MANAGEMENT QUALITY REVIEW: Annual 2024/25

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

Some changes to quality processes were successfully completed during 2024-25, including implementation of new Donor Adverse Event (DAE) and Patient Safety Incident Investigation (PSII) processes, which replace Serious Adverse Events of Donation (SAEDs) and Serious Incidents (SI). Please note that where new processes have been implemented, comparison has not been made to previous years' performance.

Whilst the overall volume of SABRE notifications to the MHRA in 2024/25 was higher than the total for the previous year, the number of notifications fell at the end of the year. In contrast the number of HTA SAEAR reported events decreased compared to the previous year, and the CQC notification process has settled into a standard part of reporting. Quality continue to monitor volumes of regulator notified events, and data is provided by Q&G at SMT meetings to aid in identifying trends and drive improvement actions.

External inspection performance continues to be positive, with only two Major, and no Critical findings raised from any regulatory (MHRA, HTA, or CQC) inspections. The Major findings that have been received this year are being managed appropriately and actions are ongoing to check that the same issues do not exist at other NHSBT sites.

Although the Quality self-inspection audit schedule KPI was not achieved at the end of the year, performance across the year has been encouraging, with the KPI being met in most months. This is the first year in which we have had regular complete data to track progress of the schedule, and processes in place to help manage issues and support auditors, and this year's performance will provide a baseline for making improvements in 2025-26.

It continues to be a challenge to keep up to date with reviews of suppliers with a quality impact. Whilst quality issues with suppliers are managed within the QMS as they arise, overdue reviews impact on the organisation's ability to foresee where issues may be emerging. A review of the process in Q4 identified some opportunities to minimise the administrative burden of the process. A new approach is currently being piloted and is expected to reduce overdue supplier reviews. If the pilot is successful the new process will be rolled out in full during Q2 2025-26.

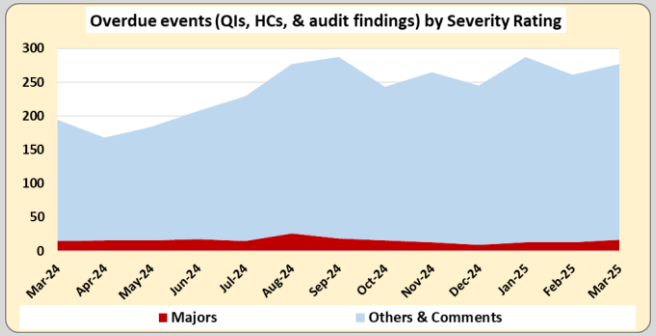
Reducing the volume of overdue QMS events has continued to be an issue throughout 2024-25, and for the second consecutive year all three of the corporate overdue KPIs were missed at the end of the year. Quality are leading activities to improve the incident management process, which should help to reduce the number that are not closed by their target dates. It is also important that all departments take responsibility for the events that they own, and manage their events proactively.

MANAGEMENT QUALITY REVIEW: Annual 2024/25

Overdue events

The volume of overdue events vary daily.

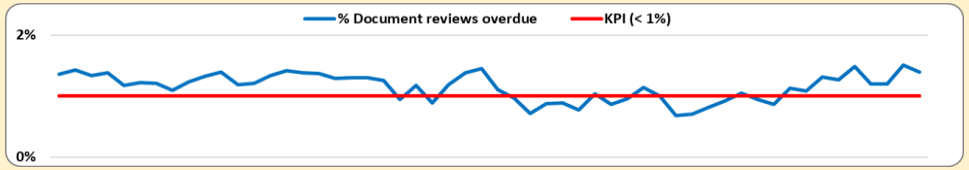
There has been a notable increase in the overall volume of overdue events this year, however the number of overdue Major events (including Quality Incidents, Hospital Complaints, and Audit findings) has remained consistent.



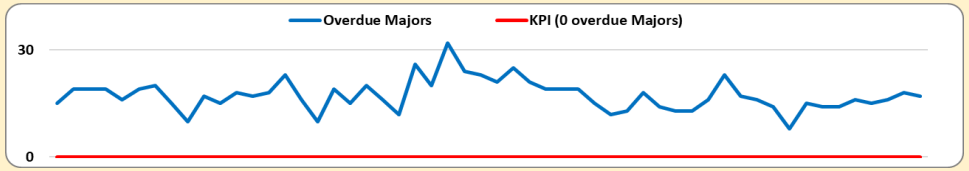
Performance against the three overdue event KPIs

This year ends with none of the three KPIs being met. The graphs below show performance at every Monday throughout the 2024-25 year.

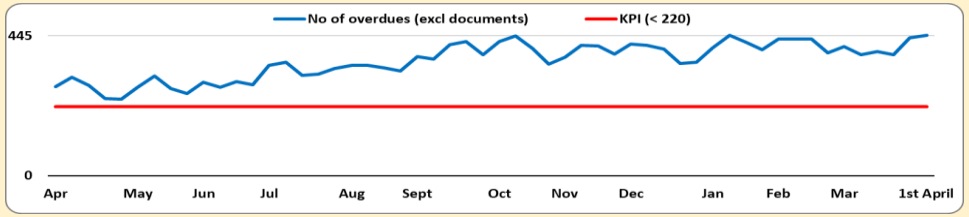
KPI 1
Target: < 1% documents with an overdue review



KPI 2
Target: Zero overdue Majors



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



Actions being taken to improve incident management

At the end of 2024, a survey was circulated to Q-Pulse users across NHSBT to better understand what issues are faced in managing QMS events effectively.

