NHSBT Board Meeting
28th May 2020

Annual Management Quality Review
April 2019– March 2020

Status – Official

1. Executive Summary

1.1 This was an extremely active, but successful year for regulatory oversight, with 29 external regulatory and accreditation inspections managed effectively, ten more than last year.

1.2 There were no critical findings, but there were 5 major findings raised during inspections. There were 4 majors raised by the Medicines and Healthcare products Regulatory Agency (MHRA) and one raised by BSI during a Business Continuity audit.

1.3 A licence breach regarding unauthorised procurement of cord tissue was identified by NHSBT which was reported to the Human Tissue Authority (HTA). This was treated extremely seriously, and an action plan was put in place swiftly to address the breach. The HTA accepted that the actions implemented were robust and would prevent recurrence. As a result no further regulatory action was taken.

1.4 The COVID-19 pandemic has impacted on the timelines of some compliance activities in Q4 and this disruption is expected to continue into early 2020/2021. This included postponement of external inspections by MHRA, HTA and other bodies until further notice. We have put in place measures to address several required process variations that have arisen as a result of COVID-19 but have ensured continued regulatory compliance; and where necessary have liaised directly with regulators to seek their input and approval.

1.5 The number of overdue quality management system events improved during Q3 but deteriorated significantly during Q4, in part due to our focus on the COVID-19 pandemic. Improvement actions were agreed with the Executive Team in Q4 and will be implemented as soon as possible, however a more strategic look at what we can do to reduce the potential for future overdue issues is needed; this will be a priority for the coming year.

1.6 This year saw the successful launch of QA Direct, giving colleagues across the organisation access to a team of Quality Assurance (QA) experts that support the delivery of patient and donor safety with consistent regulatory advice, support and guidance.

Actions Requested

The Board is asked to;

- Note the regulatory performance and trends across NHSBT during the year.
- Note the plans for development and improvement activities in 2020/21.
- Comment on this report and recommend any areas for future improvement. It should be noted that this year's report includes additional trend information as agreed in response to the PWC audit of Management Quality Review performed during the year.

2. Purpose of the paper

2.1 Continued regulatory compliance is critical for NHSBT to maintain its licences and accreditations, including its Blood Establishment Authorisation (BEA), Human Tissue Authority (HTA) Licences for Tissues, Cells and Organs, Medicinal Products licences and the Care Quality Commission registrations, all of which are essential to allow us to continue to save and improve lives. This report provides an annual overview of regulatory activity, key trends, information and assurances in line with NHSBT's strategic targets for safety and compliance.

3. External Inspection Performance and External Reports

3.1 Inspection visits

There were 29 external inspections in 2019/2020, ten more than last year, see graph 1.

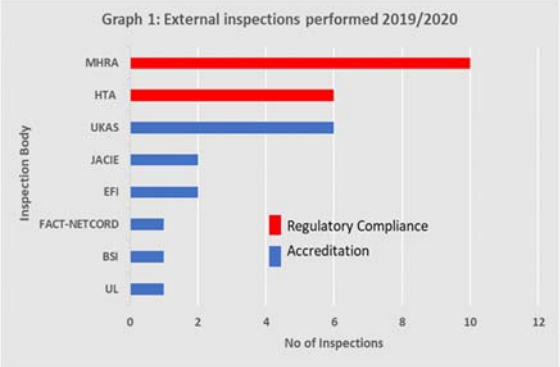
3.1.1 Inspection Outcome Summary:

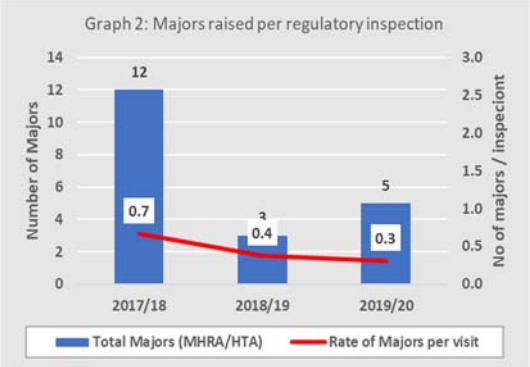
All 29 inspections were completed successfully. Five majors, 1 licence breach and various less serious others, minors and recommendations were raised.

License/Accreditation:	Visits:	Outcome:	Key findings / risks highlighted
MHRA BEA	8	3 Majors 33 Others 8 Comments	• Failure to manage out of specification irradiator dose maps (MAJ) • Investigation management insufficient (MAJ) • Data Integrity guidelines not met (MAJ)
HTA TQSR	6	1 Licence breach 12 Minor shortfalls 29 Advice & Guidance	• Cord blood tissue procured without prior authorisation by HTA (BREACH) • Single European Code (SEC) not implemented for all tissue/cell products.
MHRA IMP	2	1 Major 7 Others 2 Comments	• Investigation management insufficient (MAJ) • Cleanroom practices inadequate
BSI	1	1 Major 9 Minors 8 Improvements	• Investigation management insufficient (MAJ)
Accreditations	12	113 Findings 82 Recommendations	• No Major findings

3.1.2 Highlights:

- **No critical findings** were raised.
- Our Advanced Therapy Medicinal Products (ATMP) laboratories demonstrated **improved compliance** against our IMP licence; only one MHRA Major finding was raised compared with two Majors last year and five Majors two years ago.
- The number of MHRA/HTA Majors increased to five from three last year, however there were more inspections this year; **the rate of Majors raised per visit remained the same** and is on average less than 1 Major per inspection, see graph 2.
- Twelve accreditation visits were carried out this year; NHSBT maintained laboratory accreditation in all cases, and **assessors commented positively on three occasions on the high level of compliance.**





3.1.3 **Identified risks and actions taken**

All findings have been, or are in the process of being, addressed to the satisfaction of the relevant regulator.

