MANAGEMENT QUALITY REVIEW: Annual 2025/26

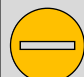
Headlines for the year, and any key risks and issues for attention

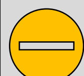
NHSBT's resilience framework has been in place for a number of years to ensure a flexible response to any critical incident and has again this year proven to be effective. Exercise Pegasus helped improve this framework and raise the profile of Business Continuity/ Organisational Resilience both internally and with Central Government.

Although for most of the year it was a challenge to keep up to date with reviews of suppliers with a quality impact, the year ended on a high, achieving the KPI (for less than 5% of supplier reviews to be overdue). This has been achieved by improvement work lessening the administrative burden of supplier reviews, and organising the Account Managers into Cohorts that can provide better support and flexibility to share workloads.

The overall volume of regulator reported incidents decreased compared to recent years. This change follows increased volumes of SABRE and SAEAR notifications in each of the last two years, and the number of reports submitted this year is similar to previous years. Quality & Governance continue to regularly monitor volumes of regulator notified events, and provide updates at SMT meetings to aid in identifying trends and drive improvement actions.

External inspection performance has been positive all year, with only one regulatory (MHRA, HTA, or CQC) inspection producing any Major findings. In contrast, there have been several inspections that raised no findings, including an unannounced inspection of a donor centre by the CQC. With regard to the Major findings that were raised this year, actions have already been taken to address the findings, and a follow up review has confirmed that the actions are now embedded.

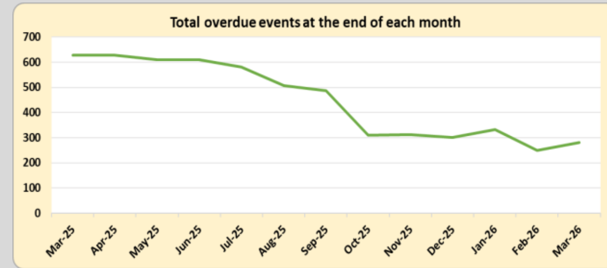

Although the Quality self-inspection audit schedule KPI was not achieved at the end of the year, performance across the year was improved compared to 2024-25, with the KPI being met in 10 months. Improvement work has taken place but is taking time to embed, further improvements are planned for 2026-27.


Reducing overdue QMS events was a struggle for most of this year, and only one of the corporate KPIs was met at the end of the year. However, work to improve the incident management process has progressed and towards the end of the year is starting to have an impact on overdue events, with all three KPIs having been achieved at least once during Q3-Q4. Improvements made so far include updates to the incident management SOP, a new reporting template, and a revised risk matrix used to classify the severity of incidents. Further work is planned for the coming year, and will include measures to support more effective trending of incidents and CA/PA management. It also remains important that all departments take responsibility for proactively managing the events that they own.

MANAGEMENT QUALITY REVIEW: Annual 2025/26

Overdue events

The volume of overdue events varies daily, but there was a notable decrease towards the end of this year in the overall volume of overdue QMS events.



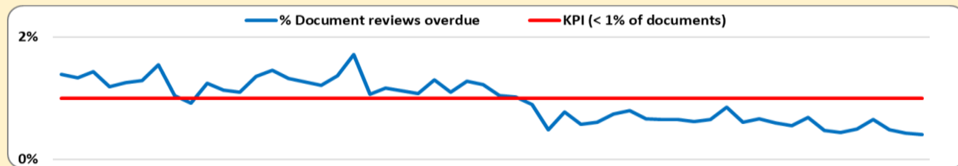
Performance against the three overdue QMS event corporate KPIs

Whilst the year ended with only one of the KPIs being met, there has been a clear improvement in performance against all three KPIs during the second half of the year.

The graphs below show performance at every Monday throughout the 2025/26 year.

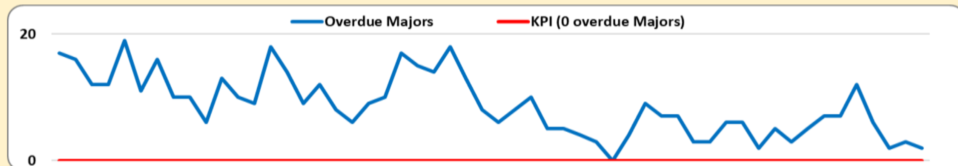
KPI 1

Target: < 1% documents with an overdue review



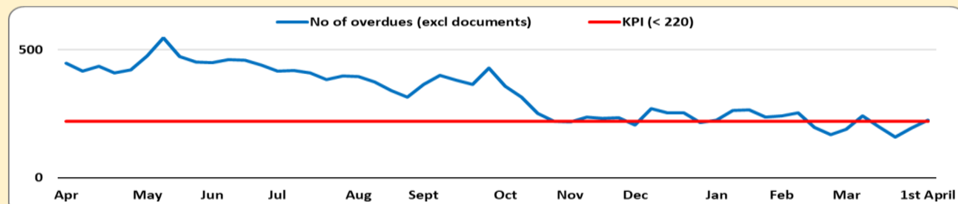
KPI 2

Target: Zero overdue Majors



KPI 3

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



Incident Management improvement work

Following last year's Value Stream Analysis event, the Incident Management improvement work was split across 3 workstreams:

1. Data – In: Improving the quality of data into the system so that proportionate, risk-based decisions are easier and faster.

So far, the reporting template has been updated, and comprehensive reporting guidance rolled out to QA teams for cascade. A SharePoint site has also been established for guidance and supporting materials. The next steps are to build a library of good examples specific to operational areas.

