MANAGEMENT QUALITY REVIEW: Annual 2022/23

Headlines for the year, and any key risks and issues for attention

External inspection performance has been very good throughout this year, with no Major or Critical findings raised from any MHRA or HTA inspections. 2022-23 was the first time that NHSBT has had a well-led inspection from the CQC and there were 'Must' actions which were internally recorded as 'Majors'. Preparation for inspections and accreditation visits should remain a key priority, as the organisation should expect more inspections in 2023-2024.

The volume of SABREs and SAEAR reported events decreased compared to the previous year. The SABRE target (for no more than five reports to be submitted in any month) was achieved in all months, and actions introduced last year to address issues with the completion of Donor Safety Check (DSC) forms appear to have been effective. It is important that data provided by QA at SMT meetings continues to be reviewed by the relevant teams to look for trends and any actions needed for improvement.

The volume of serious incidents (SIs) and Serious Adverse Events of Donation (SAEDs) also decreased this year.

Recall events have increased overall for this year, with the biggest increase in repeat reactive recalls. A problem was identified with HTLV assays and action was taken to replace the affected equipment. Whilst still high, the volume of repeat reactive recalls fell during Q4, suggesting that the issue may have been resolved, although this will need to be monitored into the coming year.

Overdue events has continued to be an issue throughout 2022-23, with two of the three corporate overdues KPIs being missed at the end of the year. A working group has been formed within the Quality directorate and is looking at the overall incident management process, and we are confident that improvements made will support better oversight of risks within the QMS. Whilst reducing our overdue events remains a priority, the focus is shifting towards better and more sustainable management of incidents and the associated risks. It is vital that support for this work continues.

Performance against the Quality Self inspection audit schedule has been a challenge this year, and the target (for no more than 25% of the audits scheduled within the previous three months to be overdue by more than a month) was only met in five months. Risks are being mitigated by continuous Quality oversight, and the situation is under review by the Quality directorate, with actions due to be implemented in Q1 2023-24.

MANAGEMENT QUALITY REVIEW: Annual 2022/23

Overdue events

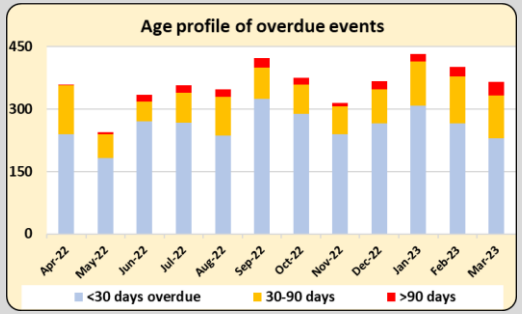
Note: the overdues data is a snapshot taken on the first calendar day of each month. Please bear in mind that the figures change daily, and can go down as well as up.

Year end overdues 2022/23
(last year: 335)

365 ↑

The volume of overdue events continues to fluctuate.

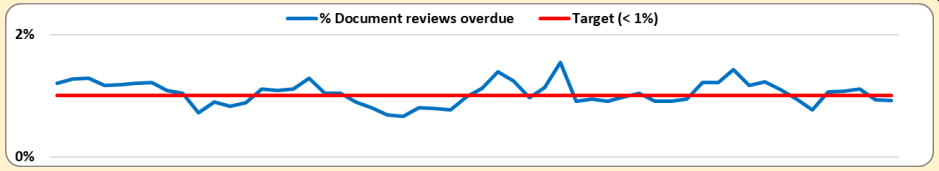
During this year an increase has been seen in the proportion of overdue events which were more than 90 days past their target dates, which has risen from 0.3% in April 2022 (1 event overdue by more than 90 days) to 8.8% of the overdues at the end of March 2023 (32 events).



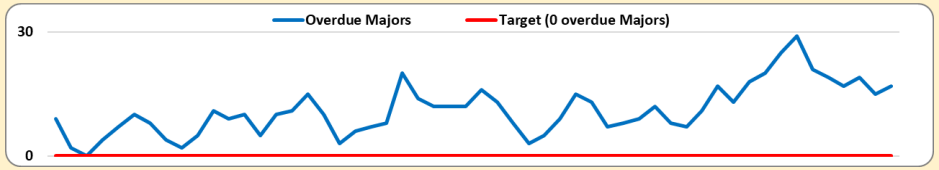
Performance against the three overdues KPIs

This year ends with only one of the three KPIs being met. The graphs below show performance at every Monday throughout the 2022-23 year.

