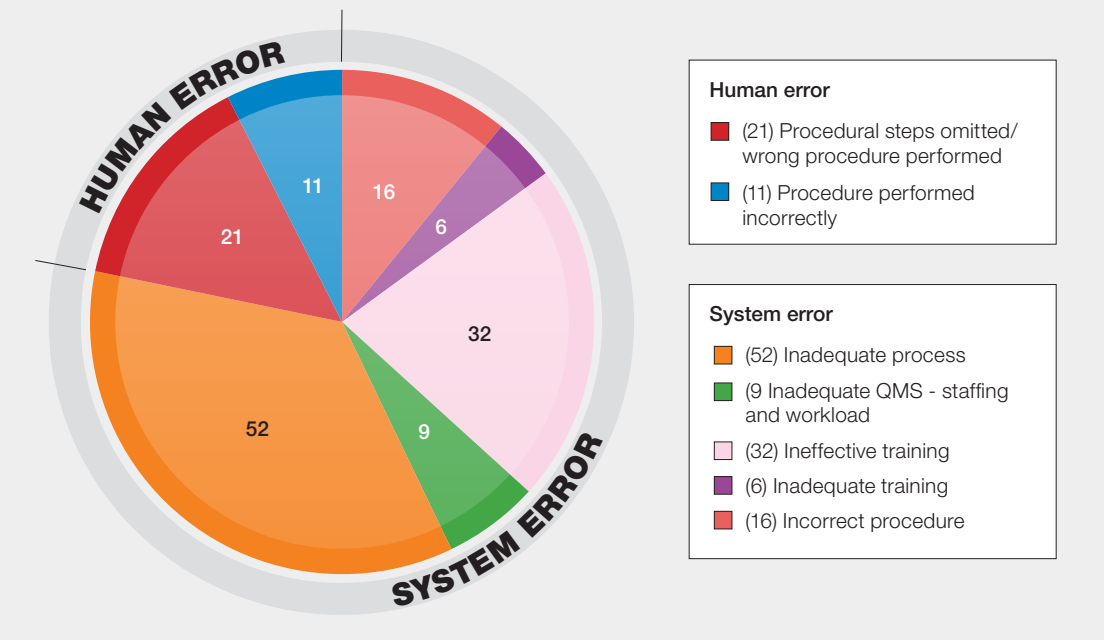


Figure 28.5: Pre-transfusion testing error (PTTE) (n=148)

QMS=quality management system
1 equipment failure is not included in the figure

78% of PTTE are due to 1 or more weaknesses in the quality system. 21% appear to be due to slips and lapses in concentration. The most commonly reported cause of PTTE 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 (11%) and training issues (26%). 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.

