26 MHRA Report on Blood Safety and Quality Regulations (BSQR) in 2020

Author: Chris Robbie

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
HTM	Haemovigilance Team Manager
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 a difficult year for everyone coping with the effects of the COVID-19 pandemic. Changes to clinical focus and practice, process affecting the quality and safety of blood and blood components, workloads, staffing levels, skill-mix and education and training mean that comparison of data from 2020 to previous years is difficult. Lower blood usage would inevitably affect the numbers of reports made so this report has been written to try and interpret the data with relevance to the pandemic rather than a comparison to previous data.

Although the number of SAE reports was less than last year, rather than all categories of reports reducing, some stayed the same as the previous year or even increased from previous years. This may indicate that unplanned changes to processes had an adverse effect on quality and safety in some areas. Categories where numbers reduced may be a reflection on lower blood usage but may also be

an indication of the robustness of the processes involved that they were able to cope with the many challenges faced.

SABRE report data

Table2 6.1 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 total numbers of reports submitted remains similar to last year there has been an increase in the numbers of SAR reported and a decrease in the numbers of SAE reported.

	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
SAE	810	931	705	762	764	1027	1076	1198	1197	1093
SAR	444	343	345	346	262	464	508	408	497	590
Total	**1254**	**1274**	**1050**	**1108**	**1026**	**1491**	**1584**	**1606**	**1684**	**1683**

Table 26.1: Submitted confirmation reports 2011–2020

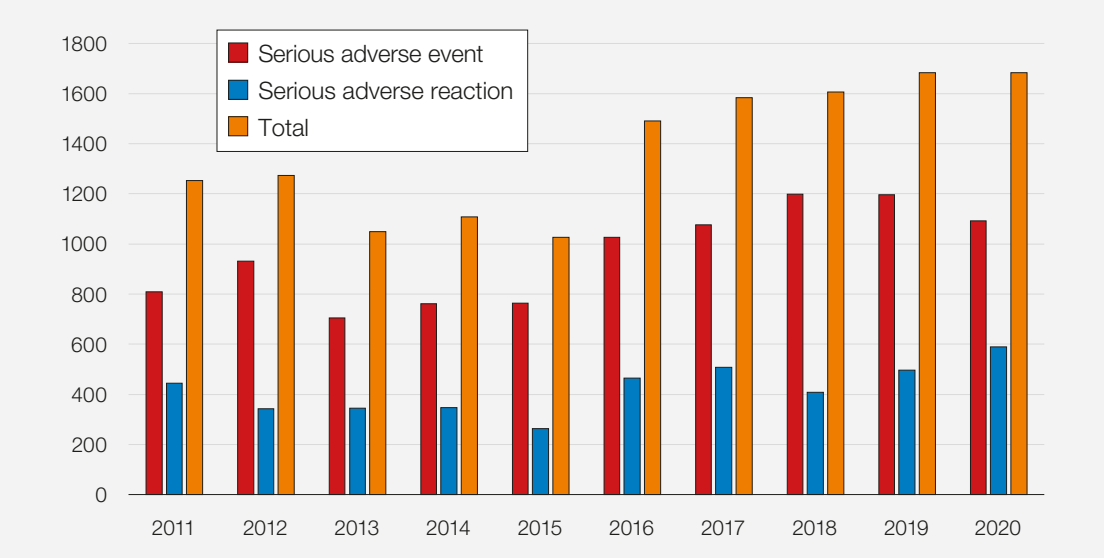


Figure 26.1: Submitted confirmation reports 2011–2020

Figure 26.2 compares the number of reports received by month for 2019 and 2020 to demonstrate the effect of the pandemic on reporting figures. The reporting numbers were comparable, with a slight dip in the peaks of the pandemic, both in the first wave and the second. Increased reporting in the months of September and December, which could potentially reflect easing in the pandemic effect.

