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Blood Consultative Committee Meeting

06 February 2018

Agenda

13:00 – 13:05	Introduction and apologies for absence	MB
13:05 – 13:15	Approval of Minutes of previous meeting held 01 November 2016. Matters arising from minutes: Item 7 – Collaborative working (standalone agenda item) Item 8a – Perfusion of organs for transplantation – proposed traceability model.	MB JJ/IB
13:15 – 14:15	Collaborative working: Update on collaborative working with other agencies Results of BCC member survey Proposal for BCC format and frequency On-line forum for blood stakeholders: Review and future use Suggested ways of working and round table discussion e.g. task and finish working groups Process for committee members to submit agenda items for BCC	 MB MY MB SG MB MB

Agenda

14:15 – 14:30	SABRE Update	CR
14:30 – 15:15	BCR process update 2018/19 BCR process forward look 2017/18 BCR process review 2017/18 inspection trends	 DC VR VR
15:15 – 15:30	Regulatory Update, to include: Review of the EUBD and EUTCD which is due to report end 2018 Joint action on regulatory controls for new blood components and new tissue components which is due to start Q2 2018 Adoption of Good Practice Guide for Blood	 IR IR IR
15.30 – 16.00	AOB	All

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Collaborative Working



Collaborative working

Update on collaborative working with other agencies

Results of BCC member survey

Proposal for BCC format and frequency

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Feedback from BCC Members Survey

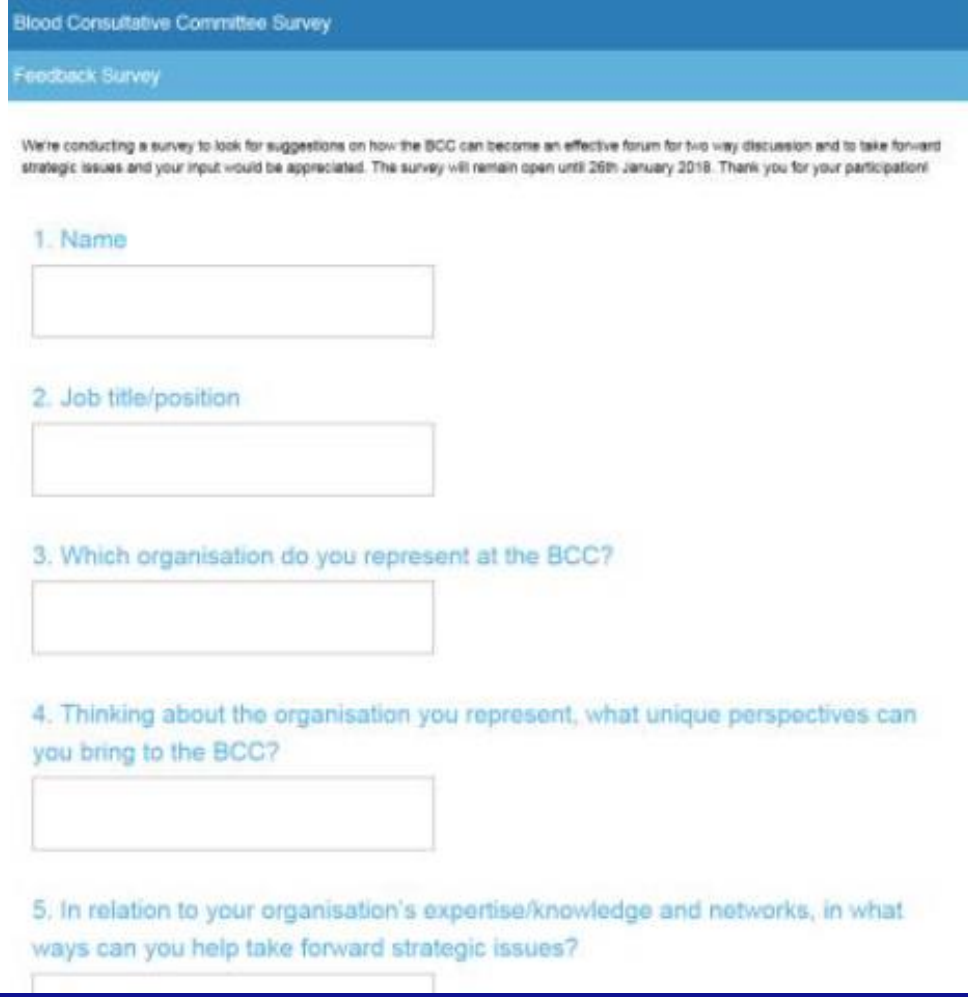
Michelle Yeomans, Operations Manager

Background and Purpose of Survey

- At BCC meeting November 2016, MHRA agreed to commission a survey to capture your thoughts and ideas about the evolution of the BCC
- This was in part due to the successful launch of the on-line Blood Forum as a means to disseminate standard BCC agenda updates
- The survey asked members to consider how the existing BCC format could be evolved to better meet the objectives of providing a forum for two way discussion on the potential impact of future regulatory changes and to take forward strategic issues
- The output from the survey was to be used to develop a new meeting format and terms of reference for the BCC

Survey Details

- The survey questions were developed with input from MHRA's Stakeholder Engagement Team, Communications Division
- The survey was initially launched in January 2017 for a period of 6 weeks
- Survey re-opened for a further 10 days in January 2018 in an attempt to gain more responses


Blood Consultative Committee Survey

Feedback Survey

We're conducting a survey to look for suggestions on how the BCC can become an effective forum for two way discussion and to take forward strategic issues and your input would be appreciated. The survey will remain open until 26th January 2018. Thank you for your participation!