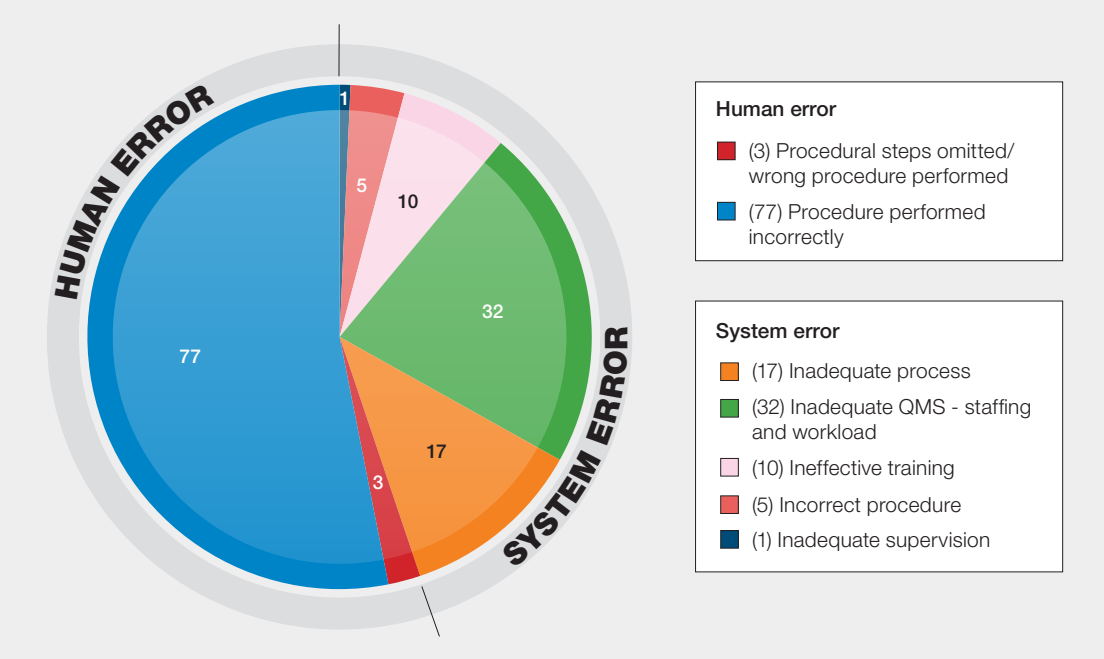
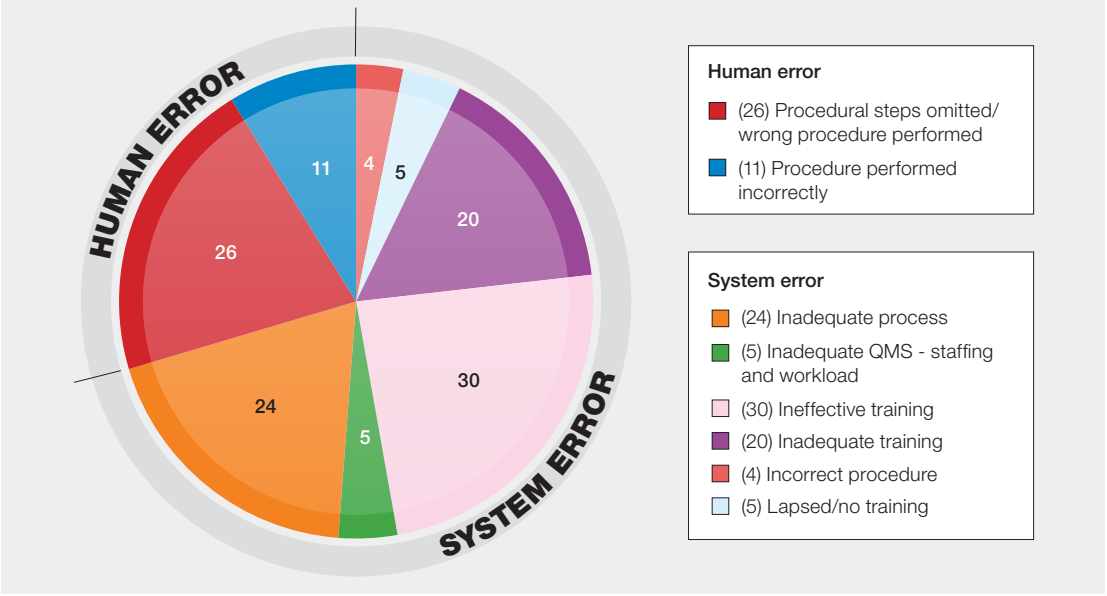


Figure 28.6: Sample processing error (SPE) (n=146)

QMS=quality management system
1 equipment failure is not included in the figure

SPE fall into similar human factor sub-categories as last year. The sample acceptance 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, 22% 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 and increase in available capacity to assist staff conducting these tasks.