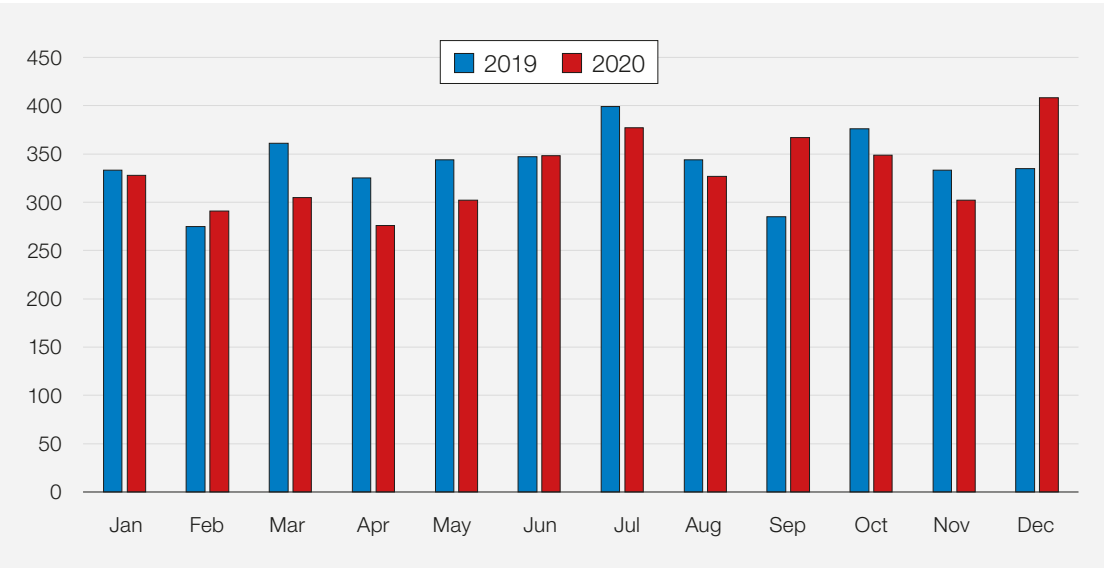


Figure 26.2 Comparison of SAE/SAR reports received by month 2019 and 2020

Serious adverse events n=1093 (-104)

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.

Storage data n=274 (-3)

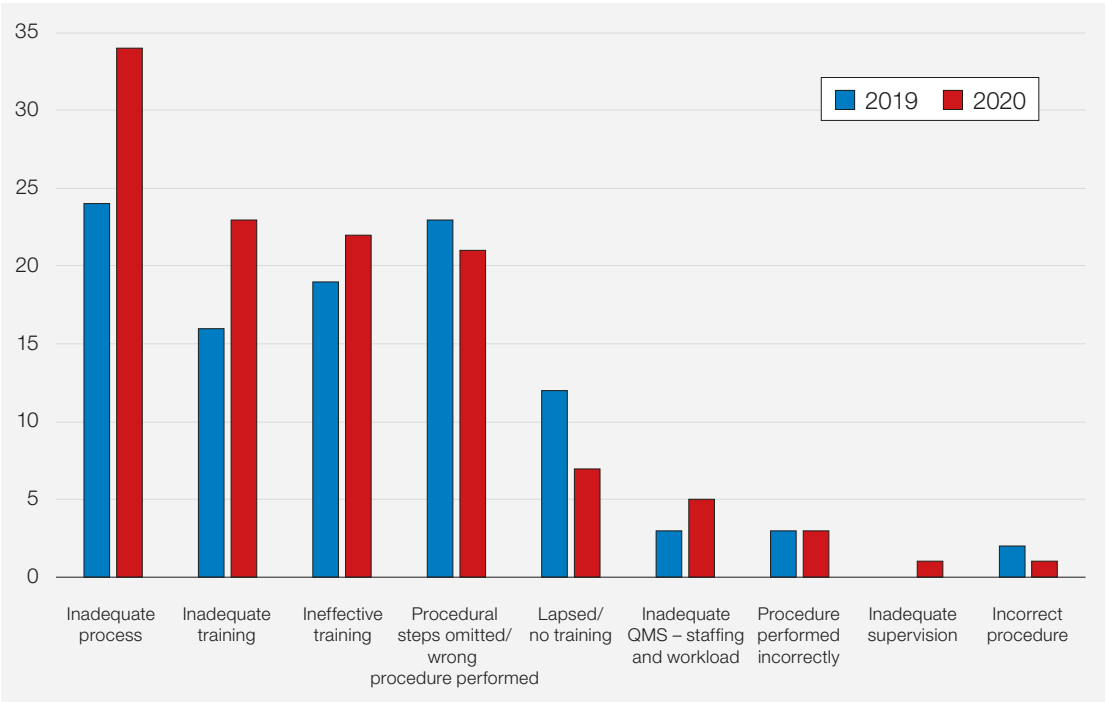
Storage remains the second largest individual error category (after "Other") and comprises of all BSQR reportable Storage SAE in both the laboratory and clinical areas. The MHRA has broken this category down further to try and identify specific storage error sub-types, Table 26.2. For a description of the sub-categories used, see appendix 1.

