Blood Consultative Committee Newsletter, April 2021

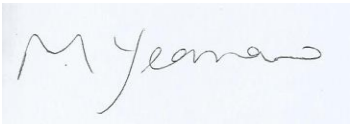
Introduction

Welcome to this newsletter update from the MHRA, which has been prepared in place of the annual Blood Consultative Committee meeting for 2021. This is in recognition of the workload associated with responding to the COVID-19 pandemic, for both the MHRA and the UK health services.

I don't think any of us could have predicted the events that have occurred since our last meeting. The three main areas of work for the Inspectorate over the past year have been supporting the agency's COVID-19 pandemic response, developing guidance following the end of the EU exit transition period, and developing our office-based inspection programme to maintain regulatory oversight to protect patients and the supply of critical medicines during an unprecedented period.

Since 1 January 2021, MHRA is the UK's standalone medicines and medical devices regulator. Our role as Competent Authority for blood continues. MHRA is now undertaking a transformation or 'size and shape' review which is considering the future operating model processes, skills, structures and ways of working we need in the future to deliver our vision and mission.

I look forward to being able to provide updates on our progress as we move forward with transforming the agency to achieve our vision to be a patient focused, enabling regulator, deploying resources in a risk proportionate way.



Michelle Yeomans

GMDP Unit Manager

Content

The topics covered in this newsletter are:

Blood Consultative Committee action update

At the March 2020 meeting, committee members were actioned to notify MHRA of any groups that would be appropriate to participate in the committee to cover any gaps in representation. MHRA were actioned to review and update the website information about the committee, incorporating any new groups and updating other information. As no additional nominations were received, the website has now been updated to bring the existing information up to date.

Inspectorate update

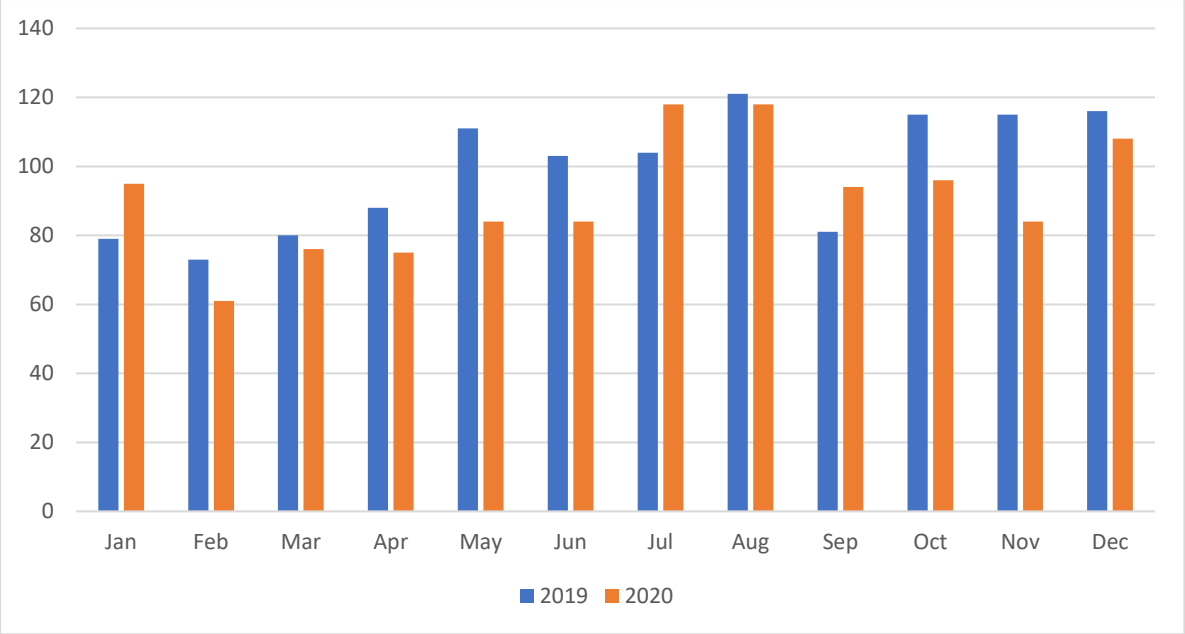
Michelle Yeomans was appointed as GMP/GDP Unit Manager in March 2020, replacing Richard Andrews who had left in February 2020 as reported at the last meeting.