Finding/risks highlighted	Risk to donor/patient safety or NHSBT	Actions taken or in progress	Measure of success
Unauthorised procurement of tissue	Potential for a condition to be placed on our licence, leading to restriction or suspension of activity.	Training for staff working under the Human Tissue Act updated to highlight regulatory responsibilities. Licence variation process and oversight improved.	No further licence breaches. Licences updated before new or changed activity takes place.
Failure to manage irradiator dose maps	Potential for patients to receive non-conforming product.	National review and update of procedures completed.	No further incidents. Management of dose maps in the QMS as quality incidents.
Poor incident investigation and management (raised at three inspections, inc BSI)	Potential for ineffective corrective and preventive actions to result in repeat incidents and hence not reduce the risk to donor/patient.	Procedures on Managing Risk and Quality Incidents updated. Holistic review of all aspects of incident management planned in 20/21.	A decrease in external findings for poor investigation and management of incidents.
Data Integrity processes inadequate	Potential for harm if unreliable is used to make a clinical decision and/or significant regulatory finding raised.	Data Integrity Steering Group established to manage implementation. Project initiated to develop an automated Data Integrity assessment tool.	Improved data integrity processes, reduced inspection findings through education to embed principles in staff.
SEC not applied on all tissue and cell products	Significant regulatory finding and potential instruction to cease moving products.	Software modifications to equipment to allow full SEC application.	HTA closed shortfall. implementation of future directives on time.

3.2 Serious Adverse Blood Reactions and Events (SABRE)

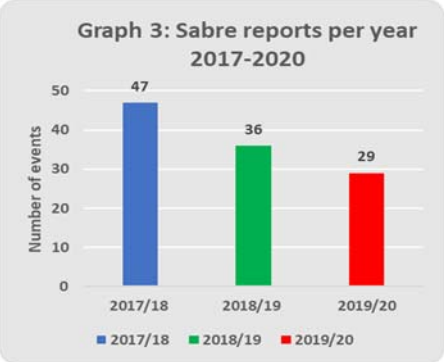
There were 29 serious adverse events reported to MHRA this year, **a decrease on previous years,** see graph 3.

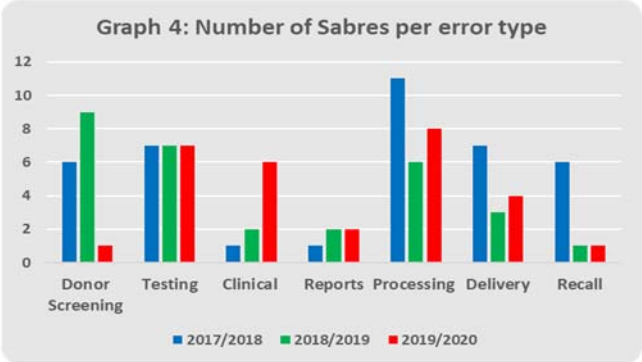
The two most common reporting reasons were processing errors (a series of one-off events, no trend) and testing errors leading to incorrect results reported to hospitals, primarily from RCI laboratories. There were no significant trends identified within RCI, however improvement work has been done to reduce overall reporting errors. There were four late delivery events in Q1/Q2 resulting in a delay to patient treatment – this has been addressed and no further incidents noted. A spike in Clinical SABRE reports was partially due to two one-off Donation Lookback events, see graph 4.

3.2.1 **Highlights:**

- **Donor screening has improved**, due to a decrease in Discretionary Testing errors of 80% over the past year. Improvement initiatives including a change to the processes in Blood Donation, consideration of human factors in data entry and focused support for teams with high error rates has resulted in this significant improvement.

- **Recall events remain very low** for the second consecutive year. Improvement initiatives have included requiring that recalls are performed only by a smaller number and more highly skilled group of authorised Hospital Services staff – this ensures these staff perform recall tasks more regularly and therefore through improved familiarity with the process, are less likely to make errors.





3.2.2 **Identified risks and actions taken**:

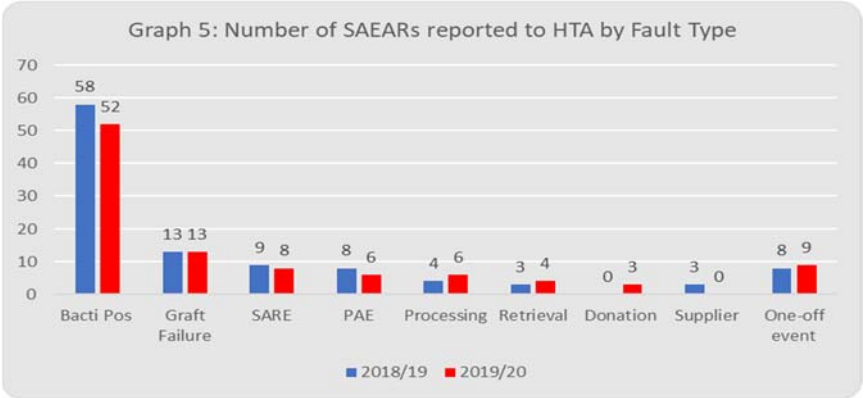
Key finding/risk	Risk to donor/patient safety or NHSBT	Actions	Measure of success
Testing errors leading to an incorrect result (primarily in RCI).	Patient safety - incorrect testing and transfusion advice can lead to the wrong product being given to a patient causing serious harm or death.	Addressed human factors issues (fatigue e.g. on shift work, lapse of concentration). Improvement events held on reporting results.	Decrease in reportable incidents.
Urgent product delivered late to hospitals on four occasions.	Potential to delay patient treatment resulting in inconvenience or harm.	Additional drivers recruited Revised training packages for courier drivers Reinforcement of the need for communication between all stakeholders.	Decrease in reportable incidents.

3.3 **Human Tissue Authority (HTA) Tissue and Cells Serious Adverse Events and Adverse Reactions (SAEARs)**

There were 101 SAEARs reports made to the HTA this year for tissue and cell products, compared with 106 last year. Numbers of events in categories were very similar to last year, see graph 5.

