MANAGEMENT QUALITY REVIEW: Annual 2023/24

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

Whilst the volumes of both SABRE and SAEAR reported events increased compared to the previous year, the data is regularly reviewed at the relevant SMT meetings, including the findings of a SABRE deep dive conducted during Q4. 2023-24 is the first year that we have full data on events reported to the CQC and therefore we do not yet have sufficient data to identify trends. Quality continue to monitor volumes of all regulator notified events, and it is important that data provided by QA at SMT meetings continues to be reviewed by the relevant teams to identify trends and any actions needed for improvement.

External inspection performance has been good overall, with only one Major, and no Critical findings raised from any regulatory (MHRA, HTA, or CQC) inspections. The initial BSI ISO22301 re-certification audit in December 2023 identified four major non-conformities. These were the management of the Southampton roof incident, the management of supplier audit, quality audit of the Business Continuity (BC) system, and the management of audit findings. These were addressed promptly and led to re-certification in January. During activation and exercising of some of the organisation's departmental business continuity plans it was identified some areas of the plan required improvement, and the BC Team is helping facilitate this using an improved Business Impact Analysis template.

Completion of the Quality self-inspection audit schedule on time has been difficult this year, due to auditors' conflicting priorities and a lack of data to oversee the schedule. A project was carried out in Q4 to improve the audit process, including the addition of a new field in the Q-Pulse system and a new monthly meeting to track progress and manage issues. It is anticipated that improvement should be seen in 2024-25.

It continues to be a challenge to keep up to date with reviews of suppliers with a quality impact. Quality SMT are looking at ways to resource the completion of reviews effectively. Whilst quality issues with suppliers are managed within the QI system as they arise, the overdue reviews impact on the organisation's ability to foresee where issues may be emerging.

Overdue events has continued to be an issue throughout 2023-24, with all of the three corporate overdue KPIs being missed at the end of the year.

MANAGEMENT QUALITY REVIEW: Annual 2023/24

Overdue events

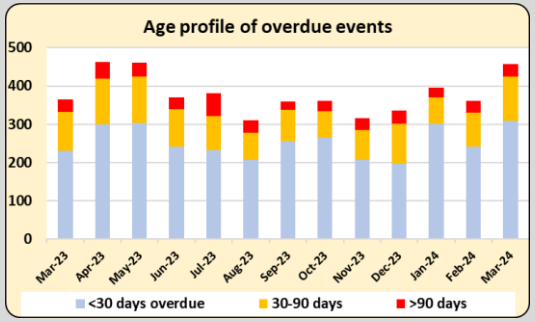
Note: the overdue data is a snapshot taken on the first calendar day of each month. Please bear in mind that the figures change daily, and can go down as well as up.

Year end overdues 2023/24
(last year: 365)

457 ↑

The volume of overdue events continues to vary.

Whilst the proportion of the overdues which are more than 90 days past their target has fallen compared to the same point the previous year (7% at the end of March 2024 reduced from 8.8% at the end of March 2023), there wasn't any change in the number of events overdue by more than 90 days, which remained at 32 events.



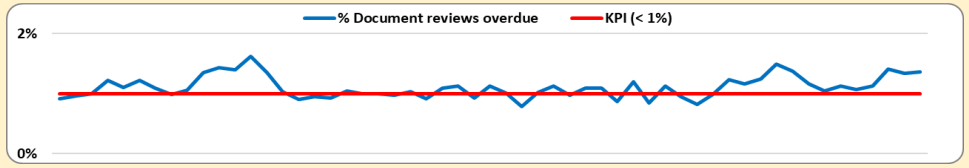
Actions taken within the year by Quality Assurance

- Increased focus on incidents open more than 90 days at organisational SMTs
- Adding this activity to the PDPR objectives of the Lead Quality Specialists
- Targeted initiatives to reduce longstanding overdue major incident.
- Creation of Quality Plans for each directorate
- Weekly review meetings with relevant business areas

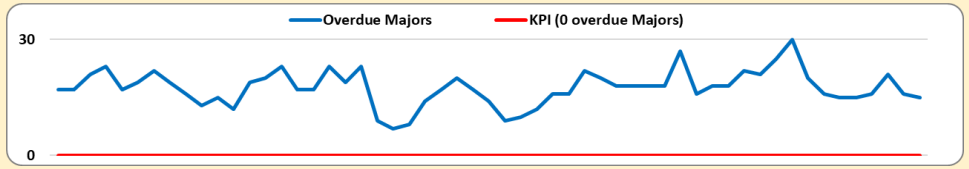
Performance against the three overdue event KPIs

This year ends with none of the three KPIs being met. The graphs below show performance at every Monday throughout the 2023-24 year.

