1	**Date / title of meeting**	**28th May 2015 / NHSBT Board Meeting**
2	**Title of paper**	**Management Quality Review Annual Report – April 2014 to March 2015**
3	**Status**	Official and discloseable.
4	**Tweet (max 140 characters)**	Successful reduction in the number of external major non compliances within NHBST.
5	**Executive Summary**	NHSBT finished the year with two Major non-compliances from the nineteen external inspections carried out. Both Majors were raised during MHRA inspections, one at the Clinical Biotechnology Centre (CBC) (DTS) in April 2014 and the other at Colindale (Blood Supply) in March 2015. Although not fully in line with our ambition of zero Majors, this represents a significantly improved performance on the 11 Majors received last year. See full report attached.
6	**Action requested**	The Board is asked to :- o Note the current levels of regulatory performance across NHSBT. o Comment on the actions being taken to achieve quality improvements and address the weaknesses and issues identified. o Comment and feedback on this report and recommend any areas for future improvement.
7	**Background and customer promise**	The report provides annual information and assurances in line with NHSBT strategic targets for safety and compliance.
8	**Why is this important?**	The report demonstrates an improved regulatory compliance that is critical for NHSBT in maintaining its licenses and accreditations, including the Blood Establishment Authorisation, Human Tissue Authority licenses for Tissues, Cells and Organs and the Care Quality Commission, all of which are essential for us to operate.
9	**Who else has been involved so far?**	This report was reviewed by the Executive Team at its meeting on the 20 May 2015. Quality Assurance team members provided input and data.
10	**Costs and benefits**	N/A
11	**Significant next Actions**	Actions are detailed in the report, particularly in the Quality Improvement Plan included.

12	**How does this impact on Equality and Diversity?**	N/A
13	**What is the impact on sustainability?**	N/A
14	**Employee impact?**	N/A
15	**Donor/Patient/Customer impact?**	N/A
16	**Taxpayer impact?**	N/A
17	**Author**	Jenny Chan (Compliance Officer) and Betty Wickens (National Audit Manager) Edited by Fidelma Murphy, Head of QA and Regulatory Compliance.
18	**Responsible Director**	Ian Bateman, Director of Quality.
19	**NED input**	N/A
20	**Additional Documentation Available on Request**	N/A

NHS BLOOD AND TRANSPLANT

20th May 2015

MANAGEMENT QUALITY REVIEW ANNUAL REPORT
April 2014 to March 2015

1. EXECUTIVE SUMMARY

NHSBT has had a positive year in terms of the outcomes of the nineteen regulatory compliance and accreditation inspections which took place. There were no "Critical" and two "Major" external inspection findings, both raised by the Medicines and Healthcare products Regulatory Agency (MHRA), one at the Clinical Biotechnology Centre (CBC) and the other at the Colindale Blood Centre inspection, details of the findings can be found in Appendix 1.

Two MHRA inspections at Leeds and Colindale due in October/November 2014 were postponed by MHRA until March 2015 which eventually caused significant congestion in the schedule with six inspections having to be completed in March. Currently MHRA appear to be struggling with the resource to complete their inspection schedule to plan, this may have an affect on the 2015/16 schedule with the possibility of some inspections being delayed and the risk of continued congestion.

There were 29 Serious Adverse Blood Reactions and Events (SABRE) reported to the MHRA in 2014/15 compared to 22 in 2013/14. There were 11 events reported to the Human Tissue Authority's (HTA) Serious Adverse Events and Reactions System (SAEARS) under the Tissue and Cells Regulations, two more than in 2013/14. None of these events resulted in increased regulatory action or inspection.

A Quality Improvement Plan has been developed following significant analysis of previous external and internal inspection findings. This has been done with full engagement of front line staff and Operational and Group Services Senior Management Teams, see Appendix 2. A communications plan will be developed to ensure that this plan is effectively launched and promulgated across the organisation starting in June 2015. Future MQR reports will provide updates on progress.

NHSBT has continued to be closely involved in the debate on the proposed changes to the recast Medical Device and In Vitro Diagnostic Directives as there are still a number of potential risks which could cause significant regulatory compliance issues and significant additional costs should they be realised. This potential issue has also been raised with our DH sponsor.

On the 1st April 2015 NHSBT took over responsibility for the running of the two CTS Eye Banks in Manchester and Bristol. There have been significant quality issues with the Bristol eye bank, which had to be shut down prior to us taking it over due to a microbiological contamination issue. This has affected supply of cornea and resulted in significant facility remedial works being required. The plan is to reopen the bank in May

and then transfer the activity to Filton in September/October this year. The Manchester eye bank has been able to take over supply during this shut down, however there have been a small number of surgery cancellations during this period. Discussions have and are being held with the HTA regarding the quality compliance levels of the bank at point of handover.

During Q4 NHSBT detected an increase in leucodepletion (LD) failures with MacoPharma top and top packs. Whilst the overall process remained within specification one centre (Sheffield) had more failures than others which necessitated increased levels of quality monitoring. Investigation of the incident by MacoPharma confirmed a change in the tool used to cut the filter mattresses had created a defect resulting in increased risk levels. A clinical risk assessment was completed which justified continued use while replacement stocks were sourced and the affected packs were swapped out. However this has left supplies lower than planned and has necessitated very close stock management between MacoPharma and NHSBT. Discussions are now ongoing with MacoPharma on the fate of the affected batches as a further clinical risk assessment has concluded that the packs should not be used within the UK. This issue has again highlighted the potential risks around a single source supply for this critical component.

2. PERFORMANCE AGAINST STRATEGIC PLAN TARGETS

Performance against the 2014/15 quality/regulatory related strategic plan targets were as follows:

- Zero Critical Regulatory non-compliances - met
- Zero Major Regulatory non-compliances – not met - two during the year
- Zero Overdue Regulatory non-compliances - met
- 10% reduction in the causes of Major quality incidents – not met - Blood Supply (BS) and Diagnostic and Therapeutic Services (DTS) Senior Management Teams are evaluating their historical data in order to set targets for specific improvement projects to achieve this KPI. A number of National Quality Incidents have been raised to manage the improvement activity within the Operational Directorates.

3. EXTERNAL INSPECTION PERFORMANCE

There were nineteen regulatory compliance and accreditation inspections during 2014/15. There were no "Critical" and two "Major" external inspection findings, both raised by the MHRA, 1 at CBC and the other at Colindale blood centre. Chart 1 below shows a clear improvement in MHRA and HTA performance this year with a reduction in external Majors from 11 in 2013/14 to two this year. In addition there has been a marked reduction in the number of Other severity non-compliances and Comments received from the regulators. This indicates a general improvement over an extended number of years.