3.3.1 **Highlight:**

- Bacterial contamination reports excepted, the **number of SAEARs reported annually remains small** and consistent with previous years., Excluding clinical events (e.g. PAE / failed engraftment), there were only 24 events raised that were attributable to NHSBT. These are being managed, with no identifiable trends.



3.3.2 **Identified risks and actions taken**

Key finding/risk	Risk to donor/patient safety or NHSBT	Actions	Measure of success
Contamination of cornea broth (15% of bacti-pos results)	Potential for cornea to be infected causing patient harm or product to be withdrawn.	Additional training of operators with focus on aseptic technique.	Decrease in reportable incidents.

3.4 Organ Donation and Transplantation (ODT) SAEARs reported to HTA

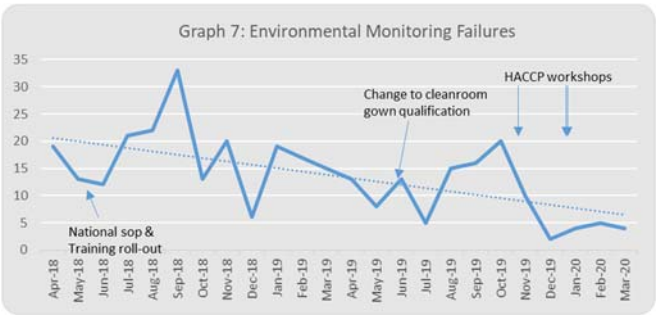
As part of its Assisted Function role, NHSBT reports all incidents submitted by transplant centres to the HTA; there were 105 events reported this year. **There were no SAEARs events** directly attributable to NHSBT activity. We continue to provide support and work with the transplant sector in order to maximise all transplant outcomes.

4.0 Quality Management System Performance Update

4.1 Critical and Major Internal Quality Events**: there were no internal events classified as Critical during 2019/20 and major events reported fell by 9%.**

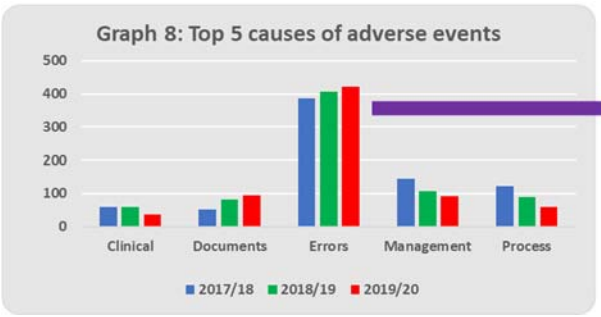
4.1.1 **Highlights:**

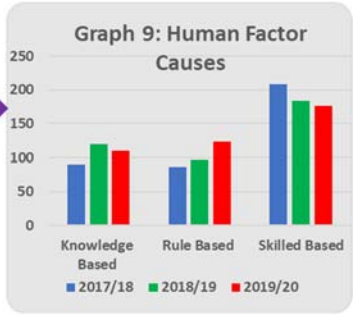
- **Arm Pain Events decreased:** Continuous Improvement activity during the past two years including introduction of an e-learning module and procedural changes have resulted in the reduced levels below, see graph 6 and 5.1.1.
- **Environmental monitoring failures in clean rooms fell by over 45%:** An enhanced training package and standardised procedure rolled out in 2018 has started to take effect. Further work looking in depth at processes at each site has been completed in the latter part of this year which aims to identify further areas of risk and put actions in place to further minimise errors, see graph 7 and 5.2.3.



4.1.2**: Common Root Cause Trends of Adverse Major Events:**

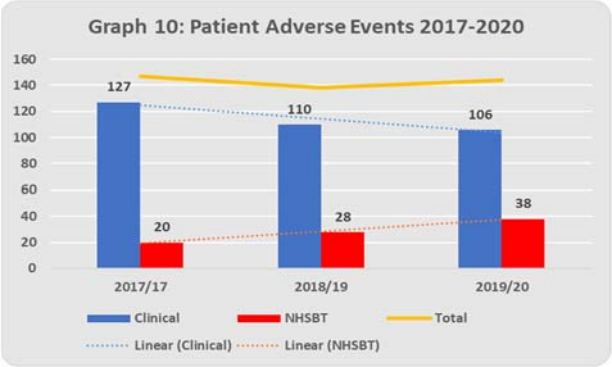
The top five root causes of adverse events have remained the same over the past three years. **Errors with a human factor cause made up 49% of identified causes** this year, with rule-based errors (failure to follow procedures) rising by 43% in two years. Initiatives to improve this rate will be investigated further in 2020/21.



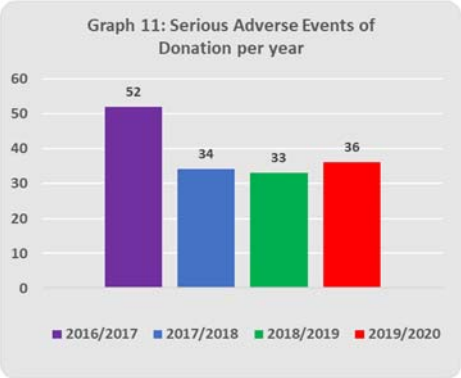


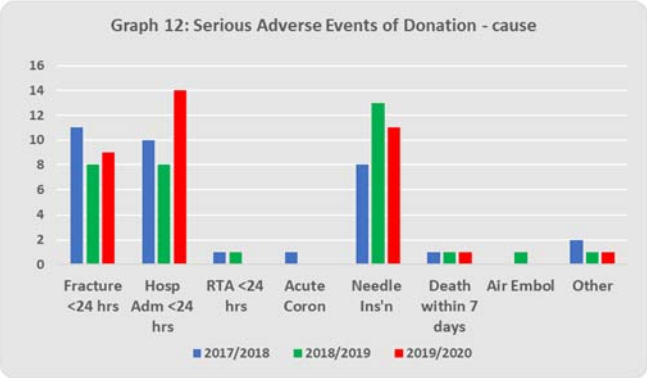
4.2 **Patient Adverse Events (PAEs)**: numbers have remained similar to previous years with 144 events reported. No significant trends have been identified among the reports

received, with the majority (74%) being reported as clinical events, however it is noted that over the past two years the number of Clinical events (non-NHSBT cause) has shown a downward trend and events (potentially) attributable to NHSBT have trended upwards at a similar rate. This will be further monitored over the coming year, see graph 10. All PAEs have been reviewed by the CARE groups and no major issues/trends noted.