One blood inspector, Kevin Page (Senior GMDP Inspector), retired in November 2020 having delayed his retirement from April to support the MHRA's response to the coronavirus pandemic. Richard Parker (Senior GMDP Inspector) and Stephen Grayson (Senior GMDP Inspector) both partially retired during 2020 and continue to inspect on a part time basis.

SABRE update

Reporting Activity

A comparison of reports received in 2019 and 2020 was performed. Between January and March, the numbers of reports received was largely similar between the two years, but from April to June the numbers of reports received fell away somewhat as hospitals started to experience the first wave of coronavirus cases. From July onwards the numbers of reports received started to pick up again during a period when daily cases remained at low levels. As coronavirus cases started to rise again from October, another reduction in reporting can be seen in the data.



"Other" reports sub-categories

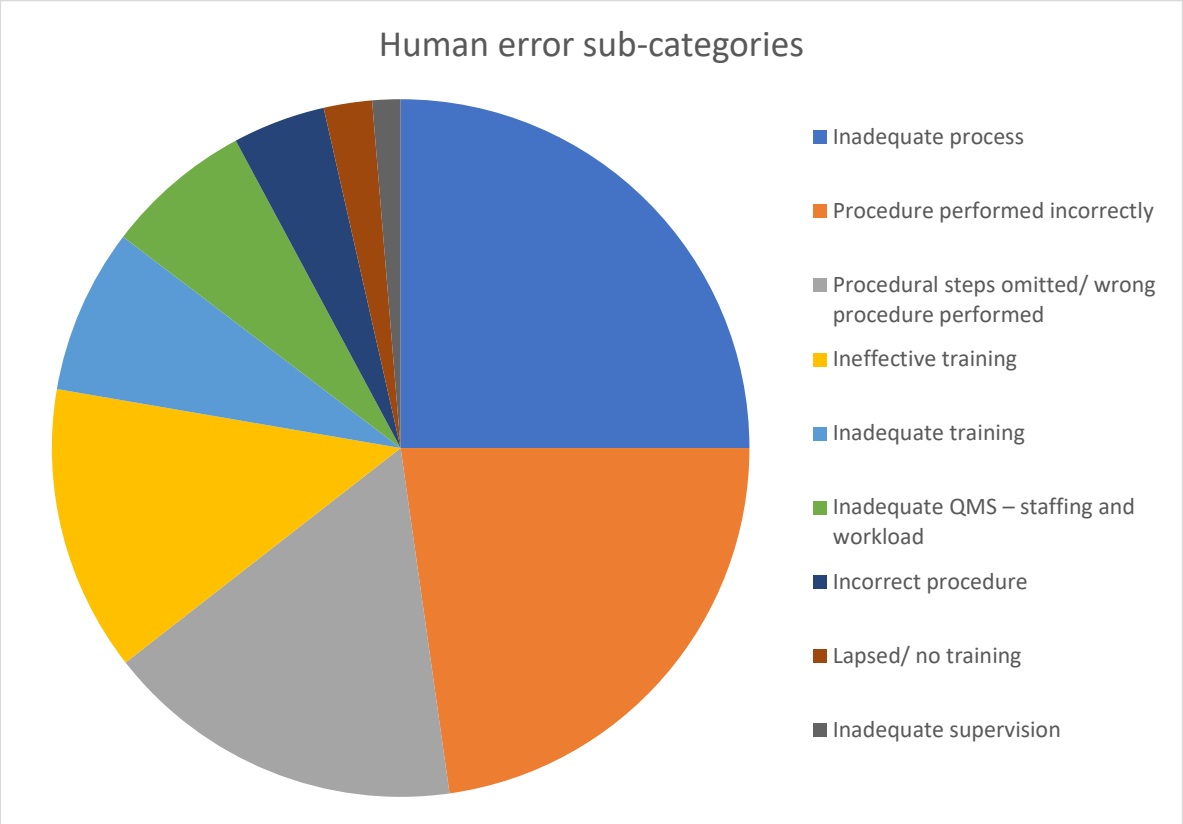
A reduction in the overall number of reports received is potentially a reflection of the reduction in blood usage during the pandemic, which can be seen in a reduction of 'Sample Processing Error' (SPE) and 'Incorrect Blood Component Issued' (IBCI) errors in the table below. However, not all categories of SAE have reduced, with some categories remaining similar to last year or even increasing.