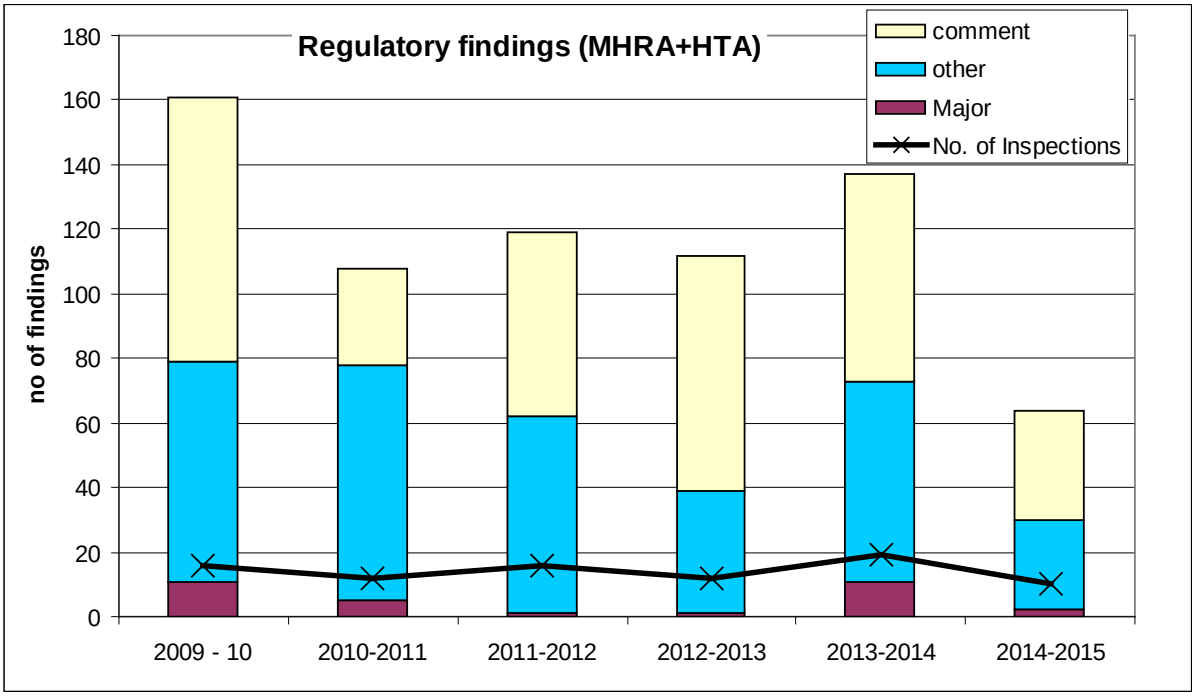

Chart 1: External Regulatory Inspection Findings by Year

A schedule of the expected external inspections due in 15/16 is included in Appendix 3.

Following the increase in MHRA inspection findings in 2013/14 a review of inspection data and information has been performed and a draft Quality Improvement Plan

developed, see Appendix 2. The plan is built around three improvement themes of culture/behaviour, leadership/commitment and continuous quality improvement.

One key part of the plan is to reduce the complexity of some elements within the Quality Management System (QMS), for example, document use/control and temperature mapping. Workshops have been held with all Directorates, who have provided feedback and items for inclusion, such as specific actions, responsibilities and timelines. The main aims of the plan are to drive further towards a culture of continuous quality improvement and improved regulatory performance. The final plan is being presented to the Executive Team and NHSBT Board as part of this report and will be launched at the end of May 2015. Quality Assurance staff will then work with each directorate to develop specific action plans which match their requirements. A plan has already been completed by Tissue Services (TS) and QA are working with TS on its implementation.

During the development of the plan a key action has been completion of a programme of regulatory site briefings, which has continued across all sites during the year. There has been good attendance and engagement with front line staff, including an opportunity to input into the plan. Twelve sites have been visited during the year and in excess of 42 briefings have been delivered. There are three sites remaining to complete the programme in early 2015/16. The briefings are aimed at ensuring that all staff are aware of previous and current regulatory performance and to ensure there is a thorough understanding of NHSBT's continued ambition in terms of regulatory compliance, what standards are required; and what individual staff can do to contribute to achieving this ambition.

4. QUALITY MANAGEMENT SYSTEM UPDATE

4.1 Quality Management within ODT

4.1.1 EU Organ Donation Directive (EUODD) Compliance

The EU Directive for Standards of Quality and Safety of Human Organs intended for Transplantation was implemented in the United Kingdom on 27th August 2012. NHSBT holds a procurement licence covering the activities of the Specialist Nurses – Organ Donation and the Duty Office in ODT. In July 2014 the Regulations were revised to include reporting of incidents from the European Union (EU) and traceability of organs which are imported and exported from the UK within the EU and to 'Third Countries'. NHSBT has ensured compliance with the new requirements.

NHSBT was audited under the original Regulations in 2013 and the next planned audit of the sector is in 2016. During 2015 NHSBT will be required to complete a compliance assessment for the HTA; this brings the Organ Donation and Transplantation sector in line with the other sectors regulated by the HTA.

This year, there has been one area of compliance with the Regulations regarding characterisation of organs, which was the subject of significant discussion with the HTA and where there was risk of regulatory action. However, following extensive communications and a meeting with the HTA CEO and Director of Regulation (in January 2015), a way forward was agreed. The agreement involves NHSBT documenting the

assurance it currently employs in determining the suitability of laboratories to provide testing results within the QMS. No further action will now be taken by HTA on this matter.

4.1.2. Licensing under the Human Tissue Act for the Quality in Organ Donation Project

During 2013/14 NHSBT agreed to extend its HTA Research License, held at Liverpool, to license a number of satellite sites within hospitals, enabling the collection of tissue samples in support of the Quality in Organ Donation research project. This was necessary as within England, Northern Ireland and Wales tissue cannot be retrieved for research unless the retrieval is performed on licensed premises. During Q3 2014/15 this project closed and the collection of samples under the NHSBT satellite licenses now continues as a business as usual activity. The systems established have worked well, with a few minor incidents relating to the collection and transfer of samples. However there was one serious incident in Q4 where tissue was collected from an unlicensed establishment in error. This has been fully investigated, HTA informed and ODT and the University of Oxford, have put corrective and preventive actions in place. HTA has confirmed it will not be taking any regulatory action in relation to the incident.

4.2 Quality Improvement Activities

A number of quality improvement activities have continued to be progressed, these include;

4.2.1 Reduction in Reconciliation Errors

These are incidents where we lose traceability of blood components by issuing them outside the PULSE system, hence potentially losing the ability to recall a component should there be a subsequent quality/safety issue. The numbers involved remain very low, but significant as they increase potential risk.

The improvement plan has continued to be managed and reviewed regularly by the Blood Supply Senior Management Team (BS SMT). Numbers of errors have remained static during the year. Work to review the design of the process and the potential for human error was completed in Q2 with the help of a consultant in human factors. Two workshops were held in January 2015 and an action plan has been developed to address the consultant recommendations. This will continue to be closely monitored by BS SMT.