Table 26.2: SAE storage error sub-classifications

Storage sub-classification	2020 (+/- 2019)	2019 position
Incorrect storage of component	117 (+15)	1
Component expiry	55 (-16)	2
Sample expiry	30 (-9)	3
Return to stock error	21 (-1)	4
Failure to action alarm	16 (+4)	6
Storage temperature deviation	13 (-2)	5
Security	12 (+7)	8
30- or 60-minute rule	6 (+3)	9
Miscellaneous	4 (-4)	7
Total	**274 (-3)**	**not applicable**

Although unofficial data from BE suggest a 30% reduction in blood usage in 2020 during the COVID-19 pandemic, the number of Storage errors remain similar to last year. The reduction in Component and Sample expiry is probably explained by a reduction in the number of units in circulation. There has been an increase in the number of incorrect storage of components and this increase has largely been seen due to a number of factors relating to changes in staffing and practice during the pandemic.

Figure 26.3: Incorrect storage of component by Specification 2019 and 2020



QMS = quality management system

Figure 26.3 compares the RCs of incorrect storage of components for 2019 and 2020. It is notable that there has been an increase in the sub-categories:

- Inadequate process
- Inadequate training
- Ineffective training

There was a subsequent reduction in "procedural" errors noted. 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.

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

Other n=725 (-54)

Table 26.3: 'Other'

Other sub-category	2020 (+/- 2019)	2019 position
Incorrect blood component issued (IBCI)	157 (-33)	1
Pre-transfusion testing error (PTTE)	127 (+8)	3
Component collection error (CCE)	118 (+1)	4
Component labelling error (CLE)	114 (-5)	5
Sample processing error (SPE)	109 (-33)	2
Data entry error (DEE)	60 (+6)	6
Failed recall (FR)	12 (+6)	10
Component available for transfusion past de-reservation (CATPD)	11 (+1)	7
Unspecified (UNSPEC)	6 (-3)	8=
Expired component available for transfusion (ECAT)	5 (-4)	8=
Incorrect blood component ordered (IBCO)	4 (-1)	11
Incorrect blood component accepted (IBCA)	3 (+2)	13
Other – LIMS Failure	2 (N/A)	x
Handling damage (HD)	2 (+1)	12
Total	**725 (-54)**	**not applicable**

Table 26.3 shows the number of reports in the "Other" category of SAE. A reduction in the overall number of reports received is probably a reflection of the reduction in blood usage during the pandemic as can be seen in a reduction of IBCI and SPE error. However, not all categories of SAE have reduced, with some categories remaining similar to last year or even increasing. Although workloads in HBBs reduced as fewer components were used, laboratories were not immune to the effects of the pandemic with

reductions in staffing levels as staff were sick, isolating, or re-deployed. Even without the pandemic laboratories are still affected by other factors including staff vacancies and loss of experienced staff, training of new staff and inexperienced members of staff trying to cope with reduced supervision. Please see appendix 2 for a description of the sub-categories.

