NHS
Blood and Transplant

Board Meeting in Public

Tuesday, 20 May 2025

Title of Paper	Clinical Governance Committee Board Assurance Report	**Agenda No.**	5.2.2
Nature of Paper	☒ Official	☐ Official Sensitive	
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Presenter(s) at Meeting	Charlie Craddock, Non-Executive Director (Chair 2024/25) Lorna Marson, Non Executive Director (Chair 2025/26)		
Presented for	☐ Approval ☒ Assurance	☐ Information ☐ Update	

Executive Summary (max 300 word count)

The purpose of this report is to summarise the Clinical Governance Committee's activity across 2024/25 financial year and demonstrate that it has effectively discharged its delegated responsibilities, as set out within its terms of reference. The report will also inform the Accountable Officer's Annual Governance Statement 2024/25.

The following gaps in assurance were noted:

- CQSGG has not yet operated for a year and therefore an assurance report has not been presented to CGC for the year 2024/25. From 2025/26 such an assurance report will be required annually.
- The assurance report in relation to nursing staff revalidations is outstanding. However, during 2024 GIAA completed a review of the nursing revalidation process which resulted in a substantial assurance rating. It was agreed that it was not necessary for reports to be received by the Committee for professional roles these fall under various registration bodies that have CPD requirements. The Committee Terms of Reference will be updated to reflect this.
- Four clinical audits have been completed during 2024/25, three of which were part of the 2024/25 audit programme and one form the 2025/26 programme (completed ahead of schedule). The clinical audit programme for 2024/25 contained eight audits. The five outstanding audits have been carried forward to the 2025/26 year. Twelve actions arising from clinical audit activity were overdue at the year-end and are being actively managed. No outstanding actions relate to an audit that was assesses as providing limited or unsatisfactory assurance.

Previously Considered by

Clinical Governance Committee – 10 April 2025. Updates were made as a result of discussions at the CGC meeting and amendments circulated thereafter. Further amendments requested by the Chief Nursing Officer have also been incorporated. The Assurance Report was received by ARGC on 2 May.

Recommendation	The Board is asked to receive the Clinical Governance Committee Board Assurance Report for assurance.

Risk(s) identified (Link to Board Assurance Framework Risks)

N/A.

Strategic Objective(s) this paper relates to: [Click on all that apply]

☐ Collaborate with partners ☐ Invest in people and culture ☐ Drive innovation

☐ Modernise our operations ☐ Grow and diversify our donor base

Appendices:	Appendix 1 - Gap analysis against Clinical Governance Committee delegations.

COMMITTEE BOARD ASSURANCE REPORT 2024-25

Status: Official

Introduction

The Clinical Governance Committee (CGC) is established by the Board of NHSBT as a committee of the Board, with the powers and responsibilities delegated to it within the NHSBT Standing Orders, Schedule of Delegations, Standing Financial Instructions and the Terms of Reference.

The purpose of this Board Assurance report is to summarise the Clinical Governance Committee's activity during 2024-25 and demonstrate that it has effectively discharged its delegated responsibilities, as set out in its terms of reference. The report will also inform the Accountable Officers Annual Governance Statement 2024-25.

Purpose of the Clinical Governance Committee

The purpose of the Committee is to provide assurance to the Board that NHSBT has a robust framework for the management of all critical clinical systems and processes. This is a framework through which NHSBT is accountable for continuously improving the quality of services and safe-guarding high standards of care by creating an environment in which excellence in clinical care will flourish. It includes systems for, but not limited to:

a) Clinical Incident and complaints management and reporting information
b) Clinical quality improvement
c) Clinical Audit
d) Maintaining clinical competence
e) Compliance with the Care Quality Commission (CQC) essential standards of quality and safety
f) Clinical effectiveness, including Research and Development
g) Education, training and staff management
h) Patient and public involvement.