2. Process: Streamlining the process, and improving the tools and guidance so that people have the right materials and skills to identify effective actions to improve quality and safety.

So far, the risk matrix has been made less risk averse, setting more events to monitor and reducing the volume of incidents in the system. Best-practice guidance has been developed for Investigation, Causal Analysis, and Action determination which is available to QA colleagues initially. The next steps include trialling a new way of managing incidents in Q-Pulse that separates the investigation and cause analysis from action completion.

3. Trending and analysis: Improving trend analysis so that low-risk, high-frequency events as well as underlying themes can be identified and managed in a proactive and holistic manner.

Working with stakeholders, trending categories have been refined and systematic methodologies developed for identifying and managing trends. The next steps are to implement the new categories in Q-Pulse and determine the reporting mechanisms.

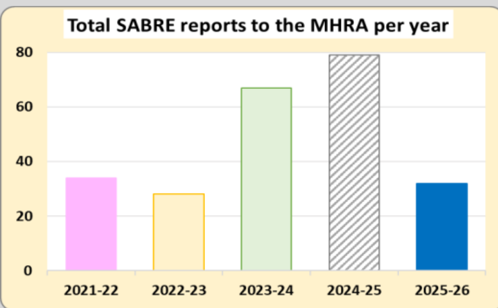
MANAGEMENT QUALITY REVIEW: Annual 2025/26

Serious Adverse Blood Reactions and Events (SABRE)

MHRA reported incidents

Total SABREs 2025/26
(Last year: 79)

32



The total number of SABRE reports submitted decreased this year, with fewer than half as many as were submitted during 2024/25.

However, the volume of SABRE reports this year is similar to previous years (e.g. 2021/22, and 2022/23), prior to an increase in SABREs related to donor screening incidents involving the drug finasteride.

Themes noted in the incidents reported to the MHRA this year included:

- Incidents occurring during 'non 9-5' shifts. The impact of shift patterns varies, with some incidents referencing ineffective handovers between shifts, while others note that the staff member was working alone. However, some records suggest that routine lone worker checks were successful in identifying the incident and enabling corrective action to be taken promptly.

"Ineffective handover between day shift operators and on-call … (assumption made by day shift that there was no need for written handover due to the fact that 6 cases were handed over as 'ready to issue'), local handover form not being utilised and no notes taken by the on-call BMS."

"The incident occurred as a result of a failure to follow procedure. ... Although it was quiet at the time the BMS felt the perceived pressure to try and get the crossmatch out as quickly as possible in case it got busy later"

- System/ IT issues contributing to delayed recalls, incorrect testing results, and errors with appointment booking.
- Documented processes not being followed in full.
- Staff feeling under pressure to rush cases. Even where overall workloads are not high staff members may still feel a need to complete cases quickly.

Serious Adverse Events and Adverse Reactions (SAEAR)

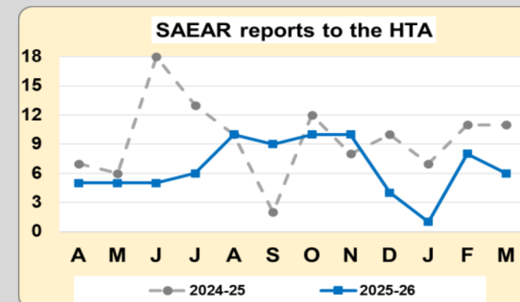
HTA reported incidents

Total SAEARs 2025/26
(last year: 115)

73

Overall, the number of SAEAR reports submitted to the HTA this year has been lower than in each of the previous two years.

The majority (63%) of the reported incidents were for Clinical Services, 29% were in OTDT-TES, and 8% were in OTDT-ODT.



As in previous years, the most common type of event to be reported to the HTA had the title 'bacteriology positive'.

"Source of contamination is most likely from bone marrow collection procedure. No NHSBT fault identified."

Whilst all incidents are investigated, in many cases the source of the bacteria could not be confirmed. Although several of the incidents note that the collection process is thought to be the most likely source of contamination.

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

- Failed engraftments, and serious adverse reaction events that led to engraftment failures;
- Incidents that had the potential to transmit infection from donor to recipient;
- Processing incidents;
- Courier/ transport issues

*"cornea sent for DMEK, but not used, surgeon reports graft was too sticky and did not unfold despite rewashing.
Patient was anaesthetised but graft not used."*

In addition to the above, 83 SAEARs (65 Serious Adverse Events and 18 Serious Adverse Reactions) were reported by NHSBT on behalf of the transplant sector, under the Assisted Function role.

MANAGEMENT QUALITY REVIEW: Annual 2025/26

CQC notifications

CQC reported incidents

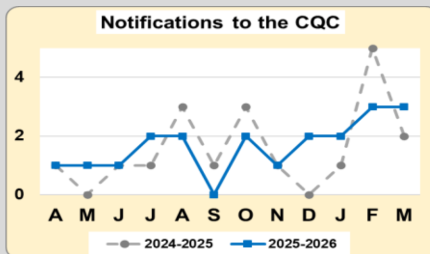
Total CQC notifications 2025/26
(Last year: 19)

20

The number of CQC notifications submitted across the year was similar to the previous year.

The incidents were reported under three categories:

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



The types of injuries that were reported as 'serious injury' included:

- Arm pain
- Injuries sustained from fainting/ vasovagal reaction
- Headache and blurred vision
- Incorrect blood issued for a sickle cell patient, leading to heightened sensitisation to future treatment

"he was already unwell with deteriorating biochemical profile and a major haemorrhage. PEX was commenced at the time point that ITU team felt he was clinically able to tolerate this however had to be abandoned part way through."