1. Name

2. Job title/position

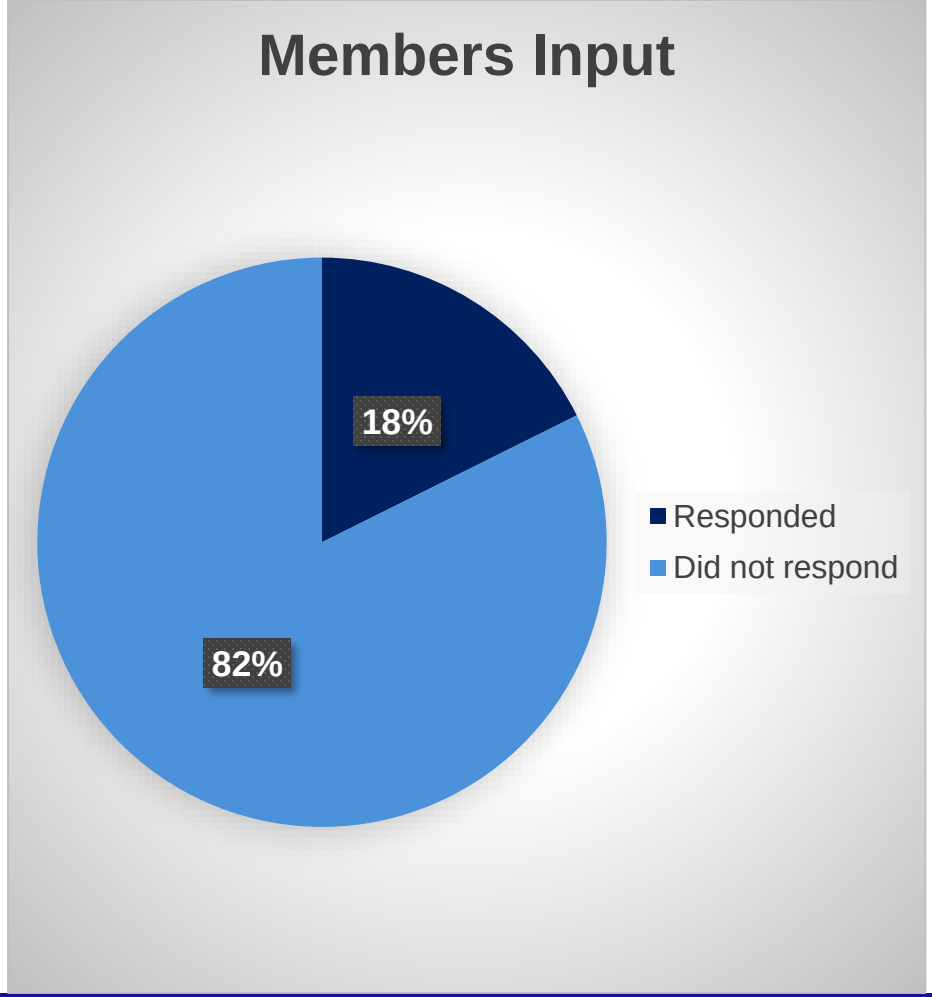
3. Which organisation do you represent at the BCC?

4. Thinking about the organisation you represent, what unique perspectives can you bring to the BCC?

5. In relation to your organisation's expertise/knowledge and networks, in what ways can you help take forward strategic issues?

Survey Responses

- Of the 17 non-MHRA organisations represented at BCC, only 3 organisations submitted a response to the survey
- Meaningful analysis will be limited, given the poor response rate



Survey Feedback – What unique perspectives can your organisation bring to the BCC?

- Understanding and evidence based challenges facing HBB staff from collaborators working across the industry
- Open sharing of information and ideas
- Much greater understanding of regulatory issues from a National perspective
- Very close liaison with clinical, laboratory and transfusion practitioner staff
- Insight from acting as a Responsible Person
- Link with UK guidelines and Council of Europe activities

Survey Feedback – Which organisations need to be represented at BCC?

- CQC
- UKAS
- The four UK Blood Services
- DHSC
- Representatives from hospital transfusion practice

Survey Feedback – How can your organisation help take forward strategic issues?

- Access to devolved health plans
- By sharing info
- Translate Directives and other requirements into UK guidelines
- Provide expert advice on issues from UK blood service perspective

Survey Feedback – How often should BCC meet and what format?