A number of themes emerged, including:

- Clarity and suitability of actions;
- Unrealistic timescales and target dates;
- Dependency on other teams to complete actions;
- Workload, capacity, and resources to enable staff to focus on QMS events

> "*having to rely on other stakeholders outside of the department*"

Following the survey, a Value Stream Analysis event was held in Q4 to consider what actions to take to improve the incident management process.

Quality are setting up two separate workstreams which will be the focus over the coming year:

1. A tactical workstream looking at improving the management of 'high frequency low risk' Quality Incidents (QIs). Implementation date is 27th May, and improvements are anticipated in the first 3 months.
2. A longer-term piece to improve the overall incident management process so that less effort is needed to manage incidents, thereby freeing up resource to complete meaningful corrective and preventative actions.

Whilst Quality are leading on the above activities, many respondents to the survey cited resource and workload as a constraint on their capacity to manage their QMS events. Therefore, it is important that each directorate also considers what actions they can take to improve their team's ability to progress their events and prevent them becoming overdue.

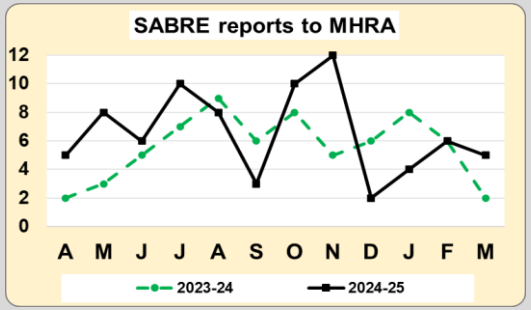
> "*Staffing in department and QA, as well as workload in department. We have other work to do.*"

MANAGEMENT QUALITY REVIEW: Annual 2024/25

Serious Adverse Blood Reactions and Events (SABRE)

MHRA reported incidents

Total SABREs 2024/25
(Last year: 67)
79 ↑



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

However, the volume of notifications was lower towards the end of the year.

In the previous year (2023-24) a national trend was identified in the SABREs data, with a number of the reported incidents involving donors who were taking the drug finasteride.

There have been further incidents involving finasteride notified to the MHRA this year, and therefore it is important that all staff who interact with donors are made aware of guidance and restrictions relating to medication.

"DSC – Donor ticked yes to Q22) Changes to prescribed medications. Told DC started Finasteride 2 weeks ago for enlarged prostate. Correctly referred to nurse. Nurse assessed donor (PSA normal range, no further investigations) and accepted for donation."

"we have an ongoing local rule where units placed in the RCI shelves are not to be used by Hospital Services. The operator that issued request is relatively new and is unlikely to have awareness of the local rule."

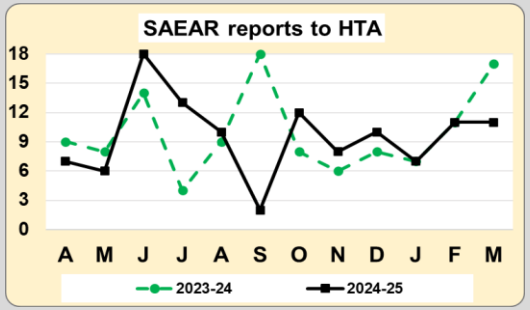
Other themes observed in incidents reported to the MHRA this year include:

- Locally agreed processes and inter-departmental communications contributing to errors.
- Inaccurate donor eligibility information provided by the call centre.
- Staffing pressures and high workloads.

Serious Adverse Events and Adverse Reactions (SAEAR)

HTA reported incidents

Total SAEARs 2024/25
(last year: 119)
115 ↓



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

The majority (59%) of the reported incidents were for Clinical Services, just over a third (38%) were in OTDT-TES, and 3% were in OTDT-ODT.

"This is a known risk of bone marrow collection, the pre-processing sample was also positive so it indicates a true contamination so there was no error from NHSBT and the NHSBT has appropriately detected and communicated it with the parties."

Similar to previous years, the most common type of event to be reported to the HTA had the title 'bacteriology positive'. These accounted for around a quarter of the SAEAR reports across the year.

Particularly for bone marrow, a number of incidents note that the collection process cannot be entirely sterile. Therefore, although all incidents are investigated, bacterial contamination is a known risk.

Other issues which have been reported to the HTA this year include:

- Failed and/or delayed engraftments;
- Stock management issues, including where cells were lost and unable to be transfused;
- Temperature excursions;
- Processing and labelling errors

"During the cryopreservation process … the operator found the bag had leaked from the seal and about half of the product volume was lost."

In addition to the above, 86 SAEARs (58 Serious Adverse Events and 28 Serious Adverse Reactions) were reported by NHSBT on behalf of the transplant sector, under the Assisted Function role.

MANAGEMENT QUALITY REVIEW: Annual 2024/25

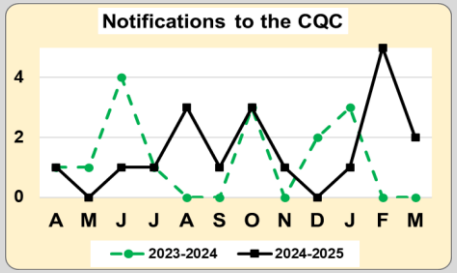
CQC notifications

CQC reported incidents

Total CQC notifications 2024/25
(Last year: 15)

19 ↑

The total number of CQC notifications for the overall year was slightly higher than the previous year.