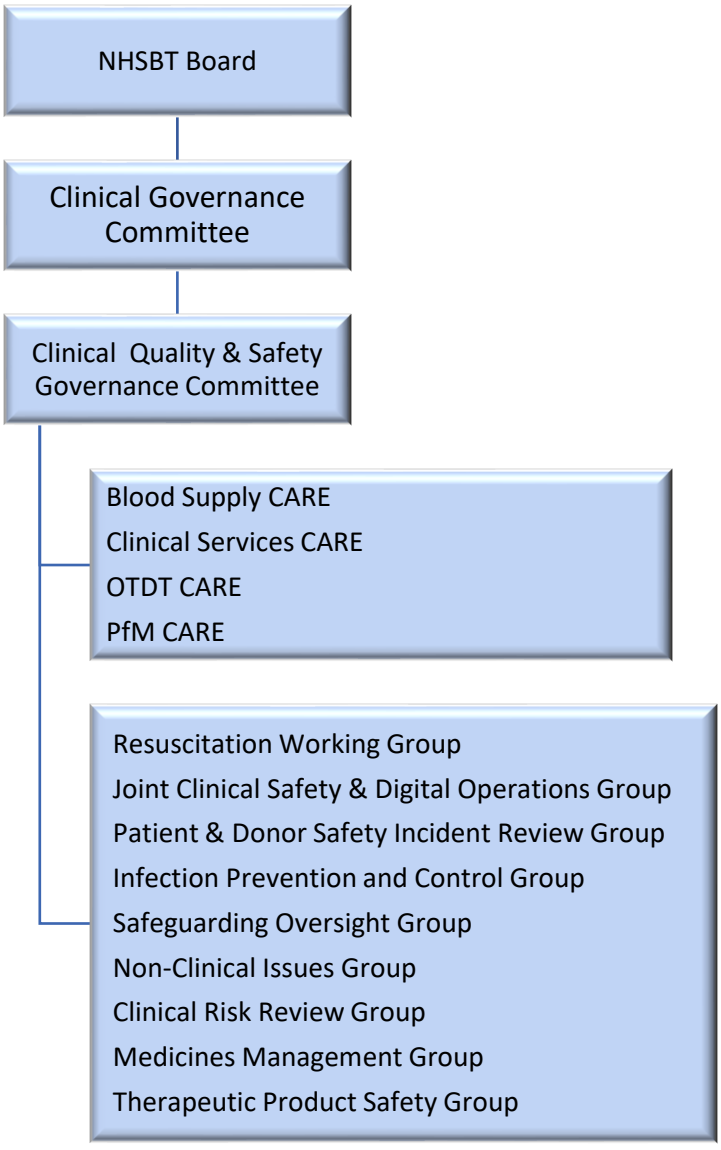
The Clinical Governance Committee (CGC or the Committee) sets the tone and direction for patient/donor safety, clinical effectiveness, patient outcomes and patient/donor experience. It supports the operating directorates in the development, implementation and monitoring of a robust framework for clinical governance, meeting donors' and patients' needs.

Reporting structure

The Clinical Governance Committee is a Committee of the NHSBT Board and reports its activities to the Board, escalating concerns via quarterly reports.

An Executive Clinical Quality and Safety Governance Group (CQSGG) was established during 2024-25. This Group has a role in ensuring thorough internal review of reports before escalation of significant matters to the CGC, to optimise efficiency and strengthen the effectiveness of the CGC's role in oversight and assurance.

The Directorate Clinical Audit, Risk and Effectiveness (CARE) Groups and the nine additional groups report to CGC via the CQSGG.



Committee membership and attendance 2024-25

During 2024-25, the Committee met five times. Meetings have been well attended and quoracy achieved on all occasions. The annual attendance of voting (V) and non-voting (NV) members is shown below:

Members	14.05.2024	12.07.2024	13.09.2024	7.11.2024	9.01.2025	**Total**
Charlie Craddock, Non-Executive Director (V)	√	√	x	√	√	**4/5**
Lorna Marson, Non-Executive Director (V)	x	√	√	x	√	**3/5**
Dee Thiruchelvam, Chief Nursing Officer (V)	√	√	x	√	√	**4/5**
Gail Miflin, Chief Medical Officer and Director of Clinical Services (V)	√	x	√	√	√	**4/5**
Helen Gillan, Director of Quality (NV)	√	√	√	√	√	**5/5**
Anthony Clarkson, Director of Organ and Tissue Donation and Transplantation (OTDT) (NV)	x	√	√	√	√	**4/5**
Gerry Gogarty, Director Plasma for Medicines and Interim Director for Blood Supply (NV)	x	√	√	x	√	**3/5**
Paul O'Brien, Director of Blood Supply[1]	√	x	x	-	-	**1/3**

[1] Paul O'Brien left NHSBT in September 2024.