- Six monthly
- face to face meeting
- Interactive and less formal approach would be better, where there is relaxed and open communication with the inspectors

Survey Feedback – Any other comments or improvement suggestions

- Review the Agenda and ask the right questions
- There seems to be very little communication and openness about significant issues from attendees- need to determine why
- There needs to be more issues raised from outside the MHRA
- Maybe task and finish groups which bring back recommendations to the main meeting?
- Only 2 or 3 people bring any issues and most of the meeting is from the MHRA perspective
- I think the forum will be a useful tool as times continues

Survey Conclusions

- Response rate is typical of feedback that only a limited number of organisations actively participate in BCC meetings
- Expressed preference is to retain a six monthly face to face meeting with same organisations represented with addition of CQC
- For the BCC to evolve, we need to understand the reasons why there is a lack of engagement from the wider membership before an effective meeting agenda and format can be adopted

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Online forum for blood stakeholders: Review and future use

Stephen Grayson, Senior GMDP Inspector

Online forum

- MHRA provide the forum to:
  - Promote the sharing of ideas within the community
  - Assist with understanding where necessary
  - As a general BSQR communication platform
- Some issues with spam
- In discussions with JPAC regarding transfer of related content from their website to the Forum

Online forum

Since launch on 01 November 2016, the forum numbers are as follows:

Threads	67
Posts	154
Views	251,411

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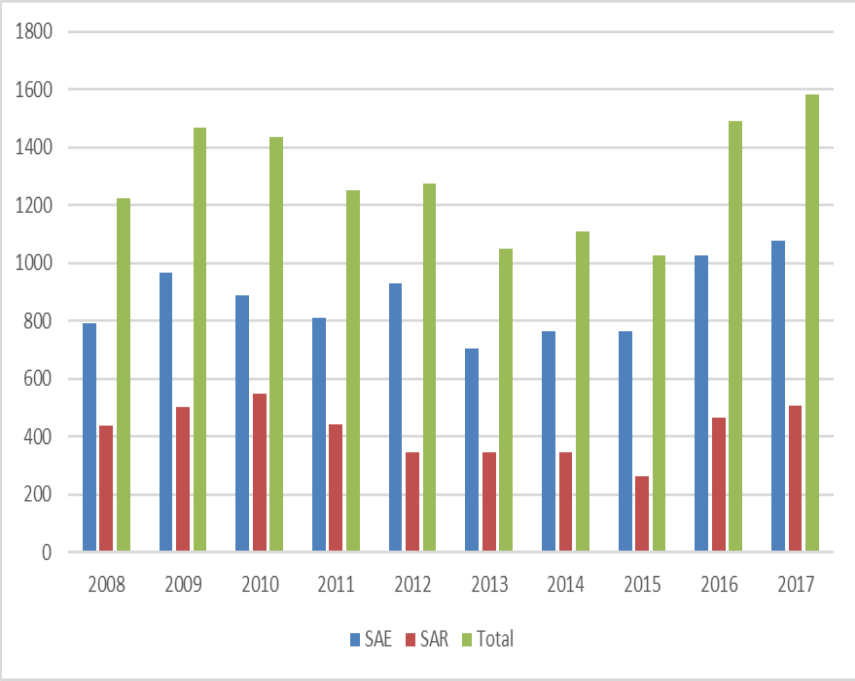
SABRE BCC report Feb 2018