4.2.2 Reduction in Irradiation Errors

These are incidents where an error has been made during the irradiation process, including errors during labelling or issue of incorrect components, which is a potential high risk in terms of patient safety.

There has been a modest decrease in the numbers of events from 25 in Q3 to 20 in Q4. Progress with the improvement plan has continued to be managed closely and regularly reviewed by BS SMT. As in 4.2.1 above, two workshops were held in January 2015 and an action plan has been developed to address the recommendations made by the human factor consultants.

During the year MHRA confirmed that they are happy with progress to date on both irradiation and reconciliation improvement plans and will not require any further written updates. However they will be confirming effective implementation of actions during future inspections.

4.2.3 Reduction in Diagnostic Laboratory Reporting Errors

During 2014/15, the average number of reporting errors in RCI and H&I logged as adverse events in the quality system has shown no significant reduction, remaining at about 40 and 10 incidents per annum respectively. Levels and the potential clinical impact of reporting errors continues to be monitored regularly by DTS CARE.

Work to reduce reporting error rates by the redesign and/or streamlining of processes has continued within RCI and H&I. Data analysis has demonstrated that the root causes of reporting errors are varied, but a significant number result from the interaction between staff and the Hematos system. Another key cause identified has been distraction during the critical preparation, review and checking of reports before they are authorised. The establishment of dedicated reporting cells to address this is progressing within the laboratories, but is still not fully embedded across all sites as more time is required to assess the impact of this change. Laboratory management within DTS have commenced consideration of the use of Human Factors analysis to inform potential improvements to the processes and hence reduce errors further.

4.3 Quality/Regulatory Compliance Issues

4.3.1 Impact of the Review of the Medical Device Directives by the EU Commission

Progress in finalising the Medical Device and In Vitro Diagnostic Medical Device (IVD) Directives has been significantly delayed by the European Commission. The revised timetable is now to agree the EU Council position/text by end of June 2015 with the EU Council adopting their formal first reading position in December 2015. The new regulations would then come into force early in 2016 and take effect from 2019 for medical devices and 2021 for IVDs.

In the absence of revised text, the MHRA has been unable to confirm the wording/full impact of the ‘in house exemption’ other than to confirm that this was still agreed for all classes of IVD and with likely caveats as has been discussed previously.

Slippage of the effective date means that the joint UK tender for HLA typing/antibody screening reagents will not now be affected by the recast, avoiding potential additional costs estimated as being in excess of £3 million.

A meeting was held with the MHRA to explore the potential impact of the Directives on IT systems utilised for therapeutic and diagnostic work. The MHRA confirmed that IT systems used as a diagnostic tool, or applying algorithms to provide blood components will be impacted by the recast Directives. The MHRA view is that discrete modules rather than the entire systems will need to be CE marked depending on their functionality. MHRA is now establishing which modules might in future need to be CE marked. This will be an important factor to consider in future IT projects such as Pulse replacement.

The NHSBT MD and IVD Group has ensured that the current NHSBT adverse event reporting processes capture serious incidents concerning ‘in house’ and ‘off label’ exempt IVDs. It has also prepared IVD risks and issues logs for each current ‘in house’ and ‘off label’ IVD to allow user functions to mitigate and update their strategic plans as appropriate. The group continues to follow progress of the recast Directives closely, flagging concerns and lobbying for change as required through the MHRA (who are the UK representatives on the EU MD&IVDD Working Group) the NHS Confederation and the EBA. The DH has confirmed that any communications on the directives should be handled through the MHRA.

4.3.2 Transition from Clinical Pathology Accreditation to ISO15189

As part of the transition from the existing Clinical Pathology Accreditation standards to the new ISO15189: 2012 standard, Medical Laboratories, Requirements for Quality and Competence; and the new UKAS inspection regime, a significant amount of review and compliance work has continued. Precise dates have yet to be agreed for RCI's inspections under these new regulations, but they are expected during August/September 2015, with H&I’s inspections extending into 2016. Preparations have continued to fill the 'gaps' between the CPA Handbook and ISO15189 Standard. RCI and H&I are focussing on the major outstanding work including the retrospective validation of long standing assays, providing a valid means of competency assessment (preferably linked to processes), materials and supplier management (including the stringent requirements around calibration) and assessing measurement uncertainty for remaining quantitative assays.

4.3.3 Ocular Project - CTS Eye Bank Transfer

NHSBT’s project to bring the Manchester and Bristol CTS Eye Banks into direct Tissue Services line management has continued. The CTS Eye Bank HTA licences have now ceased and as of 1 April 2015 the activity of both banks falls under the NHSBT Liverpool license as satellites; and the oversight of the single NHSBT Designated Individual.

The Manchester Eye Bank has remained in its current location following an acceptable due diligence quality and compliance audit by NHSBT in November 2014. The processing and issuing of ocular tissue continues from this site under the NHSBT licence.

Late in the project, a decision had to be made to retain the Bristol eye bank at its current location as it became clear that sufficient temporary clean room facilities at Filton would not be available. Remedial work to make good unacceptable deterioration to the Bristol eye bank facility was therefore planned to allow continued operation from the current site. However, just prior to transfer, a significant fungal contamination of ocular tissue occurred. The Bristol Eye Bank Designated Individual took the decision to close the Bank and reported the issue to the HTA. Subsequent investigation has linked the contamination to a reagent made up by the bank. This incident resulted in one patient having to have a contaminated graft removed following surgery and has also impacted the stocks of available ocular tissue, with a number of surgical procedures having to be postponed. As this incident took place as NHSBT was about to take over the Bank, it was registered as a serious untoward incident (SUI) in the NHSBT quality system to allow actions and outcomes to be recorded, but responsibility for the affected tissue remained legally with the previous Bristol Eye Bank DI as the incident occurred before ownership

was transferred. Discussions have and are being held with the HTA regarding the quality standards within the eye bank at point of handover.

4.3.4 Bristol Heart Valve Bank

During 2014/15 NHSBT were approached by the University of Bristol and asked whether we would take over responsibility for the running of the Bristol Heart Valve Bank as they were considering closing it. Following a thorough quality audit, where significant deficiencies were raised, NHSBT declined to take over the Bank.

During the year the University of Bristol were unable to secure the future of the Bank and a decision was taken to close it and its HTA licence was revoked. Due to the potential clinical value of some of the stocks of cardiac tissue NHSBT agreed, through a transfer agreement in accordance with HTA regulations, for these stocks to be transferred to Liverpool along with the consent, collection and processing records. The NHSBT DI agreed that the tissue could be evaluated under risk assessment for potential addition to NHSBT stocks in accordance with NHSBT policy. The tissue has been held in quarantine and the programme of evaluating and deciding the fate of the tissue has now commenced. It was expected that any immediate demand for cardiac tissue could be met adequately from current stocks at NHSBT and other banks. However there has been a sudden and unexpected urgent demand for some cardiac tissue (surgical patches) only available from the Bristol Bank stock. This resulted in clinical and QA staff performing urgent risk assessments in order to release the tissue for this urgent clinical need.