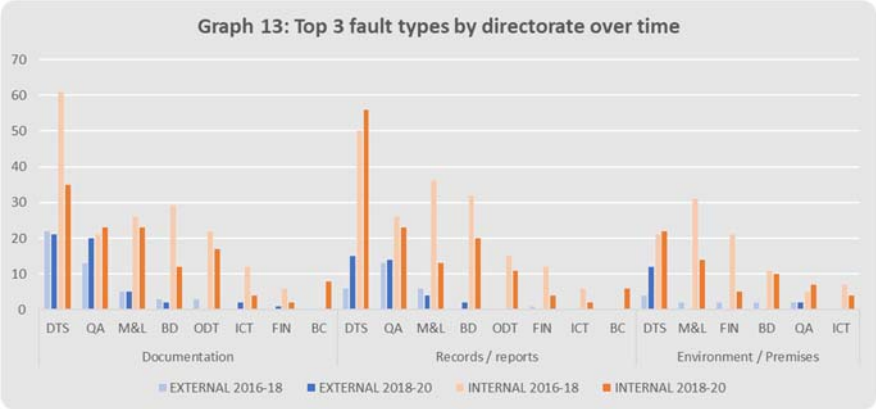


4.3 **Serious Adverse Events of Donation (SAED**): the numbers of SAEDs has remained similar over the past three years, with 36 events reported in 19/20. **Hospital admission within 24 hours of donation events rose to 14 from 8 last year and was the most frequent cause** and needle insertion issues fell very slightly, see graphs 11 and 12.





4.4 **Self-inspection:** internal audit outcomes continued to show **a strong and positive correlation between internal and external inspection findings.** This provides assurance that our self-inspection process remains effective, and we are meeting our legal obligations. Trend analysis has identified the most common fault types, see graph below. Training has previously been in the top 3 fault types but has moved down to 5th with a 54% reduction in the number of findings compared with a 20-25% reduction in other fault types. See graph below and Appendix 1 for further details on audit trending. Due to the COVID-19 pandemic and resulting restrictions, the self-inspection process has been reviewed in line with guidance from MHRA, HTA UKAS and educational resources (NSF International). In order to provide a pragmatic solution to continuing to obtain self-inspection assurance, whilst observing government advice and prioritising immediate patient safety, a 3-step process has been developed. Starting with a desktop assessment of licenses and quality system data the outcome will be used to prioritise the need for a more in-depth remote inspection which will look at easily available data provided by departments. Where necessary follow-up will be in the form of self-assessment performed locally or a delayed physical audit when conditions allow.

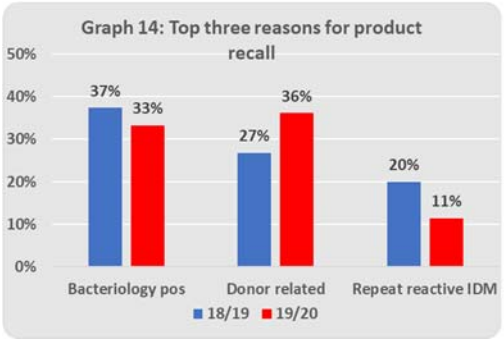


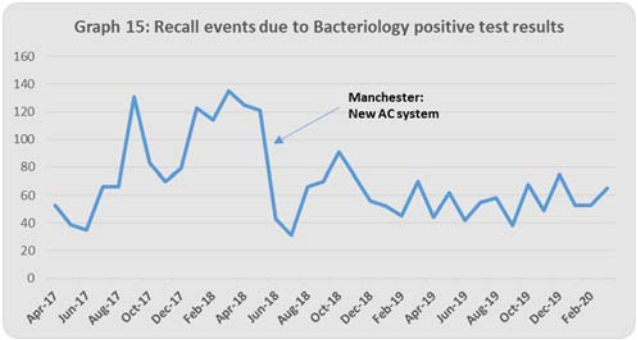
4.5 Seven **supplier audits** were completed in 2019-20; this included 2 new suppliers, 4 routine re-audits and an audit of a manufacturer (of Copper Sulphate). The latter revealed several significant findings which are subject to several corrective and preventive actions.

In response to an inspection finding by MHRA in Liverpool last year, improvements have been made to the Supplier Management Process (for Quality Critical Items and Services). A review of the process of risk assessing items/services purchased and subsequent evaluation and ongoing oversight of suppliers was completed this year. Procedures and training materials have been rewritten and the improved process is due to go live in July 2020. These improvements will provide data to enhance forward planning of the supplier audit schedule ensuring audits are prioritised based on risk. A 3-5 year supplier audit plan is being developed.

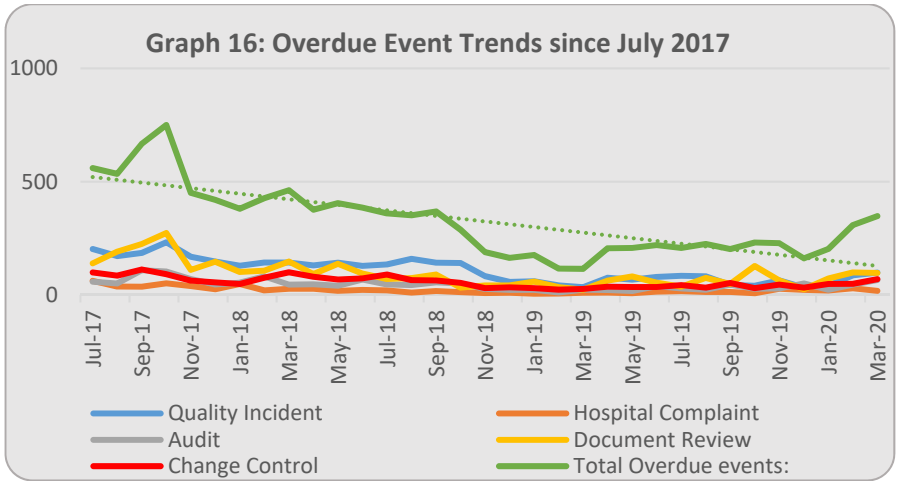
4.6 **Product recall** events fell by 12% to 1994 this year.