All of the deaths that were reported related to TAS patients who were already very unwell when their treatment began.
In some cases treatment had to be stopped, while in others the patient's family chose to withdraw life support.

The two incidents that were reported as stopping the service running safely & properly were both related to legionella being discovered in the water supply at NHSBT centres. In both cases there is no indication of any impact on the safety of either products or donors.

"No impact on clinical products, only blended supply outlets returned positive results. … Impact mitigated as outlets were immediately taken out of use and filters were installed."

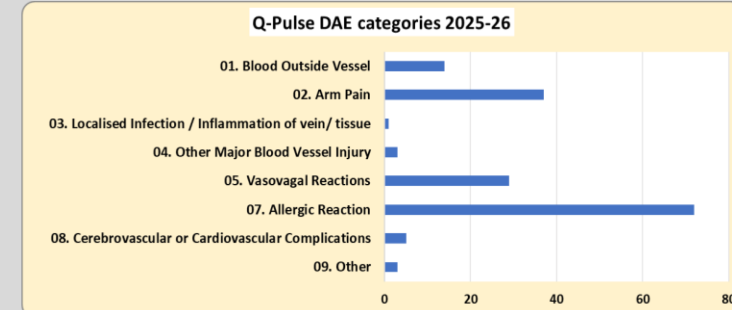
Donor Adverse Events (DAEs)

Total DAEs on Q-Pulse 2025/26
(last year: 20 SAEDs & 70 DAEs)

164

This is the first full year that the DAE process has been in operation.

The most common category for DAEs logged on Q-Pulse throughout the year has been allergic reactions to chloraprep wands.



*"post donation event where a donor experienced an ocular migraine
Four weeks on the donor then diagnosed as having had a stroke"*

A couple of events involved more serious outcomes for the donors, such as stroke or physical injuries sustained through fainting.

All DAEs are investigated so that any actions needed (such as duty of candour or withdrawing the donor) can be taken.

Upcoming changes to the DAE process

The current process of categorising, reporting, and investigating DAEs was introduced in October 2024, to assist in trending and benchmarking. A review of the change a year later identified a number of errors in the selection of the category types. Amendments to the documentation (based on review and user feedback) will be rolled out in April 2026, with the aim of achieving more consistent reporting.

It is anticipated that an increase in the number of DAEs logged in Q-Pulse will be seen from May 2026, due to the mandating of reporting and investigation of all severity grade 3 DAEs to ensure the appropriate learning is achieved from these more serious events.

MANAGEMENT QUALITY REVIEW: Annual 2025/26

Internal Quality Self-Inspection Audit

Audits completed within (or not yet past) 2 months from scheduled date (Target = >75%)

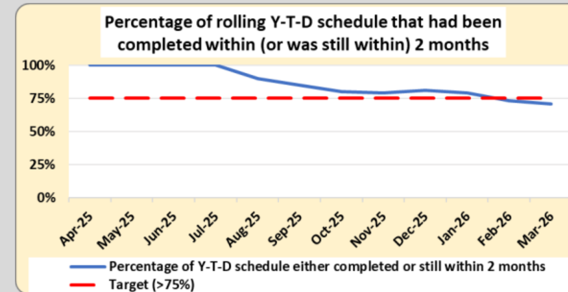
Position @ end March: 71%

Quality Audits are a key component of a Quality Management System.

The self-inspection audit program seeks to provide assurance that internal processes are safe and effective, and offers an opportunity to identify areas where improvements can be made in order to keep our products, patients and donors safe.

For the purpose of tracking the schedule, audits are classed as 'complete' when the report has been distributed.

Overall performance of the annual audit schedule has been positive, and was improved this year compared to the previous year.
The KPI was met in 10 out of 12 months during the year. However, the position at the end of the reporting year was below target.



Improvements made to the Quality self-inspection process during 2025/26

Improvement work built on the improved data collection process implemented in 2024/25, and focused on raising the profile of self inspection, and improving performance against the KPI.

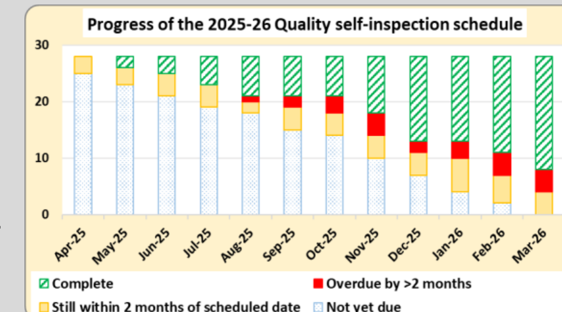
- Audit Charter launched, together with guidance for managers to help them support auditors
- Audit week took place in July with a range of blogs, seminars, discussions, and a quiz
- A single site multi-standard audit was undertaken as a pilot to investigate ways to scope and schedule audits differently. This has led to an options appraisal which will inform work going forward into 2026/27.
- 12 new auditors approved, and further Cohort trained to replace movers and leavers in the Auditor pool.
- Work started on reviewing and improving the auditor training including tracking of trainees' progress, and training material and delivery methods. This will continue into 2026/27.

Some of the themes noted this year

- **Issues with the management of temperature-controlled environments**: A range of issues have been noted this year, including the management of temperature controls (e.g. "*evidence of temperature logs being kept in the storage area for several months without being reviewed*") and the locations of thermometers (e.g. "*thermometers are not located where the consumables are stored*").
- **Insufficient security**: In addition to findings related to data security and IT systems, concerns have also been raised regarding the security controls at some sites, which could pose risks to staff and/or product safety (e.g. "*the rear door of the garage was not fully secure and was easily opened when pushed*").
- **Deficiencies in the management of QMS events**: Work is ongoing to strengthen the incident management process, but issues have also been found with the control of change (e.g. "*No actions have been completed, no RIA has been completed, record is approximately 2 months overdue, and no justification recorded*").

