MHRA Report on Blood Safety and Quality Regulations (BSQR) in 2021

26

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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 preventative 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
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

- Hospital transfusion teams must review their own incidents alongside the findings in this chapter to identify their most frequently occurring SAE and RC
- Attention should be made to the SAE and RC highlighted in this chapter to ensure these are being reported consistently and that QMS are reviewed for robustness and effectiveness

Summary

It was another difficult year for everyone coping with the effects of the COVID-19 pandemic. As last year, changes to clinical focus and practice, process affecting the quality and safety of blood and blood component, workloads, staffing levels, skill-mix and education and training mean that comparison of data from 2021 to previous years is difficult. The number of events received increased, presumably due to increased blood usage as hospitals struggled to get back to normal. Although the spread of the categories of reports was largely consistent to previous years, there was a marked increase in some individual reporting categories.

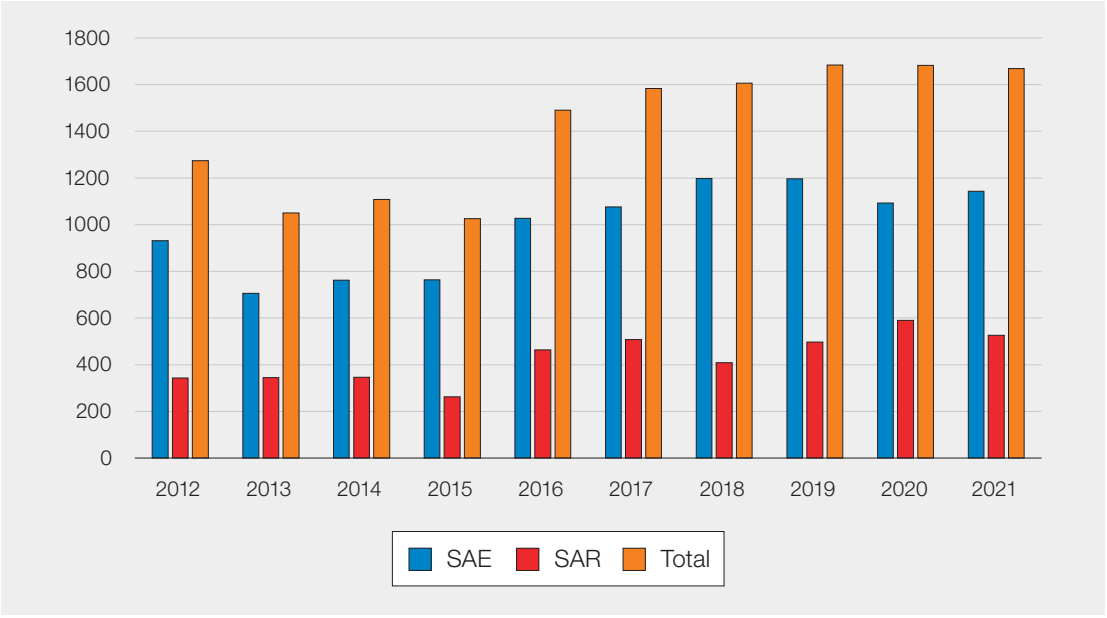
SABRE report data

Table 26.1 and Figure 26.1 show the total numbers of reports and the numbers of reports submitted as SAE and SAR for the previous 10 years. Although the figures remain broadly similar to previous years, the data show a slight decrease in the total number of reports overall with a decrease in SAR reports received and an increase in SAE reports. The reasons for the increase in SAE reports will be explored later in the chapter.

Table 26.1: Submitted confirmation reports 2012–2021

	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
SAE	931	705	762	764	1027	1076	1198	1197	1093	1143
SAR	343	345	346	262	464	508	408	497	590	526
Total	1274	1050	1108	1026	1491	1584	1606	1684	1683	1669

Figure 26.1: Submitted confirmation reports 2012-2021



SAE=serious adverse event; SAR=serious adverse reaction

Serious adverse events n=1143 (+50)

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 (BSQR 2005).

Storage data n=293 (+19)

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 26.2. For a description of the subcategories used, see Appendix 1.