Chris Robbie, MHRA

Reporting Activity 2017

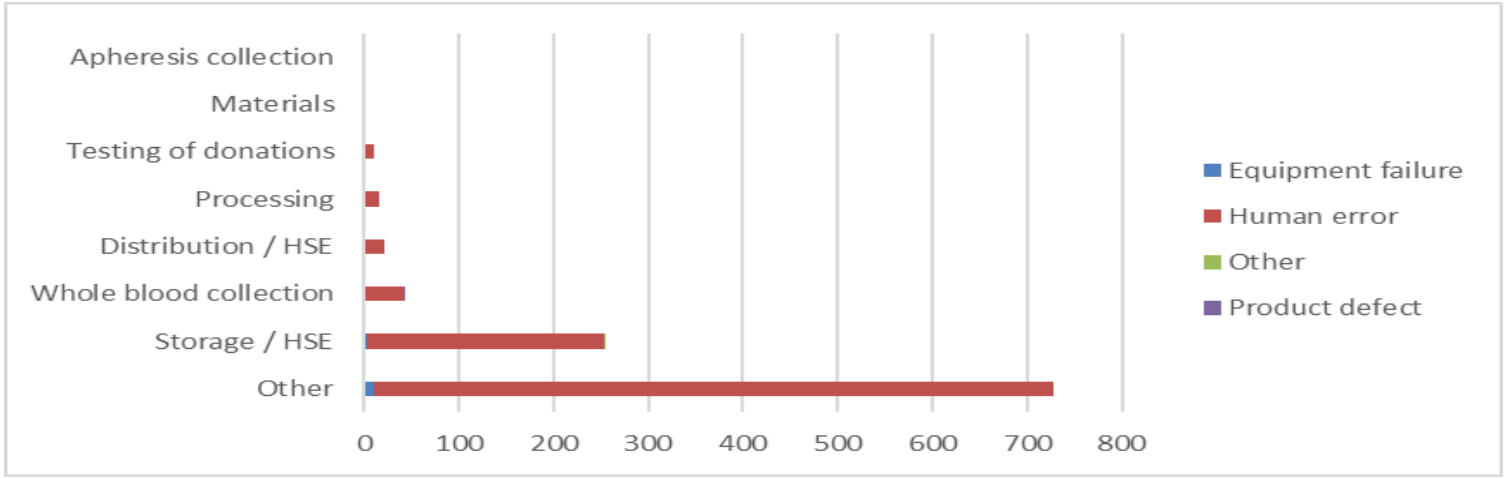


The total number of reports received that meet EU reporting requirements has increase by around 6%

SAR reports have increased at a higher rate than SAEs

Increase in SAEs have mostly come from Blood Establishments and not HBB

SAEs by Deviation 2017



The proportion of reports in each category remains broadly similar to previous years although there are some changes to the sub-categories reported

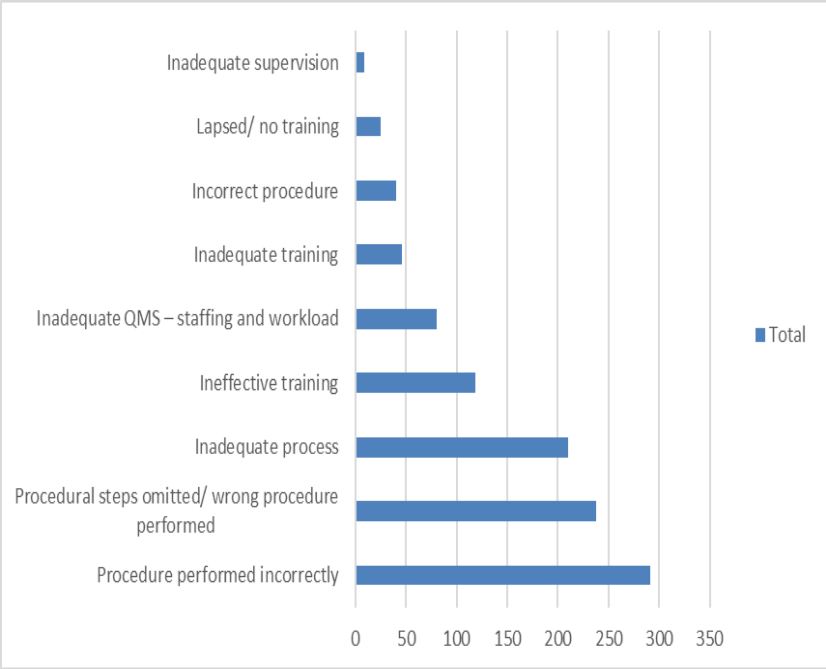
Human Error is still the highest single SAE deviation

Other reports sub categories 2017

Sub Category	2017	2016 position
Incorrect blood component selected and issued (IBCI)	175 (-17)	1
Sample processing error (SPE)	123 (-11)	2
Component labelling error (CLE)	114 (+8)	4
Pre transfusion testing error (PTTE)	104 (-6)	3
Component collection error (CCE)	94 (+16)	5
Data entry error (DEE)	71 (+13)	6
Failed recall (FR)	18 (+1)	7
Unspecified (UNS)	9 (+7)	10=
Component available for transfusion past de-reservation date (CATPD)	5 (+2)	9
Expired component available for transfusion (ECAT)	5 (+3)	10=
Incorrect blood component ordered (IBCO)	5 (-9)	8
Handling Damage (HD)	2 (0)	12
Incorrect blood component accepted (IBCA)	1 (+1)	13
Total	726 (+8)	

Little change in relative positions. Reduction in IBCI and PTTE (better control via QMS?)
Reduction in SPE (Improvements in sample collection? Fewer samples? However increase in WBIT errors - automatically excluded)
Increase in CLE and DEE (manual processes, not easily controlled by technology)
Increase in CCE (Analysis shows that increase is reflected in manual process and those controlled electronically – RC linked to ineffective training)

Human factors



- Little change in spread of reports
- Highest proportion of reports still linked to slips and lapses
- Still concerns of the quality of SABRE reports/ investigations not thoroughly investigating RCs linked to the design of the process/ QMS and incorrectly assigning responsibility to staff error

Human factors

Reporters must continue to investigate thoroughly to identify all root causes and contributory factors

Detailed CAPA needs to be produced to address human factors involved

Work needs to be done to make processes more robust and SOPs written that are detailed enough for staff to know exactly what to do, even when tasks don’t go to plan

MHRA will continue identify staffing and workload issues and inspectors often raise this at inspection

MHRA will continue to support the industry in addressing it

Future activity

SABRE moving from Lotus Notes software to bespoke Appian software

Look and feel of SABRE will be quite different (including SHOT branding)

Functionality will be largely the same, with improvements where possible

Link to SHOT will remain and functionality with SHOT database will be unchanged

No changes to haemovigilance reporting process and working relations with SHOT

New Principal Haemovigilance Specialist starting March.