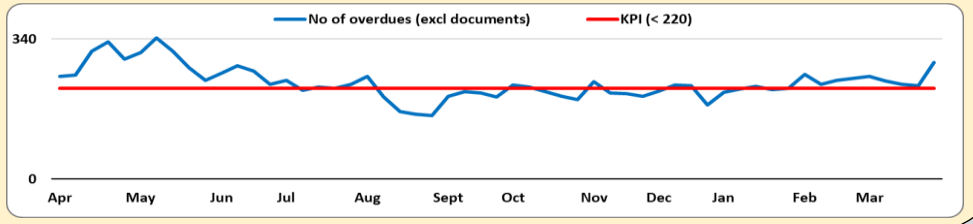
KPI 1
Target: < 1% documents with an overdue review



KPI 2
Target: Zero overdue Majors



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



Commentary for Performance against KPIs

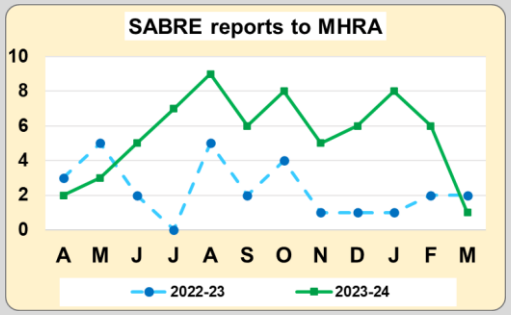
- Despite not achieving the KPI, there is no indication of any adverse patient or donor impact

MANAGEMENT QUALITY REVIEW: Annual 2023/24

Serious Adverse Blood Reactions and Events (SABRE)

MHRA reported incidents

Total SABREs 2023/24
(Last year: 28)
66 ↑



The total number of SABRE events reported to the MHRA increased to more than double the number submitted the previous year.

There was a particular increase during the summer (Jun-Aug 2023), coinciding with both the scrapping of a SABRE target (to report no more than 5 per month) and an MHRA inspection finding related to incidents not being reported.

Increase in incidents reported as SABREs

Analysis of the incidents reported this year identified several themes, including:

- A rise in SABREs for non-Blood Supply directorates. Note that this relates to when the incident was logged, and the directorate can be changed .
- An increase in the volume classed as 'donor screening', many of which related to donors who had either travelled to a country of concern, or who were taking medication that should have made them ineligible to donate. Several incidents involved the same drug, finasteride, for which JPAC guidance has changed. Regular donors are not asked about un-altered medication, and therefore there is potential for further donors to be taking medication that was correctly declared and accepted under previous rules, but which would now not be allowed.
- A potential seasonal increase in incidents being attributed to BS-M&L.

> "*On his first donation donor declared that he takes finasteride for hair loss and was accepted. In the next donations donor did not declare finasteride as he became a regular donor and his medication was not altered.*"

A more detailed investigation is underway to look at the themes and trends, and to determine what (if any) action should be taken.

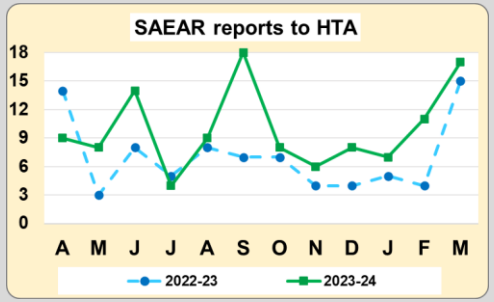
Serious Adverse Events and Adverse Reactions (SAEAR)

HTA reported incidents

Total SAEARs 2023/24
(last year: 84)
119 ↑

The number of SAEAR reports has fluctuated throughout this year, with four months having more than ten reports submitted.

The majority (68%) of the reported incidents occurred in Clinical Services, almost a third (29%) were in OTDT-TES, and 2% were in OTDT-ODT.



In addition to the above, 96 SAEARs (65 Serious Adverse Events and 31 Serious Adverse Reactions) were reported by NHSBT on behalf of the transplant sector, under the Assisted Function role.

> "*Directed cord blood collection reported Bacteriology POSITIVE … The bacterium involved is typical of mucus membranes and urinary tract infections so contamination during collection probable*"

The most common type of event to be reported to the HTA were those classed as 'bacteriology positive'. These accounted for over a third of all the SAEAR reports across the year.

In many cases it is noted in the incident record that the bacterium concerned is one commonly found in the human body and is likely to have been transmitted during collection.

Other issues which have been seen this year include:

- Issues relating to packaging, such as bags of cells/ tissues leaking;
- Failed engraftments/ primary graft failures
- Reconciliation and record keeping errors;
- Errors in lab reports
- Concerns about the quality of products issued

> "*lab received a phone call to say a stem cell bag was leaking at the time of infusion.*"

> "*Tissue provided was irregular shape and was not suitable*"

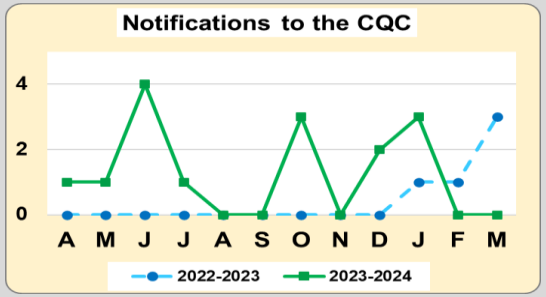
MANAGEMENT QUALITY REVIEW: Annual 2023/24

CQC notifications
CQC reported incidents

Total CQC notifications 2023/24
(Last year: N/A)

15

CQC notifications began being submitted towards the end of the 2022-23 reporting year. Therefore this is the first time that this metric has been included in the annual MQR, and we do not have any previous complete years to compare with.



What are CQC notifications

Similar to the MHRA and HTA, the CQC require providers to notify them of certain incidents. In particular, we are obliged to notify the CQC of any incidents which affect the service or the people who use the service.

The majority of incidents that have been reported to the CQC during this year are classed as 'Serious injury to a person who uses the service'.

As CQC reporting is still a fairly new process for NHSBT there may be some learning required around the types of incidents which need to be notified, and it is possible that we may have over-reported in the short-term.