4.3.5 Liverpool Reagent Contamination Issue

During July 2014 a number of CE marked reagent products manufactured by NHSBT Reagents in Liverpool had to be recalled due to haemolysis. The cause was traced back to a solution manufactured by the supplier, Source Biosciences Ltd. Following this, in September 2014, a number of microbiological organisms were isolated from several solutions manufactured by the same supplier, which affected several batches of tissue products. The majority of affected tissues, including a significant quantity of skin, were released for issue following expert microbiological review and clinical risk assessment. In response, additional goods inwards microbiology testing on all consignments from Source Biosciences was implemented and some critical solutions used by tissue services were sourced from an alternative supplier. It was not possible to find alternative suppliers for all of the solutions as they are bespoke to NHSBT and a small number of other users.

The manufacture of the solutions transferred to a new Source Biosciences facility in Rochdale in December 2014 and the facility became operational in January 2015. The facility was visited by NHSBT QA, Tissue bank and Reagents staff prior to transfer and many of the recommendations made by this team were incorporated into the final design. The first solutions have been received from this facility with no contamination issues reported. A thorough audit by QA and the Head of the National Bacteriology laboratory was completed in early March 2015 and the company has agreed to comply with all recommendations made by the audit team.

4.3.6 Irradiator Dose Mapping Issues

NHSBT utilises gamma irradiators at 13 sites to irradiate blood components in order to prevent Graft versus Host Disease (GvHD) in recipients. These irradiators are dose mapped annually using radiochromic film to ensure that blood components are exposed to doses between 25 and 50 Gy. During late 2013 it was identified that the national and international accepted dose mapping procedure being used did not completely measure the radiation dose at the extremities of the canister used to hold blood components during irradiation. Concerns were therefore raised that it could not be guaranteed that the entire product is irradiated within the specification.

A clinical risk assessment was performed by Dr. Sheila McLennan which concluded that irradiated products were safe and that irradiation could continue pending an alternative solution being found. The issue was also discussed with the MHRA as it was a national and international issue with the current irradiation method. MHRA agreed that further work was required to assess the issue and to find a solution. A significant amount of work has been carried out, both in house and with our approved contractor, and during Q4, a solution was agreed. The solution involves adding a second film to the canister to measure the extremity. A programme is now being put in place to re-map all of the irradiators using the new process during 2015/16. Given the national and international impact of this issue we aim to publish the findings of this work.

4.3.7 Transport Bag Validation

It is a regulatory requirement that we validate our transport containers to ensure that they maintain blood products at the required temperatures across potential extremes of ambient conditions. Review of the historical data (from 2002) has identified some weaknesses in our current validation data at extremes of temperature (low) and where we use part filled boxes. We have therefore put measures in place to control the number of units in each container and are also ensuring transport times are closely managed.

To complicate things further, more stringent specifications for maintaining blood products at greater than 20C (rather than the current 18 C) are due to be introduced in future. The solution to this issue and this longer term change is the introduction of a new, fully validated container system, the tender for which has now been completed. This new system will be in use prior to the next winter period and hence we will be in full compliance going forward.

4.3.8 Retention of Records for MHRA Inspections

The MHRA has requested that NHSBT retain a full set of Quality Records for two years on all sites inspected. Their grounds for this are that they are required to review a sample of two years worth of records during their inspections; and therefore this is what must be available. Following an internal review by QA, it was concluded that this would cause significant issues in terms of space and environmental control; and present additional risk to our long term storage of records. As a result NHSBT has written to the MHRA explaining our concerns and stated that we will be maintaining our current process which we believe is compliant. We have stressed the fact that the agreement with our external records storage contractor includes a 4 hour retrieval service, which we believe will allow us to readily present records to an inspector when requested. The MHRA have now

responded inviting NHSBT to a meeting to discuss this issue further with a view to agreeing a compromise where only certain records might be retained for inspection purposes.

5. EXTERNAL REPORTS TO MHRA AS SERIOUS ADVERSE BLOOD REACTIONS AND EVENTS (SABRE)

During 2014/15 there were a total of 29 events reported to SABRE compared to 22 in 2013/14. The detail of the reported events can be seen in Appendix 4.

During the year a review of SABRE reports was performed as it had been suggested by the Serious Hazards of Transfusion (SHOT) team that not all required reports were being submitted to SHOT and SABRE. The review revealed that slight adjustments were required to our classification of incidents and this has now been completed. Reports have been submitted to ET, CARE and GAC to provide more detail. The review also examined the spike of reports in November, which revealed the main cause as a delay in reporting in October, which resulted in two months being reported in November. There were also a series of recall failures during the same period which inflated the numbers. The latter is going to be subject of a rapid improvement event in May 2015 aimed at improving the recall process, which is felt to be too complex.