Table 26.2: SAE storage error sub-classifications

Storage sub-classification	2021 (+/- 2020)	2020 position
Incorrect storage of component	137 (+25)	1
Component expiry	50 (-5)	2
Sample expiry	40 (+10)	3
Return to stock error	17 (-4)	4
Security	16 (+4)	5
Storage temperature deviation	13 (NC)	7
Failure to action alarm	13 (-3)	5
Miscellaneous	6 (+2)	9
30 or 60 minute rule	1 (-5)	8
Total	**293 (+19)**	**x**

Unofficial data from BE suggest a slight increase in blood usage in 2021 during the continuing COVID-19 pandemic. It would not therefore be considered unusual then for the number of storage errors to increase by approximately 7%. Similar to last year, there has been an increase in the number of incorrect storage of components and again this increase has largely been seen due to a number of factors relating to changes in staffing and practice during the pandemic.

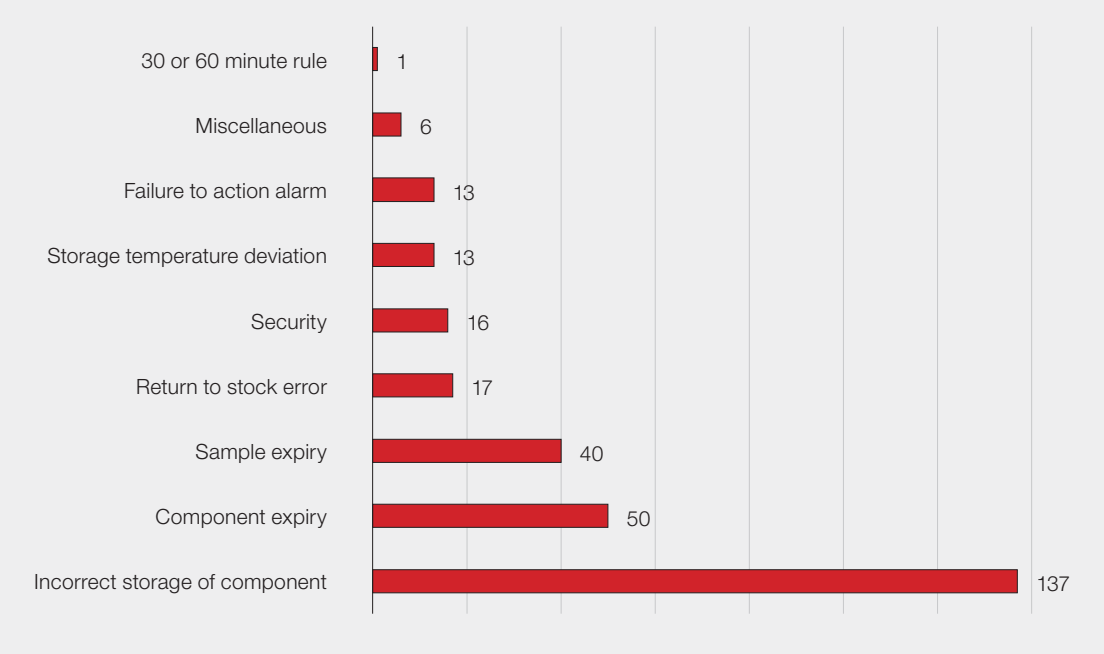


Figure 26.2: Incorrect storage of component by specification 2021 (n=293)