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)	X

Human factors

The vast majority of SAEs reported were categorised as 'Human Error', however events in this category can be broadly sub-divided into system weaknesses and true human errors. System weaknesses made up around 60% of reported 'Human Error' SAEs during 2020; this includes process and/or environment design (Inadequate process), quality of documentation (Incorrect procedure), Training (effectiveness, adequacy and delivery), Supervision (i.e. leadership and support of trainees and inexperienced staff), and staffing and workload, including skill-mix of staff at the time of the error that was due to not meeting elements of the capacity plan.



Storage errors

Although anecdotal evidence suggests a 30% reduction in blood usage in 2020 during the pandemic, the number of 'Storage' errors remained similar to 2019. The reduction in 'Component expiry' and 'Sample expiry' errors 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' errors and this increase has largely been seen due to a number of factors relating to changes in staffing and practice during the pandemic.

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)	x

Recommendations

- Ensure all changes to storage processes are adequately managed through a business continuity plan to ensure the new processes are robust, covered by updated SOPs and that re-training of staff is adequately planned and delivered.
- All reporters must continue to thoroughly investigate all SAEs, even those with no actual harm to patients. It is through thorough investigation that improvements can be identified to reduce risks to the quality and safety of blood and blood components and reduce the risk of harm to patients.
- Ensure that training regimes adequately cover the process or task being trained
- Ensure any training plan is robust enough to ensure that staff are trained to cope with any and all changes made before any change is implemented and as part of an effective business continuity plan
- Review QMSs to ensure the processes involved in the most frequently occurring SAEs 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
- Review SAEs closed by MHRA and take note of the root cause sub-category and event sub-category to trend and identify a site's own most commonly occurring SAE and root cause.

Regulatory update

Common Framework

The Blood Safety and Quality Provisional Common Framework supports the continuity of good working relations, open communication and the maintenance of a

compatible minimum set of high standards of safety and quality for blood and blood components.

The framework has been jointly developed by the UK government and devolved administrations and has since received Joint Ministerial Committee (EU Negotiations) provisional approval.

Evaluation and revision of the EU legislation on blood, tissues and cells.

The EU Commission has been running an online public consultation on the revision of EU legislation on blood, tissues and cells on the Have Your Say portal of the European Commission, which closed on 15 April 2021. In parallel to the public consultation, a targeted consultation was also launched, with the same closing date. The results are under analysis and a Summary Report will be published on the dedicated DG SANTE webpage, where further information on the revision process can also be found.