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HBB compliance: BCR and Inspection changes

David Churchward, Expert GMDP Inspector



HBB compliance

- HBB activities are critical to public health
  - Risk of harm from errors
  - Limited opportunity for end of process quality checks prior to use of results

- Regulatory actions also risk public health impact
  - Often no alternative provision available
  - Wide range of ‘medically critical’ services reliant on transfusion.

2015: HBB compliance review

UK regulations permit HBB inspection ‘for cause’

- 2005-2014:average 60 inspections per year
- Number of critical and major deficiencies reduced

No CMT or IAG cases in FY 2014/15

HBB sector compliance justified reduction in inspection oversight

- Approx 20-25 inspections per year.

2016/2017 inspection outcomes

Declining compliance in Hospital Blood Banks

Despite a reduced inspection programme following the 2015 review, the number of IAG and CMT cases has increased:

Financial Year	CMT	IAG
2016	1	2
2017	5*	0*

* FY 2017 inspection programme ~60% complete at time of BCC.

Inspection failures: causes

- Symptoms differ, but all cases show some elements of:
  - Failing quality systems
  - Lack of management oversight and resourcing
    - Lack of visibility to Trust Exec, or failure to act
    - Lack of resources
    - Failure to implement previous inspection commitments
  - Falsification of BCR submissions.

Drivers of non-compliant behaviour

- Known / perceived deferral of inspection reduces compliance focus
  - BCR close-out letters
  - Extended notice of inspection plans

- Competing organisational priorities with other regulatory requirements.

Proposed changes:

BCR:

- Close-out letter will not indicate assessment outcome

Inspections:

- Maximum 7 days notice
  - Unannounced inspection remains a possibility (existing practice)
- Publication of inspection findings.

Rationale for changes

- Deterrent for inaccurate BCR submissions
  - Increases risk of detection
  - Less time to align practice with submission

- Compliance driven by knowledge of inspection cycle
  - Reduced focus if inspection considered as ‘unlikely’
  - Possibility of inspection maintains compliance as priority
  - Senior management engagement (resources etc).

Rationale for changes

- Publication of inspection findings
  - Educational tool
  - ‘Reputational element’ as further incentive to maintain compliant operations.

Unaffected elements of risk based inspection:

- Selection of sites for inspection
  - BCR assessment
  - Ad-hoc public health risks
- Blood Establishments not in scope
- Inspection conduct and standards
- Post inspection non-compliance actions.

Implementation

- Inspections performed from 01 April 2018

- 2018 BCR submissions

- Communication to stakeholders prior to implementation
  - Email
  - SABRE platform message
  - Blood Forum message.

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Questions

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Blood Compliance Report (BCR) Process Update

Vivian Rowland, GMDP Inspector



Topics for discussion

2016/17 Preparation and Changes

2016/17 BCR Assessment - Common Issues and Outcome

2016/17 Inspection Outcome

2016/17 Inspection Common Deficiency Finding Examples

2017/18 Improvement and Further changes

2016/17 Preparation and Changes

Preparation:

- Revised Hospital Blood Banks (HBB) BCR and declaration forms for HBB and Facilities
- Revised HBB Guidance Notes and text on webpage
- Placed announcement on Blood Forum
- Developed and revised new Admin Work Instructions and training presentations on BCR assessment process

2016/17 Preparation and Changes

Scoring Program:

- High risk sites were included (from SABRE and inspectors)
- High risk site received a score of 10
- Risk score for late submission changed from 10 to 5

HBB BCR:

Section E Q7.4 added to include question on on-going staff issue that are impacting on lab workload, training or QMS tasks

2016/17 Preparation and Changes

Post BCR assessment:

- Withdrawal of the graded compliance letters
- Change of post assessment communication to advise sites that they have been assessed
- Risk based inspection approach – short notification of inspection

(https://mhrainspectorate.blog.gov.uk/2017/06/26/an-inspector-calls-part-1-gmp-short-notice-and-unannounced-inspections/)

2016/17 BCR Assessment - Common Issues and Outcome

Common Issues

- Late submission of HBB BCRs or Declaration forms
- Incorrect Hospital name or Trust / Private Healthcare Organisation Name
- Missing Facility Declaration Forms
  - Facility managers must fill in the blood facility declaration form

Blood Facilities

A hospital ward, hospice or care home etc which receives blood from a hospital blood bank for transfusion purposes (but does not perform compatibility tests on site) is defined as a ‘Facility’.