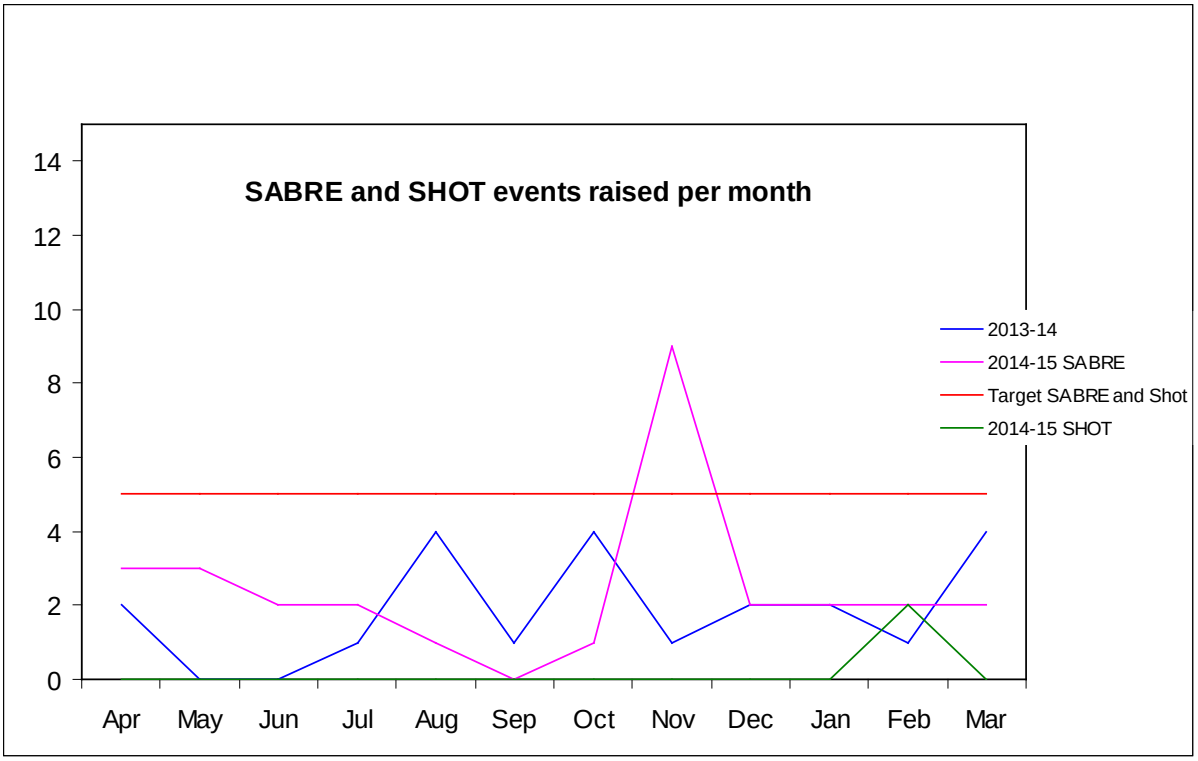

Chart 2: Sabre and SHOT Events reported per month

6. EXTERNAL REPORTS TO THE HUMAN TISSUE AUTHORITY (HTA) AS SERIOUS ADVERSE EVENTS AND REACTIONS (SAEARS)

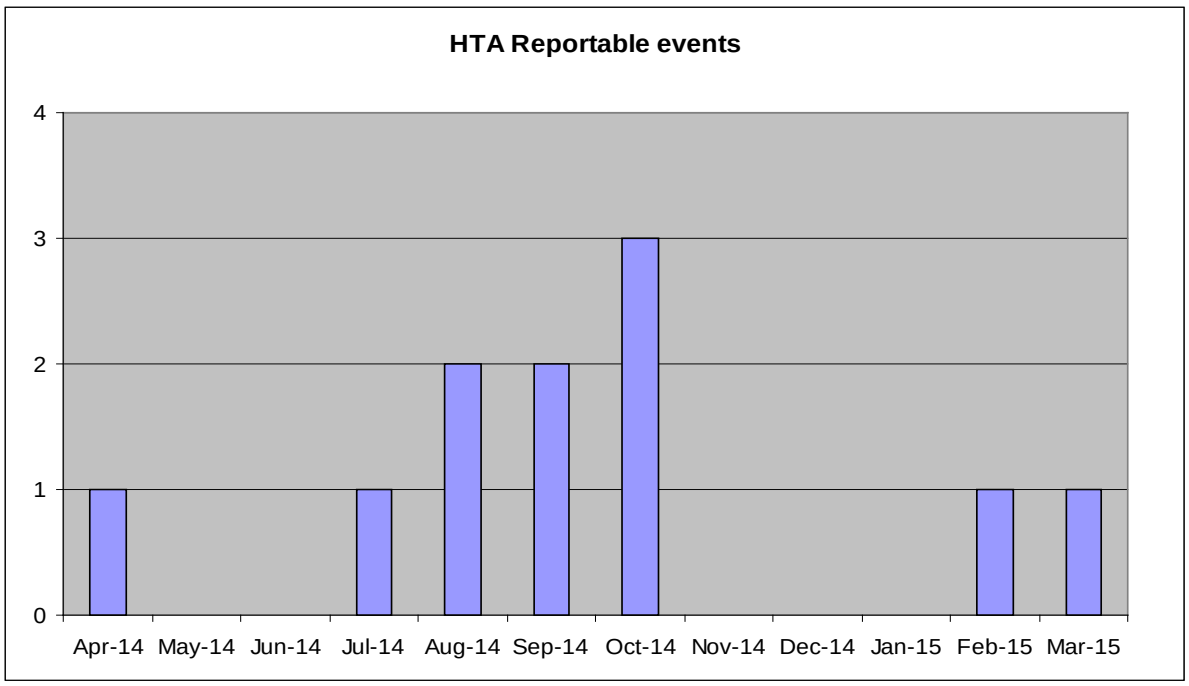

Chart 3: HTA reportable events per month

There were 11 SAEARs reports made in 2014/15 under the Tissue and Cells Regulations which is slightly higher than the 9 reported in 2013/14. No trends have been identified in the data and all events have been investigated and managed to conclusion on an individual basis. The details of the reported events can be seen in Appendix 5.

7. ADVERSE EVENT MANAGEMENT

7.1 Serious Untoward Incidents (SUI)

Serious Untoward Incident detail is reported in the Medical and Research Directors Clinical Assurance Risk and Effectiveness Reports.

7. 2 Critical and Major Adverse Events

It is important to note that data from Organ Donation and Transplantation is not included in the information below. It is intended that this data will be included in the MQR reports during 2015/16.

There were no internal events initially categorised as Critical during Q4.

The trend of internal events classified as Critical and Major by function for 14/15 can be seen in chart 4.

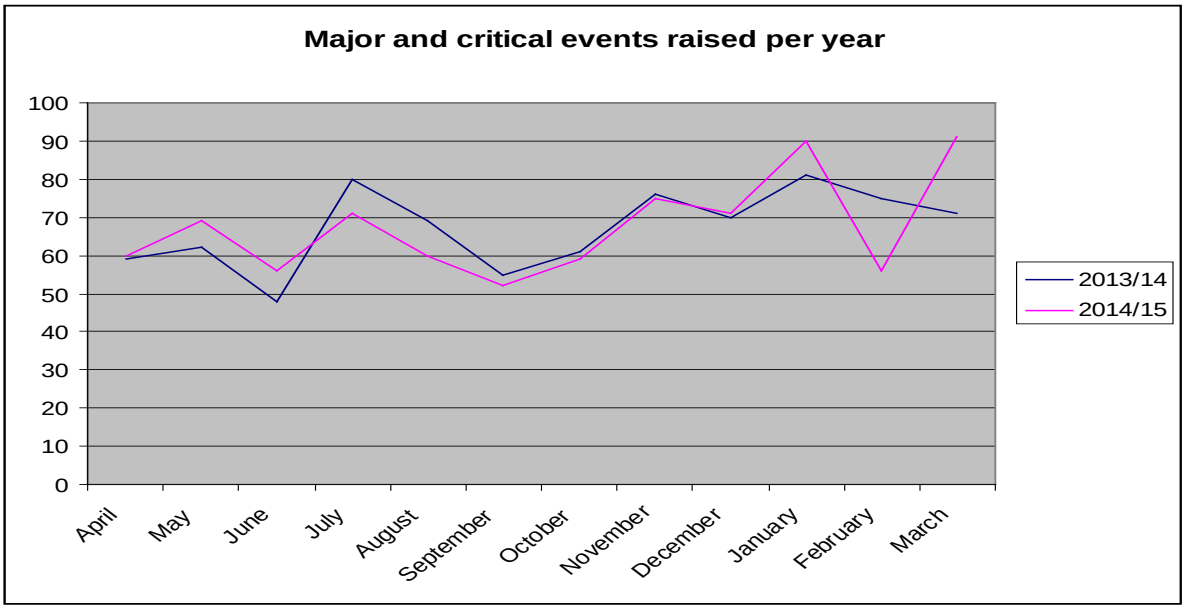

Chart 4: Rolling 12 months Major and Critical Adverse Events Raised

The chart shows that the overall numbers have followed a similar pattern in 2014/15 as 2013/14. QA are working closely with Directorates to establish quality improvement projects to decrease the causes of Major (and Other) events.