Human error category and human factors

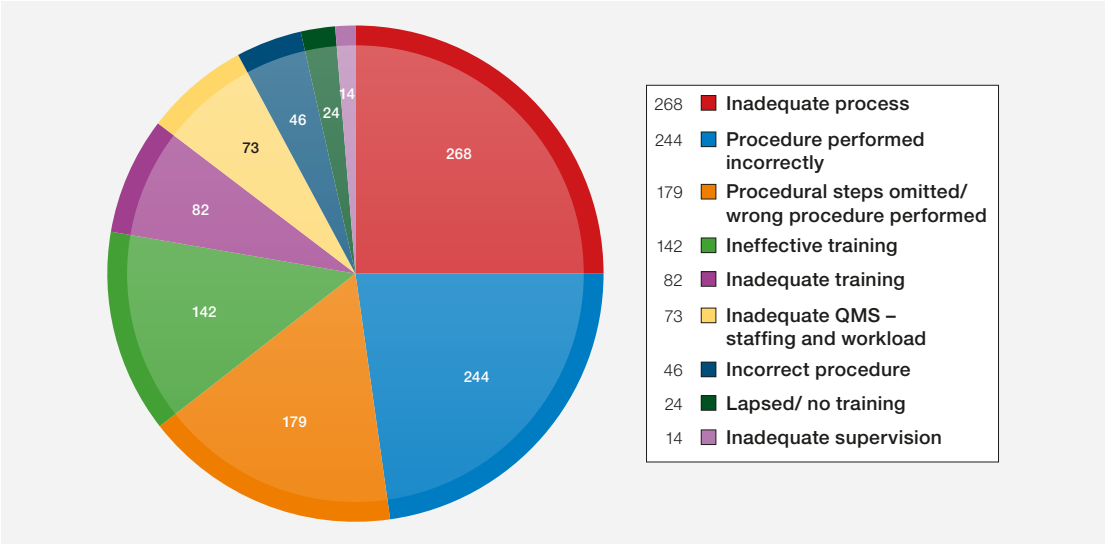
To understand reports in the human error category, the MHRA have continued to use sub-categories which can be applied to the report narratives to help understand the human factors involved. For a description of the categories used, see appendix 3.

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

Table 26.4: Human error sub-category, 2020

Human error sub-category	Total 2020 (+/- 2019)	2019 position
Inadequate process	268 (-14)	2
Procedure performed incorrectly	244 (-66)	1
Procedural steps omitted/wrong procedure performed	179 (-20)	3
Ineffective training	142 (+2)	4
Inadequate QMS – staffing and workload	90 (-8)	5
Inadequate training	82 (+24)	6
Incorrect procedure	46 (+10)	7
Lapsed/no training	24 (-3)	8
Inadequate supervision	14 (-1)	9
Total	**1072 (-101)**	**not applicable**

Figure 26.4: Human error sub-category



QMS = quality management system

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

There were 101 fewer "human error" reports in 2020 from 2019, again a reflection of the reduction in reporting due to the reduction in blood usage. For the first time since this category was sub-categorised, the highest proportion of SAEs fall into the "inadequate process" category. "Procedural errors" account for 40% of all human error reports which is a decrease of 4% from last year. That means that 60% of all human error reports have been reported proposing improvements to QMS within the CAPA. An increase in SAE sub-categorised as "Inadequate training" is likely to be in part a reflection of training regimes that did not adequately reflect changes to processes changed at short notice due to the pandemic.

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

Action: Hospital transfusion teams

Top 5 SAE

SAE deviation sub-category	Specification sub-category
Pre-transfusion testing error (PTTE)	Inadequate process
Incorrect blood component issued (IBCI)	Inadequate process
Component collection error (CCE)	Ineffective training
Incorrect storage of component	Inadequate process
Incorrect storage of component	Inadequate training

Table 26.5: Top 5 SAE with human error sub-category

"Procedural" errors resulting from slips and lapses in concentration from staff are either genuine human error SAE or an indication that the investigation was not thorough enough to identify the true RC and contributory factors involved. This accounts for 40% of all human error reports. The remaining 60% of human error reports demonstrate "System errors". These have been assessed and presented as a "top 5" most commonly occurring SAE and RC.

PTTE – Inadequate process (n=45)

SAEs that fall into this sub-category will typically involve:

- Use of out of date reagents or controls
- Failure to exclude from EI and to manually crossmatch
- Failure to accurately interpret results
- Failure to complete testing or resolve anomalous results

From the report narratives, RCs often involve:

- Inadequate change control where errors in the LIMS were not identified
- Inadequate design of processes that did not direct staff in the correct actions to take under different circumstances

IBCI – Inadequate process (n=43)

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 the NHSBT Specialist Services electronic reporting using Sunquest's Integrated Clinical Environment (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.

CCE – Ineffective training (n=35)

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.

From the corrective actions proposed to resolve this SAE (re-training of staff involved) the implication is that staff have either not understood the training initially or have forgotten it. Although training packages might be deemed to be "robust", thought must be given to the ability of the staff being trained and the frequency of re-training. Some staff may require more in-depth training than others, and staff that perform the tasks less often may need to be trained more often than other staff.

Storage/ Incorrect storage of component – Inadequate process (n=34)

SAE in this category can involve 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

While these points are to be made, it is not to criticise actions taken under extreme circumstances but should be taken as a learning point that demonstrates the importance of proper change control and change management to ensure quality and safety is maintained.