The incidents were reported under three categories:

- Death of a person using the service (11)
- Serious injury to a person who uses the service (7)
- Event that stops the service running safely & properly (1)

"A clinical review of the event was performed and confirmed that the patient was critically ill and this procedure was a last resort … the outcome is unfortunate but not unexpected. No NHSBT fault identified"

Whilst death was the most common reason for reporting to the CQC, many of the incidents noted that the patients were already seriously unwell, and investigations found no NHSBT fault.

Other reported incidents included:

- Vasovagal reactions
- A fire alarm that could not be heard in all areas of the donor centre

Note regarding Plasma notifications

Two of the events reported this year occurred at Plasma donor centres. It is important to note that due to the wording of the regulations which the CQC regulate under, the collection of plasma solely for use in manufacturing medicines (i.e. not for transfusion) is not currently regulated by the CQC.

Therefore, although these events were similar to other reported incidents, they did not need to be reported to the CQC.

"*Management of supply of blood and blood derived products*
the management of — (a) the supply of blood, blood components and blood derived products intended for transfusion"
(Health & Social Care Act 2008)

Donor Adverse Events

Total SAEDs & DAEs 2024/25
(last year: N/A)

20 SAEDs & 70 DAEs

Serious Adverse Events of Donation (SAEDs) were replaced mid-way through the year by a new Donor Adverse Event (DAE) process. As a result, it is not possible to compare the total figure for 2024-25 with previous years, when only the SAED framework was in use.

How are DAEs different to SAEDs?

- Under the SAED process only events that fell into one of the 10 defined categories were recorded as being SAEDs.
- The SAED process did not capture severity, and some of the categories were based on events post donation, more than the donation process itself. For example, a next-day hospital admission for an unrelated reason may be classed as a SAED, whereas a vasovagal reaction that occurred immediately after donating but didn't result in a broken bone or hospital admission would not.
- In contrast, under the new process all DAEs are recorded on the Pulse system and linked to the donor's Pulse record. Each incident is coded by combining the category and type of event with a severity grading of 1-5.
- There are only 3 categories that are always logged in the QMS (Apheresis related suspected air embolisms, haemolysis events, and any suspected allergic reactions). Events that are graded either 4 or 5, and/or where there is potential for learning and improving our processes will be managed as QIs, promoting a proportionate approach to incident management.

Many of the DAEs recorded on Q-Pulse during the first 6 months of the new process were categorised as:

- 'allergic reaction', often to a chloraprep wand, or
- 'arm pain'.

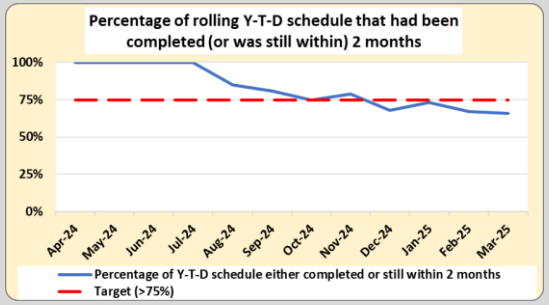
"Donor complained of discomfort during donation. ... DC completed needle adjustment based on this to resolve discomfort and flow. Donor stated that this resolved the discomfort. ... Needle shouldn't have been adjusted to resolve discomfort, should have been removed."

MANAGEMENT QUALITY REVIEW: Annual 2024/25

Internal Quality Self-Inspection Audit

Audits completed within (or not yet past) 2 months from scheduled date (Overall year position @ end March)

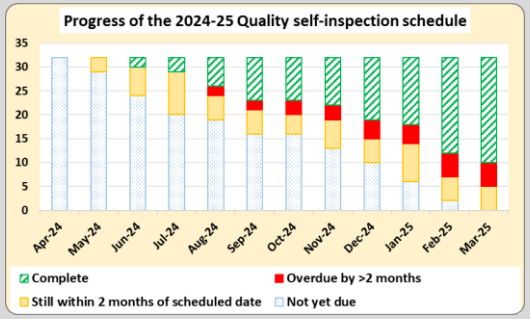
66%



Overall performance of the annual audit schedule has been positive, and the KPI was met in 8 out of 12 months during the year. However, the position at the end of the reporting year was below target.

Audits are 'complete' when all the testing has been finished, and the report distributed.

At the end of March there were 5 audits overdue. There were a further 5 audits that were not yet fully complete, these audits were scheduled to be carried out in Q4 and are therefore not classed as being overdue.



Improvements made to the Quality self-inspection process during 2024-25

- SOP1480 updated and a new field added to the Q-Pulse system to capture better quality data. This has enabled more accurate timely tracking of the annual audit schedule.
- Monthly call established between the Audit Administration team and lead auditors. In addition to monitoring the progress of audits, this call provides a forum for getting support and advice when needed.
- Creation of a 'quality self-inspection audit' SharePoint site to share documents, aid collaboration between auditors, and encourage auditors to proactively volunteer for audits.
- Development of trainees: 15 new auditors signed off during 2024-25, and a further cohort completed the auditor training course. Lead auditor training course also run.