"the event still does not meet the full requirement for reporting however it was felt that notification to the regulator may be beneficial."

"received a call from a Health Protection Practitioner … advising the donor had been diagnosed with acute hepatitis A infection. Patient subsequently diagnosed hepatitis A."

Of the 15 events reported to the CQC in 2023-24, 7 were classed as Serious Adverse Events of Donation . The remaining incidents included:

- A hepatitis transmission
- A patient on red cell exchange who had not communicated that she was pregnant
- A patient who passed away due to sepsis

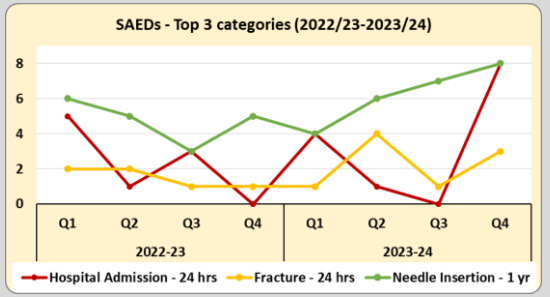
Serious Adverse Events of Donation
(SAED)

Total SAEDs 2023/24
(last year: 39)

56 ↑

Overall for the year SAEDs increased by 44% compared to the total for 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 year that the donation was made.



Problems relating to Needle Insertion persisting more than 1 year **25** ↑

- Needle insertion events continues to be the top category across the year. However, since this category requires that symptoms have persisted for more than a year before an SAED is recorded then none of the incidents relate to donations made during the 2023-24 year.
- Individual incidents are investigated and in many instances no specific NHSBT fault has been identified. Information about post-donation care is routinely provided to donors.

Hospital Admission within 24 hours & Fracture within 24 hours

- Both hospital admission and fracture events categories included incidents where the donor fainted.
- In addition to fractured bones, the 'fracture' incidents included broken teeth, as well as additional cuts, grazes, and bruising.
- The hospital admission category captures any hospital admission within 24 hours of donation, regardless of the cause, and includes some cases that are unlikely to have been caused by donating, or where other factors may have contributed.

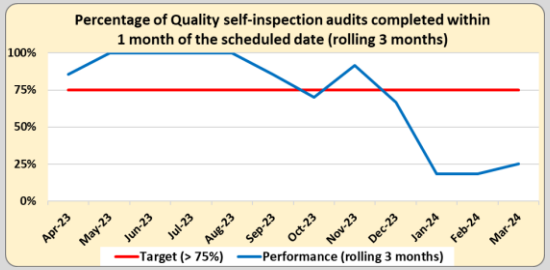
"In the morning went for a walk with his two dogs did feel a little pull across his chest … continued with walk and did some gardening felt fine went to donate. Donated 5pm - all okay … 2am pressure feeling returned felt unwell and clammy - woke his wife and they called 999."

MANAGEMENT QUALITY REVIEW: Annual 2023/24

Internal Quality Self-Inspection Audit

Audits completed within (or not yet past) 1 month from scheduled date (Overall year position)

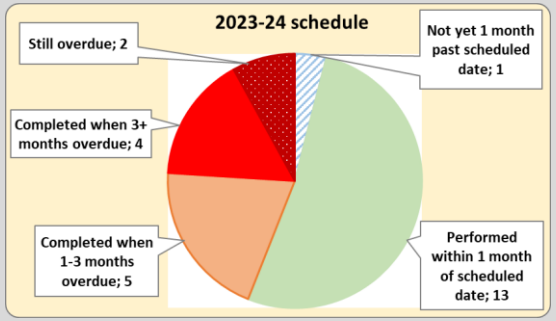
54%



Whilst the year ended with only a quarter of the audits that were scheduled within the previous three months having been completed within a month of their scheduled date, across the year the target (for at least 75% of the Quality Self-Inspection audits scheduled within the previous three months to be performed within a month), was met in seven months.

Oversight of the quality self-inspection schedule has been difficult, and therefore a project was completed during Q4 to make improvements for the following year.

Changes made include improving the clarity of the process; introducing monthly meetings to monitor progress of the schedule and enable issues to be addressed in a timely manner; and a new field created in Q-Pulse to better record audit completion.



Example internal quality self inspection audit finding:

"*The monitoring of incubator temperature only provided a single timepoint snapshot each month that would not identify if it had been out of the defined specification during use - Consumables requiring ambient controlled storage are being stored in general areas that are not monitored and have not been mapped to demonstrate their suitability.*"

Example regulator inspection finding:

"*A review of the temperature monitoring data identified some issues with the records, including: some missing data points; and, excursions from the expected temperature range not being identified as an out-of-specification reading, and not being actioned as such.*"

There continues to be a positive correlation between themes found by internal quality self-inspection audits and regulatory inspections, which gives assurance that our audit program has an important role in helping NHSBT to remain compliant with regulations.

However, this does make it even more important that effective action is taken to address audit findings promptly, in order to prevent more significant issues developing.

Some of the themes noted this year

- **Training**: Several audits have identified issues relating to the completion and recording of training (e.g. "*There is no evidence of training to SOP1353*")
- **Record keeping**: In addition to records not being updated fully or in a timely manner (e.g. "*No evidence of facility cleaning logs in any storerooms documenting floor cleaning*"), some findings suggested issues with how records are controlled/ overseen locally (e.g. "*Multiple versions of the same document are being uploaded by different colleagues*")
- **Root Cause Analysis (RCA) and Corrective/ preventative actions (CAPA)**: The MHRA gave us a finding this year related to the completion of RCA and setting robust CAPA, and internal audits have also raised concerns (e.g. "*no CAPA was undertaken. Guidance within the CAPA stage states that if no CAPA is proposed, this should be justified. No justification provided in this record.*")

Audit findings are often only able to confirm that the records were insufficient or not up to date, however where there is not sufficient evidence of training, cleaning, document maintenance, or a robust investigation, we must consider the possibility that they were not done, and that local controls (such as training matrices and cleaning logs) are not being used effectively.