Storage/ Incorrect storage of component – Inadequate training (n=23)

SAE in this category primarily involve clinical staff but may also involve other staff categories. These SAE typically involve staff that have been trained in the correct storage processes but that the training was not thorough enough to cover the errors made, or is not adequately rolled out to enough staff to ensure trained and competent staff perform the storage tasks. RC often involve:

- Staff who should have been trained but have not
- Untrained staff, who do not have responsibility for component storage being directed to store components instead of trained staff
- Training that does not distinguish between component types or monitored and unmonitored storage locations

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

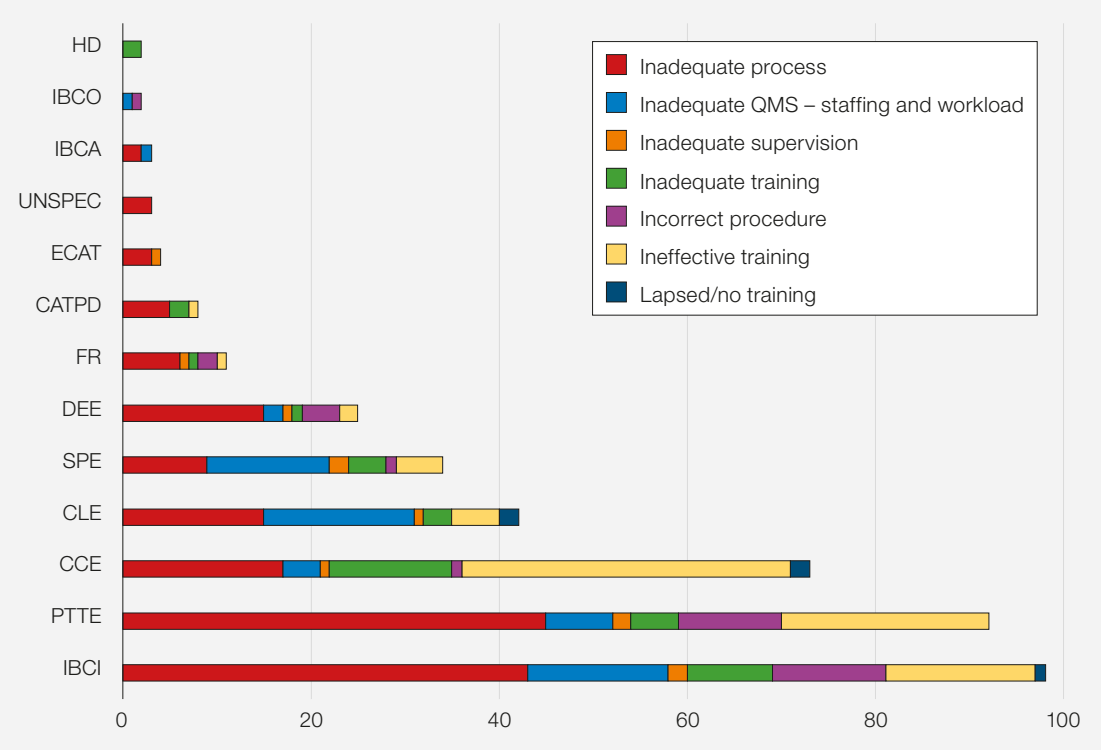


Figure 26.5: Other sub-category and root cause for all SAE other than procedural steps omitted/ wrong procedure performed and procedure performed incorrectly

HD = handling damage; IBCO = incorrect blood component ordered; IBCA = incorrect blood component accepted; UNSPEC = unspecified; ECAT = expired component available for transfusion; CATPD; component available for transfusion past de-reservation; FR = failed recall; DEE = data entry error; SPE = sample processing error; CLE = component labelling error; CCE = component collection error; PTTE = pre-transfusion testing error; IBCI = incorrect blood component issued

Figure 26.5 demonstrates all the most frequently occurring SAEs that fall into the other category and their root causes where the QMS was deemed to have been insufficient.