Figure 28.7: Component collection error (CCE) (n=127)

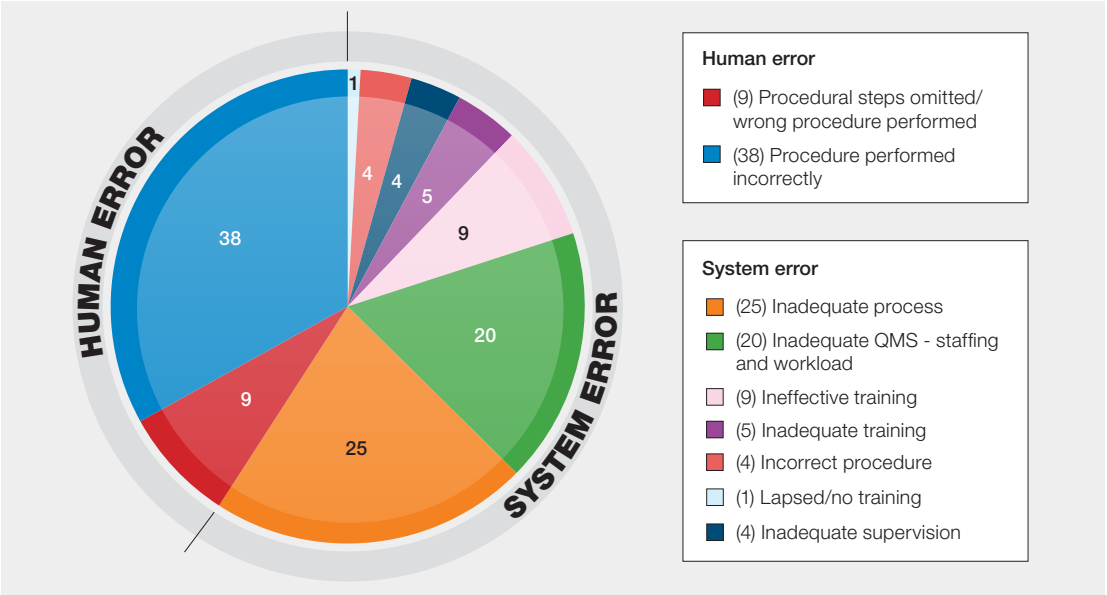


QMS=quality management system
2 equipment failures is not included in the figure

As a largely manual process that relies on visual checks around 29% of CCE are reported to be a result of human errors. However, where investigations have been conducted to an acceptable level of depth 71% of reports have been concluded to be a result of some form of system error. Training issues account for 44% whether that is because people haven't been trained at all or because training has been poorly delivered or not clearly understood.

CCE must always be thoroughly investigated and RC and CAPA identified due to the possible knock-on effects. Many undetected collection errors end up being detected at the bedside. Unfortunately, not all do, and there are a small number of cases where blood has been transfused to the wrong patient as a direct result of an initial CCE.

Figure 28.8: Component labelling error (CLE) (n=115)



QMS=quality management system

53% of CLE in the previous year's report were determined to be due to slips and lapses. However, last year this percentage dropped to 41% indicating improvements to investigations which identified process and system deficiencies.

39% of reports were due to staffing and workload or weak processes identifying one or more system or process deficiencies. It is important to fully define the process for labelling components that map out all the required steps and checks and that that process is described in a comprehensive SOP. This will ensure standardisation of practice and guard against individuals improvising and following non-standard practices increasing the risk of error.

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
- Where staffing and workload is determined to be a factor, these factors must be addressed with a plan to increase staffing or to re-prioritise workloads, or both, to support safety for patients and staff
- Distractions must be designed out of processes and where they cannot be, mitigations must be put in place to minimise their effect

Action: Hospital transfusion teams

Blood establishment reporting n=145 (+33)

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 28.10 displays the reported BE SAE in 2023.

