NHS
Blood and Transplant

NHSBT Board
25 May 2017

Annual Management Quality Review
April 2016 – March 2017

Status – Official

1. Executive Summary

1.1 There were seventeen regulatory and accreditation inspections during 2016/17. There were no Critical non-compliances raised, however there were two Major non-compliances raised by the Medicines and Healthcare products Regulatory Agency (MHRA) at one inspection.

1.2 The number of overdue items has remained one of the main Quality Management System (QMS) issues this year. Although there have been some improvements in the age profile of the overdues, the numbers are still too high.

1.3 The recording of Quality Incidents (QIs) directly into Q-Pulse by reporters was introduced in October 2016 with the implementation of the Occurrence and Incident module. This has been very successful and has resulted in a reduction in the number of incidents being managed as formal QI's.

1.4 We have continued to modify our QMS and approach to accommodate the new Agile development process for the Core Systems Modernisation and ODT Hub projects. There has been good engagement with regulators to ensure they are aware of the modifications being made and our plans for release of new software.

1.5 This year we have been very successful in the transition from Clinical Pathology Accreditation to United Kingdom Accreditation Services (UKAS) standards within Red Cell Immunohaematology (RCI), National Bacteriology Laboratory (NBL) and National Transfusion Microbiology Reference Laboratory (NTMRL).

Actions Requested

The Board is asked to;

- *o* Note the regulatory performance across NHSBT during the year.
- *o* Comment and feedback on this report and recommend any areas for future improvement.
- *o* Note that the full annual MQR report will now go to the Governance and Audit Committee.

2. Purpose of the paper

2.1 Continued regulatory compliance is critical for NHSBT to maintain its licenses and accreditations, including its Blood Establishment Authorisation, Human Tissue Authority (HTA) licenses (for Tissues, Cells and Organs), medicinal products licenses and the Care Quality Commission registrations, all of which are essential to allow it to save and improve lives. This summary report provides an annual overview of regulatory activity and assurances in line with NHSBT's strategic targets for safety and compliance.

3. External Inspection Performance and External Reports

3.1 There were five MHRA inspections and five HTA inspections in year. In addition, there were seven accreditation inspections. UKAS also completed inspections of all NHSBT's RCI laboratories. There were no Critical findings raised in any of the inspections, however two Major findings were raised, both by MHRA during the Investigational Medicinal Products (IMP) inspection at Filton.

3.2 Discussions have been held with the MHRA and HTA as their planned 2017/18 inspection schedule was very extensive with around 18 MHRA and HTA inspections due by the end of Q3. MHRA has agreed to scale back on some of its inspections, share information from HTA inspections and carry out two office based desk top inspections rather than visit all sites. This will reduce the inspection burden by around 12 man days and alleviate the pressure significantly.

3.3 Serious Adverse Blood Reactions and Events/Serious Hazards of Transfusion (SABRE/SHOT) reports; during 2016/17 there were a total of 22 events reported to SABRE, a slight increase on the 19 in 2015/16. There were no significant adverse trends in the data and all events have been investigated and managed to conclusion on an individual basis.

3.4 Human Tissue Authority Serious Adverse Events and Adverse Reactions (SAEARs): there were 23 Tissue and Cell SAEARs reports made in 2016/17 compared with five in 2015/16. Although this appears to be a significant increase, 12 of the reports related to cornea graft failures which were not included in last year's report, none of the reports resulted from an NHSBT error. There were also eight ODT HTA reports in 2016/17; again ODT events were previously not included in this report. All events have or are being investigated and managed to conclusion on an individual basis.

4. Quality Management System Performance Update

4.1 Critical and Major Events: there have been no internal events categorised as Critical and the number of Major events raised has decreased from 519 in 2015/16 to 482 in 2016/17. The way we log and manage Quality Incidents changed in October 2016, this change formalised the use of a risk matrix to more consistently assess incident severity. There have been no significant new trends identified in the year.

4.2 Patient Adverse Events (PAE's): PAE numbers have decreased from 174 in 2015/16 to 138 during 2016/17. No new or significant trends have been identified among the reports received.