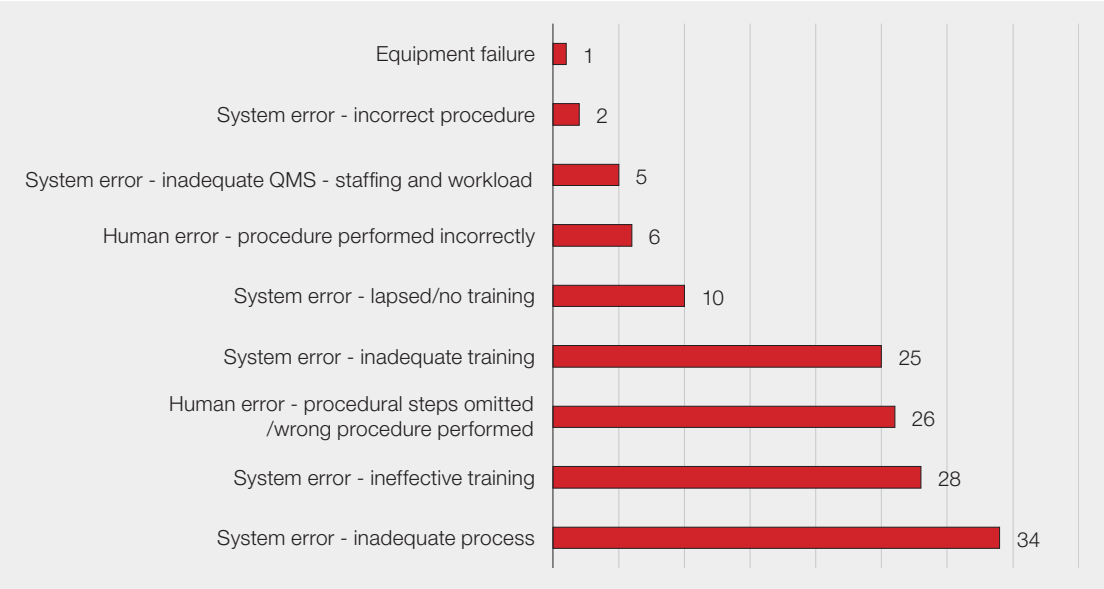


Figure 26.3: Root causes of the incorrect storage of components subcategory in 2021 (n=137)

QMS=quality management system

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 23% of the errors are assessed as 'human error' with the remaining 77% a result of 'system errors'.

From last year's chapter it was stated that;

'As hospitals adapted processes to cope with the effects of the pandemic, storage locations were either moved or became inaccessible as areas of the hospital were adapted into 'hot' or 'cold' areas. Staff were also redeployed to unfamiliar areas. Therefore, errors in the Incorrect storage of components were

likely to be the result of poor business continuity planning, resulting in inadequately planned changes to storage processes, with a lack of thought to how the changes made might affect how components might be correctly stored. Further factors highlighted within the narrative of the reports received demonstrated poor communication of these changes to staff, failure to provide adequate training and ensuring shifts were covered by staff with the correct access to storage locations. It is accepted that coping with the pandemic presented hospital staff with many challenging circumstances and staff should not be criticised for the increase in Incorrect storage errors, but it does demonstrate how errors can be prevented using robust change management controls.'

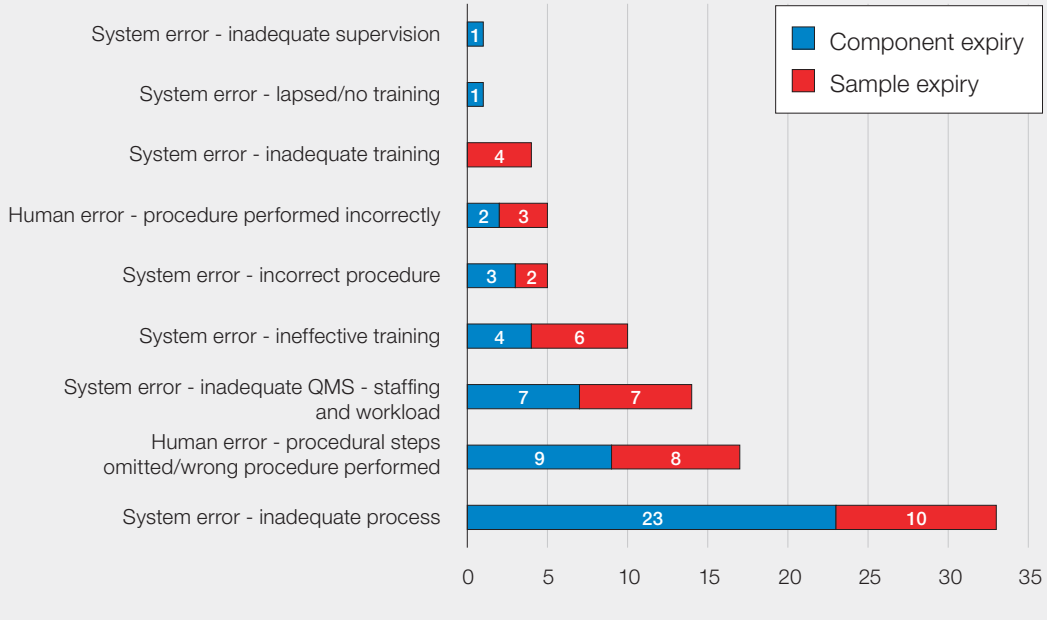
It would appear that last year's recommendation, repeated below, was not taken up by all HTT.