Some of the themes noted this year

- **Adherence to procedures**: Audits of several areas of NHSBT, and covering different standards, have identified issues relating to documented procedures not being followed (e.g. "*MPD408/3 'Dress Code and Change Regime for NHSBT Manufacturing, Hospital Services, Testing and other GMP laboratory areas' not being complied*")
- **Incident management**: An incident management audit was conducted this year which identified a range of issues (e.g. "*Corrective actions were not completed in a timely manner and a number of actions had an inappropriately long target date.*"). As noted earlier, Quality will be leading workstreams to update the incident management process, but it is also vital that all departments proactively manage their incidents and complete their actions on time.
- **Environmental issues**: Issues included a lack of records to evidence regular cleaning, quarantined products not fully segregated, and potential sources of contamination (e.g. "*shelving was located under the air conditioning unit which was dripping into the reagent basket*")

The quality self-inspection audit program plays an important role in providing assurance that procedures are up to date, that they are being followed across different teams and sites, and that NHSBT overall remains compliant with regulations.

In recent years there has been a positive correlation between themes found by internal quality self-inspection audits and regulatory inspections, which reinforces the importance of supporting the internal audit schedule and addressing audit findings promptly and effectively, before more serious issues develop.

MANAGEMENT QUALITY REVIEW: Annual 2024/25

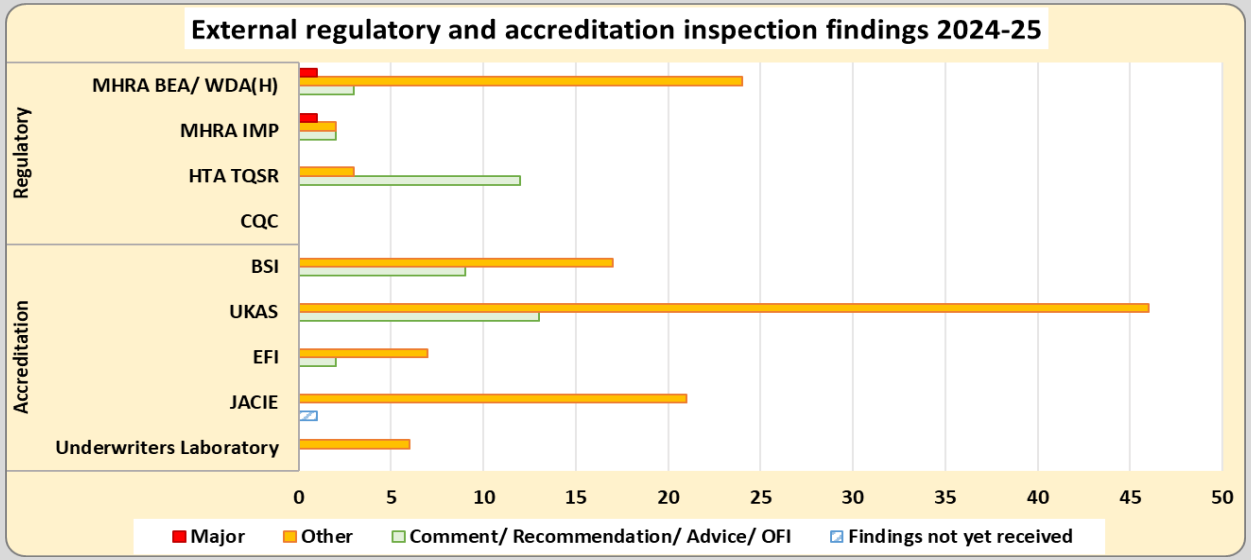
External Inspection Performance

External Regulatory Majors & Musts
(Target = 0)
(Last year: 1)

2

Overall, there have been good results from external inspections in 2024-25, with no Critical findings raised, and only two regulatory Majors.

Licence / Accreditation	Inspections	Outcome
MHRA BEA/WDA(H)	7 inspections (Birmingham, Newcastle, Plymouth, Oxford, Liverpool, Basildon, and Southampton)	1 Major 24 others 3 comments
MHRA MIA-IMP & Specials	1 inspection (Liverpool)	1 Major 2 Others 2 Comments
HTA TQSR	3 inspections (Barnsley, Filton, and Liverpool licence #11018)	3 Minors 12 Areas of advice & guidance
CQC	1 inspection (Brixton donor centre)	Inspected as part of registration, no findings
Accreditations	22 inspections • 4 UKAS: 1 RCI (various sites), 1 H&I (Colindale & Barnsley); IBGRL, and MSL Colindale • 3 EFI: all H&I (Tooting, Birmingham, and Colindale) • 1 Underwriters Laboratory (Liverpool Reagents) • 3 JACIE: CMT & TAS Birmingham, CMT & TAS Filton, CMT & TAS Barnsley • 1 FACT/Netcord: Cord Blood Bank • 13 BSI: National, and various sites	0 Majors 97 Non-conformances 24 Areas of advice & guidance



Major findings

The two regulatory Major findings were both from MHRA inspections, and both related to NHSBT's internal controls.

The first Major was from the BEA/WDA inspection of Newcastle, that "*The Quality Management System had failed to ensure that blood components were stored in appropriately controlled and managed equipment*". Actions are ongoing to address this locally and also to ensure that the same issue doesn't exist at other sites.

The second regulatory Major was from the IMP inspection of Liverpool ATU which found that "controls around sterility assurance were deficient". Actions are progressing as required.

MANAGEMENT QUALITY REVIEW: Annual 2024/25

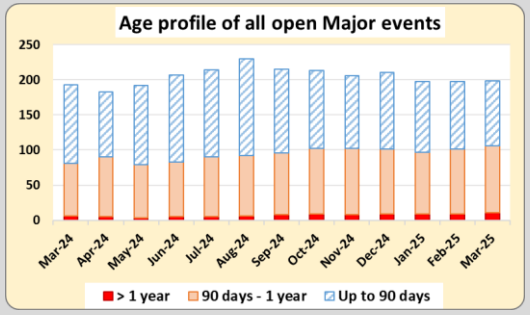
Quality Management System Performance

Patient Safety Incident Investigations (PSIIs)

8

NHS England's new Patient Safety Incident Response Framework (PSIRF) was successfully rolled out in mid 2024. One of the changes made was to replace the old Serious Incident process with a new Patient Safety Incident Investigation process.