Furthermore, without full and accurate records we will be less capable of identifying risks and issues, and we cannot presume assurance that issues which do exist (or which may emerge in future) would be promptly identified. This could therefore affect our ability to provide assurance to our regulators.

MANAGEMENT QUALITY REVIEW: Annual 2023/24

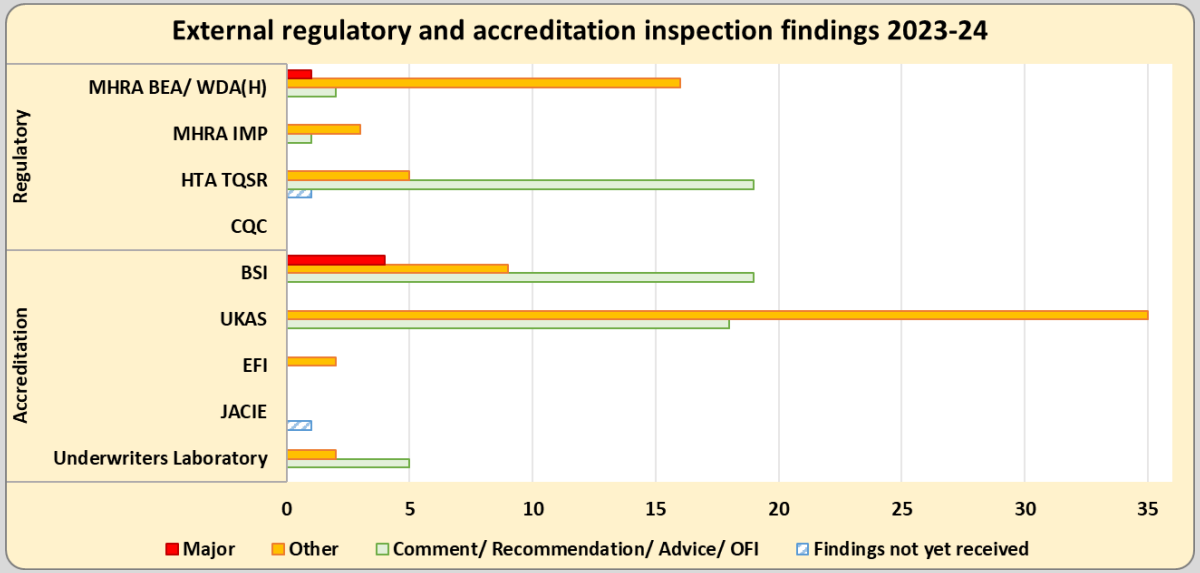
External Inspection Performance

External Regulatory Majors & Musts
(Target = 0)
(Last year: 6)

1

Overall, there have been good results from external inspections in 2023-24, with no Critical findings raised, and only one regulatory Major.

Licence / Accreditation	Inspections	Outcome
MHRA BEA/WDA(H)	3 inspections (Colindale, Tooting, and Manchester/ Lancaster)	1 Major 16 others 2 comments
MHRA IMP	1 inspection (Barnsley)	3 Others 1 Comment
HTA TQSR	5 inspections (Oxford, Birmingham, Southampton, Colindale, and Liverpool research licence)	5 Minors 19 Areas of advice & guidance
CQC	1 inspection (Stratford donor centre)	Inspected as part of registration, no findings
Accreditations	22 inspections • 6 UKAS: 2 RCI (various sites), 2 H&I (various sites); IBGRL, and MSL • 1 EFI: H&I Filton • 1 Underwriters Laboratory (Liverpool Reagents) • 1 JACIE: CMT Southampton • 13 BSI: National, and various sites	4 Majors 48 Non-conformances 42 Areas of advice & guidance



Major findings

The only Major finding from any of NHSBT's three regulators (the MHRA, HTA, and CQC) was that "*Quality assurance based on the principles of quality risk management was not fully implemented as known and ongoing risks were not always kept under appropriate review and comprehensively evaluated*". Action has been taken, and the finding was closed in November.

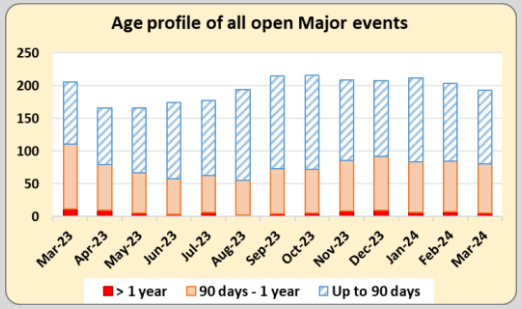
There were also four Major findings from the national BSI accreditation inspection in December. The findings related to the management of the Southampton roof incident, the management of supplier audits, quality audit of the Business Continuity system, and the management of audit findings. Recertification has already been achieved, and work is ongoing to strengthen future controls.