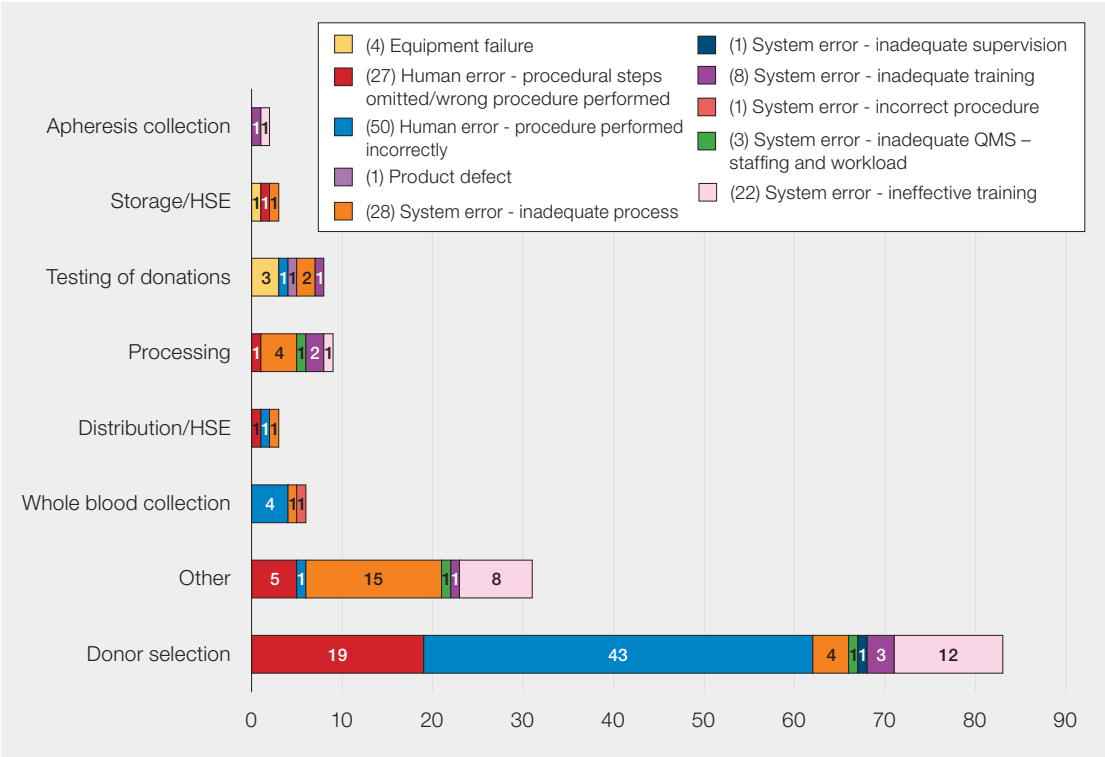


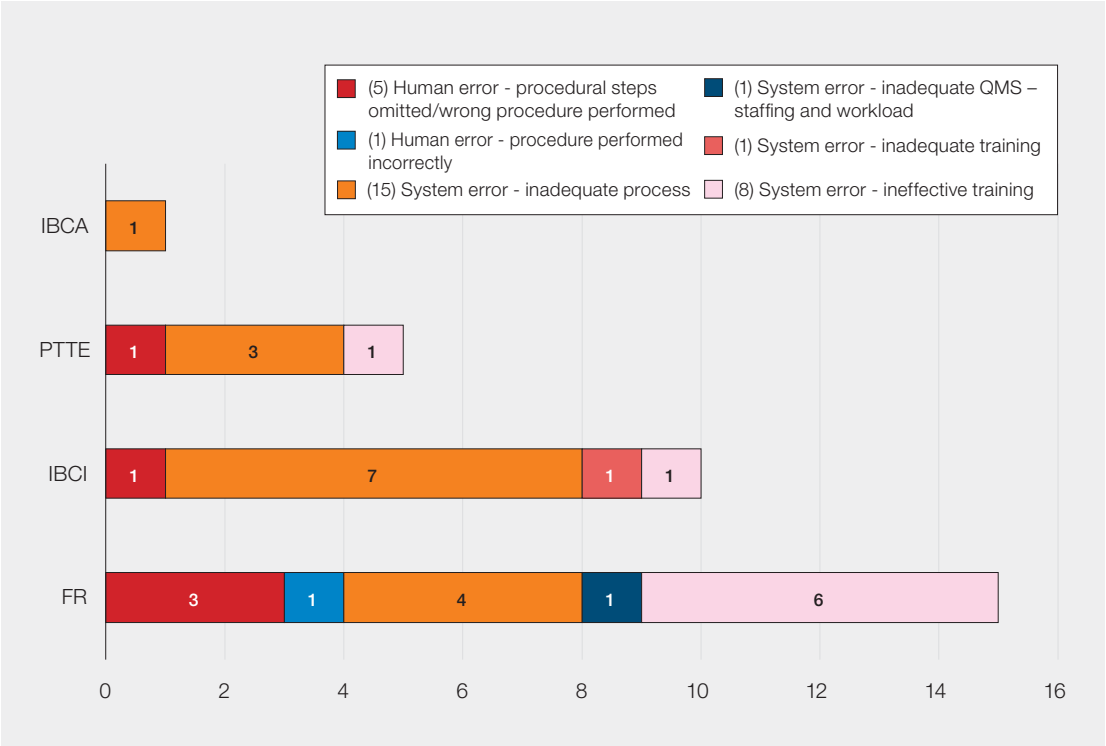
Figure 28.9: Blood establishment SAE event category by specification (n=145)