At the end of March four audits were overdue (more than 2 months past their scheduled date).

There were a further four audits that were not yet fully complete, but were scheduled to be carried out during Q4 and are therefore not classed as being overdue.



MANAGEMENT QUALITY REVIEW: Annual 2025/26

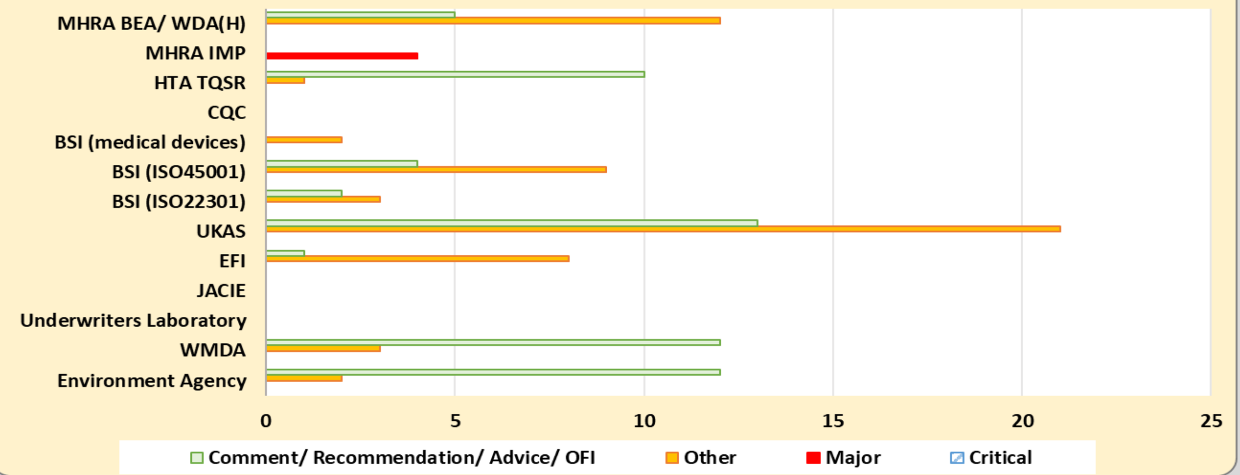
External Inspection Performance

External Regulatory Majors & Musts
(Target = 0)
(Last year: 2)

4

Overall, there have been good results from external inspections in 2025/26, with no Critical findings raised, and only one inspection raising any Major findings.

Licence / Accreditation	Inspections	Outcome
MHRA BEA/WDA(H)	3 inspections (Filton, Barnsley, and Cambridge)	12 others 5 comments
MHRA MIA-IMP & Specials	1 inspection (Birmingham)	4 Majors
HTA TQSR	4 inspections (Oxford, Birmingham & Coventry, Southampton, and Colindale)	1 Minor 10 Areas of advice (2 inspections still awaiting final reports)
HTA OQSR	1 inspection (ODT)	No findings
CQC	1 inspection (West End donor centre) 2 registration inspections (Southampton & Brighton donor centres)	No findings
Accreditations	38 inspections/ external audits • 4 UKAS: H&I, IBGRL RCR, MSL, and RCI • 2 EFI: H&I (Barnsley & Newcastle) • 1 UL: Reagents (Liverpool) • 1 WMDA: SCDR (Filton) • 14 BSI: 1 IVDR inspection, 1 ISO22301 business continuity inspection, and 12 ISO45001 health & safety inspections • 15 Environment Agency • 1 JACIE: TAS & CMT (Northwest sites)	48 Non-conformances 44 Areas of advice & guidance (final reports not yet available for 14 inspections)



Major findings

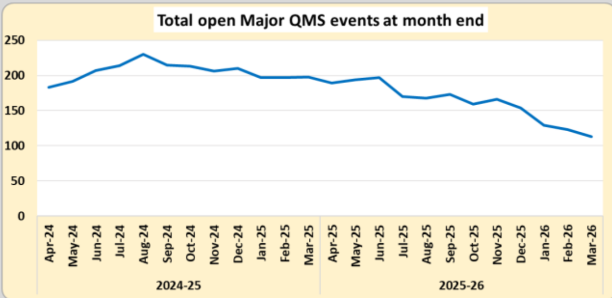
All of the Major regulatory findings were from the MHRA inspection of Birmingham ATU and related to internal controls: of contamination; sterility assurance; the pharmaceutical quality system (PQS); and documentation and process instructions.

The findings impact on the management and assurance of sterile products that are manufactured in the controlled environment (Clean room) and that are released to the end user prior to sterility results being in place, with failures in the PQS also posing risks to operators following standard process for manufacture of safe, quality, and efficacious products.

Most of the findings related to historic deficiencies that had already been addressed, and actions have been implemented for the remaining findings. There has been a follow up review of the actions that were implemented, providing assurance that the actions are well embedded, and processes are now in control.

