NHS Blood and Transplant

NHSBT Board
25 May 2016

Annual Management Quality Review
April 2015 – March 2016

Status – Official

1. Executive Summary

1.1 There were twenty one regulatory and accreditation inspections during 2015/16.

1.2 Performance against the 2015/16 quality/regulatory related objectives within the strategic plan were as follows:
- Zero Critical Regulatory non-compliances - met
- Zero Major Regulatory non-compliances – not met, five in the year
- Zero Overdue Regulatory non-compliances – met

1.3 One of the main Quality Management System (QMS) issues this year has been the number of overdue items. There are some positive indications that this is being addressed, management focus needs to continue to reduce this significantly as soon as possible.

1.4 A key challenge to the QMS and our regulatory compliance has been the implementation of Scaled Agile into the ODT Hub and Core Systems Modernisation development programmes. Work is underway to ensure that our QMS is adjusted to accommodate this new way of working so that we can continue to demonstrate control to the regulators.

Actions Requested
The Board is asked to:-
- *o* Note the regulatory performance across NHSBT during the year.
- *o* Specifically review and agree the plans for improvement activities for 2016/17.
- *o* Comment and feedback on this report and recommend any areas for future improvement.

2. Purpose of the paper

2.1 Continued regulatory compliance is critical for NHSBT to maintain its licenses and accreditations. The report provides an annual overview of trends, information and assurances in line with NHSBT's strategic targets for safety and compliance.

3. External Inspection Performance and External Reports

3.1 There were twelve MHRA inspections and four HTA inspections during 2015/16. In addition there were five accreditation inspections. There were no Critical findings, however five major findings were raised, one each at five of the MHRA inspections.

3.2 Serious Adverse Blood Reactions and Events/Serious Hazards of Transfusion (SABRE/SHOT) reports; during 2015/16 there were a total of 19 events reported to SABRE, a significant reduction on the 29 in 2014/15; there were also seven events reported to SHOT.

3.3 Human Tissue Authority Serious Adverse Events and Adverse Reactions (SAEAR): there were five SAEARs reports made in 2015/16 compared with eleven made in 2014/15.

4. Quality Management System Performance Update

4.1 Critical and Major Events: One internal event was categorized as Critical during 2015/16, this related to the death of a patient after a transfusion, however investigation confirmed that there was no fault on the part of NHSBT. The number of Majors raised has decreased significantly from 819 in 2014/15 to 591 in 2015/16 However, this decrease is due in part to the decision to stop recording no significant bacterial screening events as major. There was also work completed to ensure greater consistency and logging of majors by introduction of a risk matrix.

4.2 Patient Adverse Events (PAE's): The numbers have increased slightly, from 164 in 2014/15 to 174 during 2015/16. There are no adverse trends.

4.3 Serious Adverse Events of Donation (SAED): there was a significant decrease to 33 events in 2015/16 compared with 42 during 2014/15.

4.4 Self Inspections: Across the year 81% (35/37) of scheduled self inspections were completed within 1 month of the scheduled month, this is slightly lower than the 87% achieved in 2014/15.

4.5 Supplier Audits: 13 supplier audits have been completed in the year. Implementation of the improved risk based approach to supplier management has continued throughout the year.

4.6 Product Recalls: There has been a decrease in the total number of recalls through 2015/16 (2858) compared with 2014/15 (3844). In particular there has been a decrease in donor related recalls due to a change in the way we reflect the recall data, recalls are now only logged in this dataset where product has been issued and hospital recall is required.

4.7 Document Management: the percentage of overdue documents has decreased with 1.3% overdue at the end of 2015/16 compared to 1.7% at the end of 2014/15.

4.8 Change Control Management: The percentage of overdue change controls has reduced from 10% at the end of 2014/15 to 7.9% at the end of this year: the age profile of the overdues has also improved.

4.9 Event Management: The number of overdue events had increased at the end of 2015/16 to 429 compared to 242 at the end of 2014/15. However, there was a large increase over the March (and Easter) month end. Performance since then has improved significantly with overdue figures down to 245 in mid-April. The age profile of overdue events has improved significantly in year.

5. Quality and Compliance Activities/Issues

5.1 A number of quality and compliance activities/issues have been successfully dealt with over the year, these include;

- The move to Scaled Agile development has been a challenge to the QMS and a review is still underway to map the current system to the new practices. This is a must if we are to maintain compliance throughout this major programme of change.
- Transition to ISO15189: United Kingdom Accreditation Services (UKAS) are completing the inspection of the RCI network of laboratories. The laboratories are highly likely to achieve the more stringent ISO15189 accreditation.
- Overdue events and documents: following a number of comments and a major finding at MHRA inspection this issue has been subject of very focussed performance management at Director level and is showing signs of turnaround. This will be ongoing into 2016/17 and must be maintained as a clear focus.
- Investigational Medicinal Product (IMP) licence: CMT Birmingham will shortly be granted a licence for Advanced Therapy manufacturing following inspection by MHRA.
- Reconciliation and Irradiation failures: improvement plans are nearing completion and improvements have been seen in performance, however there is still some variability and this continues to be monitored.

6. Improvement activities for 2016-2017

6.1 A number of improvement activities have been identified for 2016-17;

- Documentation: using the QA Strategy Deployment initiative further steps are being taken to improve performance in this area. These include reduction in numbers of documents to reduce the overheads in the writing and maintaining them and the development of new formats for work instructions and records which are easy to use and easy to navigate.
- Change Control, Validation and Qualification: QA are introducing a procedure for standard changes which will reduce the number of change controls that need to be raised for implementing, moving and decommissioning standard items of equipment.
- Data Integrity: the compliance gaps identified against the MHRA Data Integrity Guidelines are being prioritised and addressed to ensure that NHSBT is fully compliant by the end of 2017.
- Overdue Quality Activities: the focus on reducing overdue issues will continue. The weekly reports will be continued and improved to assist Operations in ensuring actions are closed prior to target dates.

Note: Detailed data for all the points above is available on request.

NED Scrutiny N/A

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