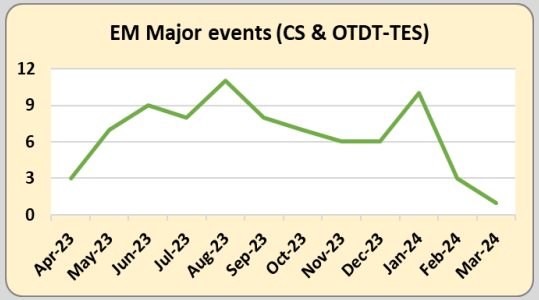
MANAGEMENT QUALITY REVIEW: Annual 2023/24

Quality Management System Performance

The overall volume of all open Major QMS events (including Quality Incidents, Hospital Complaints, and Audit findings) at the end of 2023-24 (193) was slightly lower than at the same point the previous year (206 open Major events at the end of March 2023).

In addition, the proportion of open Majors which were more than a year old was cut by half this year (from 6% to 3%).





Environmental Monitoring (EM) Majors

EM Majors increased over the summer, which was similar to the previous year. The cause of the rise is unclear, although there were a few changes made to the EM cleanroom procedures, effective from the 1st June.

The spike and then drop off in Q4 is related to cleanroom repairs in OTDT-TES, which began towards the end of January and lasted 4-5 weeks followed by validation work.

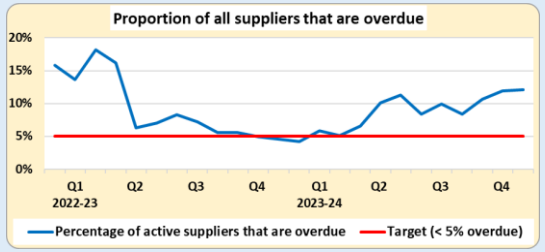
Serious Incidents (SIs)

6 ⬆

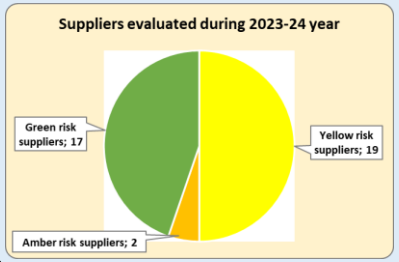
- May: 2 – Donor suffered anaphylaxis during donation & was admitted to A&E
  – Donor was bled in error and later presented at hospital with anaemia
- June: 1 – Air introduced into the donor's circulation during red cell exchange
- September: 2 – Issue with the malaria antibody screen in Testing
  – Patient suffered a transfusion reaction requiring admission to ITU
- March: 1 – Mis-communication led to patient being prepped for stem cell transplant on the wrong date

Supplier management

Completion of supplier reviews on time has been a challenge throughout this year, with the target (for fewer than 5% of active suppliers to be overdue) being missed in 11 months.



Overdue red suppliers are a concern, with 5 of the 6 red suppliers overdue at the end of the year. However, the majority have undergone a supplier review as part of the current International Blood Pack contract tender and are in the process of having desktop audits scheduled for 2024-25, and one supplier is currently being assessed.

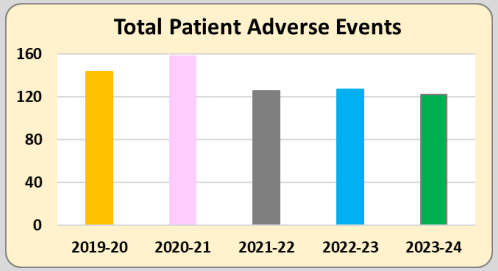


In total 38 suppliers were evaluated during 2023-24; 17 by certification, 19 by questionnaire and 2 by audit.

At the end of the 2023-24 year 7 suppliers were being managed as "conditional"; this reflects that risks have been identified and additional checks or actions are in place to mitigate the risk.

Patient Adverse Events (PAEs)

Overall there was no significant change in total number of Patient Adverse Events recorded during this year (122, compared to 127 recorded the previous year).



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Business Continuity (BC)

The response framework was activated 8 times this year. This led to the organisation responding effectively to a number of incidents, most notably, the closure of the Southampton centre and response to false NAT- positives in Filton Testing.

The BC team worked closely with colleagues from DHSC and NHSE as part of the Strategic Emergency Preparedness Board to ensure a joined-up approach to BC and emergency response.

However, due to the short notice closure of the Southampton centre, some areas of the organisation, Hospital Services in particular, have fewer re-provisioning sites. This means that if there was a further unexpected closure of a site, resilience options would be more limited than plans indicate.

Business Continuity targets

The training KPIs end the year in a strong position, but LET exercises were paused during Q2 due to staff shortage, which led the KPI (LET exercise completion) falling below target. There is preparation within the BC team to restart these exercises during 2024/25, which will improve this metric.

BC exercise completion also fell below target. The main reasons for this were:

1. Staff shortage within the BC team.
2. During the preparation for specific exercises, it was identified that the plans were out of date or not fit for purpose. As a result, the exercises were postponed until these plans were updated.
3. There has been lack of engagement from specific departments, meaning these exercises have been unable to take place.

The BC team are back at full capacity so the figures are expected to improve in 2024-25. Each directorate and centre across the organisation will have an identified BC Manager providing subject matter expertise where required.

Risk

Following its creation towards the end of 2022/23, the Corporate Risk Team have worked to bring the risk management framework in line with current practice and the government Orange Book standard. A new policy and MPD were approved at RMC and ARGC and the team will be rolling out a training programme in 2024/25.