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 26.4: Root causes of the combined component and sample expiry subcategories



QMS=quality management system

The cause of error in these categories demonstrate a split of 78% system errors compared to 22% human errors, with the largest proportion relating to inadequate process design.

Recommendation

- Review processes that involve the removal of expired components from storage locations and their re-stocking or disposal to ensure they are thoroughly robust

Action: Transfusion laboratories

Other n=743 (+18)

Other subcategory	2021 (+/- 2020)	2020 position
Incorrect blood component issued (IBCI)	172 (+15)	1
Component collection error (CCE)	152 (+33)	3
Sample processing error (SPE)	132 (+23)	5
Component labelling error (CLE)	100 (-14)	4
Pre-transfusion testing error (PTTE)	84 (-43)	2
Data entry error (DEE)	60 (NC)	6
Failed recall (FR)	20 (+8)	7
Unspecified (UNSPEC)	10 (+4)	9
Component available for transfusion past de- reservation (CATPD)	4 (-7)	8
Incorrect blood component ordered (IBCO)	3 (-1)	11
Handling damage (HD)	3 (+1)	13
Expired component available for transfusion (ECAT)	2 (-3)	10
Incorrect blood component accepted (IBCA)	1 (-2)	12
Total	**743 (+18)**	**X**

Table 26.3: 'Other'

Table 26.3 shows the number of reports in the 'other' category of SAE. There has been a slight increase (2.5%) in events that fall into the 'other' category. This is most likely due to the increase in blood usage as the health service recovered from the initial effects of the pandemic. Although the number of reports increased in most categories, there was a marked reduction in the number of reports of pre-transfusion testing errors (34%) and the number of component labelling errors (12%). With the increase in blood usage, such a reduction is welcome, but unusual. With no apparent explanation for the reduction, other than improved practices, it would be interesting to see if this reduction is maintained next year. Please see Appendix 2 for a description of the subcategories.

Human and system error categories and human factors

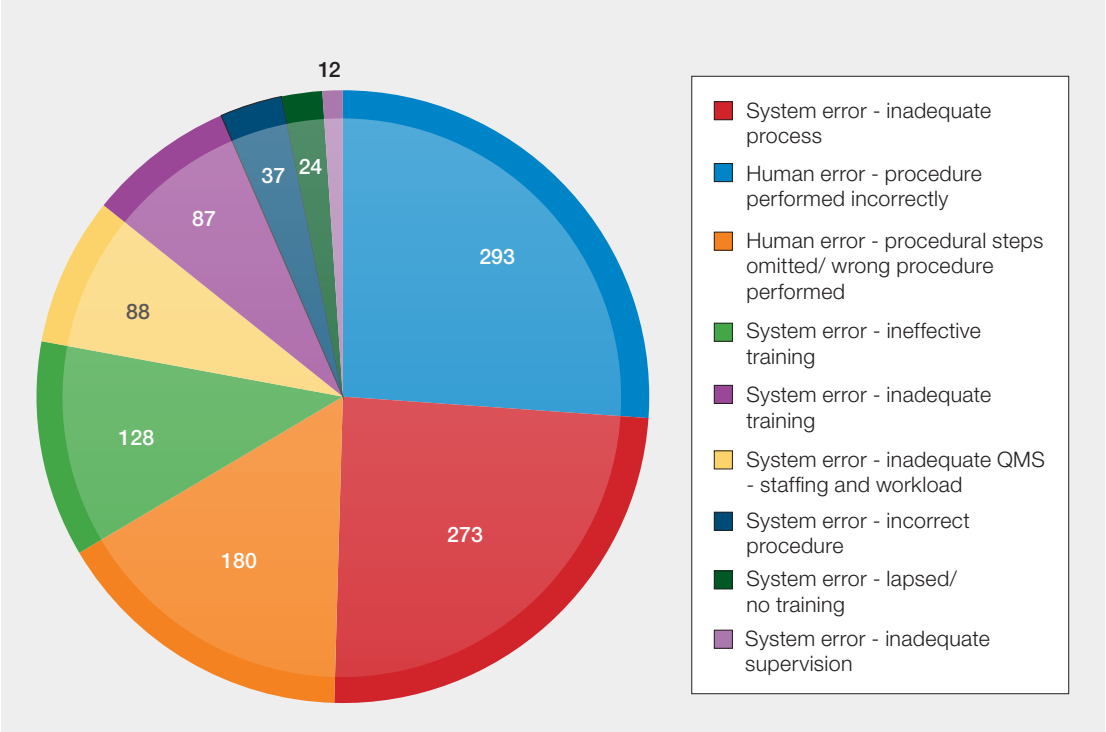
In line with the requirements of EU reporting, the category of system error has formally been adopted, based on the MHRA subcategorisation of human error reports. The MHRA assign a category on review of an SAE report to reflect the most prominent causative factor. Assessment of these reports can distinguish between events caused by system errors (human factors) and human errors (slips/lapses/omissions). For a description of the categories used, see Appendix 3.