4.3 Serious Adverse Events of Donation (SAED): there were 53 events in 2016/17, a significant increase on the 33 reported in 2015/16. The detail of the SAEDs are reported via the Clinical Assurance Risk and Effectiveness reports. Along with the other UK blood services we have submitted the annual data to the MHRA for the required submission to the EU Commission.

4.4 Self Inspections: 74% (46/50) of scheduled self inspections were completed within 1 month of the scheduled due date, which is slightly lower than the 81%

achieved in 2015/16. All non-conformances raised have agreed corrective and preventive actions which are being progressed satisfactorily. A major review of the self inspection schedules has been carried out and in agreement with the ET, changes will be made to remove duplication and ensure inspections are focused on identifying key areas of risk.

4.5 Supplier Audits: 12 supplier audits were completed in the year, four were new suppliers and the remainder were routine re-audits. Implementation of the improved risk based approach to supplier management has continued throughout the year but is not yet complete. A supplier audit schedule has been agreed for 2017-18.

4.6 Product Recalls: There has been a decrease in the total number of recalls through 2016/17 (1937) compared with 2015/16 (2858). The lower level of recalls this year is mainly due to reduced numbers of bacteriology screening and repeat reactive recalls.

4.7 Document Management: the percentage of overdue documents has slightly decreased with 1.2% overdue at the end of 2016/17 compared to 1.3% at the end of 2015/16.

4.8 Change Control Management: the percentage of overdue change controls ended the year at 10.4%, an increase on the 7.9% overdue at the end of 2015/16. This end of year figure does however mask the improved performance of previous months where levels of overdue change controls have been between 5.4% and 7%.

4.9 Event Management: at the end of 2016/17 the number of overdue events had decreased significantly with a total of 313 events overdue compared to 429 at the end of 2015/16.

5. Quality and Compliance Activities/Issues

There were a significant number of quality and regulatory compliance activities/issues which were dealt with over the year, these included;

5.1 Agile software development methodology has continued to be integrated into the QMS to support the CSM and ODT Hub through the Agile Software Development Lifecycle (SDLC). Independent regulatory advice on implementation of Agile within CSM has been provided by an ex-MHRA Inspector, the recommendations are being implemented. The CSM high-level project documentation has been shared with the MHRA, they have provided some limited feedback which has been taken into account. The MHRA expressed their appreciation that NHSBT is keeping them updated and expressed a high degree of assurance that QA are fully involved within the CSM programme.

5.2 Change Control, Validation and Qualification - QA has introduced a procedure for routine changes, which results in a simpler process for implementing, moving and decommissioning standard items of equipment. This has reduced the number of change controls being raised and managed, saving time and resource across the business.

5.3 Blood Donation - National events involving Discretionary Testing errors, an increase in the incidence of needle insertion injuries and concerns over missing DHCs were raised during the year and national corrective actions identified and implemented.

5.4 Donor Selection Guidance - The need to react quickly to the threat of the spread of Zika provided challenges to the management of required updates to donor selection guidelines. The introduction by QA of the concept of a locally generated and controlled Process Deviation/Variation ensured that rapid and safe deployment to teams could be achieved.

5.5 Revised HTA Codes of Practice – The revised codes were launched in April 2017 and are easier to navigate, more streamlined and underpinned by a set of principles drawn from the Human Tissue Act 2004. Several elements of the changes have required reviews of current processes and practice, particularly information supplied to donor families related to consent for research.

5.6 MHRA Data Integrity Guidelines – Following the completion of an extensive gap analysis and reviews of Quality Critical Software systems QA has worked with the relevant functions/departments to formulate compliance action plans which will be implemented before the end of 2017.

5.7 Overdue Event Management - The compliance concerns surrounding overdue events within the QMS has remained a key focus. Blood Donation has made inroads into the issue with improved dialogue with QA at an operational level. Good practice 'tips' have been developed and circulated to help provide consistent guidance and awareness of the status reports available to action owners. All Directors are ensuring that their senior teams are focussed on addressing the issue.