- There was a 9% decrease in the number of infectious disease repeat reactive donors however donor related recalls increased by 8%. Donor recalls are now the most prevalent recall cause, overtaking bacteriology positive events.
- The percentage of recalls due to bacteriology positive tests fell for the third consecutive year. A new air-conditioning system installed in the Manchester BacT testing laboratory has improved the temperature control and been the main contributor to the fall in numbers, see graphs 14 and 15.





4.7 **Overdue Event Management:** Despite consistent organisational-wide focus, this year saw **a rise in the number of overdue events at year end.** There was a within-year reduction in overdues at the end of Q3, but then an increase in Q4, partly due to the COVID-19 issues over February and March taking priority. The year finished with 348 events overdue (compared to 115 at the end of last year), see graph 16. A number of improvement actions were agreed with the Executive Team in Q4, which will be implemented as soon as possible. However, we need to take a more strategic look at what we can do to reduce the potential for future overdue issues; this will be a priority for the coming year.



5. Quality and Compliance Issues/Trends

5.1 Blood Supply:

5.1.1 Trend analysis demonstrated that donor arm pain events decreased significantly this year. All nurses have completed a new arm pain management training package and the standard operating procedure was updated to clarify needle adjustment guidelines. There is also now renewed focus and monitoring via Regional Lead Nurses who are reviewing ongoing performance regularly. A change control has been raised to implement a pilot of a new multi-stage causal investigation (RCA) process for arm pain events with the aim of streamlining the management of these events and to reduce the number overall.

5.1.2 Revisions have been made to the procedure for managing JPAC change notifications. Following several incidents where the website hosting donor selection guidelines and the geographic disease risk index has been unavailable, robust contingency arrangements have now been added to the procedure. The team managing these changes has also been expanded.

5.1.3 Trend analysis of events where consent to donate has not been recorded in writing has been performed. A GEMBA walk through the process highlighted several improvements were needed to be made in the procedure which have been successfully implemented to reduce events of this type. There is now focus and monitoring via Regional Lead Nurses who review ongoing performance regularly.

5.1.4 Continuous Improvement activity has also included the introduction of the STRIDES study (STRategies for Improving Donor Experience). This involves trials of several interventions to reduce the severity of vasovagal events (fainting), which is one of the main causes for hospital admission after blood donation.

5.2 **Diagnostic and Therapeutic Services** (now Clinical Services)**:**

5.2.1 Following the successful introduction last year of Chimeric Antigen Receptor (CAR) T cell Treatment for NHS patients, NHSBT has continued to expand its capacity to provide this product with three sites (Filton, Birmingham and Leeds) now operational. Leeds is yet to receive its first product but stands ready to commence operations once the restrictions brought in by the COVID-19 pandemic have lifted. Commissioned CAR-T work at other sites is continuing. QA has continued to support this with development of Quality Agreements and liaison with regulators.

5.2.2 Tissue and Eye Services (TES) have set-up a new Serum Eye Drops Strategy Group which will be supported by QA. This has a number of workstreams including one to work on the reclassification of serum eye drops as a blood component rather than a medicine (as is the case in some other EU member states). This will require a clear, evidenced rationale and regulator buy-in to achieve.

5.2.3 Environmental Monitoring (EM) improvement strategies - failures of EM specifications are now recorded as Major quality incidents as required by our regulators. This reflects the potential safety impact that EM failures could have on products processed in clean rooms; and the importance of thorough investigation of these events. There has been a significant focus on EM management processes, specifically to support the investigation of the events and implementation of effective CAPA. Considerable effort has gone into training and competency assessment of clean room operators and the use of Human Factors (HF) day to day check lists has been instigated. Work has been completed to standardise the procedural documents that support EM activities, clean room operations, and aseptic processing. Training and awareness sessions have been held to improve knowledge about clean room environment design and equipment, ensuring that they are fit for purpose. We have seen a significant reduction in EM failures this year as a result. QA is leading on the introduction of a Microbiology Control Strategy which will provide greater assurance in terms of regulatory performance and patient safety.

5.2.4 A project to improve Data Integrity compliance in our Clinical Biotechnology Centre has started. Initiatives include the use of updated equipment with specifications to enable enhanced compliance, improved back-up and retention of data and provision of specific passwords to allow for an audit trail attributable to individuals.

5.3 Organ Donation and Transplantation (ODT):

5.3.1 This year saw the passing of the Organ Donation (Deemed Consent) Act, (Max and Keira's Law), which requires individuals not wanting to donate to opt out of organ donation. ODT QA have provided training and support to transplant centres and liaised with the HTA to ensure compliance will continue to be maintained with the resulting changes to the HTA Code of Practice that deals with consent. The go-live date is planned in England on 20th May.

5.3.2 QA facilitated the RCA of a recent Serious Incident regarding Living Donor matching run and lessons learned with the wider stakeholder group in Q4. It was concluded that an inadequate checking process resulted in the error within a process that is paper based and reliant on manual checks. Inadequate supervision/leadership within the team also contributed to the error. Key actions arising from this included; the replacement of the failed checking process with an automated process, and at the final manual check, the introduction of an external validation step to be undertaken by Transplant Centres. A 'core group' has been formed to work through the actions identified and continue to improve the process in the absence of an electronic system, including a review of all associated procedures and forms. It was also recommended that the Living Kidney Sharing Scheme should be made electronic to reduce the risk of further errors.