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 28.11 shows a breakdown of the 31 reports which fall into the 'other' category.

Figure 28.10: BE reports in 'other' category (n=31)



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

Serious adverse reactions (SAR)

Definition: (Department of Health, 2005) 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 28.12.

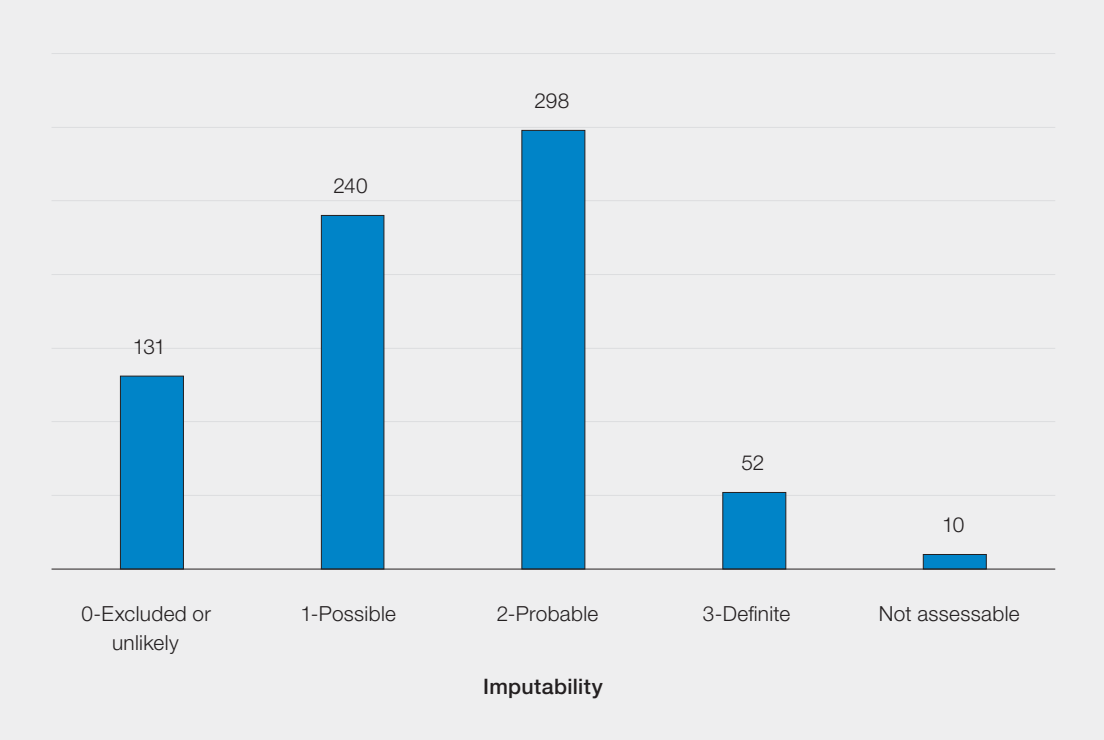


Figure 28.11: SAR reports, by imputability, reported to SABRE in 2023

Inspection report

The MHRA inspectorate have continued to verify blood compliance reports and have conducted 25 inspections since April 2023. A total of 289 BCR were submitted for review for the reporting period 01 April 2022 to 31 March 2023.

The BCR were scored and discussed at a meeting of the BCR Assessment Team (BAT) in August 2023. The BAT meeting discusses the risk scores from the BCR submitted. In addition, risks raised due to haemovigilance data from the SABRE reports received, major changes to blood banks and previous inspection history are discussed.

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
- The lack of a validation master plan (VMP) to guide management through the validation and qualification of the change.
- 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:

- Inadequate investigation for an appropriate root cause therefore the inadequate implementation of an effective CAPA to avoid reoccurrence
- Failure to consider the potential for harm as well as actual harm especially Trusts using the Datix system
- The lack of an adequate justification for human error being identified as a root cause
- The lack of justification for the late closure of deviations and performing impact risk assessments
- Tracking and trending systems employed not identifying recurring problems due to an emphasis on consequence rather than root cause
- Inspections are also identifying a worrying trend that Trusts are not reporting incidents to the competent authority as soon as known

The availability of trained and competent staff

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
- The inadequate management of risk register entries such as reducing the risk score without an appropriate justification
- Staff working significantly above their contracted hours to ensure staff rotas are adequately staffed
- Trusts failing to meet several quality metric targets

Blood collection and training

Blood collection and training was not being adequately managed in that:

- Blood collection training and competency audits showing that Trusts were not meeting their KPI for staff blood collection training