- July: 3 – Erroneous test result led to a clinical decision to give unnecessary medication
  - – Tissue released with incorrect microbiology results
  - – Incomplete information from referring team contributed to delays in treatment
- October: 2 – Delay in reporting patient results
  - – Antibody not detected, leading to treatment adjustments not being made
- November: 1 – Plasma donor reported "blood in urine" following a donation
- December: 2 – Patient blood group incorrectly reported
  - – Mix-up during testing led to patient samples being incorrectly assigned



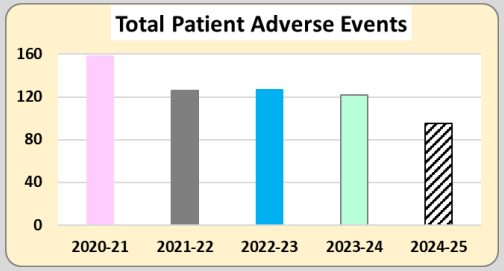
QMS Major events

The overall volume of all open Major QMS events (including Quality Incidents, Hospital Complaints, and Audit findings) at the end of 2024-25 (198) was comparable to the same point the previous year (193 open Major events at the end of March 2024).

The proportion of open Major events that are more than a year old has remained low throughout the year.

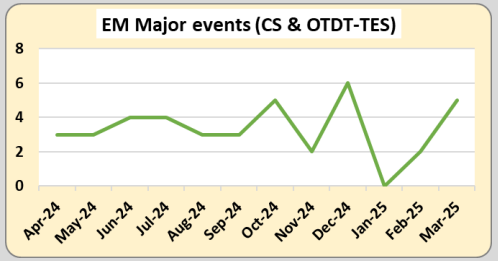
Patient Adverse Events (PAEs)

The total number of Patient Adverse Events recorded during 2024-25 was 22% lower than the previous year (95, compared to 122 recorded in 2023-24). It was also the lowest total recorded for at least the last five years.

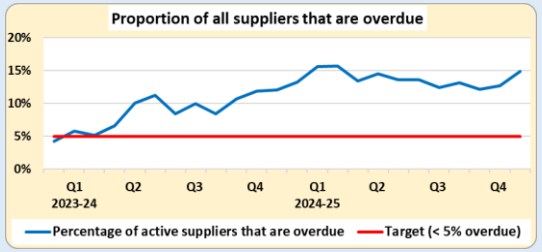


Environmental Monitoring (EM) Majors

The volume of EM Majors remained low throughout the 2024-25 reporting period, with around half the number of events recorded compared to the previous year (40 EM Majors raised this year, down from 79 during 2023-24).



Supplier management



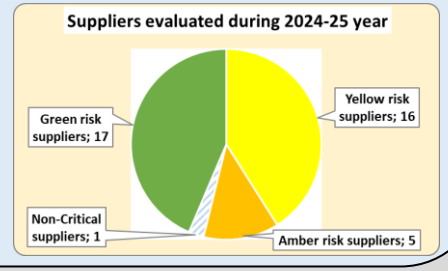
Despite many supplier reviews having been carried out this year, meeting the target (for fewer than 5% of active suppliers to be overdue) has been difficult, and the target was missed in all months.

However, improvements have been made with the volume of overdue high risk (red) suppliers, which has been reduced to just one overdue at the end of the reporting year – 83% overdue at the start of the reporting year reduced to 20%.

The supplier review process is currently under review, with plans to launch a new more streamlined process during 2025-26.

In total 39 suppliers were evaluated during 2024-25;

- 18 by certification checks;
- 18 by supplier questionnaire;
- 3 by audit.



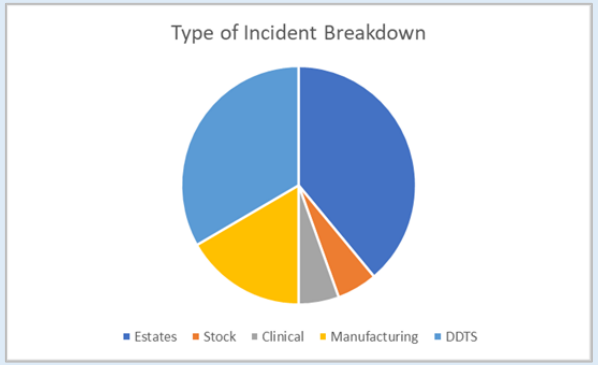
MANAGEMENT QUALITY REVIEW: Annual 2024/25

Business Continuity (BC)

Following the ISO22301 BSI Audit, the Business Continuity Team revised the business continuity exercise programme that ran until the end of March 2025. This resulted in the completion of 8 business continuity exercises and 9 Local Emergency Team (LET) exercises. The expectation is that the LET attendance figures will go up as there will be more LET exercises delivered this year.

Going forward, the 2025 exercise programme will see departments exercised as opposed to plans. There will be two different forms of exercise, the first being department level exercises, and the second will be in the form of 2 larger multi-department exercises run each year.

NHSBT's Critical Incident Plan was activated 18 times across the year.