NHSBT has arrangements in place regarding the identification and management of any conflicts of interest. Members' interests are included on the agenda for visibility. During the year, no conflicts of interest requiring management were raised.

Summary of Activity

In 2024-25, efforts have been made to establish and embed the CQSGG, which serves as the reporting body for the Clinical Audit Risk and Effectiveness (CARE) groups and other clinical groups.

The CQSGG offers a platform for detailed review of reports before significant matters are escalated to the CGC. From November 2024, the CQSGG has provided an integrated assurance report to the CGC. This is currently a manually produced report and further work is required to ensure triangulation of data sets across the organisation for assurance.

This report summarises activity and highlights areas for scrutiny by exception. This additional layer of scrutiny ensures that the CGC has sufficient information and time within meetings to provide a well-informed view on assurance. Whilst the integrated report has been introduced its form and content continues to evolve in order to provide a rounded view of both qualitative and quantitative clinical risk and assurance information from across the organisation.

Key areas of focus for the Committee in 2024-25 have included:

a) Infected Blood Inquiry (IBI) update reports. Since May 2024, UK Healthcare, the Department for Health and Social Care (DHSC), NHS England, NHS Blood and Transplant (NHSBT), the UK Health Security Agency and others have co-operated to review the report's clinically facing findings and recommendations. Work has focused on establishing which recommendations can be implemented, to what extent and at what pace.

b) Update reports on implementation and progress with the Patient Safety Incident Response Framework (PSIRF). Phase one implementation completed during 2024-25. Stage two has been paused until a review of the incident management process (IMP) has been undertaken.

c) Patient and Donor Safety Incident Investigation Closure reports, which are reported to each meeting for assurance and to provide the opportunity to share learning.

d) Reports following the cyber security incident in Summer 2024, focused on the incident response and impact on blood stocks.

e) Deep dives into principal risks that fall within the remit of the Committee i.e. P-01, harm to donors of patients (September 2024) and P-06, failure to monitor clinical outcomes (November 2024).

f) Receipt of the following Annual reports, Organ and Tissue Donation and Transplantation (OTDT) Biovigilance Annual report, Serious Hazard Of Transfusion (SHOT) annual report, Safeguarding Annual Report, Joint NHSBT/ PHE Epidemiology Annual report, Medical Revalidations, Information Governance Annual Report, Infection Prevention and Control, Serious Incident and Never Events Annual Report, Clinical Claims Annual Report, Non Clinical Issues Annual Report and Mandatory Training of Clinical Workforce Annual report.

g) Regular Clinical Audit programme updates and clinical audit reports. The Committee also monitored progress with the clinical audit annual plan and completion of actions arising from audits.

   Four audits have been completed during the 2024/25 financial year, three of which are part of the 2024/25 programme and one other from the 2025/26 programme which completed ahead of schedule.
   - 2024/25 - Blood Donation - AUD5066 - Audit of Confidentiality on Mobile Sessions
   - 2024/25 - Blood Donation - AUD5091 - Audit of Suspected Chlorhexidine Reactions
   - 2024/25 - Organ Donation - AUD4338 - Audit of Serious Incident Action Plans
   - 2025/26 – Tissue and Eye Services - AUD5184 - Audit of Medical Deferrals in Eye Donation

   The Clinical Audit programme for 2024/25 contained eight clinical audits, with the remaining five being carried forward into 2025/26.

Twelve actions arising from clinical audit activity were overdue at the year end and these are being actively managed. No actions relate to an audit that was assessed as providing limited or unsatisfactory assurance.

A GIAA audit of Clinical Audit Process was published in January 2023, receiving a limited assurance rating and containing a total of 17 actions against 14 specific recommendations.