Table 26.4 shows the breakdown of reports in the human/system error subcategories.

Human error subcategory	Total 2021 (+/- 2020)	2020 position
Human error/procedure performed incorrectly	293 (+49)	2
System error/inadequate process	273 (+5)	1
Human error/procedural steps omitted/wrong procedure performed	180 (+1)	3
System error/ineffective training	128 (-14)	4
System error/inadequate QMS – staffing and workload	88 (-2)	5
System error/inadequate training	87 (+5)	6
System error/incorrect procedure	37 (-9)	7
System error/lapsed/no training	24 (NC)	8
System error/inadequate supervision	12 (-2)	9
Total	**1122 (+33)**	**x**

Table 26.4: Human/system error subcategories in 2021

Figure 26.5: Human/system error subcategories in 2021 (n=1122)



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

- The RC of incidents are usually the result of many contributory factors. The subcategory 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 subcategory rather than choosing a category that best fits the main SAE reported
- The subcategory 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 subcategorised appropriately

An increase in the number of SAE due to the increase in blood usage was to be expected. The split of root causes mirrors previous years with 42% being identified as human error and 58% as system error.

Investigations and reporting on SABRE

While the MHRA recognise that time pressure and lack of resource affect a transfusion team's ability to investigate events, it is a vital part of the quality system. The EU Good Practice Guidelines for Blood Establishments (GPG 2018) apply to HBB as well as BE. They apply to all SAE reportable under the BSQR including SAE that have occurred in a clinical area. One of the requirements relates to the investigation of root cause:

- 9.4.6. An appropriate level of root cause analysis work should be applied during the investigation of deviations. In cases where the true root cause(s) cannot be determined, consideration should be given to identifying the most likely root cause(s) and to addressing those. 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

Most SAE reports to SABRE initially lack depth and attribute the root cause to human error without first addressing system errors and human factors. This same finding is frequently raised during inspection. SABRE reports that lack depth will require additional contact from the SABRE Haemovigilance Team and will either require further investigation or further detail in the SABRE report. Therefore, the same recommendation from last year is repeated below.

Recommendations

- All reporters must continue to thoroughly investigate all SAE, 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 recurrence

Action: Hospital transfusion teams

Top 5 SAE

SAE deviation subcategory	System error subcategory
Incorrect blood component issued (IBCI)	Inadequate process
Component collection error (CCE)	Inadequate process
Incorrect storage of component	Inadequate process
Component collection error (CCE)	Ineffective training
Incorrect storage of component	Ineffective training

Table 26.5: Top 5 SAE with system error subcategory

Incorrect blood component issued – inadequate process (n=59)

SAE that fall into this category will typically involve blood being issued that does not meet a patient's specific requirements.

RCs will often be due to:

- Processes that do not require a BMS to access Sp-ICE
- Information from a clinical area not acted upon in a timely or consistent manner
- Poorly kept patient history on the LIMS that is easily overlooked or misunderstood

Although functionality within a LIMS should be used to provide warnings and barriers to issuing the incorrect component, the overall process should focus on the selection of the correct component in the first place, rather than a reliance on systems to detect errors already made.