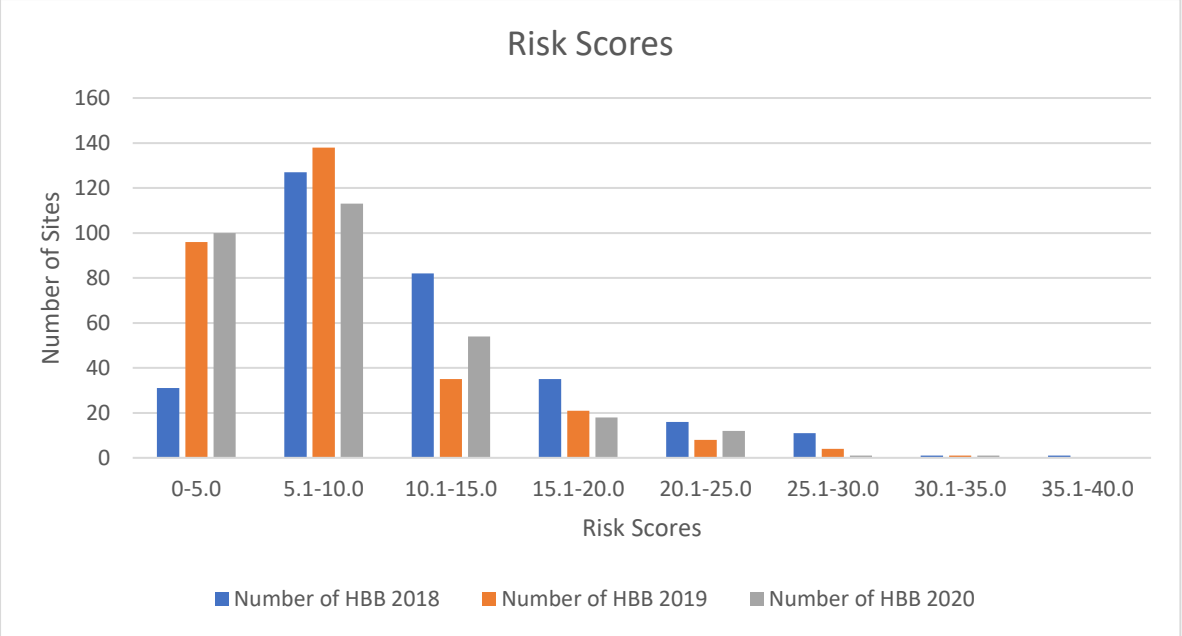
Blood Compliance Report (BCR) update

Introduction

The 2021 Blood Compliance Report (BCR) is available on the Blood Authorisations and Safety Reporting area of the GOV.UK website. The report covers the period 1st April 2020 to 31st March 2021 and should be submitted to bcr@mhra.gov.uk by 30 April 2021. This year there have only been a couple of minor changes to the form.

One change to the process this year is the removal of the requirement for blood facilities to submit an annual declaration form. The purpose of the declaration was to indicate that the person responsible for the management of a facility was aware of their responsibilities under the Blood Safety and Quality Regulations 2005 (as amended). A clear agreement between hospital blood banks (HBB) and the facilities that they supply should include a requirement for facilities to comply with the BSQRs and cover any arrangements made concerning traceability and SABRE reporting. The BCR now contains a clear question concerning this agreement in section R. Where HBBs supply blood components to other sites within the same Trust, shared quality systems and standard operating procedures may be relied on in lieu of an agreement.

The 2020 BCR process was completed in May last year with a total of 300 BCR forms submitted. We allowed HBBs to request extra time to complete their submission due to the first peak of the coronavirus pandemic, 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 risk scores from the BCRs are shown below and illustrate that the pattern of scores has remained similar over the past 3 years.



Information from the 2020 BCRs

The BCR provides a snapshot of HBBs at the end of March in a particular year. Here are some reflections from the 2020 BCRs (1st April 2019 to 31st March 2020):