Facilities may perform three key tasks which are covered by the scope of a blood compliance report (BCR). These are:

- The control of monitoring, maintenance and calibration of any controlled temperature storage equipment on site
- Reporting of serious adverse events and reactions to SABRE
- Maintenance of traceability records

Blood Facilities

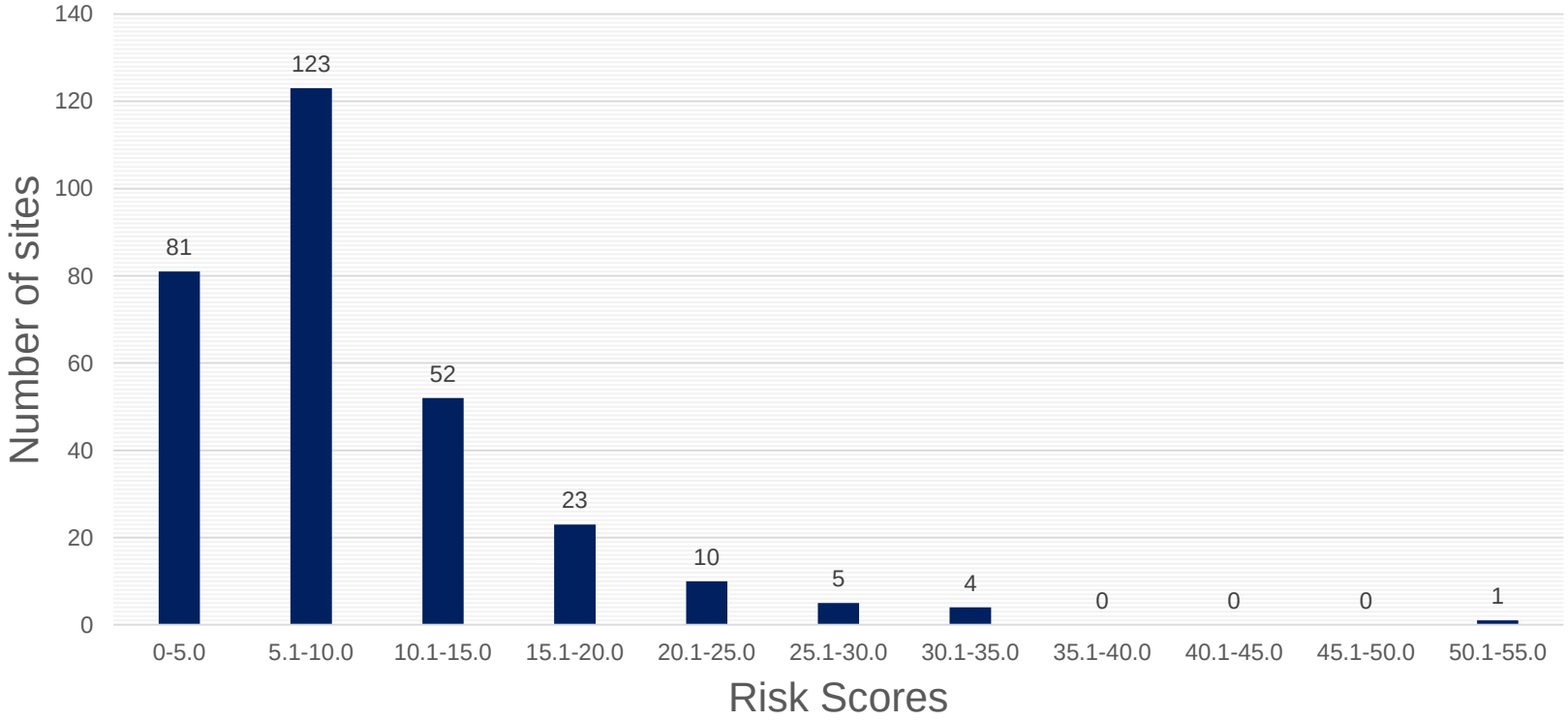
A ‘Facility’ should have a Service Level Agreement (or similar document) in place if the supplying Hospital Blood Bank is responsible for these functions.

Blood Facilities are required to complete the Blood Facility Declaration Form.

BCR Assessment Outcome

HBB BCR received	299
Late submission (after 30 April 2017)	14
No. of high risk site	42
BAT referral required	43
Range of risk score	1 to 51.5
Site required inspection	27 (including 6 control sites)
No. of inspection to date	18 sites, 19 inspections

