Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Minutes for Blood Consultative Committee (BCC) Meeting
17th March 2016, 13:00-16:00
MHRA Buckingham Palace Road Offices, G1

Attendees:

Marie McQuade (SCTAC)
Chris Elliot (IBMS)
Alison Watt (SHOT)
Fidelma Murphy (NHSBT)
Jot Hyare (NTLMS)
Ann Benton (NHS Wales)
Brian Alexander (SNBTS)
Shirley Stag (HTA)
Shalinee Wickramasinghe (NHSBT)
Joan Jones (Wales NHS)
Stuart MacDonald (MOD)
Rashmi Rook (NHS)
Liz Carroll (Haemophilia Society)
Shubha Allard (NHSBT)
Jeremy Grindrod (MOD)
Jan Stewart (TDL Pathology)
Will Bowen (NHS)
Emma Lowe (NIHR)

MHRA:

Mark Birse (IE&S) – Chair
Beverley Malin-Smith (minutes)
Vivian Rowland (IE&S)
Chris Robbie (SABRE)
Rosalind Polley (Devices)
Michelle Rowson (IE&S)
David Churchward (IE&S)
Ian Rees (IE&S)
Kevin Page (IE&S)

1. Apologies Received

Sandra Gray (Retired)
Johnathan Wallis (NBTC)
Ian Bateman (NHSBT)
Paula Bolton-Maggs (SHOT)
Allan Morrison (NTLMS)
Cyril Taylor (TDL Pathology)
Tony Docherty (SNBTS)
Sheila MacLennan (JPAC)
Stephen Bassey (NTLM)
Angela Macaulay (NIBTS)
Caroline Lewis (Wales NHS)
Chris Phillips (NHSBT)

2. Introductions and Apologies for Absence

Mark Birse opened and chaired the meeting. He thanked everyone for attending, welcomed any new members, and noted the apologies. The minutes from the previous meeting held on 23rd September 2015 were reviewed. These were accepted and 3 ongoing actions were noted:
i) MHRA to create an online forum for Blood Stakeholders **– on agenda for today**
ii) Updated TOR **– any further comments requested by end of April 2016**
iii) BCC members to confirm the names of the primary representatives nominated to represent their respective organisation **– any further updates requested by end of April 2016**

3. SABRE Update

Chris Robbie provided an overview of reporting activity for 2015:

- The Deviation error category ‘other’ and Storage continue to be the highest reported error types but show very little change from reports received in 2014.
- Human Error is still the highest single SAE deviation.
- The increase in SAEs falling in the “other” category is largely a result of changes to SAE reporting arrangements where SHOT and MHRA see all reports. It is not thought to demonstrate a worsening of performance.

- For SAR reporting, Phase 1 of the Joint Haemovigilance Project was released on time with no major problems. Phase 2 is under construction which will incorporate SAE reporting.