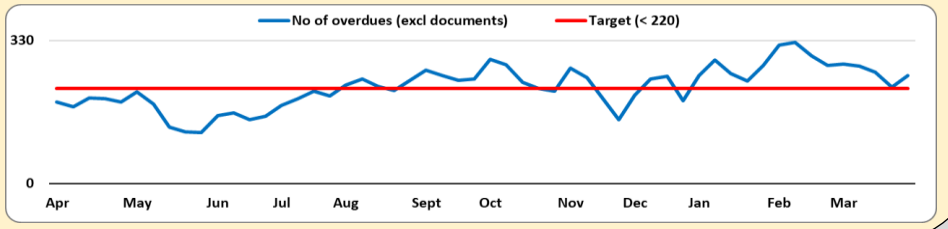
KPI 1
Target: < 1% documents with an overdue review



KPI 2
Target: Zero overdue Majors



KPI 3
Target: < 220 overdue QIs, HCs, Audit findings, and Change Controls



Actions being taken by the QA Incident Management Working Group

During 2022 it was identified that target dates were routinely being extended to prevent incidents becoming overdue. Whilst this was reducing the number of events classed as being 'overdue', it was making it more difficult to see a true picture of incident management and to monitor the level of risk in the QMS.

A working group was formed during 2022 to evaluate the complete incident management process, taking into account upcoming regulatory requirements such as PSIRF and specific processes within the OTDT directorates and other business areas. It is anticipated that over the coming year this will also improve the quality of the QMS data and aid better oversight of QMS performance.

Actions taken so far include:

- The criteria for applying extensions to events has been strengthened to ensure that a risk assessment is always carried out before targets are changed.
- A review was completed in Q4 2022-23 of all open Major incidents that were more than a year old. Each case was assessed and a decision taken on whether it was possible to close the event, or if not a justification for non-closure was documented.

The next phase, to commence during Q1 2023-24, will focus on Major QIs that are more than 6 months old.

Talks are also currently being held with external training providers to enhance the Quality directorate's ability to make risk-based decisions, with a particular initial focus on incident management. The ultimate goal is to improve the level of support offered to other departments within the organisation.

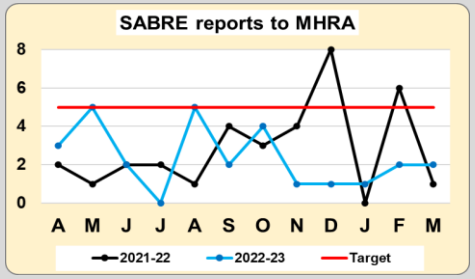
MANAGEMENT QUALITY REVIEW: Annual 2022/23

Serious Adverse Blood Reactions and Events (SABRE)

MHRA reported incidents

Total SABREs 2022/23
(Target </= 5/month: equivalent to 60/year)
(Last year: 34)

28



The total number of SABRE events reported to the MHRA decreased compared to the previous year.

Furthermore, the target (for no more than five reports to be submitted per month) was met in all months.

Update on SABREs relating to Donor Safety Check forms (DSCs)

During the second half of the previous year (2021-22) there were a number of SABRE incidents that noted issues with completion of the DSC form. A lookback exercise was carried out and actions put in place to address the issue.

Actions include that all DSCs are checked twice (on session and by donor records) and any errors/ omissions are reviewed. It is understood that a reduction has been seen in the number found to be incomplete, but also in the volume that were not identified until after the donation had already been issued, thereby reducing the risk to recipients, and the need for SABRE reporting.

The review of the DSC form was delayed, but this has been re-initiated and is anticipated to be ready for implementation by March 2024.

Staffing was identified as a cause/ contributing factor in several of the incidents, including where the number and/or skill mix of staff on shift was not sufficient to manage the workload.

"*Senior staff not available due to their requirement during the week to cover long term sick and annual leave. Operator confirmed the shift was busier on the day than normal.*"

Serious Adverse Events and Adverse Reactions (SAEAR)

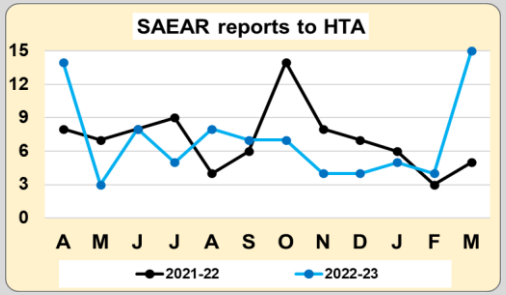
HTA reported incidents

Total SAEARs 2022/23
(last year: 85)

84

The number of SAEAR reports has stayed fairly steady across this year, with between four and eight reports per month, in all except two months.

The majority (64%) of the reported incidents occurred in Clinical Services, a quarter were in OTDT-TES, and 10% in OTDT-ODT.



In addition to the above, 65 SAEARs were also reported by NHSBT on behalf of the transplant sector, under the Assisted Function role.

"*The patient clinician has also indicated that they did not suspect any issue with the tissue itself and stated that they believe the patient may have had underlying issue that led to the tissue not engrafting..*"

A number of the SAEAR incidents reported this year were categorised as 'Primary/ secondary graft failure' or 'failed engraftment'. Incidents included both stem cell and cornea transplants.

In several cases the resulting investigation found no NHSBT fault, and some noted external factors which may have contributed to the graft failure.