Within DTS there are generally less than 10 major incidents/month, this remains unchanged from previous reports. Adverse events within DTS are predominately related to reporting errors as discussed in paragraph 4.2.3.

The majority of Major events are raised within Blood Supply and are reviewed weekly by the BD Leadership Team, including the identification of any trends. Within BD, Heads of Region also review the outcome of all root cause analysis meetings to ensure that the actions will prevent recurrence and to share learning from events nationally. A National Quality Incident is raised when there are any specific areas of concern and an action plan created to address persistent areas of weakness. Three trends have been identified during 14/15 and quality improvement initiatives have commenced to address these within BD, they are discretionary testing, health screening and equipment management.

Within BS manufacturing the main focus has been on the reconciliation and irradiation projects during the year as described above.

7. 3 Overdue events

Chart 5 shows a snapshot of current performance regarding overdue events at the end of Q4. The overall number has increased slightly with a total of 242 events overdue compared to 231 at the end of 2013/14. The number of events overdue by over 30 days has increased slightly from 60 at the end of 2013/14 to 68 at the end of 2014/15.

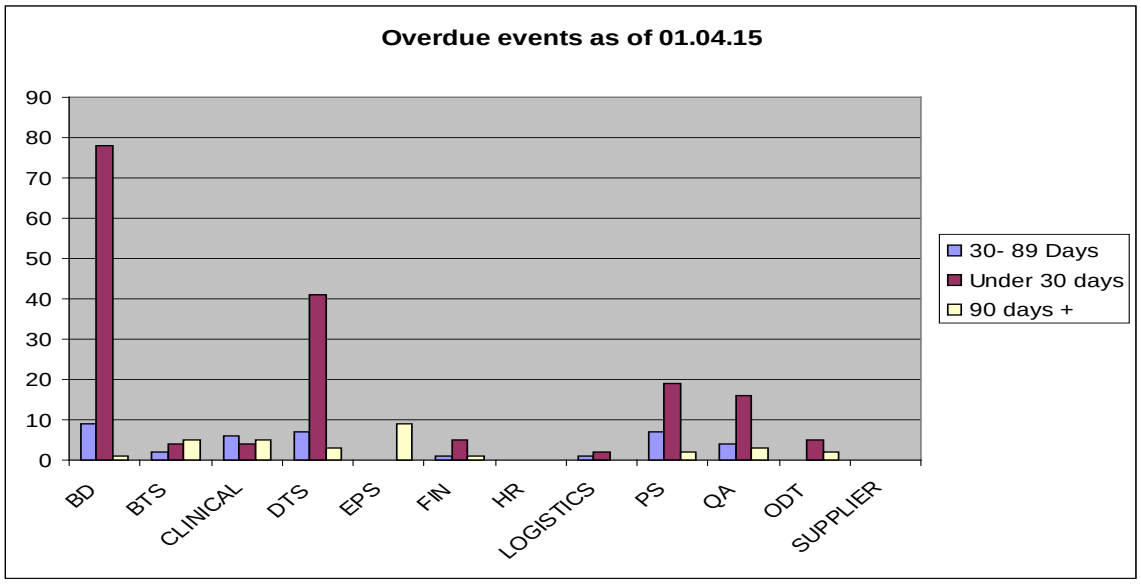

Chart 5: Overdue Events (as 01/04/2015)

This level of overdue events is not acceptable and all Directorate SMT's have again been asked to ensure that their staff are actively reviewing and addressing this issue. This is an area where we must improve as we are at risk of significant criticism from our regulators if we do not. At recent MHRA inspections in Leeds and Colindale the inspector reiterated that the level of overdue issues needs to be addressed.

8. PATIENT ADVERSE EVENTS (PAE's)

Chart 6 shows the numbers of PAE's recorded over the last 12 months.

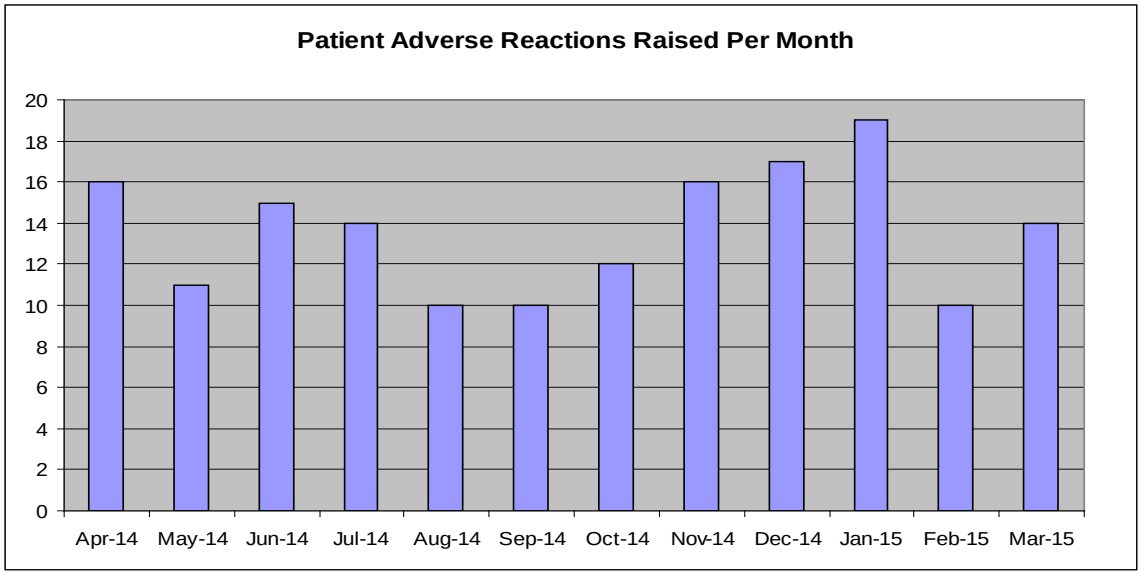

Chart 6: Patient Adverse Reactions Raised per Month

PAE's include all reported events associated with patients, including serious adverse reactions, for example potential TRALI events. There have been no significant trends or underlying causes identified among the reports received.

Specific data on potential TRALI incidents is reported in the Medical and Research Directors Clinical Assurance Risk and Effectiveness Reports.

9. SERIOUS ADVERSE EVENTS OF DONATION (SAED)

Chart 7 shows the trend of SAED's over the last 12 months.