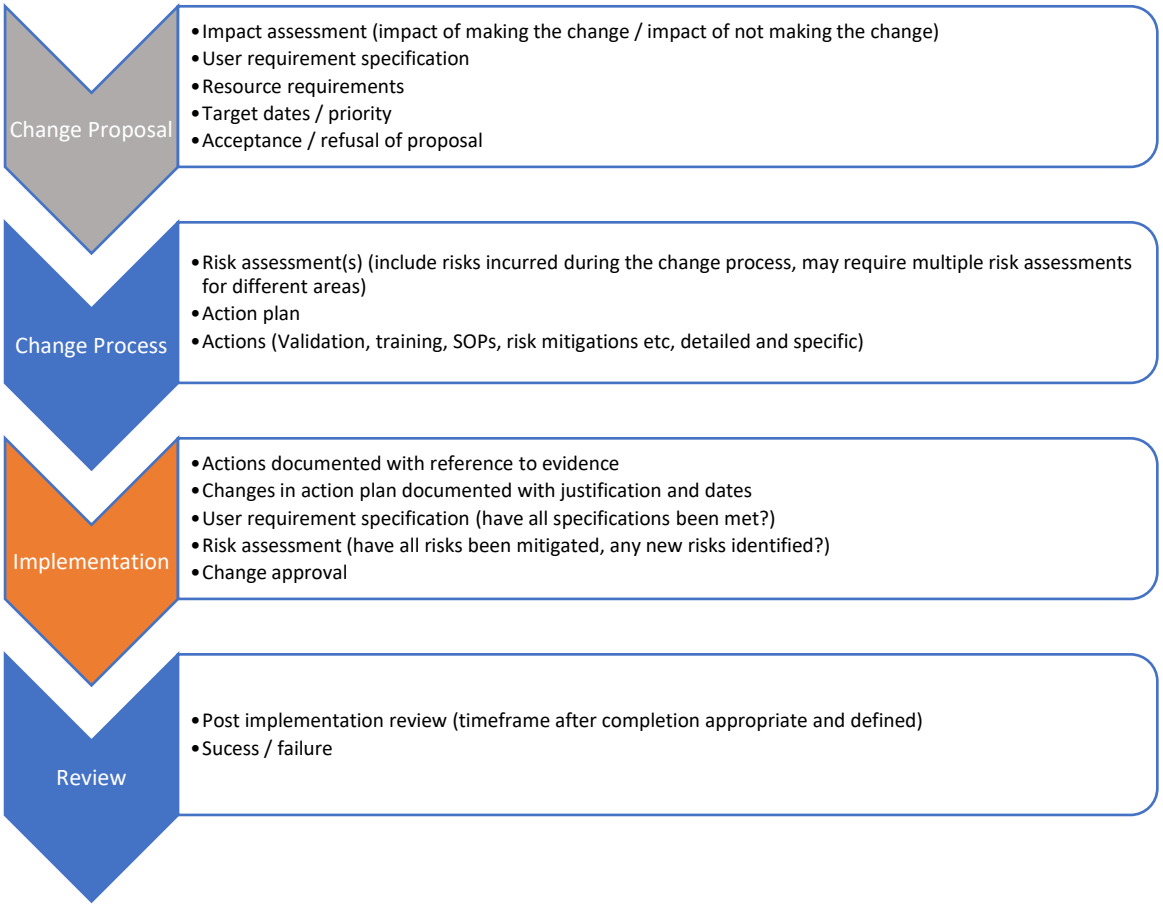
- 36 HBBs reported that they were more than 20% understaffed.
- 18 HBBs reported an issue with the timescales for the closure of investigations. This was either a failure to apply a reasonable timescale or a failure to ensure that investigations were closed consistently within that timescale.
- 76 HBBs reported an issue with maintaining their self-inspection schedule or closing actions from audits within planned targets.
- 225 HBBs indicated that they had achieved 100% traceability for all 4 quarters of the 2020 BCR reported period.
- More than 750 facilities were listed in the 2020 BCRs
- 234 HBBs supply blood components to facilities outside their own hospital.

Common Inspection Deficiencies from Blood Inspections

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.

The following steps are key parts of change control and must be considered for all changes that will impact the blood establishment or HBB:



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.

There is a useful discussion on investigations in the GMDP environment available on the MHRA Inspectorate Blog. This has some relevant suggestions that can be applied to blood establishments and hospital blood banks.

Hospital Blood Bank Closures

Hospital blood banks that cease to carry out pre-transfusion compatibility testing are now required to fill in a Hospital Blood Bank Closure Form. This should be submitted to gmpinspectorate@mhra.gov.uk at the time of closure.