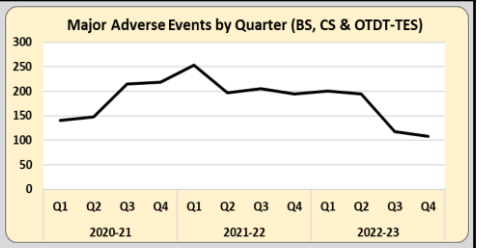
Other themes which have been seen this year include:

- Issues relating to packaging, such as bags of cells/ tissues leaking;
- Staffing; including training, or where staffing pressures led to processes being rushed;
- Procedure documentation that did not include specific instructions

"*a number of operators had been trained to the incorrect gowning MPD. … outer packaging of double bagged and sterile pots is removed outside of the clean room and staff do not wear hair coverings at this point, providing a possible route for the hair to have been introduced ... and there could be several uncapped bottles being worked on at one time, increasing the likelihood*"

MANAGEMENT QUALITY REVIEW: Annual 2022/23

Quality Management System Performance



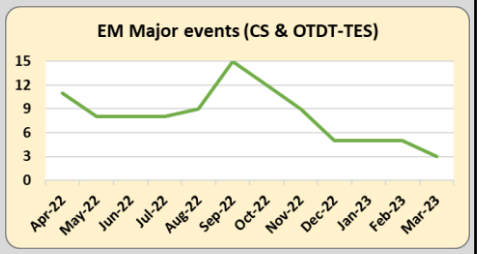
Overall, there were fewer Major events logged by the three largest directorates (Blood Supply, Clinical Services and OTDT-TES) than the previous year (620, reduced from 849).
One of the biggest changes was in Blood Donation, where a review of the types of incidents classed as 'mandatory majors' led to a significant reduction during Q3 in the volume of Major Quality Incidents raised.

Serious Incidents (SIs) — 5 ⬇

- April: 1 – Donated organs offered to non-compatible patients.
- August: 1 – Patient developed an infection and the cornea had to be replaced.
- September: 1 – Donated organs offered to non-compatible patients.
- November: 1 – Patient developed line sepsis following a Plasma exchange.
- December: 1 – Intermittent false negative results for FFP titre levels.

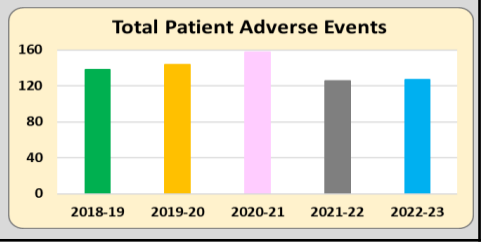
Environmental Monitoring (EM) Majors

EM Majors increased over the summer. The cause of the rise is unclear, however it coincided with contamination issues at the Birmingham ATU. Volumes fell towards the end of the year, which may be related to several cleanrooms being out of action.



Patient Adverse Events (PAEs)

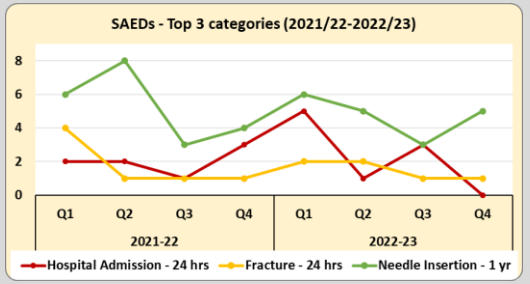
Overall there was no significant change in total number of Patient Adverse Events (PAEs) recorded during this year (127, compared to 126 recorded the previous year).



Serious Adverse Events of Donation (SAED)

Total SAEDs 2022/23 (last year: 42) — 39 ⬇

Overall for the year SAEDs decreased compared to the previous year.
It is important to bear in mind with SAEDs that events are recorded when NHSBT are notified, which may not be during the same quarter (or even year) that the donation was made.



Problems relating to Needle Insertion persisting more than 1 year — 19 ⬇

- Needle insertion events continue to be consistently the top category across all four quarters. However, by definition the events under this category must relate to donations made more than a year prior to the SAED being recorded, and in one case it is noted that the donation was made as far back as 2015.
- Individual incidents are investigated and in many instances no specific NHSBT fault has been identified. Post donation care advice is given routinely.
- Action is ongoing to reduce numbers of SAEDs due to arm pain, including discussions at session management face-to-face days and CARE meetings, and inclusion in training on Brightspace.

Hospital Admission within 24 hours & Fracture within 24 hours

- Both hospital admission and fracture events categories included incidents where the donor fainted. How individual events are categorised is likely to be affected by the surrounding environment (e.g. what surface the donor fell on, or the behaviour of other people in calling for an ambulance).
- However, the hospital admission category captures any hospital admission within 24 hours of donation, regardless of the cause, and therefore includes some cases which the investigation has deemed unlikely to have been caused by donating.