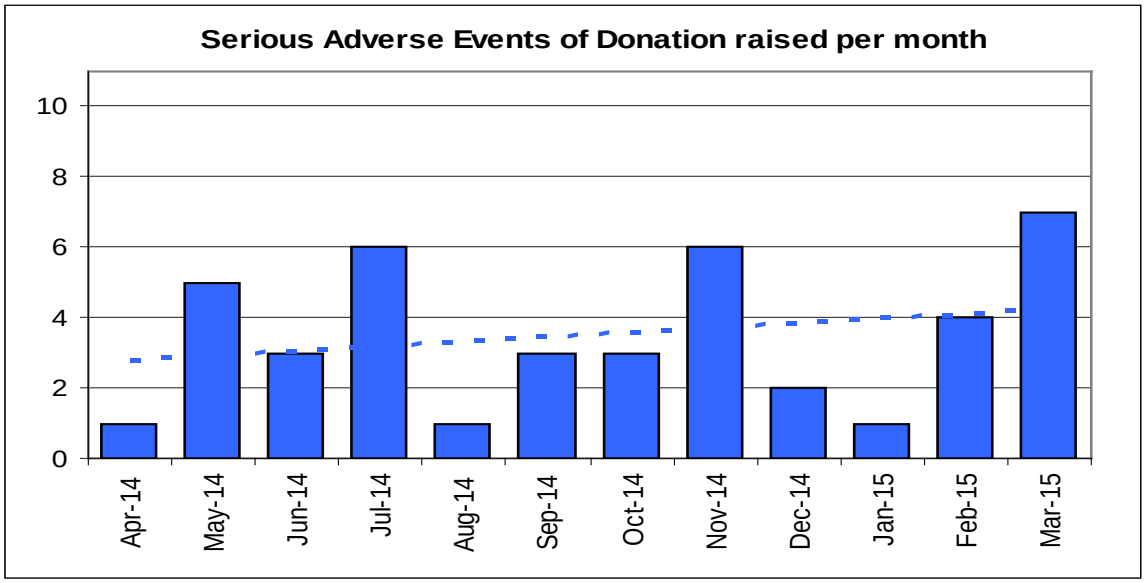

Chart 7: Serious Adverse Events of Donation Raised Per Month

There were 42 events in 2014/15 compared to 40 in 2013/14. Of the 42 events 56% (25) resulted in hospital admissions, 18% (8) related to a fracture, 17% (8) were related to needle insertion and 2% (1) related to acute coronary care.

10. SELF INSPECTIONS

There have been issues in completing self inspections to schedule this year as reported in previous MQR reports. Some inspections and reports were significantly delayed (over 3 months), however due to significant effort in the last quarter of the year all scheduled self inspections were completed by the end of March. Over the year 85% of self inspections were completed within 1 month of their scheduled date, which is a drop from 91% in 2013-14. Inspections scheduled for 2015-16 are being carefully monitored to ensure the schedule does not fall behind again.

Resource remains a challenge with dates for self inspections often being rearranged due to competing priorities. This is an area we must keep under review as failure to complete our internal audit schedule within reasonable timeframes would be a significant regulatory compliance issue.

Twelve major self inspection non-compliances were raised during the year, two more than in 2013-14. Six were raised at Manchester/Lancaster and related to training, cleaning, quarantine logs, premises for team kitting and venepuncture; five were raised in Colindale related to temperature mapping, management of equipment, change control, document control and training; and one was raised in Newcastle related to a number of examples of

a lack of detail in the recording of adverse events. Root cause analysis and corrective actions are being progressed in all cases.

A review of internal inspections and MHRA findings published in 2014 showed that although the self inspection programme is being effective in picking up similar issues, we are not always being effective in learning from these findings. In particular local actions are not always being effectively shared with other sites. There are also some areas where self inspections may not cover findings with the necessary rigor. An action plan has been developed and is progressing with some actions linking into the Quality Improvement Plan.

11. QUALITY MONITORING (QM)

During 2014/15 NHSBT complied overall with the Blood Safety and Quality Regulations and Red Book Guidelines for component specifications, although local and national management of a number of QM incidents has been required to maintain compliance.

Steps have been taken to improve specification compliance of apheresis triple dose platelet counts at individual Donor Centres. Compliance has improved partly due to a continuing reduction in the proportion of triple dose platelets collected as part of the change to an increasing proportion of pooled platelets.

Between November 14 and January 15 both Colindale and Filton reported non-compliant cryoprecipitate factor VIII and fibrinogen results. On investigation, the root causes were confirmed as QM testing errors which have now been resolved.

Since January 15 we saw a significant worsening in WBC leucodepletion failures with MacoPharma Top and Top Red Cell packs. Overall NHSBT specification compliance has been maintained, but the random incidence of failures resulted in Sheffield having to implement an increased QM sampling level. MacoPharma confirmed the root cause as a manufacturing change of the filter cutting tool, which increased the number of filters cut from each sheet, to reduce wastage, but resulted in occasional inclusion of loose filter material that allowed WBCs to by-pass the filters. A national quality incident group was convened to manage the incident and all affected lots have been removed from the supply chain. MacoPharma has prioritised supply of unaffected lots to NHSBT (with filters cut using the previous tool) and as these have been introduced, the WBC leucodepletion performance has returned to pre-incident levels. This has permitted Sheffield to return to routine QM sampling frequency. Stock levels of these packs remains low due to the incident, but this is being closely managed with MacoPharma.

12. SUPPLIER AUDITS

In Q4 three supplier audits were completed bringing the total performed to sixteen during 2014-15. These consisted of two “for cause” supplier audits, two as a result of the supplier moving premises, four due to new contracts, one was a follow up audit and the rest were routine re-audits.

An improved supplier management process was developed and finalised during the year. Key stakeholders have now been trained and roll out of the process has commenced. The improved process uses quality risk management principles to identify the criticality of

purchased items/services, ensures there are clear specifications for critical items; and that suppliers are appropriately assessed and reviewed. This will ensure we can focus our audit resource where it is most needed in future. Full implementation and review of current quality critical suppliers using the new risk assessment tool is a significant piece of work which is being planned through 2015/16. During implementation of the new process the current supplier audit programme is being maintained.

We continue to work with the other UK Blood Services and the EBA to share supplier audit resource where possible.

As mentioned in Section 10 above, it is becoming more difficult to access sufficient qualified and experienced auditor resource to carry out the required supplier audits. This needs to be kept under close review.

13. PRODUCT RECALLS

Chart 8 shows a summary of the blood component recall numbers for the last 12 months.