Range of risk scores

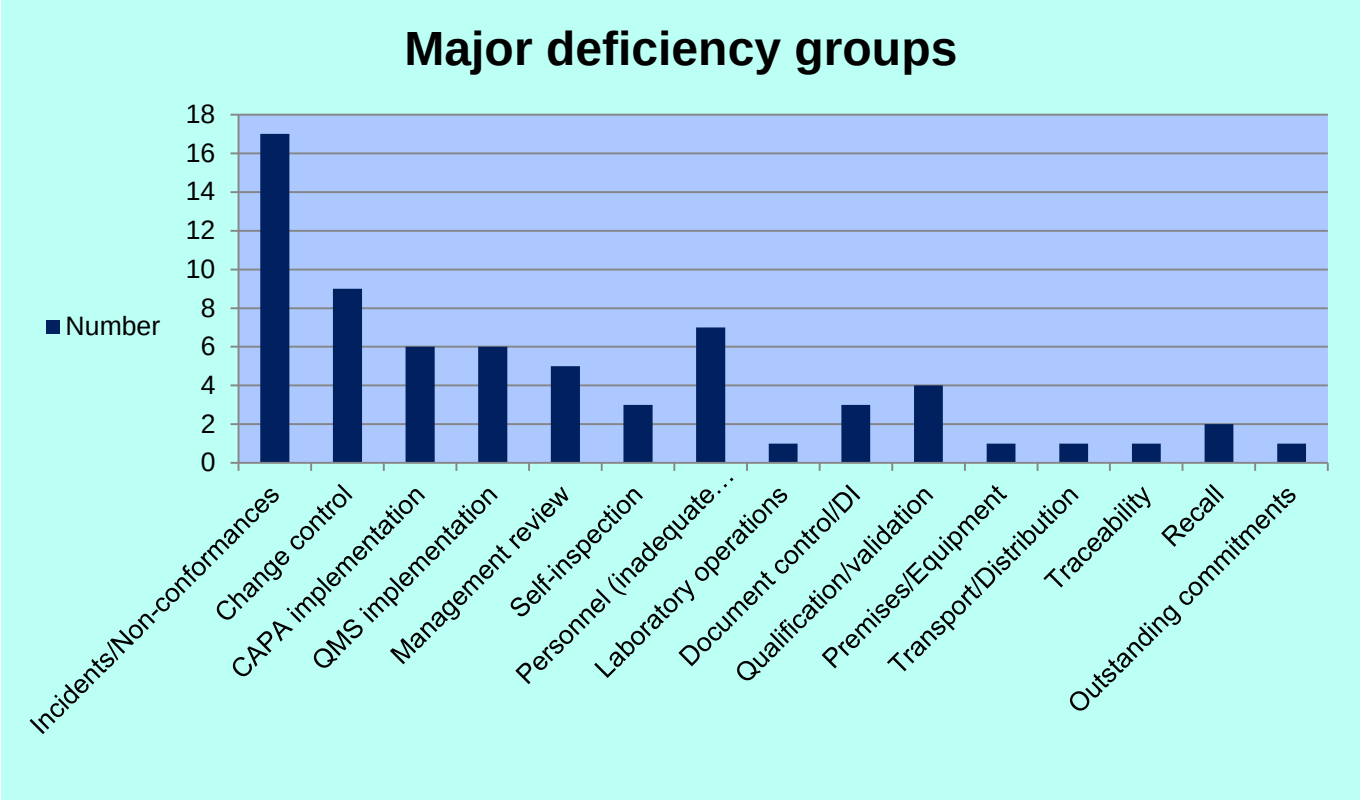


2016/17 Inspection Outcome

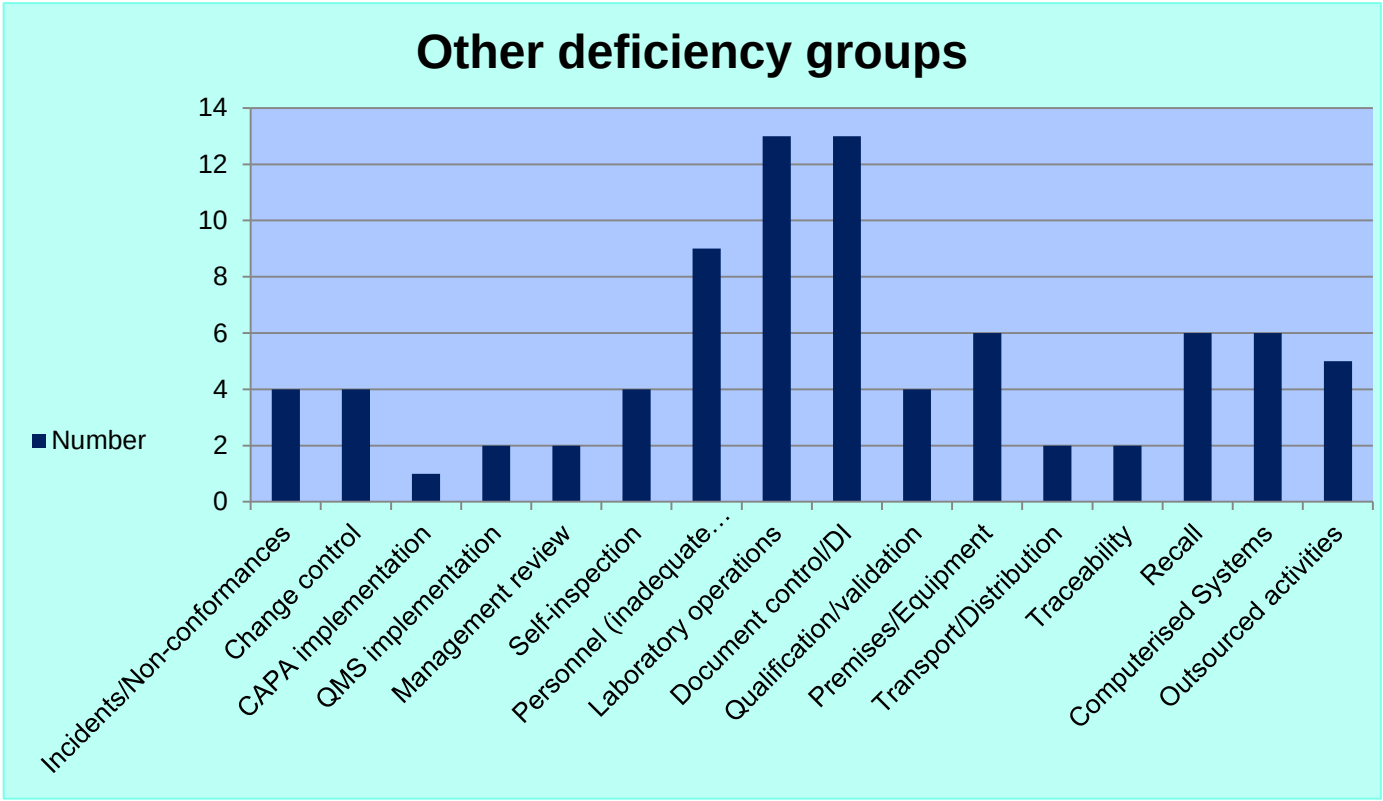
2016/17 Inspection Outcome

Number of inspection	19
Critical Deficiency	0
Major Deficiency	42
Other Deficiency	76
IAG referral	0
CMT referral	5

2016/17 Inspection Outcome



2016/17 Inspection Outcome



2016/17 Inspection Common Deficiency Finding Examples

Inadequate QMS

- The QMS was not comprehensively designed, correctly implemented, and adequately resourced with competent personnel, to ensure adequate safety, efficacy and quality of blood components
- Incident records were incomplete with investigations being poorly conducted or not completed at all. Root cause analyses were not conducted nor were corrective and preventive actions always implemented

Inadequate QMS

- The site failed to identify the overall number of CAPA generated from QMS, hence the effective implementation of CAPA could not be monitored
- Change control had not been raised as required
- There was no tracking and monitoring process for the implementation of change control

Ineffective Management Review

- There was a lack of senior management oversight as the Trust failed to ensure effective implementation of the quality systems and to identify opportunities for continual improvement of processes and system itself through the monthly quality meetings
- Ongoing issues were not adequately reported to the Hospital Transfusion Committee
- The overdue quality items reported in the monthly quality metrics and exception reports were not discussed in the senior management meetings to identify the root cause for the delay and the additional resource required to ensure the continual suitability and effectiveness of the QMS

Inadequate Resource

Adequate resource was not available to establish and maintain a quality system

There were impacts on:

- Self inspection program
- Training and competency assessment
- Qualification and validation

Document Control/DI

- The integrity of data was not assured in that information which was false and misleading was presented to the inspector
- Documentation practices were poor as demonstrated by uncontrolled deletions, obliteration and overwriting in several document sets reviewed during the inspection
- There was no mechanism to ensure that staff were aware of changes in procedures at the time they became effective