Development of an NHSBT assurance map is also underway. An organisational Assurance Framework has again been approved at RMC and ARGC and plans are to present the first assurance map to the ARGC in January 2025.

The corporate risk team have also taken responsibility for the management of GIAA audit actions, resulting in a reduction in the number of overdue actions across the organisation.

The introduction of 10 principal risks has improved Board oversight and assurance around risk management and details are presented monthly through the Board Assurance Framework.

Principal Risk	Appetite Level	Detail/Commentary
P-01 Donor & Patient Safety		1 contributory risk in judgement zone
P-02 Service Disruption		1 contributory risk at risk limit
P-03 Service Disruption – Loss of Critical ICT		1 contributory risk at risk limit
P-04 Donor Numbers & Diversity		2 contributory risks in judgement zone
P-05 Finance		Risks at or below tolerance
P-06 Clinical Outcomes and Health Inequalities		Risks at or below tolerance
P-07 Staff Capacity/Capability/Recruitment/Retention		1 contributory risk in judgement zone
P-08 Leaders and Managers		Risks at or below tolerance
P-09 Regulatory Compliance (Primary Regulators)		Risks at or below optimal level
P-10 Change Programme Scale & Pace		Risks at or below tolerance

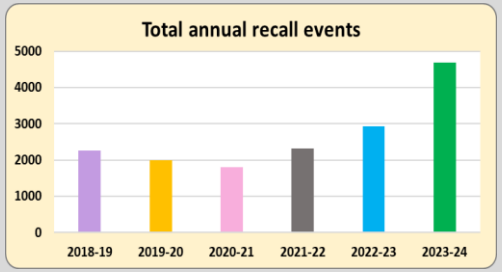
MANAGEMENT QUALITY REVIEW: Annual 2023/24

Recalls

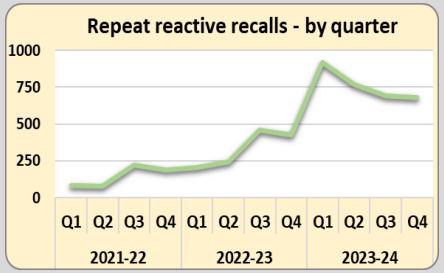
Total Recalls 2023/24
(last year: 2921)
4686 ↑

The overall number of recalls increased by 60% compared to the previous year.

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



Repeat reactive recalls (65% of recalls in 2023/24)



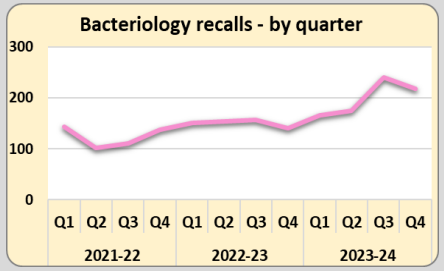
During Q1 and Q2, anti-HBc testing was at its peak, and syphilis testing was switched to a new analyser in March 2023, which caused an increase in the number of genuine reactive results.

But by Q3 and Q4, once many regular donors had a historical anti-HBc result and didn't require re-testing, and had been tested with the new syphilis assay, there was a slight decrease in the number of reactives each month.

Bacteriology recalls (17% of recalls in 2023/24)

The second most common recall category, bacteriology recalls increased by 33% compared to the previous year.

The increase was due to a known problem whereby temperature fluctuations in the lab cause 'false positives' to be flagged within the Bacterial Screening analysers, thus leading to the recalls. Although the issue is mainly in Manchester, there was a spike in positive platelets in Colindale in December 2023, also due to temperature issues.



Regulatory update

Good Blood Guide 21st Edition

Revision of the 21st Edition of the Guide to the preparation, use and quality assurance of blood components ("the Blood Guide"). A gap analysis has been complete and change control updated to reflect ongoing actions, the target date for completion is 28th June 2024.

Patient Safety Incident Response Framework (PSIRF)

The Patient Safety Incident Response Framework (PSIRF) will replace the Serious Incident Management process. Project will include the implementation of actions resulting from the Ockenden review, the Cumberledge Report, the Paterson Inquiry and an update to Duty of Candour.

PSIRF Phase 1 is now underway. The go-live date for the new PSIRF processes is 3rd June, at which point the new PSII policy will replace the SI policy.

EU Medical Device Regulations

Work is ongoing with DDTS to update the Hospitals and Science website to make translated instructions for use available to customers.

Work is ongoing to resolve two minor change requests to label templates before Using Acceptance Testing can start. There have also been problems accessing the NiceLabel application through the NHSBT network, thought to be due to the firewall, which DDTS are working to resolve.

Work is ongoing to complete performance evaluation and create the required technical documentation for conformity assessment and CE certification under the IVDR. Overall percent of documents currently at 85%, an increase of 2% on the previous month.

MANAGEMENT QUALITY REVIEW: Annual 2023/24

Quality plan objectives (note: due to limited space not all objectives are listed below)	
Blood Supply	• Take action to support Effective QMS Management – Develop scorecard metric to support QI and Audit closure. • Continuous Improvement – with a focus on data integrity compliance. • Regulation – Continue to prepare for regulatory inspections.
Clinical Services	• RCI – Accreditation Compliance, Data Integrity and continued work on Internal ISO15189 Audit. • Reagents – Continued work on Effective QI / complaint management, Supplier management / consumables / Equipment management and development of risk management plan for compliance with ISO13485 and ISO14971. • H&I – Continued work on accreditation compliance an Improve ease of internal ISO15189 audit scheduling. • Clinical Trial Unit – continue to develop robust documenting and tracking of Serious Adverse Events as part of Pharmacovigilance procedures • Other objectives include dealing with longstanding change controls, document management and HTA annual activity returns.
OTDT-TES	• Take action to support effective Supplier management / Consumables / Equipment management. • Ensure effective QI Management / Complaints. • Good Documentation Practice / Documentation / Standard Operating Procedure (SOP).
OTDT-ODT	• Supplier management / Consumables / Equipment management. • Ensure effective incident Management and take actions as appropriate. • Implementation of new procedures and training plans. • Data Integrity assurance.
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.