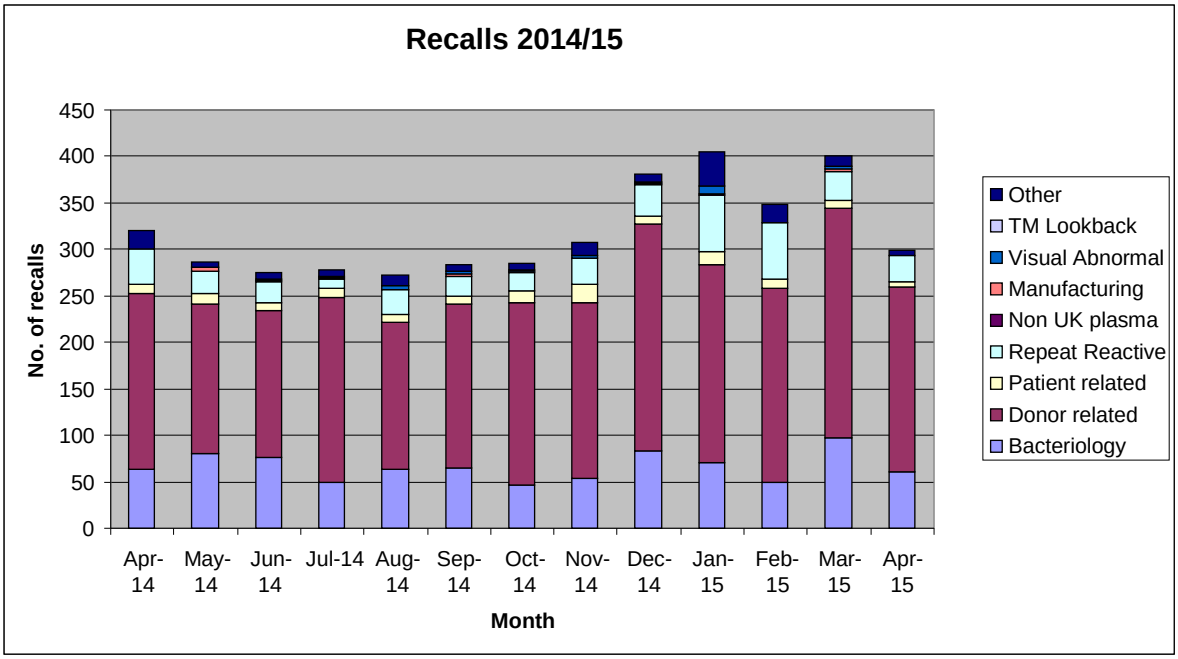

Chart 8: Recalls 2014/15

There were an increasing number of recalls through Q3, mainly due to the seasonal increase in donor related and bacteriology recalls. During Q4 there was an increase in the number of repeat reactive recalls due to false positive results caused by a faulty lot of syphilis test kits, which has now been resolved.

During the year there have been several failures to recall components within the timescales required, of these 18 were due to errors (0.05%). Most of these caused a delay in retrieving the components, but none had a direct, clinical patient impact. An analysis of these errors has prompted a rapid improvement event to relook at the process and reduce the complexity as this seems to be contributing to the error rate.

14. DOCUMENTATION MANAGEMENT

There has been a slight increase in the percentage of overdue documents from 1.8% at the end of 2013/14 to 2.0% at the end of 2014/15. The QA Document and Change Control Manager and local QA teams are continuing to review performance with individual departments. During 2015/16 a full review of the document management system is planned, looking at document design and use, better templates; and the use of photographs and training videos. This work will be lead by the Document and Change Control Manager and the review will involve users from each directorate.

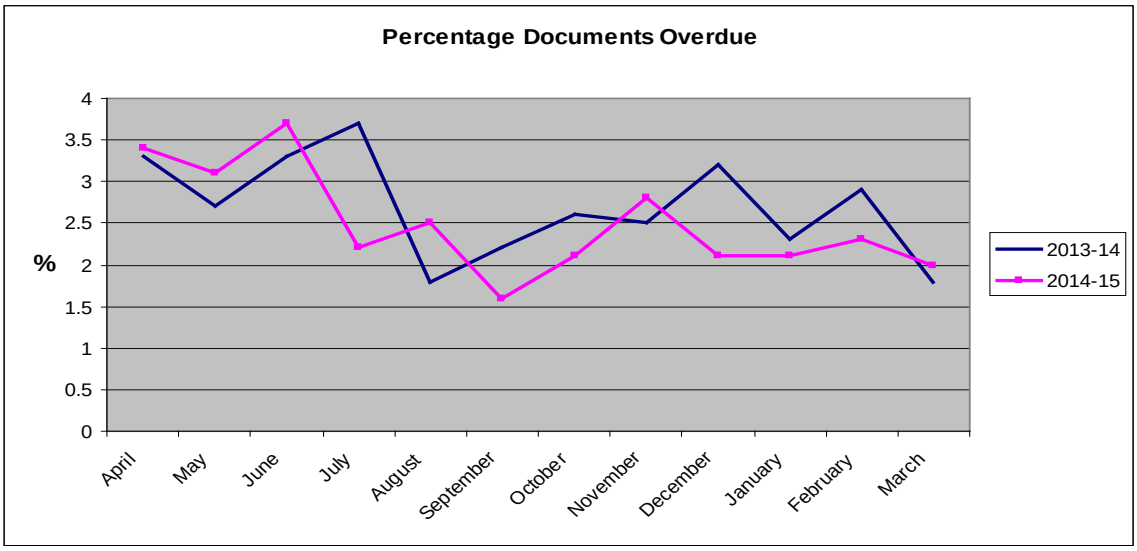

Chart 9: Overdue QMS documentation

A breakdown of performance by Directorate can be seen in Appendix 6.

15. BENCHMARKING

Data across the UK Blood Services

We continue to work with the other UK Blood Services in an attempt to identify data that can be used to benchmark performance and to improve practice.

It has been agreed that a review of benchmarking will be completed and a report taken to GAC in September 2015. This will explore the benefits being accrued from the current data and what opportunities there are for extending the benchmarking in future, including EBA and ABO data.

16. REGULATORY HORIZON SCANNING

The changes to regulations and accreditation standards shown in Appendix 8 are expected during 2015/16. The Quality team are working with relevant operational staff to ensure we are ready for the changes and that the necessary amendments are made to our QMS's to accommodate them.

16.1 Data Integrity

One key area of change will be in meeting new data integrity requirements. In January 2015 the MHRA published new guidance on data integrity expectations for the pharmaceutical industry which was set out to complement existing EU GMP standards. Requirements cover the need for both an overarching data governance system to cover relevant policies, staff training in the importance of Data Integrity and the procedural and technical controls that need to be applied to different areas of the quality system. While it is recognised that the requirements apply equally to both paper and electronic systems there is an MHRA expectation that manufacturers will meet key electronic system requirements by the end of 2017 and that failure to do so would result in non-compliance (under the EU Directives).

A review of NHSBT's current systems and processes is under way and a paper will be submitted to the Executive Team in June 2015 detailing the requirements and proposing a way forward.

Ian Bateman
NHSBT Director of Quality

May 2015