- Many legacy procedures applicable to the overall laboratory were still in place and there was no overall clarifying index or document to demonstrate which local QMS documents were regarded as live for the transfusion area

Laboratory Operations

- There was no formal justification available for the sample preparation centrifuge speed of 5 minutes at 4000 rpm adopted. It was also noted that the procedures still referenced the previous conditions of 3000 rpm
- Prepared solutions within the laboratory were ineffectively labelled to enable the identity of the contents, the person preparing the solution, the preparation date and expiry date to be established
- The causal factors of IQC failures were not consistently documented with several being absent from the failure sheet

2017/18 Improvement and Further changes

Improvements

- Submitted BCR will be pre-reviewed on receipt (including missing answers and outstanding CAPA that leads to possible high risk)
- BCR Admin Team request for HBB Declaration Form if not submitted with the BCR
- Revise Guidance Note
  - colour / bold text to highlight deadline and areas that require special attention

Further changes on BCR assessment questions

Section A	General information – Full HBB/Trust/Organisation name
Section C	Previous Compliance Reports - Changed from compliance report to assessment letter for company and site number
Section E	Key personnel - Request for the level of understaffing
Section F	Training – Questions on training completion and assessment
Section G	QMS – Include question on the effectiveness of senior management oversight
Section H	CAPA – Confirmation if investigations include details, root cause analysis, risk impact assessment
Section L	Self Inspection – If QMS procedures are assessed against requirements of BSQR
Section M	Equipment maintenance and calibration – If the maintenance program is monitored for compliance
Section N	Qualification, validation and CC – Include DI requirements
Section O	Computerised systems & Data management – Requirement on revalidation

Important messages

16 February 2018	Revised BCR and declaration forms, guidance notes on Gov.uk website Announcement to be published on Blood Forum
30 April 2018	Deadline for BCR, declaration form submission
Blood Facilities are required to complete and submit the Blood Facility Declaration Form.	

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Thank you

Any questions?

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Regulatory Update

Ian Rees, Expert GMDP Inspector

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