"donor had been admitted to hospital with 'twisted ovaries'"

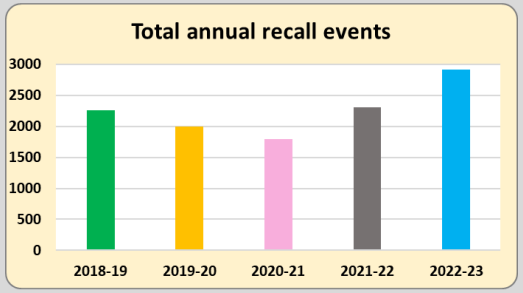
MANAGEMENT QUALITY REVIEW: Annual 2022/23

Recalls

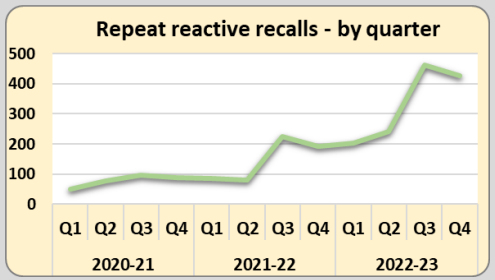
Total Recalls 2022/23
(last year: 2309)
2921 ↑

The overall number of recalls increased by 27% compared to the previous year.

The top reasons for recalls remained the same as in each of the last three years: repeat reactive recalls, donor related recalls, and bacteriology recalls.



Repeat reactive recalls (46% of recalls in 2022/23)



For the first time, repeat reactive recalls made up the highest proportion.

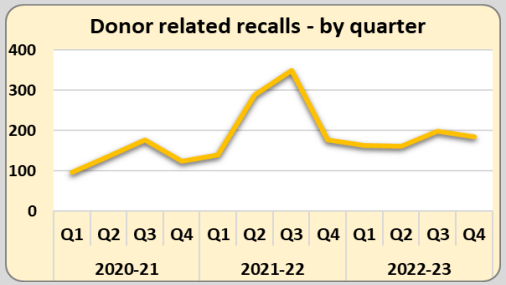
A problem was identified around the middle of the year with HTLV assays, which may have led to more donations being recalled than was needed.

The affected equipment was replaced, and fewer repeat reactive recalls were seen during Q4.

Donor related recalls (24% of recalls in 2022/23)

The second most common recall category, donor related recalls, fell by 26% compared to the previous year.

This category had been affected by the Covid pandemic, with donors making contact post-donation with a positive Covid result. The recall criteria was changed towards the end of last year, which led to a drop in recalls in Q4 2021-22, and levels have remained lower throughout this year, suggesting that the action taken was effective.



Regulatory update – Eudralex and ISO15189

Eudralex Vol. 4 GMP Annex 1 (Manufacture of Sterile Medicinal Products)

The long-awaited revision of Annex 1 was published in August 2022. The new Good Manufacturing Guidelines for the manufacture of sterile products has expanded significantly from 16 pages to a 50-page document. Quality Risk Management principles are embedded throughout the guidelines and there is a new requirement for a comprehensive Contamination Control Strategy (CCS). NHSBT took a proactive approach and sites affected by this change commenced assessment and implementation of their site-specific CCS in 2020. The organisation is on track to meet the August 2023 deadline

ISO15189:2022 Medical laboratories - Requirements for quality and competence

A revised version of ISO15189 was released in December 2022. This standard applies to medical laboratories, which includes RCI, MSL, H&I and IBGRL NHSBT activities. The revised version includes a significant reformatting to align with the parent standards ISO17025:2017 (General requirements for the competence of testing and calibration laboratories) and ISO9001:2015 (Quality Management Systems) and a focus on understanding clinical risk and how it impacts the patient. The revised version of the standard is less prescriptive, which may present a challenge in how the standard is interpreted. However, the intention is to encourage laboratories to consider, justify and document their chosen processes and procedures.

NHSBT ISO15189 accredited laboratories have commenced gap analyses of the new standard against their current practices and will implement changes as required. Inspection and accreditation against the new standard will begin in 2024.

MANAGEMENT QUALITY REVIEW: Annual 2022/23

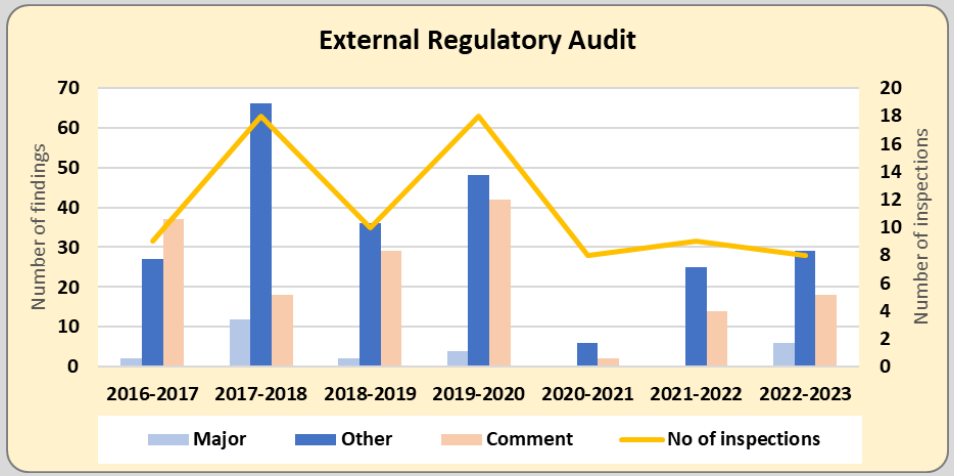
External Inspection Performance

External Majors
(Target = 0)
(Last year: 0)
6

There were no CRITICAL findings raised during 2022-23, and no MHRA or HTA Major findings.