As at the financial year end only one part action remains open, that has a target closure date of 31 December 2025.

h) Assurance reports related to, information governance, Hepatitis E Virus (HEV) screening, data security, privacy and records management, research and development, workforce, and therapeutics and product safety.

i) Approval of the following policies, PSIRF, Therapeutic Product Safety Group (TPSG) and Safety Policy and framework, Safeguarding policy.

j) A review of the Board skills and capabilities review, specific to the CGC. Members agreed that PSIRF training for Committee members would be provided during 2025-26.

k) Received the CQSGG Terms of Reference and revised the CGC Terms of Reference (July 2024).

l) Directorate CARE reports for Clinical Services, OTDT, Blood supply and Plasma for Medicines were received by the Committee in May, July and September 2024. Since November those reports have been incorporated into the CQSGG Integrated report along with the Regulatory radar and quarterly Management Quality Review (MQR) quarterly reports.

Committee Effectiveness Review

An externally facilitated effectiveness review of the Board and its Committees was conducted by BDO LLP between November 2024 and February 2025. The report of their findings was presented to the Board at their meeting on 1 April 2025. Whilst the findings related to the Board, rather than its committees, there were two elements that each committee should give consideration to.

The first relates to succession planning and development. During 2024-25 the CGC considered the skills of its members and identified that some specific PSIRF development would be beneficial. This assessment process will be repeated annually to identify any gaps that could be filled through future appointments and to identify knowledge development that can be planned.

The second finding relates to the size of the committee/board. Corporate governance best practice recommends a size of between 8-12 members for boards to ensure effective operation. It is usual for Board Committees to be smaller as the remit of such is more focused. Whilst the formal membership of the CGC is 7-8, there are currently an additional 18 regular attendees and further attendance by other persons, often for the whole meeting, for presentation of specific items. The size of the committee presents challenges to its effective operation, and a way forward is being discussed. It is accepted that due to the breadth of activity within NHSBT and its technical nature the size of the committee may need to be larger than corporate governance recommendations.

During 2025-26 there will be an opportunity to re-focus the approach of the CGC, particularly in view of the establishment of the CQSGG, with the goal of making the most impactful use of

resources, expertise, and time. This report serves as an opportunity to express thanks to all those who have devoted their time and energy to the Committee to date. Their contributions have been valuable and appreciated. It is recommended that there should be a streamlining of Committee attendance, ensuring that time is used effectively, and that the route to achieving assurance is efficient and encourages an improvement culture across all clinical activities.

Assurance and Statement to the Board

The opinion of the CGC is that its risk management, control and governance processes are adequate and effective and may be relied upon by the Board. It should be acknowledged that the Committee is going through a period of transition as the CQSGG embeds and reporting by exception to CGC is developed. Once this is in place and embedded the Committee's operation is likely to be improved.

The following gaps in assurance were noted:

- CQSGG has not yet operated for a year and therefore an assurance report has not been presented to CGC for the year 2024/25. From 2025/26 such an assurance report will be required annually.
- The assurance report in relation to nursing staff revalidations is outstanding. However, during 2024 GIAA completed a review of the nursing revalidation process which resulted in a substantial assurance rating.
- The planned clinical audits for 2024/25 have not all been completed. The five outstanding audits have been carried forward to the 2025/26 year.

Appendix 1

Gap analysis against Clinical Governance Committee delegations

Committee Delegation	Terms of Reference	Reviewed by Committee (evidence and date)
Through the Clinical Quality and Safety Governance Group, Support and oversee the work of the operating directorates' CARE (Clinical, Audit, Risk and Effectiveness) groups and monitor their effectiveness and performance in achieving clinical effectiveness, including approval of the Terms of Reference and membership of Directorate CARE sub-groups.	5.2.1	CARE Group reports received in May, July and September 2024. CARE Group assurance summaries included in CQSGG Integrated report in November 2024 and January 2025.
Ensure effective mechanisms are in place to review and monitor the effectiveness and quality of clinical care and services across NHSBT, including ensuring actions are taken to address issues of poor clinical performance.	5.2.3	The Committee forward plan sets out the annual committee work programme for 2024-25 to ensure the Committee fulfills its terms of reference. The annual review of the Committee terms of reference ensures there is an opportunity to the delegations required to provide assurance regarding the effectiveness and quality of clinical care and services. The terms of reference were reviewed in July 2024. Assurance via the Integrated Report.
Ensure that lessons are identified for improvement and ensure these are implemented in relevant areas.	5.2.4	This has been achieved via Patient and Donor Safety Incident Investigation (PSII) Closure reports, Clinical Audit reports, GIAA audits that are reported to each meeting. Assurance via the Integrated Report.
Encourage a continuous improvement culture and gain assurance that systems are in place to deliver it.	5.2.5	The programme of reports to the Committee identified in the 2024-25 Committee forward plan provides assurance in this regard, particularly reports addressing the replacement of some manual processes with IT solutions, reports on complaints and claims, audit reports and learning detailed in PSII closure reports.