MANAGEMENT QUALITY REVIEW: Annual 2025/26

Quality Management System Performance



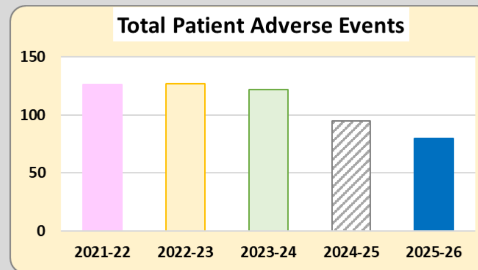
QMS Major events

The overall volume of open Major QMS events (including Quality Incidents, Hospital Complaints, and Audit findings) at the end of 2025/26 was 43% lower than at the same time the previous year.

Much of the decrease in open Major events towards the end of this year can be attributed to the changes that have been made to the incident management process (details can be found on slide 2). Since QIs make up the majority of Major QMS events (around 85-90% of open Majors recorded on the Q-Pulse system), improvements to the reporting template and risk matrix have led to fewer incidents being classified as Major severity.

Patient Adverse Events (PAEs)

The total number of Patient Adverse Events recorded during 2025/26 was 16% lower than the previous year (80, compared to 95 recorded in 2024/25). It was also the lowest annual total recorded for at least the last five years.

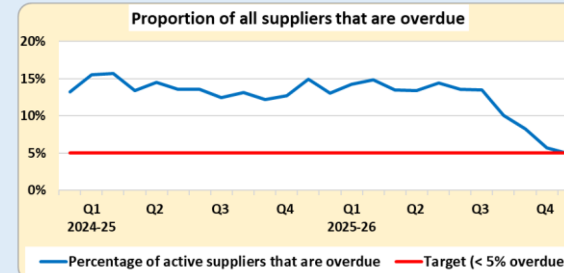


Patient Safety Incident Investigations (PSIIs)

2

- July: 1 – Sample mix-up during the dispensing of plasma into a gel card. The patient was transfused one unit but did not report any symptoms.
- September: 1 – Functionality on DonorPath questionnaire not performing as expected following system changes. Full sexual history questions not being asked.

Supplier management

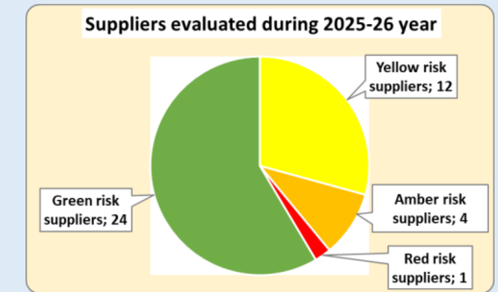


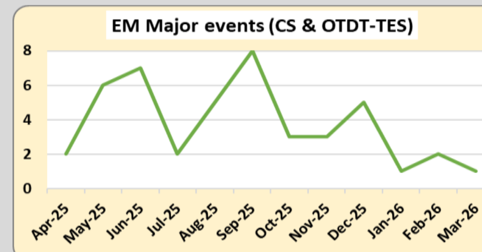
The process for supplier review has been streamlined, removing unnecessary administrative burden and providing support for account managers by organising them into Cohorts who can share the workload as circumstances require.

This has decreased the overdue supplier reviews from around 15% during the early part of the year to 4.9% at the end of March.

In total 41 suppliers were evaluated during 2025/26;

- 21 by certification checks;
- 15 by supplier questionnaire;
- 5 by audit.





Environmental Monitoring (EM) Majors

The overall volume of EM Majors raised during 2025/26 was similar to the previous year (45 EM Majors raised this year, compared to 40 raised during 2024/25).

MANAGEMENT QUALITY REVIEW: Annual 2025/26

Business Continuity (BC)

Exercise Pegasus was a Cabinet Office led exercise held over three days in September and October on the theme of pandemic disease. NHSBT had a significant role in the exercise with operational areas from across the organisation participating.

The National Power Outage Plan has been approved at Risk Management Committee and will be trained out by the end of Q1 2026/27.

NHSBT's ISO22301 BSI Audit took place in December 2025, the audit was successful with only 3 non-conformities raised this year.

This year NHSBT's Critical Incident response system was activated for 19 incidents.

Relating to the Pulse system – 9

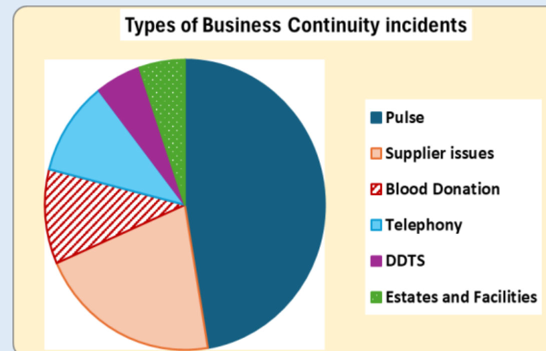
Supplier issues – 4

Blood donation process (where collections were disrupted) – 2

Telephony – 2

DDTS – 1

Estates and Facilities – 1 (team base closed due to a fire in a neighbouring unit)



Throughout these incidents, supply of key products and services was maintained.

Following the implementation of the new exercise programme in March 2025, two large multi departmental business continuity exercises took place. Exercise Wolverine focussed on Testing and the response to a short notice closure of Filton Testing. Exercise Breakpoint focussed on Pathology and the effects of a national Pulse outage.

26 Local Emergency Team (LET) exercises took place with over 330 attendees.

Risk

NHSBT continues to demonstrate stable and effective governance, maintaining an overall 'moderate' assurance rating, as reflected in the regularly reviewed and annually approved assurance map.
Internal audit action management remains strong, with zero overdue GIAA audit actions.
The Risk Management Framework has been refreshed to further strengthen organisational risk practices and updated; mandatory training will be available for appropriate stakeholders in April to support this.
Delivery of Phase 1 of the centre-based risk initiative has been completed, with five centres now operating live risk registers within the risk management system. Work will continue into 2026/27 to onboard the remaining centres and stock-holding units.
Two of NHSBTs principal risks (P-06 and P-08) were closed in 2025/26. The Board Risk Workshop was held in December, where the remaining principal risks and their associated risk appetites were agreed.