Component collection error – inadequate process (n=37)

SAE that fall into this category will often involve porters, but can also involve doctors, nurses, healthcare assistants as well as laboratory staff if the collection process directly involves them helping or handing over components. Errors can involve electronic tracking systems as well as manual processes.

Many of these reports have been assessed as a combination of multiple root causes rather than simply being a result of a poorly designed collection process. Therefore, it is essential that then designing processes that involve collection of components the whole process is considered, including but not limited to ensuring:

- The correct information is provided to the collector
- The process includes checks of all the vital patient identifiers
- All equipment used in the process works
- A written procedure is produced that describes the process

- Training material is produced that covers all aspects of the process, including what to do if something does not occur as it should
- Training is delivered, understood and assessed
- Enough staff have been identified to perform the process when necessary
- Enough trained staff are available on each shift

Storage/incorrect storage of component – inadequate process (n=34)

SAE in this category can involve both portering, clinical and laboratory staff. Many of these SAE are a direct result of the effects of coping with the COVID-19 pandemic. Changes that were necessary that affected hospital locations and environments, staffing levels, skill-mix as well as staff sickness and isolation resulted in changes to storage locations, processes and the availability of trained staff. Changes were often made without thorough planning using change control procedures and considering all the possible factors. As well as poor planning as a whole, often the RC involved multiple factors, including:

- No consideration made to changing storage arrangements
- Inadequate process design
- No or insufficient SOP
- No or inadequate training
- No review of capacity plans to ensure adequate staffing or skill-mix

Component collection error – ineffective training (n=33)

Component collection errors have been mentioned above. However, they appear a second time in the top five specifically relating to ineffective training. Where staff have been redeployed, or storage locations moved, or staff off work for sickness, this often meant new staff were identified for training in collection of components at short notice. Report narratives suggest that although training was delivered it may not have been understood at the time and staff continued to attempt to collect components when not being entirely sure what to do.

Storage/incorrect storage of component – ineffective training (n=28)

SAE in this category primarily involve clinical staff but may also involve other staff categories. These SAE typically involve staff have been trained, but have still performed the task incorrectly. This is often stated that the staff involved have either forgotten the training or had not understood it when it came to storing a component. RC often involve:

- Staff not performing storage tasks frequently enough to re-enforce their training
- Staff thinking they are doing the right thing without checking
- Being unfamiliar with less frequently used component types
- Not understanding the difference between unmonitored ward refrigerators and blood refrigerators

Recommendations

- Review QMS to ensure the processes involved in the most frequently occurring SAE are robust. Ensure that:
- The process is thoroughly defined
- Procedures are written giving full and clear instructions how to perform the task
- Training is planned, adequate, delivered and understood