Estates – 7
Stock Incident – 1
Clinical (Supporting the wider NHS during the South London cyber attack) – 1
Manufacturing – 3
DDTS – 6

Estates incidents impacted the whole site, for example failure of water supply.

Throughout these incidents supply of key products and services were maintained.

- NHSBT's ISO22301 was successful, with only two non-conformities raised this year.
- Focus in the coming year continues to be the development of a National Power Outage plan (which is a high impact, low likelihood event).

Risk

Since April 2023, the Risk Team facilitated the closing of 275 internal audit actions across the organisation. Out of the 44 GIAA audits, 32 are closed. By December 2024 we achieved zero overdue actions of any priority rating. This has continued through to the end of the financial year 2025. Evidence was submitted to the GIAA ahead of due dates for all audit actions.
NHSBT now has an assurance map and review process in place which has been supported by the GIAA. The outputs can be viewed through a Power BI report which allows users to drill through and view the full supporting data.
The team have also used the Risk Management System to capture all compliance information and actions for the 'shall' (mandatory) elements of the Government Functional Standards and the Risk Control Framework. The team will now manage these action plans through the same process as GIAA audits.
Following a Board workshop in November 2024, all Principal risks are currently being re-articulated to ensure clarity and relevance.

Principal Risk	Appetite Level	Detail/Commentary
P-01 Donor & Patient Safety		4 contributory risks in judgement zone
P-02 Service Disruption		1 contributory risk at risk limit
P-03 Loss of Critical IT		1 contributory risk at risk limit
P-04 Donor Numbers & Diversity		1 contributory risk at risk limit
P-05 Finance		1 contributory risk in judgement zone
P-06 Clinical Outcomes & Health Inequalities		Risks at or below tolerance
P-07 Staff Capacity/Capability/Recruitment/Retention		Risks at or below tolerance
P-08 Leaders & Managers		Risks at or below tolerance
P-09 Regulatory Compliance		Risk at optimal level
P-10 Pace & Scale of Transformational Change		Risks at or below tolerance
P-11 Corporate Governance		1 contributory risk in judgement zone

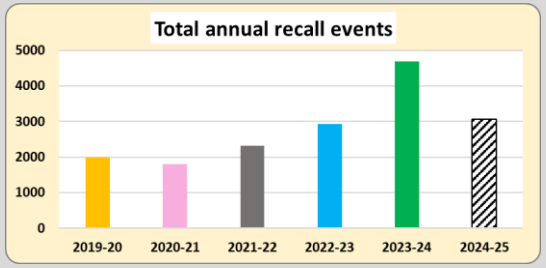
MANAGEMENT QUALITY REVIEW: Annual 2024/25

Recalls

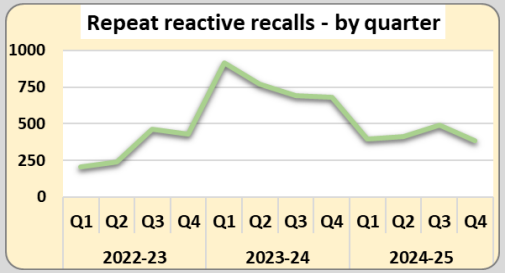
Total Recalls 2024/25
(last year: 4686)
3058 ⬇

The overall number of recalls fell by 35% 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 (55% of recalls in 2024/25)

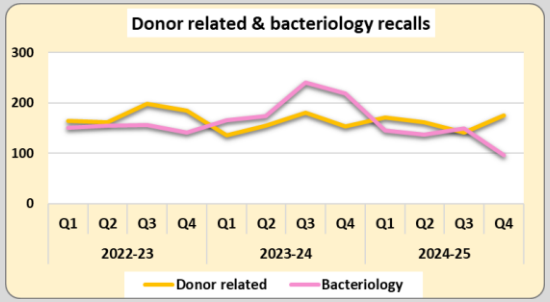


Following a peak at the start of the last reporting year, when anti-HBc testing was at its height and syphilis testing was switched to a new analyser, the volume of 'repeat reactive' recalls decreased by 45% compared to 2023-24, returning to a level that is consistent with previous years.

Donor related recalls (21% of recalls in 2024/25) and Bacteriology recalls (17% of recalls in 2024/25)

The second most common recall category, donor related recalls, remained at a similar level to the previous year.

In contrast, the volume of bacteriology recalls was 34% lower than in 2023-24. The false positive bacteriology rate is associated with fluctuations in temperature with loading and unloading bacteriology bottles. Sites are in the final stages of fully implementing a new bacterial screening contract and equipment which is less prone to temperature fluctuations.



Regulatory update

UK Medical Device Regulations

As part of the iterative approach to Device regulation in Great Britain, "The Medical Devices (Post-market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2024" will come into force on 16th June 2025. The legislation aims to facilitate greater traceability of incidents and trends related to medical devices. NHSBT is in the process of reviewing the new requirements and will implement any required changes to process.

In addition, the MHRA opened a public consultation in February 2025 concerning four policy areas:

- UKCA Marking: A Unique Device Identification (UDI) may replace the requirement for physical UKCA marking, enhancing traceability.
- International Reliance: The MHRA may allow some devices already approved by comparable regulators to enter the GB market faster.
- In Vitro Diagnostic (IVD) Devices: A risk-based classification system for IVD devices is proposed.
- Assimilated EU Law: The MHRA suggests retaining four EU-based laws within the framework to ensure continuity in safety and access to innovative devices.