Quality Plans were introduced in Q3 23/24 after a period of co-design with all respective business areas. These plans were bespoke to each directorate and was agreed by their SMTs for implementation. Monthly reviews will occur at directorate SMTs for progress and action as deemed appropriate.

MANAGEMENT QUALITY REVIEW: Annual 2023/24

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 and Adverse 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. The two slides are 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 2023/24

Patient Adverse Events

No of PAEs raised during the quarter
(no target set)

31 (Q3: 29) ⬆

Serious Incidents

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

1 (Q3: 0; YTD: 6) ⬆

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

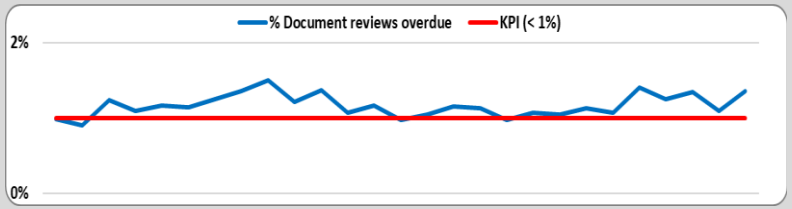
KPI 1

Target: < 1% documents with an overdue review

End of Q4 position

1.36% ⊗

(Q3: 0.98%) ⬆



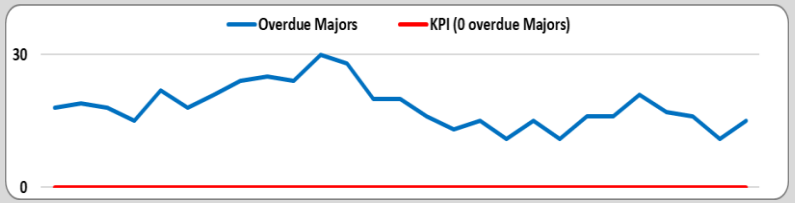
KPI 2

Target: Zero overdue Majors

End of Q4 position

15 ⊗

(Q3: 18) ⬇



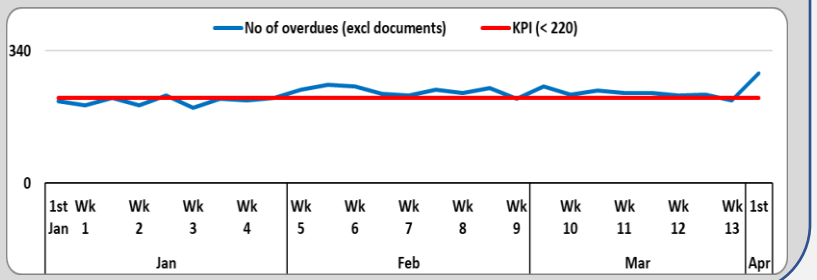
KPI 3

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

End of Q4 position

283 ⊗

(Q3: 211) ⬆

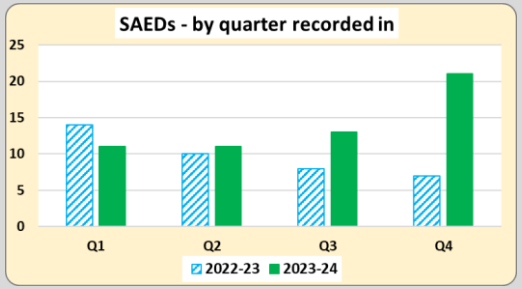


Serious Adverse Events of Donation

Rate per 100,000 donations: 5.8

SAEDs recorded during the quarter
(no target set)

21 (Q3: 13) ⬆

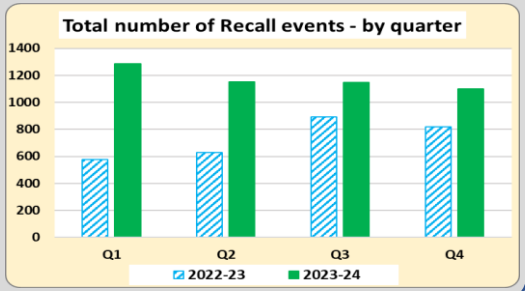


Recalls

Rate per 100,000 donations: 304.2

Recall events during the quarter
(no target set)

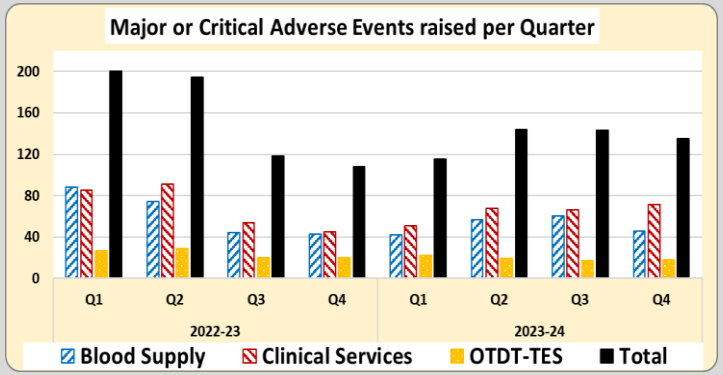
1101 (Q3: 1146) ⬇



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)