From January 1st, 2021 MHRA have been assigning human error sub-categories 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

Figure 26.6: Example of a new human error sub-category to demonstrate a system error

Recommendations

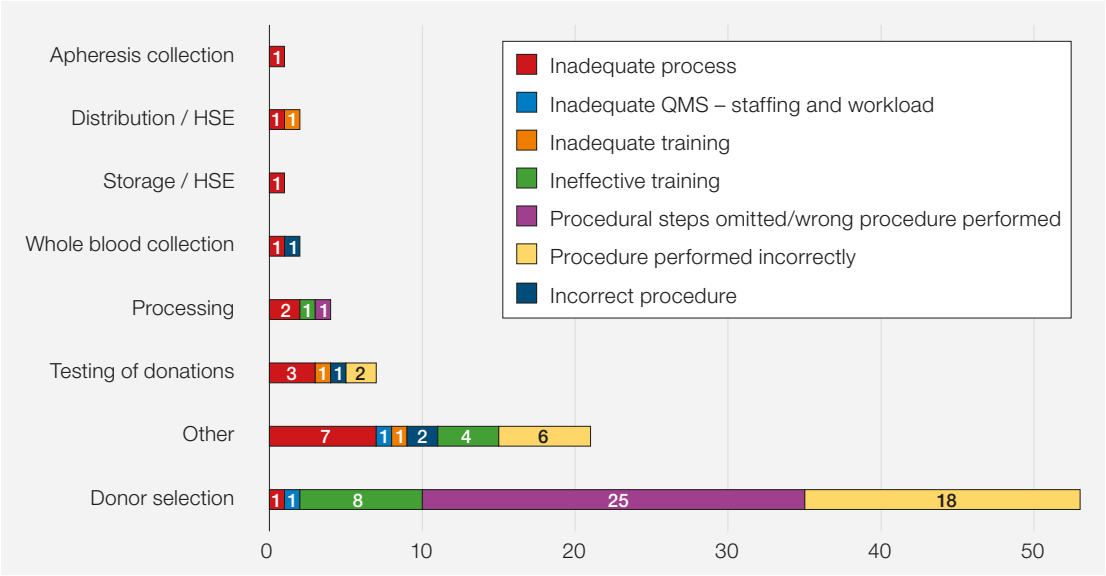
- Review SAE closed by MHRA and take note of the RC sub-category and event sub-category to trend and identify a site's own most commonly occurring SAE and RC

Action: Hospital transfusion teams

Blood establishment reporting n=95 (-28)

Although reports from blood establishments (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 26.8 displays the reported BE SAE in 2020.

Figure 26.7: Blood establishment SAE event category by specification

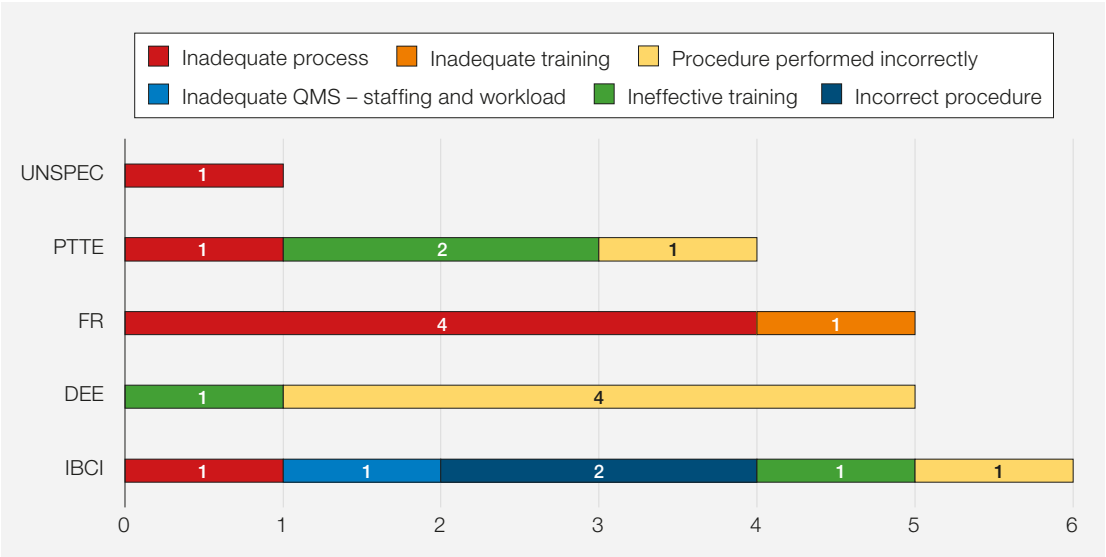


QMS = quality management system; HSE = handling and storage errors

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 lifestyle reasons.