Risk Code	Risk Title	Risk Appetite	Residual Score	Residual Risk Appetite Level	Last Assessment Date
P-01	Donor & Patient Safety	Minimal	12	Judgement Zone	26/02/2026
P-02	Service Disruption	Minimal	16	Risk Limit	06/03/2026
P-03	Service Disruption - Loss of Critical ICT	Minimal	20	Risk Limit	23/02/2026
P-04	Donor Numbers & Diversity	Minimal	12	Judgement Zone	05/03/2026
P-05	Finance	Open	20	Judgement Zone	05/03/2026
P-07	People Staffing	Open	12	Tolerance Range	03/03/2026
P-09	Regulatory Compliance (Primary Regulators)	Cautious	9	Tolerance Range	03/03/2026
P-10	Failure to Deliver Transformational Change	Open	15	Tolerance Range	26/02/2026
P-11	Corporate Governance	Minimal	8	Tolerance Range	02/03/2026

MANAGEMENT QUALITY REVIEW: Annual 2025/26

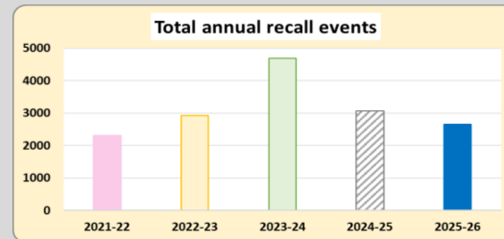
Recalls

Total Recalls 2025/26
(last year: 3058)

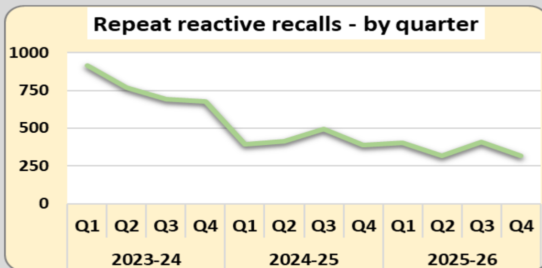
2647

The overall number of recalls fell by 13% compared to the previous year.

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



Repeat reactive recalls (55% of recalls in 2025/26)

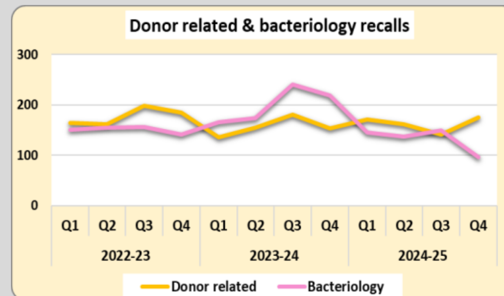


Since the changes in technology made in 2023, an improvement in the specificity rate has been observed with mandatory Microbiology Serology assays, and align with the downward trend in the number of recalls.

Donor related recalls (26% of recalls in 2025/26) and Bacteriology recalls (14% of recalls in 2025/26)

The second most common recall category, donor related recalls, was slightly higher than the previous year. However, this category is predominantly driven by information provided by donors rather than by NHSBT's internal testing processes.

There has been a clear downward trend in the number of Bacteriology recalls due to the implementation of a new bacterial screening system which loads bacterial screening bottles automatically as opposed to manually, ensuring a stable constant temperature. This has drastically reduced the number of false positives, and thus the number of recalls.



Regulatory update

UK Medical Device & AI Regulations

Following the Medical Devices (Post-market Surveillance Requirements) Regulations 2024 coming into force in June 2025, NHSBT has adapted as required to align with these enhanced safety standards. The emerging regulatory framework for AI-based medical devices, expected to be published by mid-2026, will address the unique challenges of adaptive algorithms and security. Additionally, the MHRA is finalising the International Reliance Route to allow faster market entry for devices approved by comparable global regulators, alongside a transition to Unique Device Identification (UDI) to replace physical UKCA marks.

Clinical Trials & Innovative Access

The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 will take full effect on 28th April 2026, introducing a risk-proportionate "Notification Scheme" that allows lower-risk trials to start without a 30-day wait. To further accelerate patient access, the Innovative Devices Access Pathway (IDAP) has transitioned from its pilot phase into a permanent regulatory route. This pathway is designed to expedite new technologies through the regulatory process, ensuring that innovations proven to be safe and cost-effective are approved for use at pace.

EU Substances of Human Origin (SoHO) Regulation

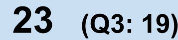
As the August 2027 effective date for the EU SoHO Regulation approaches, the DHSC, MHRA, HTA, HFEA and FSA, supported by JPAC and SaBTO, have concluded a series of legislative gap analyses. These identify where GB standards may diverge from the new EU legislation. This work formed the basis of a targeted Call for Evidence, to which NHSBT is currently coordinating a response. Formal public consultation on the UK's future regulatory landscape is expected in late 2026. This remains critical for Northern Ireland, where the regulation applies directly under the Windsor Framework. NHSBT continues to work with the three other UK blood services to understand the impact on the movement of blood & tissues.