Overall there have been good results in all the inspections with low numbers of findings. There are still a number of regulatory inspections that are beyond their due date as a result of the Covid-19 pandemic so we may see a higher than usual number of inspections in the next year.

Licence /Accreditation	Inspections	Outcome
MHRA BEA/WDA(H)	2 inspections (Plymouth; Cambridge)	5 others 1 comment
MHRA IMP	1 inspection (CBC Langford & new build at Filton)	4 Others 1 Comment
HTA TQSR	4 inspections (ODT; Barnsley; Filton; Liverpool)	3 Minors 16 Areas of advice & guidance
CQC	1 inspection (Well led & focused inspections of Birmingham, Bristol, Gloucester, Oxford & Plymouth blood donation centres, and Oxford & Bristol TAS units)	Provider-level: 6 Must actions & 7 Should actions Blood donation centres: 5 Should actions TAS units: 5 Should actions
Accreditations	5 inspections 1 UKAS: H&I (various sites); IBGRL 2 EFI: Barnsley; Newcastle 1 Underwriters Laboratory (Liverpool Reagents) 1 BSI: Cambridge/ Tooting/ Colindale	63 Non-conformances 24 Areas of advice & guidance



Major findings

The six Major regulatory findings recorded in 2022-23 relate to 'must actions' from the CQC well-led inspection. This year was the first time that NHSBT has had a specific well-led CQC inspection, and therefore the scope included areas that had never been inspected previously.

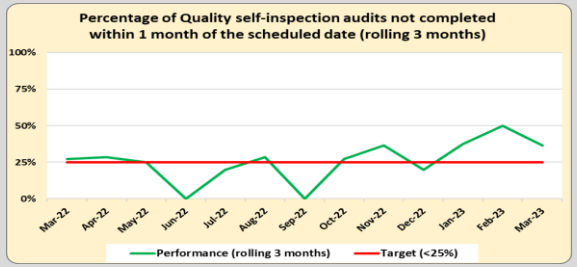
It is important to note that the CQC do not use the term 'Major' in their reports, however a decision was taken internally to record the 'must' actions as 'major non-conformances' to enable them to be tracked and reported in a standardised way.

MANAGEMENT QUALITY REVIEW: Annual 2022/23

Internal Quality Audit and supplier management

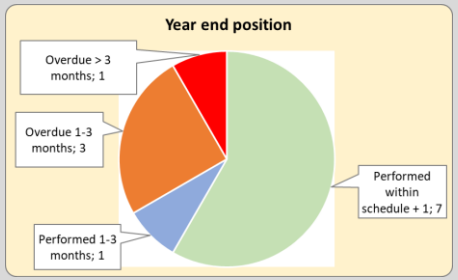
Audits completed to schedule Year end position (target: </= 25%)

36% ✗



The target for no more than 25% of the Quality Self-Inspection audits scheduled within the previous three months to be overdue by more than a month, was met in five months this year.

The year ends with 36% of the self-inspections that were scheduled within the previous three months having not been completed within one month of their scheduled date. In addition, there was one self-inspection that was overdue by more than three months.
Work is underway within the Quality directorate to initiate actions that will improve the position for the coming year.



Example internal quality self inspection audit finding:
"*The recording and tracking of actions arising from MQR reviews was unclear. … overall trend identification and any subsequent actions were not clearly captured.*"

Example regulator inspection finding:
"*Management review procedures were deficient in that: Ongoing issues … were not always fully discussed and preventive actions raised.*"

Analysis of findings continues to show strong and positive correlation between themes from internal quality self-inspection audits and external regulatory inspections.

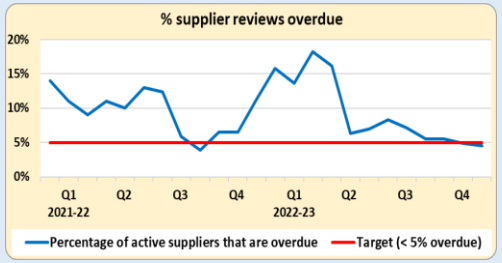
This provides good assurance that our internal quality self inspection audit program process remains relevant, and has an important role in helping us to stay compliant with regulations.

However, this makes it especially important that any actions taken in response to internal quality audit findings are thorough and effective in addressing the issues and their causes, in order to prevent more serious, repeat findings being raised by our regulators.