135 (Q3: 143) ⬇



MANAGEMENT QUALITY REVIEW: Appendix A – Q4 2023/24

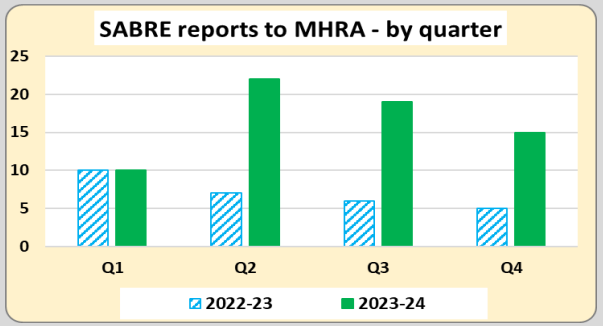
Externally Reported Events

SABRE

Rate per 100,000 donations: 4.1

SABRE reports submitted during the quarter
(no target set)

15 (Q3: 19) ⬇

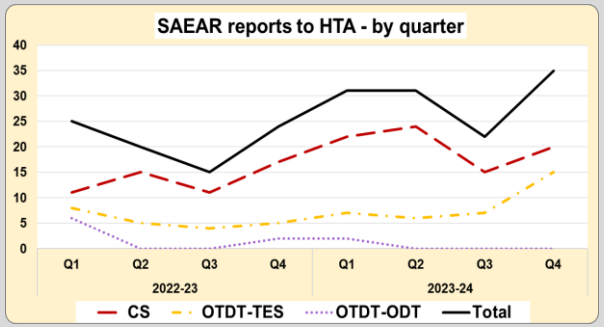


SAEAR

(figure includes NHSBT ODT SAEARs)

SAEAR reports submitted during the quarter
(no target set)

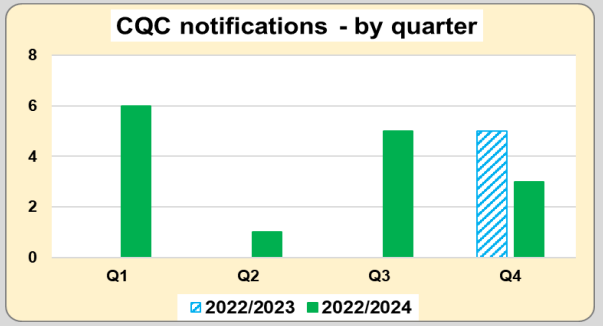
35 (Q3: 22) ⬆



CQC notifications

CQC notifications submitted during the quarter
(no target set)

3 (Q3: 5) ⬇



Business Continuity

CIM training

Percentage of CIMs who have attended CIM training in the last 3 years

End of Q4 position
(no target set)

84% (Q3: 88%)

LET training

Percentage of LET members who have completed e-learning in the last 2 years

End of Q4 position
(no target set)

89% (Q3: 86.9%)

BC exercise completion

Percentage of CIMs who have attended CIM training in the last 3 years

End of Q4 position
(no target set)

59% (Q3: 41%)

LET members attending BC exercises

Percentage of LET members who have attended a LET exercise in the last 3 years

End of Q4 position
(no target set)

55% (Q3: 63%)

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

Acronyms			
ARGC	Audit, Risk and Governance Committee	MHRA	Medicines and Healthcare products Regulatory Agency
BC	Business Continuity	MPD	Management Process Description
BEA	Blood Establishment Authorisation licence	MQR	Management Quality Review
BSI	British Standards Institute	MSL	Microbiology Services Laboratory
CAPA	Corrective Actions and Preventative Actions	OTDT	Organ and Tissue Donation and Transplantation
CIM	Critical Incident Manager	ODT	Organ Donation and Transplantation
CMT	Cellular and Molecular Therapies	PSII	Patient Safety Incident Investigation
CQC	Care Quality Commission	PSIRF	Patient Safety Incident Response Framework
DDTS	Digital, Data, and Technology Services	Q3	Quarter 3 of the current financial year (October – December 2023)
EFI	European Federation for Immunogenetics	Q4	Quarter 4 of the current financial year (January – March 2024)
EU	European Union	QA	Quality Assurance
GIAA	Government Internal Audit Agency	QI	Quality Incident
HC	Hospital Complaint	QMS	Quality Management System
H&I	Histocompatibility and Immunogenetics	RCI	Red Cell Immunohaematology
HTA	Human Tissue Authority	RMC	Risk Management Committee
IBGRL	International Blood Group Reference Laboratories	SABRE	Serious Adverse Blood Reactions and Events
IMP	Investigational Medicinal Product	SAEAR	Serious Adverse Events and Adverse Reactions
IVDR	In Vitro Diagnostic Regulation	SAED	Serious Adverse Event of Donation
JACIE	Joint Accreditation Committee ISCT Europe & EBMT	TES	Tissue and Eye Services
JPAC	Joint Professional Advisory Committee	TQSR	Human Tissue (Quality and Safety for Human Application) Regulations
KPI	Key Performance Indicator	UKAS	United Kingdom Accreditation Service
LET	Local Emergency Team	WDA(H)	Wholesale Distribution Authorisation (Human) licence

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.