5.3.3 Discussions have commenced with the HTA and Tissue and Eye Services in order to progress use of the Single European Code (SEC) on relevant ODT products.

5.3.4 A number of projects have been paused until further notice to allow staff to focus on the response to the COVID-19 pandemic, this includes the project to Increase the Number of Organs Available for Research (INOAR) and the DCD QUOD Sampling in Scotland and NI initiative, the latter requires approval of a specialist research ethics committee (planned for June 2020).

5.4 **QA Direct** was launched and became fully operational during 2019/20. Users can now request a range of QA services online via the self-service portal on Link. During Q4 QA Direct processes and procedures became embedded and feedback started to be received from stakeholders through the use of customer surveys**. Over 90% of the responses** have been positive on ease of use, customer service received and satisfaction with the resolution. In March 2020 improvements were made to a number of workflows and forms in ServiceNow in response to user feedback and to make processes more efficient. The next stage of implementation to include a further range of services was planned for Q1 2020-21, however this is likely to be delayed due to the impact of the Covid-19 pandemic.

5.5 Data Integrity Guidelines: inspection findings this year led to a conclusion that a more forensic approach is required to assess Data Integrity (DI) compliance of our quality critical systems, with well documented risk-based actions to address identified gaps. A refreshed DI improvement plan has been developed and a DI Steering Group convened to deliver this. Due to the scope of their activities there is greater scrutiny of Clinical Services (CS) DI compliance by the MHRA during inspections, which has identified recent gaps. There is therefore an urgent need to improve DI compliance within CS departments and so improvement initiatives will therefore be developed and piloted with CS. A CS Working Group is being formed, with representation from all CS departments to lead on actions. The lead of this working group will be a member of the DI Steering Group to ensure improvement initiatives are aligned and successes shared. Once the CS Working Group is established and shown to deliver improvements, similar working groups will be created in other business areas to drive DI compliance more broadly.

6. Continuous Improvement Plans for 2020-2021

A number of quality management system/regulatory compliance aspects were identified as priorities for improvement in the coming year:

- There is an urgent need to improve compliance to Data Integrity regulations, particularly in the Clinical Services areas.
- End-of-year overdue event figures finished considerably higher than last year. Regulatory focus for the coming year will need to include further consideration of new strategies to improve and then sustain performance to acceptable levels.
- Root cause analyses of major adverse events indicated that a significant majority of incidents were caused by human factors, particularly by failure to follow procedures. The use of continuous improvement and more work on human factors focussed in this area is needed.
- The management and/or recording of incidents, associated risk assessments and resulting actions were found to be lacking on several occasions during external inspections and through PwC audit. A full review of our management of incidents is planned this year to ensure we improve this critical area of regulatory compliance.
- We will continue to work with ICT to improve our software assurance processes and ensure effective software development and testing systems are in place.
- Review and re-engineer NHSBT's task based training process and recording of competency.
- Refine and improve parts of the Quality Management System including NHSBT's processes for Supplier Management (for Quality Critical Items and Services), and Document Control.
- We will be tendering for a new electronic quality management system. The specification aims to provide a common incident management system for quality and health and safety. The current Q-Pulse contract has 2 additional, optional years which will take us to the end of October 2022 aligning with the Datix contract which also ends in 2022.

7. Key upcoming regulatory changes

7.1 Medical Devices Regulations - The Quality Directorate commenced a major project this year to prepare the organisation for significant changes to the EU Medical Device Regulations (MDR), which had been due to take effect in May 2020. This legislation will impact significantly on routine diagnostic operations and substantial work is required to meet the new requirements. Implementation has been postponed for 12 months by the EU to May 2021 due to the COVID 19 pandemic, however work on the project will continue this year albeit at a reduced level. Implementation of the associated In Vitro Diagnostic Regulation implementation remains on course for May 2022.

7.2 EU Exit – we are continuing to prepare for leaving the EU following the Transition period at the end of December 2020. We modified our BEA last year to allow for blood component (e.g. plasma) movement from Europe to our manufacturing sites post EU-exit; this year two changes were made to ensure our RCI Reagents Laboratory, which provides blood grouping reagents within the UK and to the Republic of Ireland, can continue to send product to Europe post-EU Exit. NHSBT is now certified by the Polish Notified body, Polskie Centrum Badan I Certyfikacji S.A., 'PCBC' to allow us to continue to manufacture and supply CE marked diagnostic reagents post EU Exit; and further, a contract has been established with QFI (Quality First International) for them to act as NHSBT's EU Authorised Representative after EU Exit. Tissue and Cell licences will have 6 months to be updated following finalisation of agreed changes as a result of leaving the EU – we continue to remain in communication with the HTA on this issue.

7.3 Review of the EU Blood and EU Tissues and Cells Directives: the report on this EU-commissioned review was released in October 2019. This report concluded that both Directives, from which the UK regulations are derived, had increased the quality and safety of blood, tissue and cell products within the EU. However, it also highlighted significant shortfalls with the legislation, most notably that the Directives had not kept pace with innovation, disease epidemiology and changing technologies and further, that the provisions for donor protection were insufficient. The EC will now use the data from this review as a guide to potentially refine and update the Directives. NHSBT continues to monitor this evolving situation.

8. Benchmarking

During 2019/2020 QA continued with membership of the Alliance of Blood Operators (ABO) Benchmarking Group. A further deep dive into Quality Performance Metrics has been supported with the final report now approved for publication. The report has suggested 3 metrics for ongoing data collection with all ABO group members: product recalls, product related complaints, and fill rate.

The report also recommends the formation of a "community of practice" to review and discuss such issues as quality improvement initiatives, customer education and other potential collaborative opportunities, e.g. supplier audits. NHSBT membership of this community will include the Assistant Director of Quality and Regulatory Compliance and Quality Systems Audit Manager.

9. Conclusions

This was a successful and busy regulatory year for NHSBT. The organisation has continued to meet its regulatory responsibilities across all of our operations and kept external non-conformances at a relatively low level.