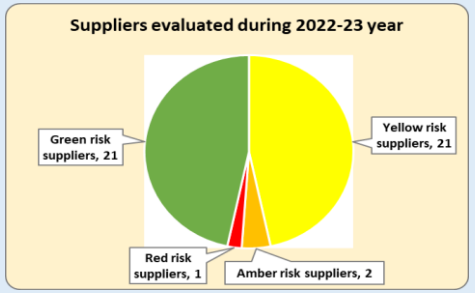
Supplier Management

Completion of supplier reviews on time has continued to be a challenge throughout this year.

Whilst the target, for fewer than 5% of active suppliers to be overdue, was missed in most months, there was clear improvement towards the end of this year, and the target was achieved in each of the final two months.



Furthermore, during Q3 QA-Direct were trained to carry out reviews on low risk 'green' suppliers, which has resulted in there being no overdue green suppliers for the last five months of the year.



In total 45 suppliers were evaluated during 2022-23; 22 by certification, 19 by questionnaire and 4 by audit.

At the end of the 2022-23 year there are 10 suppliers being managed as "conditional"; this reflects that risks have been identified and additional checks or actions are in place to mitigate the risk.

MANAGEMENT QUALITY REVIEW: **Annual 2022/23**

Quality plan & action points for the next year	
Blood Supply	• Continue to prepare for regulatory inspections. • Review Quality data that is presented at monthly SMT meetings, and take actions as appropriate. • Raise incidents in a timely manner, and manage CAPA actions to support effective closure of QMS events. • Continue to monitor regulator reported incidents, and take actions to address any identified trends. • Complete the review of the DSC form. • Monitor the volume of repeat reactive recalls, and take appropriate action as necessary if numbers remain high or increase further.
Clinical Services	• Continue to prepare for regulatory inspections. • Review Quality data that is presented at monthly SMT meetings, and take actions as appropriate. • Raise incidents in a timely manner, and manage CAPA actions to support effective closure of QMS events. • Continue to monitor regulator reported incidents, and take actions to address any identified trends.
OTDT-TES	• Continue to prepare for regulatory inspections. • Review Quality data that is presented at monthly SMT meetings, and take actions as appropriate. • Raise incidents in a timely manner, and manage CAPA actions to support effective closure of QMS events. • Continue to monitor regulator reported incidents, and take actions to address any identified trends.
Quality	• Continue to prepare for, and assist with, regulatory inspections. • Take action to support completion of the Quality self-inspection audit and supplier management schedules. • Improve the use of QMS data, with more focus on monitoring performance and identifying emerging risks. • Support the effective management and closure of QMS incidents. • Continue to support the work of the QMS Champions to reduce the volume of overdue events in the QMS. • Lead Quality Specialists will work with the Directorates to make the Quality Plan objectives SMART and relatable to the actions indicated by the MQR. • Review ways to incorporate Risk and Business Continuity into the MQR / Quality Plan
Other directorates	• Continue to prepare for regulatory inspections. • Monitor QMS performance, and take actions as appropriate. • Raise incidents in a timely manner, and work with Quality to manage CAPA actions to support effective closure of QMS events.

MANAGEMENT QUALITY REVIEW: Annual 2022/23

Background for Governance

MPD76 describes NHSBT's approach to Management Review of Quality, and how we perform regular, periodic and rolling quality reviews. This supports licensing, accreditation and Quality Improvement activities. A review of the associated datasheet 'DAT455' 'Quality Review' has been completed to ensure this report contains the information needed for the NHSBT Executive Team (ET).

ODT incidents are reported and managed via the ODT Incident Management system and are therefore not grouped together in the overdue figures with quality incidents (QIs). NHSBT (internal, not assisted function) ODT incidents are managed and investigated between ODT Clinical Governance and QA ODT, any incidents of note are escalated to the National QA Manager–ODT and Deputy Chief Nurse for onward escalation if required. Incident trends are reported to OTDT CARE, and internal Serious Adverse Events or Reactions are reported to the Human Tissue Authority.

The MQR format developed during 2021/22 has been retained for this report, and three appendices are included at the end to support interpretation:

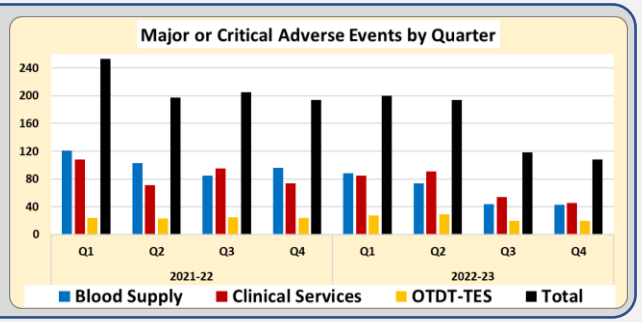
- Appendix A is a dashboard showing performance during Q4 of this year. This slide is in the same format as the Q3 MQR to facilitate a quarterly comparison of the data, with figures and arrows showing the performance in Q4 compared to Q3;
- Appendix B is a list of the acronyms used in this report;
- Appendix C gives an overview of the severity classifications ('Critical', Major', 'Other' and 'Comment') used to grade Quality Incidents, Hospital Complaints, and Audit findings.