Provide assurance to the Board that clinical complaints and incidents are managed in accordance with NHSBT procedures. This ensures that there is a robust process for serious incidents and near miss reporting, investigation and organisational learning through ensuring trends are identified, learning is shared and appropriate actions are taken.	5.2.6	This has been achieved via Serious Incident Closure reports and Serious Incident summary reports. Additionally, the Committee receives an annual clinical claims report and regular PSIRF implementation updates and approves the PSIRF framework and policy.
Conduct a serious incident deep dive annually to assure processes.	5.2.7	The SI summary report was received by the Committee in May 2024.
Gain assurance that clinical risks are managed as set out in the NHSBT Risk Management policies.	5.2.8	The Committee undertook two risk deep dives (September and November 2024) focused on the principal risks pertinent to the CGC: • P-01 Donor & Patient Safety, and P-06 Clinical Outomes and Health Inequalities.This delegation is also achieved via GIAA audit reports and Quality Assurance audit reports.
Have oversight of all corporate and business unit level risks with a clinical risk impact, review and challenge the actions and controls for those risks, ensure appropriate escalation of any areas of concern to the Board and highlight areas of good practice and shared learning.	5.2.9	The Integrated report from CQSGG escalates risk where appropriate. The Committee has undertaken two deep dives on principle risks related to the CGC's remit. Issues are escalated to the Board via the full Committee minutes (Private Board) and Public Board report.
Provide scrutiny and seek assurance from the management of the clinical claims process.	5.2.10	The Committee received a Clinical claims annual report in May 2024.
Promote positive complaints handling, advocacy and feedback including learning from adverse events	5.2.11	PSIRF reports are received by the Committee at each meeting.
Ensure that the views of patient, donors, service users and carers are systematically and effectively engaged in clinical governance activities.	5.2.12	The inclusion of Patient and Donor Safety Partners from January 2025 has strengthened the Committee in this regard.

Ensure that systems are in place for review of external national guidance (e.g., NICE) and for ensuring compliance with relevant recommendations made. Receive assurance reports in relation to compliance with regulatory and statutory duties related to matters delegated to it.	5.2.13	The Committee receives the Regulatory Radar and quarterly management quality review reports. These reports provide an overview of all regulatory activity and performance.
Monitor alerts received via the Central Alerting System and review any actions taken in response to any relevant alerts.	5.2.14	The Committee received an alerts report in May 2024. Assurance via the Integrated Report.
Monitor compliance with all relevant Care Quality Commission (CQC) outcomes and the organisation's overall preparedness for CQC inspection.	5.2.15	This section will be updated by the Assistant Director of Quality and Regulatory Compliance.
Have oversight of and approve any significant changes to Organ Allocation policies	5.2.16	No changes made during 2024-25.
Receive reports seeking clinical advice and audit-related to the Caldicott principles and Information Governance (IG) standards from the Information Governance Committee.	5.2.17	The Committee received an Information Governance update report in September 2024.
Review reports relating to children and adult safeguarding and gain assurance that effective management and process are in place.	5.2.18	The Committee received Safeguarding update reports in May and July 2024 and the Safeguarding Oversight Group Annual report in September 2024.
Link into the Management Quality Review (MQR) process and have oversight of the MQR quarterly and annual reports.	5.2.19	The MQR quarterly reports were received by the Committee in July and September 2024 and thereafter included in the Integrated Report (with full reports available in the review room).
Review and approve research proposals that relate to more than one operating directorate for which the relevant operating directorate CARE group (with expert input from the Scientific Advisory Group) have been unable to reach a decision. Disseminate learning from research findings reported to relevant groups.	5.2.20 5.2.21	The Committee received a research and development review in November 2024.