Action: Hospital transfusion teams

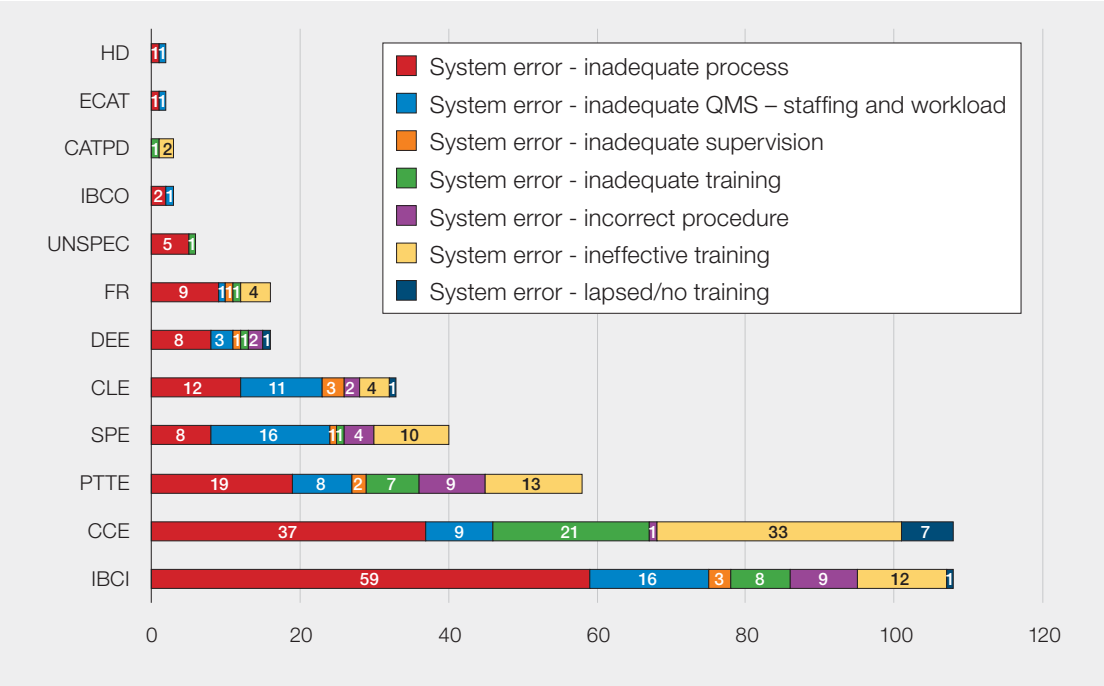


Figure 26.6
Other subcategory and system error

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

Figure 26.6 demonstrates all the most frequently occurring SAE that fall into the other category and their root causes where the QMS was deemed to have been insufficient.

From Jan 1st 2021 the MHRA have been assigning human and system error subcategories directly on individual reports once they have been reviewed and closed.

Notification

Date of event:	15 Mar 2021
Event involving:	Other
If other, please state here:	PTTE - Pre-transfusion testing error
Specification:	System error / Inadequate process
If other, please state here:	
Implicated Component:	Red blood cells
Blood component transfused:	No

Recommendations

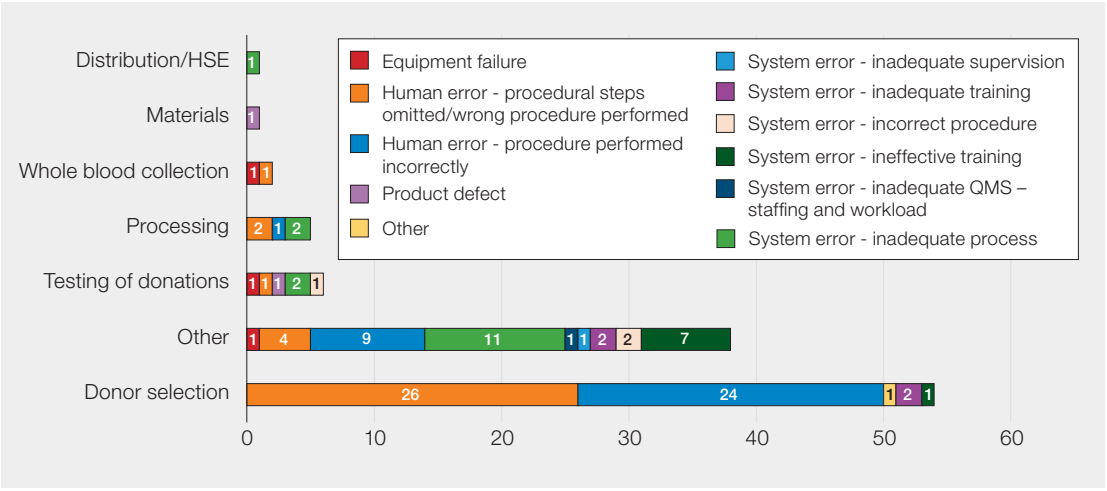
- Review SAE closed by MHRA and take note of the RC subcategory and event subcategory to trend and identify a site's own most commonly occurring SAE and RC

Action: Hospital transfusion teams

Blood establishment reporting n=107 (=+12)

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 26.7 displays the reported BE SAE in 2021.