Quality and regulatory activity related to COVID-19 has been demanding and will continue for some time to come. QA will continue to ensure that the Operational Directorates are supported to maintain regulatory compliance in the most flexible and efficient way possible. We will ensure that we are able to continue critical activities, to ensure donor and patient safety and to mitigate any regulatory compliance risks.

We will be refreshing our Quality Strategy this year and taking the opportunity to outline our vision for the future and the transformations we wish to make to our Quality Systems and how they can add value to the organisation and improve our regulatory performance even further.

NED Scrutiny N/A

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Appendix 1: Internal Audit Process Review Report

Background

The purpose of the Self Inspection system is to provide assurance that regulation and accreditation standards are being met.

The report includes 4 years of data from April 2016-March 2020, over which we have had 2 regulatory inspection cycles. Over this period there were changes to both external and internal audits which explains the decrease in internal findings in some areas and increase in external findings in the period 2016 -17. The main changes were a decrease in frequency of self inspection against some standards on the basis of risk and UKAS took over inspections from CPA.

The report comprises two sections;

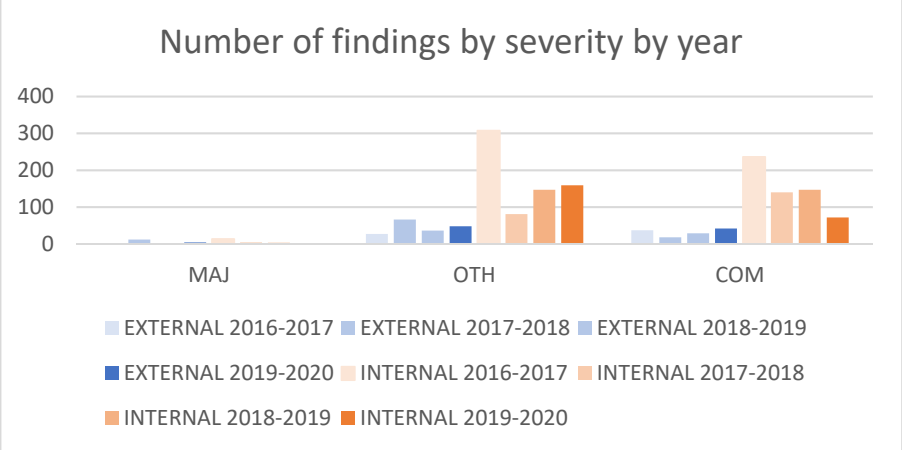
1. Regulatory inspections by Medicines and Healthcare Regulatory Agency (MHRA) and the Human Tissue Authority (HTA).
2. Accreditation audits
    - United Kingdom Accreditation Service (UKAS) for ISO15189
    - Underwriters laboratory for ISO13485
    - European Federation of Immunogenetics (EFI)
    - Joint Accreditation Committee ISCT-Europe & EBM (JACIE)
    - Foundation for Accreditation of Cellular Therapy (FACT)
    - World Marrow Donor Association (WMDA)

Headline: Internal and external findings show good correlation which demonstrates that our self inspections are effective.

Section 1: Regulatory inspections

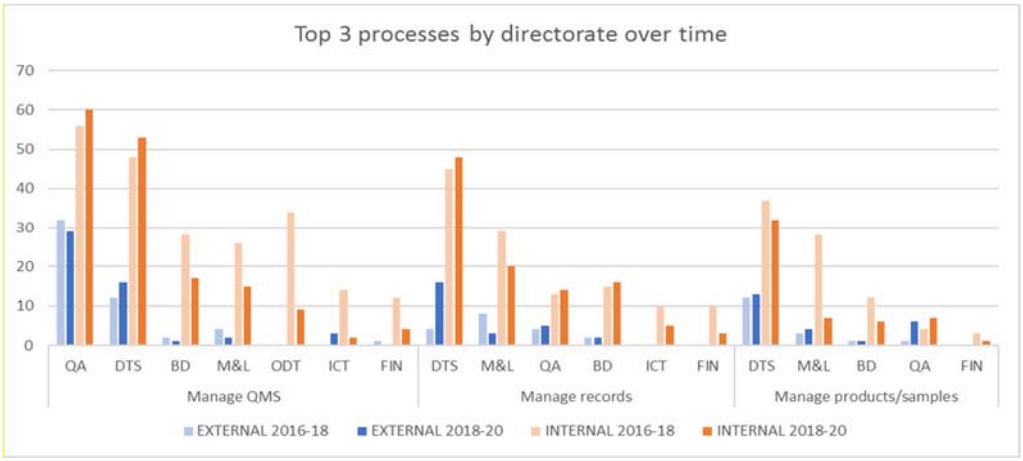
We have identified more findings internally over 4 years (2 audit cycles) than were found by external inspections.

This is to be expected and is consistent with self-inspection being more focused and identifying improvement opportunities which are raised as either deficiencies or comments. Importantly there is good correlation in the Major category where regulatory risk is higher. This is again good assurance that our internal inspection system if effective.

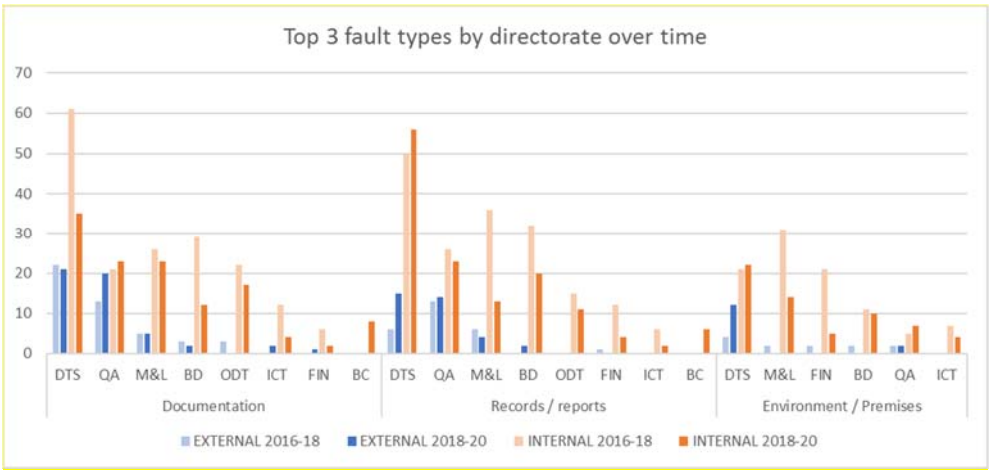


Internal and external findings show a similar profile across both processes and fault type (all audit findings are recorded against the process they impact and the kind of error that has led to the finding), again with more findings in internal inspections.