EU Substances of Human Origin (SoHO) Regulation

The new EU SoHO Regulation, effective in the EU from August 2027, has prompted the DHSC, working with JPAC and SaBTO, to collaborate with impacted UK regulators (MHRA, HTA, HFEA, and FSA). A series of gap analyses have been conducted against EU directives and EDQM guidance to understand differences between EU and GB legislation and determine the feasibility and value of alignment.

Concerns have been raised regarding the regulation's implementation in Northern Ireland, which is held to EU law. Further details and technical guidance are awaited before a final UK position can be determined.

The next step involves reviewing the gap analyses to inform upcoming consultations on the UK's response to the new EU regulation, which are expected to be opened in late 2025.

MANAGEMENT QUALITY REVIEW: Appendix A – Q4 2024/25

Patient Adverse Events (PAEs)

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

29 (Q3: 28) ⬆

Patient Safety Incidents (PSIIs)

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

0 (Q3: 5; YTD: 8) ⬇

Donor Adverse Events (DAEs)

DAEs recorded during the quarter
(no target set)

37 (Q3: 33) ⬆

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)

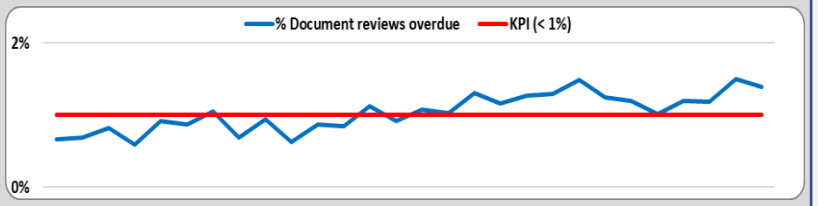
Note: figures do not include OTDT-ODT 'INC' incidents

KPI 1

Target: < 1% documents with an overdue review

End of Q4 position

1.39% ⊗
(Q3: 0.66%) ⬆

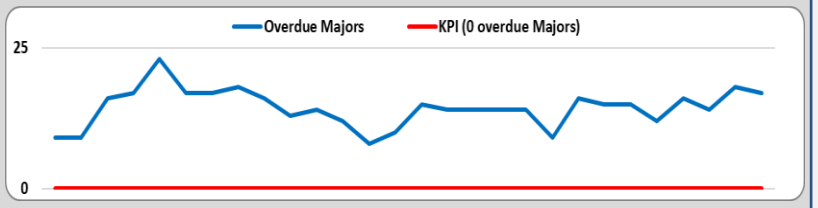


KPI 2

Target: Zero overdue Majors

End of Q4 position

17 ⊗
(Q3: 9) ⬆

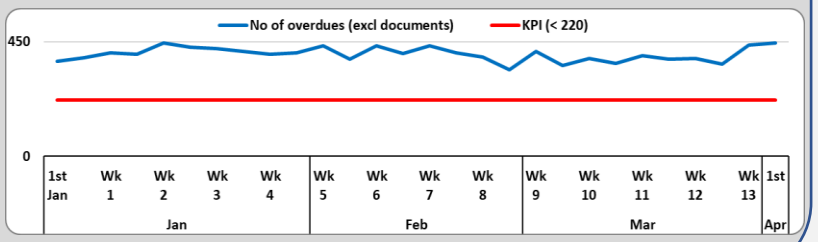


KPI 3

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

End of Q4 position

447 ⊗
(Q3: 374) ⬆

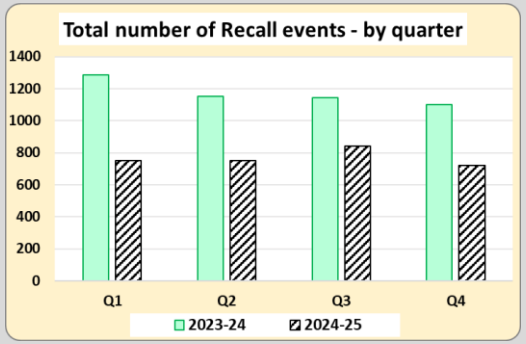


Recalls

Rate per 100,000 donations: 202.0

Recall events during the quarter
(no target set)

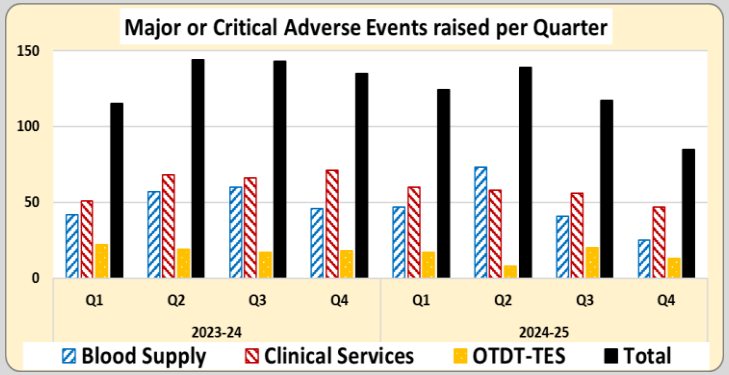
719 (Q3: 840) ⬇



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)