Figure 26.9 shows a breakdown of the 21 reports which fall into the "Other" category.

Figure 26.8: BE reports in "Other" category



QMS = quality management system; UNSPEC = unspecified; PTTE = pre-transfusion testing error; FR = failed recall; DEE = data entry error; IBCI = incorrect blood component issued

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

It is pleasing to see that despite all the additional challenges of 2020, the Transfusion Laboratory community continued to ensure appropriate adverse incidents are reported through the correct processes to MHRA and SHOT.

The small reduction in the number of SAE seen is as expected due to the reduction in the number of blood components transfused in 2020. It remains concerning that there are still a high number of incorrect blood components being issued from laboratories. Improvements within the LIMS should be considered to try and help address some of these issues, although in 2020 this was less of a priority due to the ongoing pandemic.

The incorrect storage of components remains at a similar level to previous years which is probably a result of difficulties we've all experienced in both laboratory staffing. The redeployment of clinical staff combined with the difficulties of providing face to face training has also impacted on this area. I am pleased to see an improvement in the use of human factors when investigating incidents and the fact the 60% of all human error reports have proposed improvements to the QMS shows that as a community we are reflecting on our errors and incidents and looking towards improving our process.

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 26.10

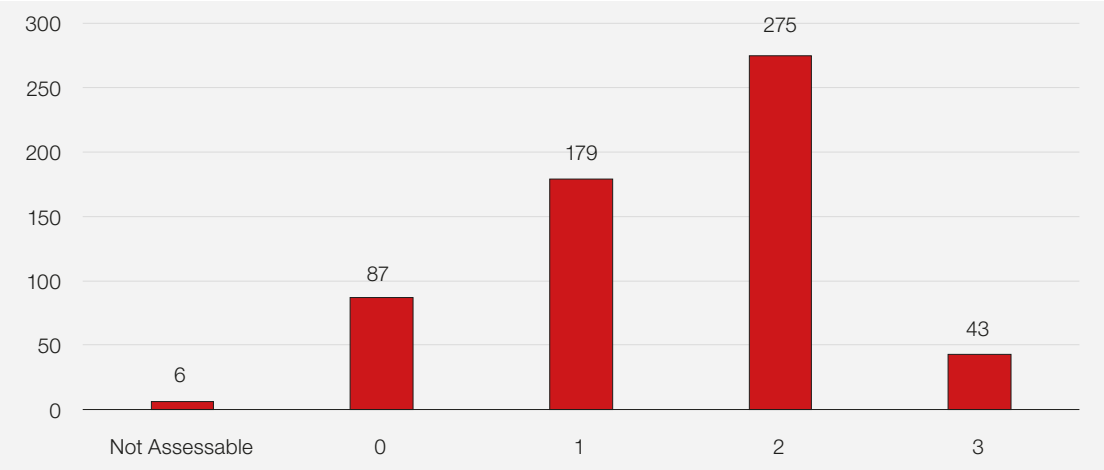


Figure 26.9: SAR reports, by imputability, reported to SABRE in 2020

Haemovigilance team managers (HTM) update 2020/21

Author: Mike Dawe

Over the past year, due to COVID-19, the Haemovigilance Team Manager has been seconded to other areas of the MHRA to support the agency's COVID-19 response. As a consequence, there is very little to report regarding the activity of the role as reported in previous years.

Findings and recommendations

Update to manufacturers not meeting a site need

There have been further concerns raised regarding a lack of meaningful support from LIMS and equipment manufacturers leading to issues where sites are concerned that they may not meet their regulatory requirements.

HBB must comply with the BSQR and part of that responsibility is to ensure that equipment is qualified and computerised systems are maintained in a validated state. This often requires information and support from the manufacturer or vendor and as such sites feel that they are left alone to deal with the regulatory issues that may arise due to poor customer engagement. Part of the HTM role is to liaise with manufacturers to ensure that they understand the regulatory framework that they are placing their product into.

As a consequence, the HTM has made manufacturers aware of the pertinent regulations that they need to provide the relevant support to the customer. The following is an example, but not limited to, of a pertinent GPG requirement that users can highlight, if relevant, to a manufacturer:

9.1.6 Deviations from established procedures should be avoided as much as possible and should be documented and explained. Any errors, accidents or significant deviations that may affect the quality or safety of blood and blood components should be fully recorded and investigated in order to identify systematic problems that require corrective action. Appropriate corrective and preventive actions should be defined and implemented.