The highest number of audit findings are detected in processes that are common across all areas of the business and are audited in every department at every site.



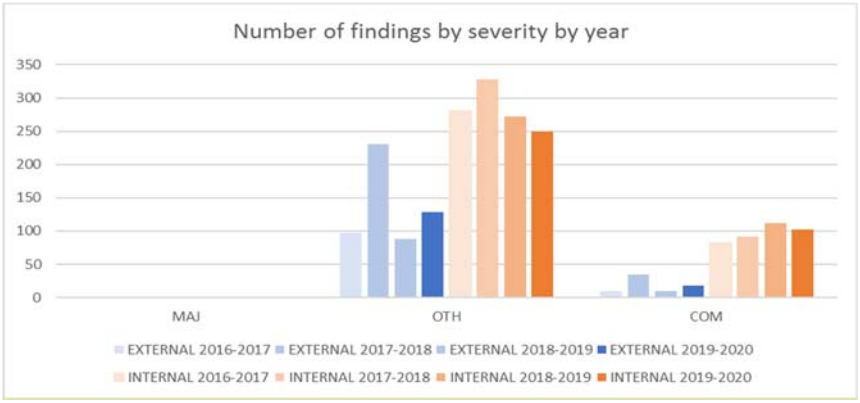
The most prevalent fault types are outlined below and are detected across all areas of the business. Training has previously been in the top 3 fault types but has moved down to 5th with a 54% reduction in the number of findings compared with a 20-25% reduction in other fault types.



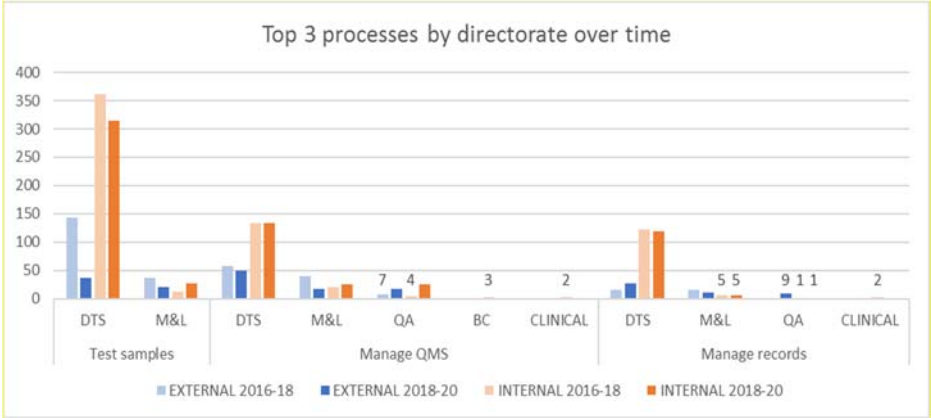
Section 2: Accreditation audits

We have again identified more findings internally over the audit cycle than were found by external inspections.

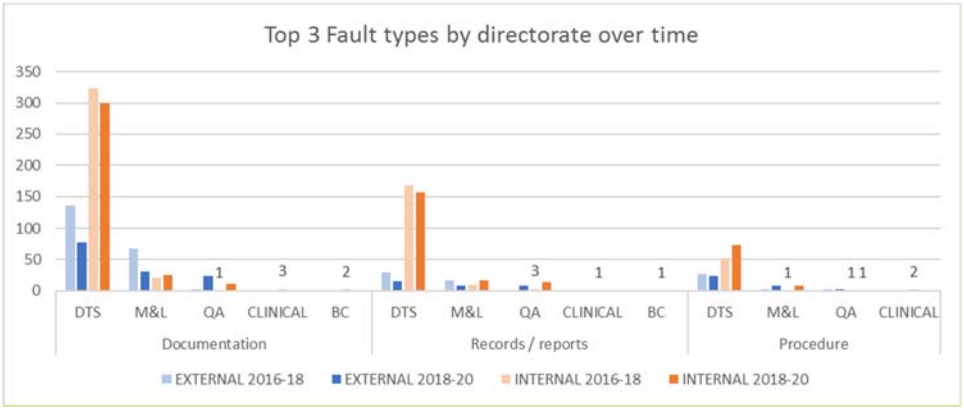
This is to be expected and is consistent with self-inspection being more focused and identifying improvement opportunities which are raised as either deficiencies or comments. This is again good assurance that our internal inspection system if effective.



Internal and external findings show a similar profile across both processes and fault type (all audit findings are recorded against the process they impact and the kind of error that has led to the finding).



The most prevalent fault types are outlined below and are detected across all areas of the business.



Conclusion

NHSBT is legally required to comply with the Blood Safety and Quality Regulations (BSQR), Tissue Quality and Safety Regulations (TQSR) and Organ Quality and Safety Regulations (OQSR). To comply with these regulations, we must have a Quality Management System (QMS), a key part of which is the self-inspection process. This report shows strong correlation between internal and external inspection findings, as expected, which provides assurance that our self-inspection process is effective, and we are meeting our legal obligations.

Self-inspection provides a continual source of information for continuous improvement to take place, with the aspiration to reduce repeat events. The top three fault types are the same for external and internal findings because they are common across all areas of the business and are audited in every department at every site.

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