MANAGEMENT QUALITY REVIEW: Appendix A – Q4 2022/23

Critical and Major Adverse Events raised (QIs and Hospital Complaints raised in Blood Supply, Clinical Services & OTDT-TES)

No. of events raised in the quarter (No target set)

108 (Q3: 118) ↓



Patient Adverse Events

No. of events raised in the quarter (No target set)

34 (Q3: 26) ↑

Serious Incidents

No. of SIs raised in the quarter (No target set)

0 (Q3: 1; YTD: 4) ↓

Overdue Quality Management System Events (graphs show the position against each KPI at the start and end of the quarter, as well as every Monday and Thursday)

Note: figures do not include OTDT-ODT 'INC' incidents

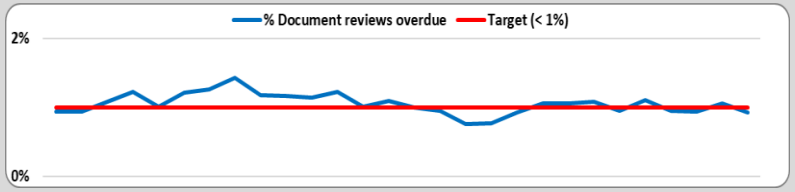
KPI 1

Target: < 1% documents with an overdue review

End of Q4 position

0.92% ✓ ↓

(Q3: 0.94%)



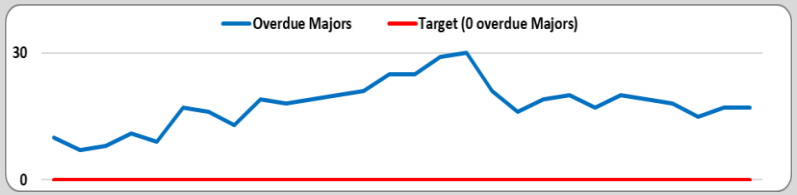
KPI 2

Target: Zero overdue Majors

End of Q4 position

17 ✗ ↑

(Q3: 10)



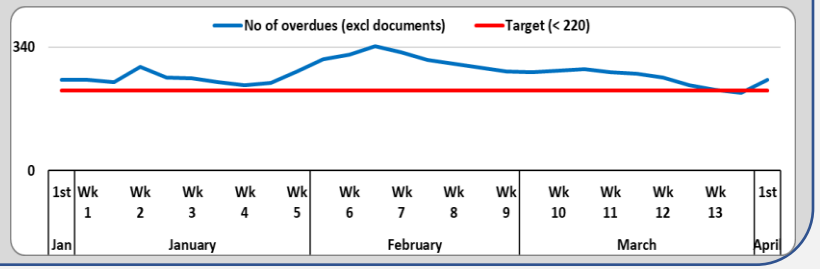
KPI 3

Target: < 220 overdue QIs, HCs, Audit findings, and Change Controls

End of Q4 position

249 ✗ ↔

(Q3: 249)



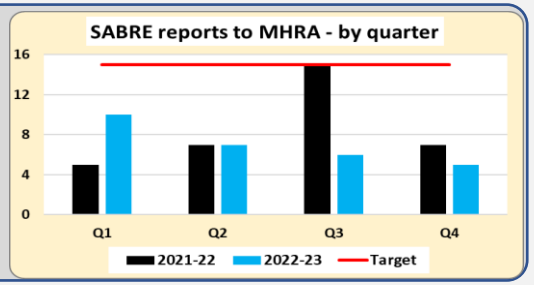
Externally Reported Events: (Serious Adverse Blood Reaction & Event / Serious Adverse Event and Reaction)

SABRE

Rate per 100,000 donations: 1.4

SABRE reports submitted during the quarter (Target </= 15/Q) ✓

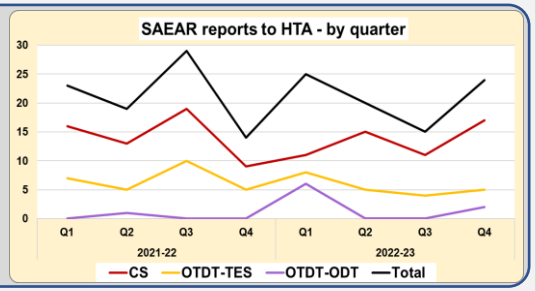
5 (Q3: 6) ↓



SAEAR (figures include NHSBT ODT SAEARs)

SAEAR reports submitted during the quarter (no target set)