85
(Q3: 117) ⬇



MANAGEMENT QUALITY REVIEW: Appendix A – Q4 2024/25

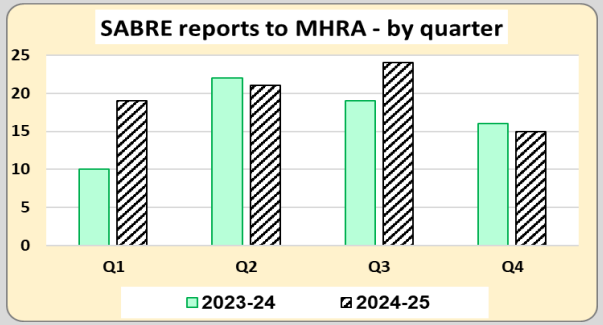
Externally Reported Events

SABRE

Rate per 100,000 donations: 4.2

SABRE reports submitted during the quarter
(no target set)

15 (Q3: 24) ⬇

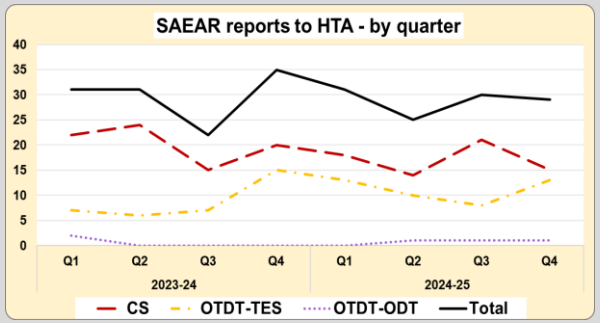


SAEAR

(figure includes NHSBT ODT SAEARs)

SAEAR reports submitted during the quarter
(no target set)

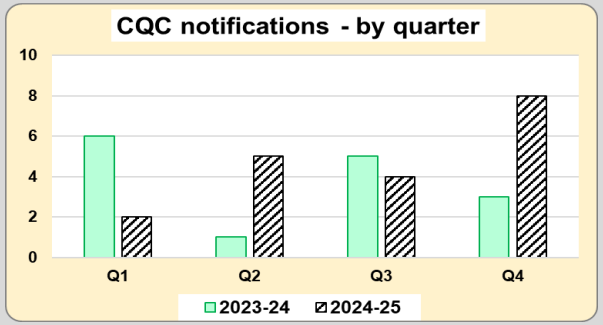
29 (Q3: 30) ⬇



CQC notifications

CQC notifications submitted during the quarter
(no target set)

8 (Q3: 4) ⬆



Business Continuity

CIM training

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

End of Q4 position
(no target set)

82% (Q3: 78%)

LET training

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

End of Q4 position
(no target set)

91% (Q3: 90%)

BC exercise completion

Percentage of scheduled business continuity exercises completed across the year to date

End of Q4 position
(no target set)

88% (Q3: 33%)

LET exercise attendance

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

End of Q4 position
(no target set)

62% (Q3: 65%)

MANAGEMENT QUALITY REVIEW: Appendix B – Acronyms used in this report (1 of 2)

Acronyms			
ATU	Advanced Therapies Unit	GMP	Good Manufacturing Practice
BC	Business Continuity	H&I	Histocompatibility and Immunogenetics
BEA	Blood Establishment Authorisation licence	HC	Hospital Complaint
BSI	British Standards Institute	HFEA	Human Fertilisation and Embryology Authority
CIM	Critical Incident Manager	HTA	Human Tissue Authority
CMT	Cellular and Molecular Therapies	IBGRL	International Blood Group Reference Laboratories
CQC	Care Quality Commission	IVD	In Vitro Diagnostic
DAE	Donor Adverse Event	JACIE	Joint Accreditation Committee ISCT Europe & EBMT
DC	Donor Carer	JPAC	Joint Professional Advisory Committee
DDTS	Digital, Data & Technology Services	KPI	Key Performance Indicator
DHSC	Department of Health and Social Care	LET	Local Emergency Team
DSC	Donor Safety Check form	MHRA	Medicines and Healthcare products Regulatory Agency
EDQM	European Directorate for the Quality of Medicines & Healthcare	MIA-IMP	Manufacturer's Import Authorisation – Investigational Medicinal Products licence
EFI	European Federation for Immunogenetics	MPD	Management Process Description
EM	Environmental Monitoring	MSL	Microbiology Services Laboratory
EU	European Union	OFI	Opportunity for Improvement
FACT	Foundation for the Accreditation of Cellular Therapies	OTDT	Organ and Tissue Donation and Transplantation
FSA	Food Standards Agency	ODT	Organ Donation and Transplantation
GB	Great Britain	PAE	Patient Adverse Event
GIAA	Government Internal Audit Agency	PSA	Prostate Specific Antigen

MANAGEMENT QUALITY REVIEW: Appendix B – Acronyms used in this report (2 of 2)

Acronyms			
PSII	Patient Safety Incident Investigation	SAEAR	Serious Adverse Events and Adverse Reactions
Q3	Quarter 3 of the current financial year (October – December 2024)	SAED	Serious Adverse Events of Donation
Q4	Quarter 4 of the current financial year (January – March 2025)	SoHO	Substances of Human Origin
Q2 2025-26	Quarter 2 of the next financial year (July – September 2025)	SOP	Standard Operating Procedure
Q&G	Quality and Governance	TAS	Therapeutic Apheresis Services
QI	Quality Incident	TES	Tissue and Eye Services
QMS	Quality Management System	TQSR	Human Tissue (Quality and Safety for Human Application) Regulations
RCI	Red Cell Immunohaematology	UKAS	United Kingdom Accreditation Service
SABRE	Serious Adverse Blood Reactions and Events	UKCA	United Kingdom Conformity Assessed
SaBTO	Advisory Committee on the Safety of Blood, Tissues and Organs	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 6)	
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.