As such this is a core part of the laboratory management responsibility. Using this requirement as an example, users can make a manufacturer aware of the regulatory impact as well as the patient safety concerns, from the regulatory perspective, that they may have. This can be reinforced by stating that continued operation as a blood bank is dependent on meeting regulatory and good practice requirements and MHRA has the power to issue cease and desist notices where blood banks are not adequately in control and are experiencing significant and recurring incidents. As a consequence, a lack of cooperation from manufactures can threaten the support of blood banks by MHRA.

If a site finds that this approach does not work please report the incident through the MHRA Yellow Card reporting system, https://yellowcard.mhra.gov.uk/, ensuring that keywords such as, but not limited to, Blood, Blood Components, Blood Transfusion are used. This will alert the Devices Safety and Surveillance Division (DSS) who can then collaborate with the Haemovigilance Team and the Blood Inspectors, if deemed appropriate, and the issue can be raised with the manufacturer directly.

Document retention

Several sites have requested advice on the retention of documents. The relevant GPG requirements are as follows:

5.5.2.2. Traceability data (that allow tracing from donor to recipient and vice versa) should be retained for a minimum of 30 years (Directive 2002/98 Article 14.3).

Whatever system or systems are used the recent infected blood enquiry has shown the importance of maintaining these records, https://www.infectedbloodinquiry.org.uk/. If a site uses a combination of traceability systems, then there must be a method of referencing an individual and or components traceability records between the systems used.

5.5.2.3. Documentation regarding investigations into Serious Adverse Events and Serious Adverse Reactions should be retained for a minimum of 15 years.

5.5.2.4. Quality System documentation and associated records should be retained for a minimum of 10 years.

Sites must consider that any quality system, and associated records, that have been linked to a SAE and/or SAR, then these records must be kept in accordance with section 5.5.2.3.

A site should carry out an audit of archived records against the above requirements before they are destroyed.

Summary

Once travel restrictions are lifted, sites that have previously arranged education days, will be contacted to rearrange a suitable alternative.

If a site has a pressing concern regarding a regulatory issue, we can arrange an online meeting so please do not hesitate to contact us for support regarding advice and help within the regulatory framework. Please contact mike.dawe@mhra.gov.uk or chris.robbie@mhra.gov.uk for further details.

MHRA Inspection activity on hospital blood banks

Author: Shirley Stagg

A total of 300 blood compliance reports (BCR) were submitted for review for the reporting period 01 April 2019 to 31 March 2020. A flexibility was put in place that allowed hospital blood banks (HBB) to request extra time to complete their submission due to the first peak of COVID-19, however, most were submitted on time and only one remained outstanding at the end of May. The BCRs were scored and discussed at a meeting of the BCR Assessment Team (BAT) in September.

The inspection process for this year was delayed due to COVID-19 and therefore some general trends from inspections are discussed rather than numerical data based on deficiencies.

Inspection outcomes

An overview of the compliance management escalation processes used by the good manufacturing practice (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 no referrals to IAG or CMT so far from this cycle of inspections.

Summary of significant issues identified at inspected sites

Management of change

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

- Failure to raise a change control
- Lack of user requirement specification
- Lack of risk assessment and actions to mitigate risks
- Incomplete validation
- Failure to carry out a post implementation effectiveness check
- Additions to validated systems not managed through change control

Management of non-conformances

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

- Failure to classify incidents consistently. This includes issues with considering the potential for harm as well as actual harm
- Lack of detailed investigation - including a lack of justification where human error is identified as a root cause
- No review of previous incident reports or other relevant information to identify recurring problems

The availability of trained and competent staff

Initial training of HBB personnel is generally found to be good. However, issues with staff availability and ongoing competency evaluation are frequently raised as an issue as highlighted by:

- Competence evaluations of laboratory personnel significantly overdue
- Incidents frequently attributed to personnel being too busy
- A lack of capacity management plan or similar document to ensure adequate resources to manage blood transfusion operations and maintain the quality management system

Information and guidance

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. http://forums.mhra.gov.uk/forumdisplay.php?60-Blood-Forum

Appendices

Appendix 1: Storage sub-categories

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 sub-categories

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 sub-categories

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

References

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-blood-establishments

The Blood Safety and Quality Regulations 2005, http://www.legislation.gov.uk/uksi/2005/50/regulation/1/made