MANAGEMENT QUALITY REVIEW: Appendix A – Q4 2024/25

Patient Adverse Events (PAEs)

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

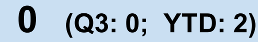
23 (Q3: 19)



Patient Safety Incidents (PSIIs)

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

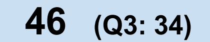
0 (Q3: 0; YTD: 2)



Donor Adverse Events (DAEs)

DAEs recorded during the quarter
(no target set)

46 (Q3: 34)



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

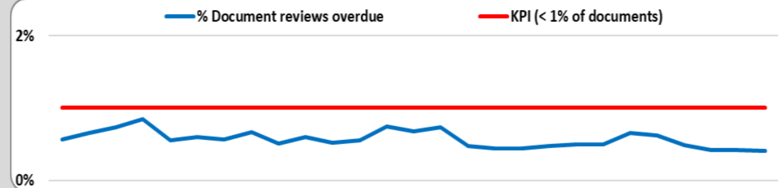
KPI 1

Target: < 1% documents with an overdue review

End of Q4 position

0.41%

(Q3: 0.56%)



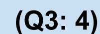
KPI 2

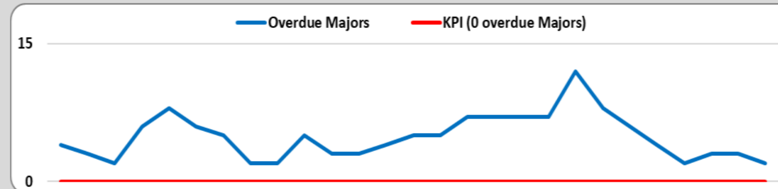
Target: Zero overdue Majors

End of Q4 position

2

(Q3: 4)





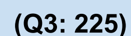
KPI 3

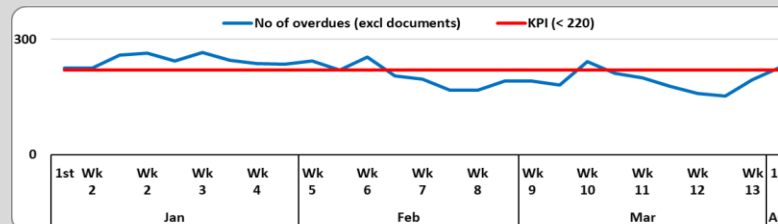
Target: < 220 overdue QIs, HCs, Audit findings, and Change Controls

End of Q4 position

226

(Q3: 225)

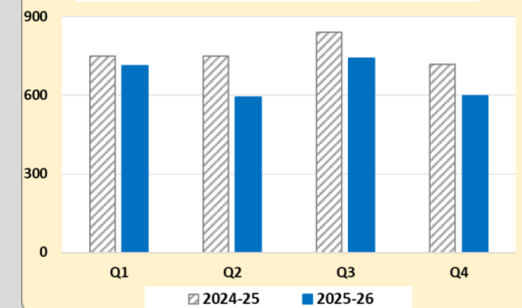




Recalls

Recall events during the quarter
(no target set)

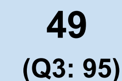
599 (Q3: 741)

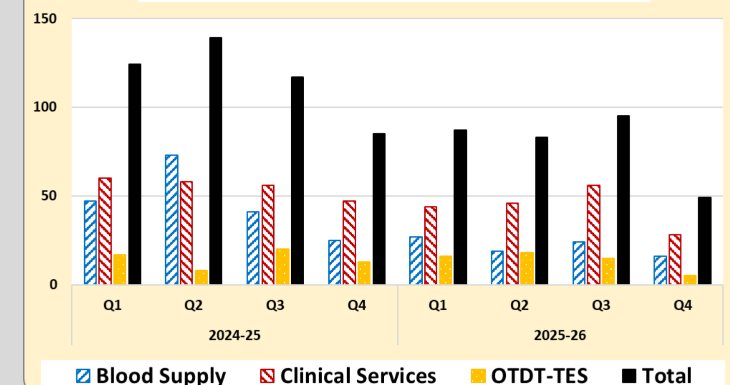


Critical and Major Adverse Events raised (only includes QIs and Hospital Complaints raised in Blood Supply, Clinical Services & OTDT-TES)

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

49
(Q3: 95)





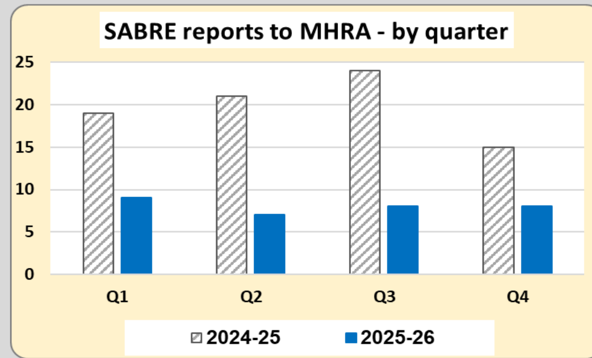
MANAGEMENT QUALITY REVIEW: Appendix A – Q4 2025/26

Externally Reported Events

SABRE

SABRE reports submitted during the quarter (no target set)

8 (Q3: 8) ⬌

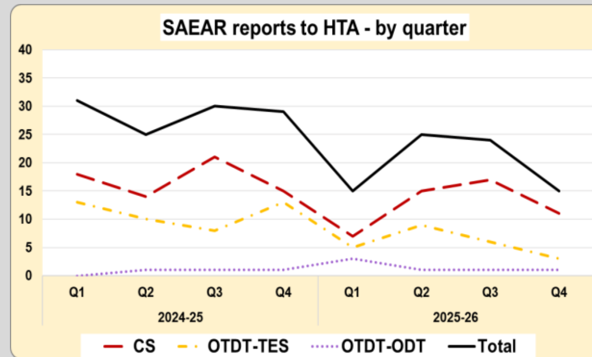


SAEAR

(figure includes NHSBT ODT SAEARs)