5.8 Implementation of the Occurrence and Incident module in Q-Pulse within blood and tissues took place in October. Data for the second half of the year shows good uptake of the self reporting system, with 65% now being self-reported. Although there has been an increase in the overall number of incidents reported, the number needing management and formal corrective action has reduced by around 30%.

5.9 Eye Banking – Tissue and Eye Services experienced a number of quality and resource related issues during the integration of eye banking operations from Manchester and particularly Bristol. However, during this period, both banks have remained licensed by the HTA and the Bristol Bank has now been successfully incorporated into the Filton HTA licence with the opening of the new clean room facility.

5.10 Manufacture of Advanced Therapy Medicinal Products - The Cellular and Molecular Therapy (CMT) Advanced Therapy Units (ATU) at Birmingham and Filton successfully obtained licenses from the MHRA to manufacture cell therapy and tissue engineered IMP's.

5.11 Application of the Single European Code (SEC) for Tissues and Cells for transplantation – To comply with new impending EU legislation, a SEC must be

applied by NHSBT to all its tissues and cells issued for transplantation. This significantly impacts TES, Cord Blood Bank, BBMR and CMT operations. Work has been ongoing this year to meet the deadline and has required changes to core IT and label printing systems.

5.12 Q-Pulse – Since October 2016 there have been a number of failures of the external reporting tool used by hospitals and transplant centres to report ODT incidents into Q-Pulse. Investigations between ICT and Q-Pulse Administration have resulted in extra memory and processing power being added to servers supporting Q-Pulse. This has improved performance, but the failure of the external submission form is still occasionally being reported and therefore investigations are continuing.

5.13 Human Factors - The development of a Safety First Culture through a Human Factors (HF) approach within NHSBT has continued. The actions agreed by the Executive Team were implemented and the majority are progressing well. This included the implementation of a training module on SHINE for all staff, the introduction of the Day to Day Observations tool shared with us by the National Air Traffic System into CMT and RCI; and the integration of Human Factor causes into Root Cause Analysis in Quality and Health and Safety.

6. Improvement and regulatory activities for 2017-2018

6.1 Documentation – The QA Strategy Deployment initiative to simplify and modernise the document control system is continuing, with priorities on reducing the overheads in writing and maintaining documents, developing new formats for work instructions and records so that these are value adding for users, providing intelligent navigation for documents and reducing the overall number of documents within the QMS.

6.2 Opportunities to use the functionality delivered by Desk Top Modernisation and new IT platforms are being evaluated and will be implemented as part of the CSM and ODT Hub programmes.

6.3 During 2017/18 H&I has its first round of UKAS ISO15189 assessments and a UKAS pre-assessment visit to the Donor Testing Laboratory at Manchester is being organised to support the intended microbiology screening of ante-natal patients.

6.4 Manufactured Red Blood Cells – NHSBT expects to obtain a Clinical Trial Authorisation from the MHRA to carry out a first-in-man clinical trial of this novel product. This will be the first time that NHSBT will have been responsible for development, manufacture and sponsorship involving an investigational medicinal product.

6.5 The Human Factors programme will continue with several key priorities and actions, including selecting the external partner to work with us on development and integration, ensuring that the CSM and ODT Hub Design Principles include the necessary HF elements, to train a small team of internal experts who can assist during the investigation of serious incidents and act as champions in commencing the culture change from within the organisation; and agree and implement formal KPI’s for tracking success of the programme.

6.6 The regulatory changes relating to the recast Medical Device/In Vitro Diagnostic Device (IVDD) EU Regulations are known and actions to ensure compliance will continue in 17/18, including any potential impacts on CSM and ODT Hub.

7. Benchmarking

7.1 QA has been working with the European Blood Alliance (EBA) to develop a Benchmarking questionnaire around Quality Management Systems. The initial questionnaire will attempt to understand the scope and extent of the quality management systems in use and is planned to be sent out in May 2017.

NED Scrutiny N/A

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