- Inadequate systems in place to control infrequent users of the system and blocking staff who had left the Trust

Recall

Although there were 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: https://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

Comment from Julie Staves, NBTC, Transfusion Laboratory Managers, Chair

This year's MHRA report on the BSQR is somewhat concerning to me and I feel it reflects the issues are being experienced across hospital transfusion laboratories.

The increase in the number of reports being made, remains a positive, it shows there is a continued commitment to reporting and the increase in the acknowledgement that errors are frequently due to process, or system deficiencies is pleasing.

70% of SAE are assigned to system errors as the causative factors which does mean that we should be able to address them. More thorough investigation of the 30% of SAE related to human errors may mean even more errors can be addressed with system improvements. This increase in errors such as incorrect blood component issues, pre-transfusion testing errors and data entry errors is something we should try and address in our own laboratories. The MHRA commentary flags the issues we are all facing daily that of maintaining adequate staffing levels who are suitably trained, and competency assessed.

The 15% increase in the storage errors being report is of concern after a reduction in these in 2022, the fact that many of these errors are related to one or more deficiencies in the quality system means that it is imperative that all Trusts/Hospitals take the time to look at their own systems and consider what changes we should be considering to prevent similar issues within our own departments, including clinical areas.

I would like to flag the recommendations with this report, they are something we should all review carefully and ensure that if we find our systems are not compliant, then we act accordingly to address the issues.

MHRA haemovigilance team update 2023

The haemovigilance team continues to provide an education service. During 2023 there have been 14 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 haemovigilance 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

Department of Health, 2005. *The Blood Safety and Quality Regulations 2005.* [Online] Available at: https://www.legislation.gov.uk/uksi/2005/50/introduction/made (Accessed 11 April 2024).

European Directorate for the Quality of Medicines & Healthcare (EDQM), 2023. *Guide to the preparation, use and quality assurance of blood components.* [Online] Available at: https://www.edqm.eu/en/blood-guide (Accessed 29 April 2024).

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