SAEAR reports submitted during the quarter (no target set)

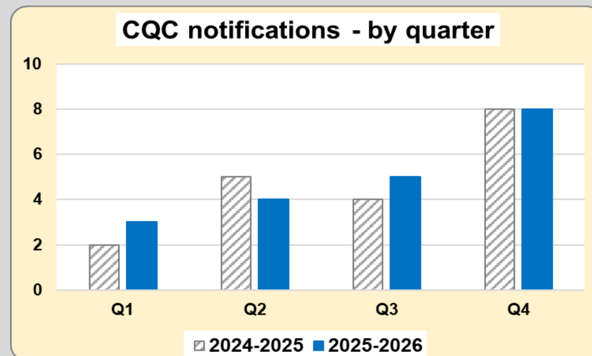
15 (Q3: 24) ⬇



CQC notifications

CQC notifications submitted during the quarter (no target set)

8 (Q3: 5) ⬆



Business Continuity

CIM training

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

End of Q4 position (Target: >90%)

85% (Q3: 86%) ✗

LET training

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

End of Q4 position (Target: >75%)

95% (Q3: 93%) ✓

LET exercise attendance

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

End of Q4 position (Target: >75%)

80% (Q3: 76%) ✓

Regulatory licence updates

MHRA licences:

- **BEA licence:** Stratford interim donor centre added to the licence
- **MIA-IMP licence:** Colindale added as a contract laboratory

HTA licences: Corporate Licence Holder contact updated for all licences to reflect new CEO, and storage of Relevant Material removed from Colindale licence

CQC registrations: Notification of new CEO, and new Nominated Individual appointed

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

Acronyms			
AI	Artificial Intelligence	H&I	Histocompatibility and Immunogenetics
ATU	Advanced Therapies Unit	HC	Hospital Complaint
BEA	Blood Establishment Authorisation licence	HFEA	Human Fertilisation and Embryology Authority
BSI	British Standards Institute	HTA	Human Tissue Authority
CA/PA	Corrective actions/ Preventative actions	IBGRL	International Blood Group Reference Laboratories
CEO	Chief Executive Officer	IDAP	Innovative Devices Access Pathway
CIM	Critical Incident Manager	ITU	Intensive Therapy Unit
CMT	Cellular and Molecular Therapies	IVDR	In Vitro Diagnostic Regulation
CQC	Care Quality Commission	JACIE	The Joint Accreditation Committee ISCT-Europe & EBMT
CS	Clinical Services	JPAC	Joint Professional Advisory Committee
DAE	Donor Adverse Event	KPI	Key Performance Indicator
DDTS	Digital, Data & Technology Services	LET	Local Emergency Team
DHSC	Department of Health and Social Care	MHRA	Medicines and Healthcare products Regulatory Agency
DMEK	Descemet Membrane Endothelial Keratoplasty (Partial-thickness cornea transplant)	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	OQSR	The Quality and Safety of Organs Intended for Transplantation Regulations
FSA	Food Standards Agency	OTDT	Organ and Tissue Donation and Transplantation
GB	Great Britain	ODT	Organ Donation and Transplantation
GIAA	Government Internal Audit Agency	PAE	Patient Adverse Event
GMP	Good Manufacturing Practice	PEX	Plasma Exchange

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

Acronyms			
PQS	Pharmaceutical quality system	SCDR	Stem Cell Donor Registry (formerly British Bone Marrow Registry (BBMR))
PSII	Patient Safety Incident Investigation	SoHO	Substances of Human Origin
Q3	Quarter 3 of the current financial year (October – December 2025)	SOP	Standard Operating Procedure
Q4	Quarter 4 of the current financial year (January – March 2026)	TAS	Therapeutic Apheresis Services
Q1 2026/27	Quarter 1 of the next financial year (April – June 2026)	TES	Tissue and Eye Services
QA	Quality Assurance	TQSR	Human Tissue (Quality and Safety for Human Application) Regulations
Q&G	Quality and Governance	UDI	Unique Device Identification
QI	Quality Incident	UK	United Kingdom
QMS	Quality Management System	UKAS	United Kingdom Accreditation Service
RCI	Red Cell Immunohaematology	UKCA	United Kingdom Conformity Assessed
RCR	Red Cell Reference	UL	Underwriters Laboratory
SABRE	Serious Adverse Blood Reactions and Events	WDA(H)	Wholesale Distribution Authorisation (Human) licence
SaBTO	Advisory Committee on the Safety of Blood, Tissues and Organs	WMDA	World Marrow Donor Association
SAEAR	Serious Adverse Events and Adverse Reactions		

MANAGEMENT QUALITY REVIEW: Appendix C – Internal event severity classifications

<table>
<tr><th colspan="2">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)</th></tr>
<tr><td>Critical</td><td><u>Critical QI events</u>
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.
<u>Critical Audit findings</u>
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.</td></tr>
<tr><td>Major</td><td><u>‘Major’ QI events</u>
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.
<u>‘Major’ Audit findings</u>
• 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.</td></tr>
<tr><td>Other</td><td><u>‘Other’ QI events</u>
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.
<u>‘Other’ Audit findings</u>
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.</td></tr>
<tr><td>Comment</td><td><u>Audit findings only</u>
Not a non-conformity yet but could get worse or pose a risk, a suggested improvement or recommendation.</td></tr>
</table>