24 (Q3: 15) ↑

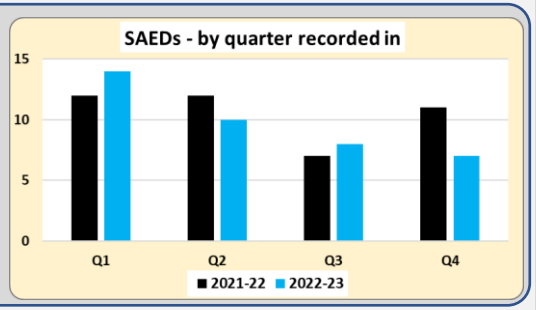


Serious Adverse Events of Donation

Rate per 100,000 donations: 1.9

SAEDs recorded during the quarter (no target set)

7 (Q3: 8) ↓

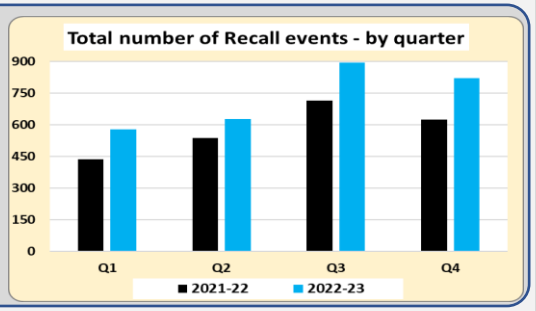


Recalls

Rate per 100,000 donations: 225.1

Recall events during the quarter (no target set)

821 (Q3: 894) ↓



MANAGEMENT QUALITY REVIEW: Appendix B – Acronyms used in this report

Acronyms			
ATU	Advanced Therapies Unit	MSL	Microbiology Services Laboratory
BEA	Blood Establishment Authorisation licence	OTDT	Organ and Tissue Donation and Transplantation
BS	Blood Supply	ODT	Organ Donation and Transplantation
BSI	British Standards Institute	PAE	Patient Adverse Event
CARE	Clinical Audit Risk and Effectiveness group	PSIRF	Patient Safety Incident Response Framework
CBC	Clinical Biotechnology Centre	Q3	Quarter 3 of the current financial year (October – December 2022)
CCS	Contamination Control Strategy	Q4	Quarter 4 of the current financial year (January – March 2023)
CQC	Care Quality Commission	QA	Quality Assurance
CS	Clinical Services	QI	Quality Incident
EFI	European Federation for Immunogenetics	QMS	Quality Management System
ET	Executive Team	RCI	Red Cell Immunohaematology
H&I	Histocompatibility & Immunogenetics	SABRE	Serious Adverse Blood Reactions and Events
HC	Hospital Complaint	SAEAR	Serious Adverse Events and Adverse Reactions
HTA	Human Tissue Authority	SAED	Serious Adverse Event of Donation
HTLV	Human T-Lymphotropic Virus	SI	Serious Incident
IBGRL	International Blood Group Reference Laboratories	SMT	Senior Management Team
IMP	Investigational Medicinal Product	TES	Tissue and Eye Services
ISO	International Organisation for Standardisation	TQSR	Human Tissue (Quality and Safety for Human Application) Regulations
KPI	Key Performance Indicator	UKAS	United Kingdom Accreditation Service
MHRA	Medicines and Healthcare products Regulatory Agency	WDA(H)	Wholesale Distribution Authorisation (Human) licence
MQR	Management Quality Review		

MANAGEMENT QUALITY REVIEW: Appendix C – Internal event severity classifications

Internal event severity classifications (note: whilst the MHRA use similar terminology, the definitions below only apply to internal event classifications, not regulatory inspection findings shown on slide 7)	
Critical	Critical QI events Incidents (acts and/or omissions) occurring as part of NHSBT that: • caused 'catastrophic' harm (death of 1 or more, or harm to more than 50) to patients, donors, or clinical trial participants; or failure to comply with legal obligations; • a Critical defect of a medical or in-vitro device; • had a significant impact on NHSBT operations or resulted in a significant loss of product in one incident. Critical Audit findings A deficiency in a process or written procedure which poses a significant risk of causing direct harm to the safety of the product, donor or patient.
Major	'Major' QI events Incidents (acts and/or omissions) occurring as part of NHSBT that: • caused life threatening or permanent harm to a patient, donor or clinical trial participant; or is considered to be of medium-significant risk level; • is a recurrent failure that has previously been logged as an 'Other' incident; • involved receipt of counterfeit medicine. 'Major' Audit findings • A non-critical deficiency which has produced or may produce a product, which does not comply to specifications; or • a significant or constantly recurring deviation from regulations or standards; or • a combination of several "other" deficiencies, none of which on their own may be major, but which may together represent a significant deficiency and should be explained and reported as such.
Other	'Other' QI events Incidents (acts and/or omissions) occurring as part of NHSBT that: • are a failure to comply with the principles of Good Practice, that is neither Major or Critical, and which needs corrective action to address. 'Other' Audit findings A deficiency which cannot be classed as either major or critical, but which indicates a departure from regulations or standards. Patients may not perceive any loss of quality but standards have not been met.
Comment	Audit findings only Not a non-conformity yet but could get worse or pose a risk, a suggested improvement or recommendation.