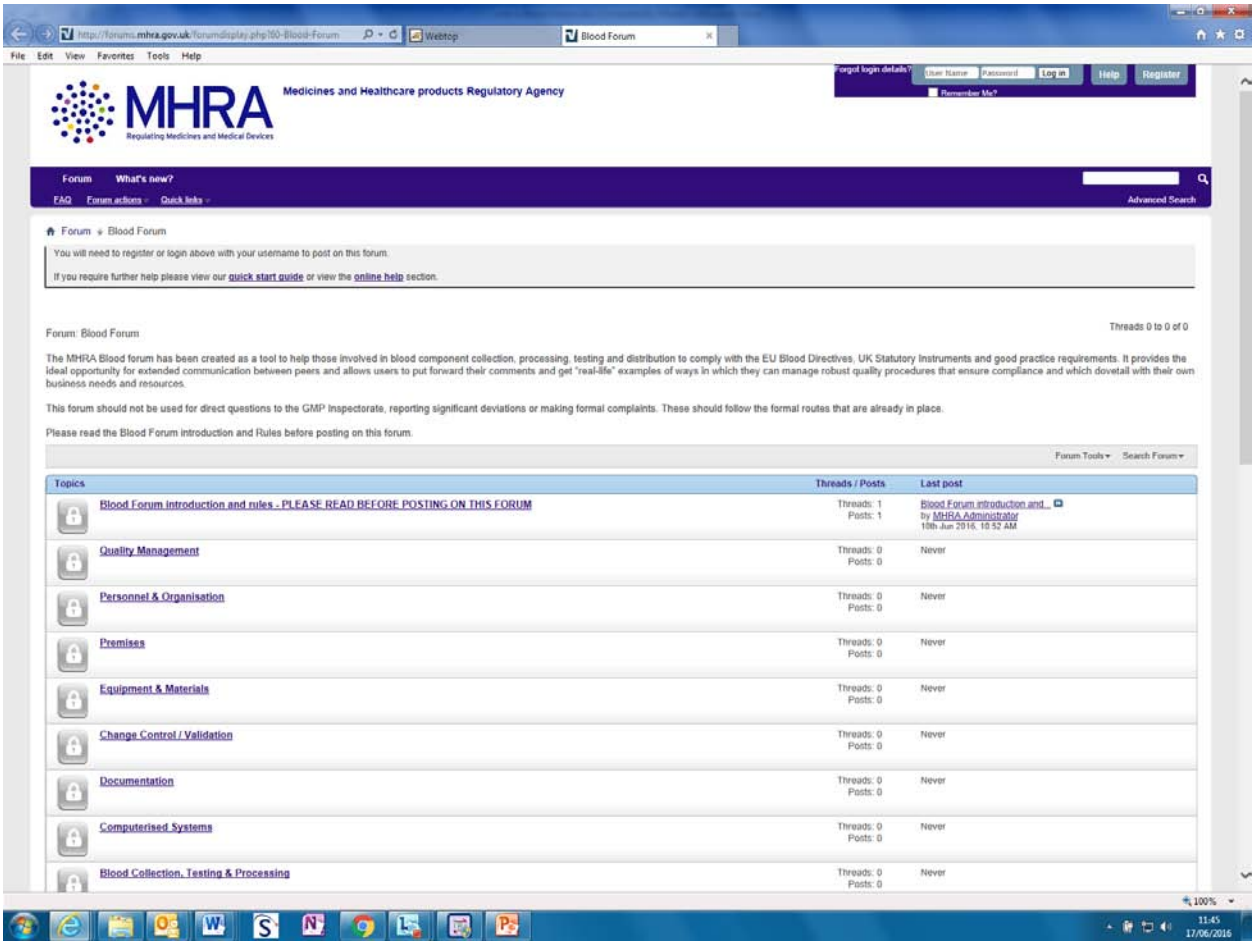
4. BCR Process Update

Vivian Rowland provided an overview of changes to the BCR report and assessment process for the April 2015 – March 2016 reporting year:

- The majority of questions requiring free-text responses have been removed to facilitate a fully automated assessment using the risk score programme.
- As a result of a reduction in the number of critical inspection deficiencies, compliance management and regulatory action cases, it is also proposed to reduce the number of inspections triggered 'for cause' as a direct result of the BCR assessment process.
- The inspectorate will develop the risk based inspection approach to react to risk factors identified throughout the year and maintain our commitment to proportionate regulation.
- Examples of non-BCR inspection triggers under consideration include notifications of significant site change and adverse SABRE reporting trends.
- Control inspections will also be performed to monitor the performance of the revised approach to BCR assessment and inspection scheduling.
- Blood Facilities will not be required to complete a compliance report for 2015. An alternative system of compliance declaration will be implemented. This will be aligned with elements of the system implemented by the Health Products Regulatory Authority in Ireland.
- Additional questions for inclusion in the BCR were proposed by BCC members. These have been considered and implemented where possible and justification provided where this was not possible, e.g. very site specific, considered too subjective, relevance to current compliance status unclear, or clinical decisions and number of staff required are not within MHRA's remit to advise.
- BCR template and guidance note added to GOV.UK on 07 March 2016. Reporting period 01 Apr 15 to 31 Mar 16.
- Jot Hyare suggests that another question for future consideration would be to ask: On how many occasions has the site dropped below the lowest threshold for qualified staff.
- It was suggested that BCC members consider benchmarking data for different Trusts versus the number of units. This is something that SHOT do and also the Welsh Blood Service do through regional transfusion committees.