Figure 26.7: Blood establishment SAE event category by specification

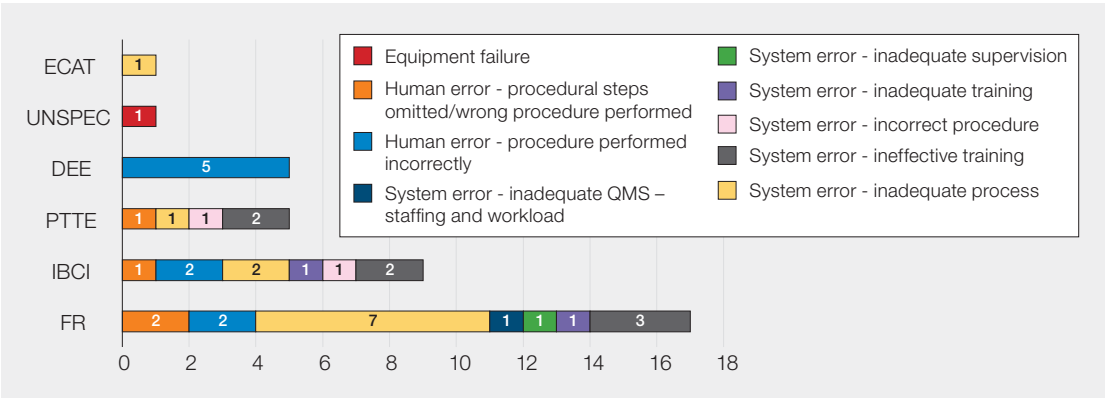


QMS=quality management system; HSE=handling and storage error

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 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 26.8 shows a breakdown of the 38 reports which fall into the 'other' category.

Figure 26.8 BE reports in 'other' category



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

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

I am pleased to see that hospital transfusion laboratories continue to engage well with haemovigilance reporting despite all the ongoing challenges we are all facing. It is important that we all continue to report these incidents so we continue to learn, not only from our own reports, but from the overall national picture.

The thorough investigation of all incidents remains important, even those which have not caused harm. This will allow us to identify potential risks to our patients and ensure we are providing safe and timely service to reduce these risks.

The 7% increase in the number of reports related to incorrect storage of components is a concern, as is the information that 77% of these errors are the result of a system error. I'd urge everyone to review their systems in light of these figures and consider what changes may be needed to prevent such incidents.

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
(BSQR 2005)

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 26.9.

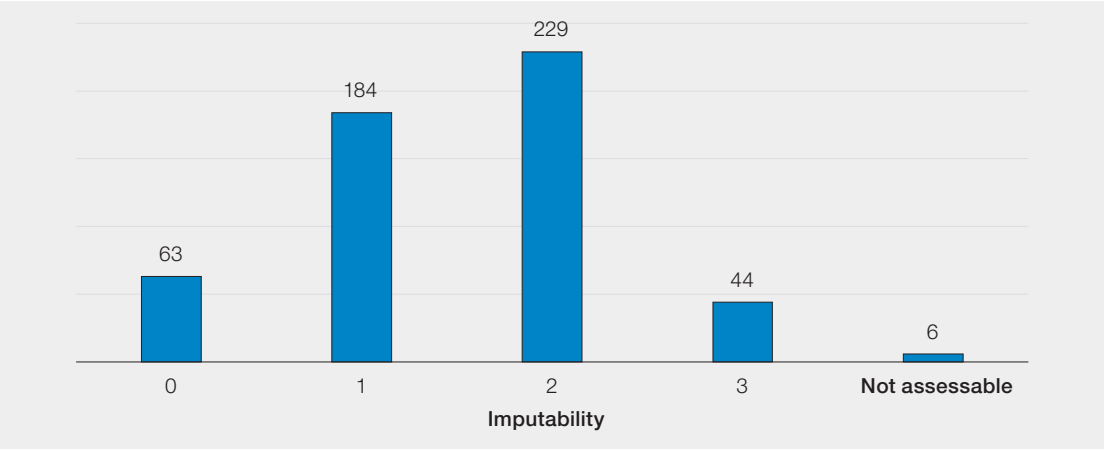


Figure 26.9: SAR reports, by imputability, reported to SABRE in 2021

MHRA inspection activity on hospital blood banks

Authors: Shirley Stagg and Mike Dawe

The Haemovigilance Team Manager is now conducting blood inspections and as such the Haemovigilance Team Manager's update will be incorporated in the inspectorate report. Blood education days are continuing and can be requested from the Senior Haemovigilance Specialist.

The MHRA inspectorate have continued to verify blood compliance reports and have conducted 23 inspections since August 2021. Although different sites have been inspected, the issues found are much the same as previous years. In lieu of a separate inspector's report, you are urged to take note of last year's section.

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, 15/02/2018 https://www.edqm.eu/en/good-practice-guidelines-for-blood-establishments [accessed 03 April 2022].

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