5. Update on on-line forum for Blood Stakeholders

Michelle Rowson provided a demonstration of the on-line discussion forum on behalf of Stephen Grayson who is leading on the project following his return to the Inspectorate. The forum is currently on a test-site and so not available for public viewing.



- The titles for the headings have been created using the Chapters of the Good Practice Guide.
- The forum will be pre-populated with useful reference material and Q&A topics MHRA have previously developed and posted on the OIG website.
- It is hoped the forum will become a reference source, opportunity to post questions and share best practice ideas.
- All questions and comments need to be reviewed and moderated before they go live so background work has gone into ground rules and information on how the site will work.
- Anyone can view posts but need to register to add information and take part in discussions. Due to some concerns around confidentiality, users can register on a home e-mail address so that other users aren't aware of where they work or who they are.
- It is hoped that the forum will be ready to go live in the Summer 2016 and there will be an update on the Inspectorate Blog (https://mhrainspectorate.blog.gov.uk/) to make people aware of the launch.

6. Pilot of updated Compliance Report for Blood sites

Michelle Rowson reported that updated compliance reports had been designed for Blood sites. Michelle explained that prior to a routine inspection of BEA sites, there is a requirement to complete a pre-inspection compliance report and to provide an interim compliance report following key changes. Although the compliance report templates were updated about a year ago with improvements to the questions asked of blood establishments, the reports were more geared towards pharmaceutical sites and so a separate template for blood sites has been developed.

The updated templates are currently being piloted with a small number of sites.
A request was made to improve the formatting of free text boxes so that full answers can be given without it affecting the template. Once finalised, the templates will be made available on GOV.UK (https://www.gov.uk/guidance/blood-authorisations-and-safety-reporting).

7. **Regulatory Update**

i) IVD Directive changes – Rosalind Polley (Devices)

- Final text agreed in June however earliest publication date is expected to be October 2016. Commission guidance on classification will be published.
- Class D devices will not need to be CE marked, but will need to notify Competent Authority and are expected to have an appropriate quality management system in place. These 'in house' devices will only be permitted for use within the same legal entity. Any wider sale will require CE marking. It was confirmed that 'Health Institutions' can receive samples from other legal entities and perform testing under this exemption.
- Post marketing Surveillance is not currently part of the Directive but will be an expectation of MHRA.
- The Directive introduces rules around software for medical purpose. Laboratory information management systems (LIMs) must be CE marked if it is performing calculations or adding to data. BCC members reported that very few if any LIMs systems are CE marked and would welcome MHRA's help in contacting manufacturers.

Action – BCC members to provide list of suppliers to Beverley Malin-Smith for Devices to follow up.

ii) GMP blood good practice guidelines update – David Churchward

- A draft was released in December 2013 which has now been considered by the Commission and is likely to be accepted. Discussions are still required relating to how this document will be maintained in line with GMP developments (work on-going with Council of Europe).
- A revision to the UK Blood Safety and Quality regulations is imminent, to implement the EU Directive revision regarding West Nile virus NAT testing. When this requirement is transposed, a previous amendment to implement end of shelf-life platelet pH updates will also be incorporated.
- Hep E negative SABTO blood guidelines were updated on 14th March 2016. Discussions were held regarding the impact and effect this will have on ongoing services.

iii) Collaborative working – Ian Rees

- A UK Blood forum has been set up involving, MHRA, HTA, UKAS and CEOs of the UK Blood Services to look at ways of working, information sharing, reliance on others work, areas of overlap, to develop closer working.
- Potential for scope of BCC to be revised or incorporated into other meetings with a strategic focus, once the operational elements are covered by the on-line forum.

8. **Update from JPAC**

Shelia MacLennan presented the attached papers for information, as the changes agreed by JPAC will affect component handling in hospitals and not just the blood services. The topics relate to:

- Extension of post-thaw shelf life of FFP to 5 days to support management of massive haemorrhage
- Deviations from 4°C temperature storage for red cells:effect on viability and bacterial growth

The papers include a summary sheet and larger background paper for each topic. The aim is to reduce the amount of blood currently being wasted. Further background documents are also available on the JPAC website.

Dates for Next Meeting:
Tuesday 1st November 2016 14:00 – 16:00 at MHRA Offices, Buckingham Palace Road