Ensure that clinical governance decision making is informed by evidence-based information and research contributions from the Scientific Advisory Committee (SAC) overseeing the NHSBT Research and Development programme and partnerships.	5.2.22	The Scientific Advisory Committee has not met during 2024-25, although will recommence its meetings in 2025-26. The Committee received a research and development review in November 2024.
Through the Clinical Quality and Safety Governance Group, seek assurance from the Directorate CARE groups that practice is evidence-based and supported by a robust process of clinical audit.	5.2.23	This is reported via the Integrated Report that is received at each Committee meeting.
Oversee and prioritise the clinical audit work plan and ensure that the schedule is aligned with internal audits and that it triangulates themes from risks, incidents, complaints, clinical claims and patient/donor feedback.	5.2.24	The Committee receives Clinical Audit Programme and Activity reports at each meeting.
Review summaries of clinical audit findings and gain assurance that the recommendations and their implementation by operational directorate CARE groups will focus on identifying any concerns or significant issues and/or where no improvements have been made since the last audit; and gain assurance that the action plan in response to the audit is implemented without undue delay, especially where limited assurance is given. The Committee will receive internal audit reports in relation to areas under its remit and will monitor progress in completing related management actions.	5.2.25 6	Clinical audit findings reports/summaires are reported to the Committee to enable scrutiny of recommendations and assurance of delivery.
Ensure that best clinical practice is provided by appropriately trained and skilled professionals with the competencies required for service delivery including ensuring that an appropriate process of revalidations is in place and operating effectively for medical, nursing and scientific and professional posts.	5.2.26	The scheduled workforce (July 2024) and medical appraisal and revalidation annual report (September 2024) were received by the Committee. A separate report on Nursing revalidations has not been received to date, although is expected to feature in future Integrated reports. The Committee discussed the level of risk

		attached to this area on 10 April 2025 and agreed that the current process of providing assurance for medical and nursing colleagues was sufficient to address the level of risk that exists. In relation to scientific roles it was noted that there is no revalidation process for such roles. They are registered as Clinical Scientists or Biomedical Scientists by the Health and Care Professions Council, a statutory register for people practicing in these roles. Part of the requirement for registration is to undertake continuing professional development audited periodically by the HCPC. It was agreed that it was not necessary for reports to be received by the Committee. Similarly, for professional roles these fall under various registration bodies have CPD requirements and the PDPR process assesses performance. The Terms of Reference will be updated to reflect this.
Monitor the education and development system for the clinical workforce that supports performance improvement within their scope of practice.	5.2.27	The Committee received a workforce report in July 2024 and Mandatory Training of Clinical Workforce Annual report.
Ensure adequate resources are allocated to support the provision of safe and responsive care and services.	5.2.28	The Committee received a Clinical workforce report in July 2024.
Provide the Board with regular clinical effectiveness updates and exception reports.	5.2.29	Committee minutes are reported in full to the NHSBT Private Board meeting and summary reports are reported to each Public Board meeting.
Provide the Board with an annual report of work undertaken, providing positive assurance that clinical governance mechanisms are in place and effective and highlighting key concerns; meeting the terms of reference for the committee and supporting the annual Governance Statement. This annual report should cover key findings from the programme of audits and the proposed plan for the subsequent year. This report should also be	5.2.30	This Committee Board Assurance reports achieves this delegation.

shared with the ARG Committee for information.		
To note safety policies affecting NHSBT and review of internal safety policy decision making and framework (i.e.through Therapeutic Product Safety Group (TPSG). Any changes to the organ allocation policies in OTDT, the policies that should come to CGC for oversight. Develop overarching clinical governance policies and procedures and ensure reviews are in line with their set review dates. Approve, or recommend to the Board for approval relevant policies.	5.2.31 5.2.2 6	This delegation has been met via TPSG reports to the Committee in May and July 2024. The following policies have been reviewed and approved in 2024-25, PSIRF, Therapeutic Product Safety Group (TPSG) and Safety Policy and framework, Safeguarding policy.
Support and oversee the work of the Clinical Quality and Safety Governance Group and monitor its effectiveness and performance in achieving clinical effectiveness, including approval of the Terms of Reference and membership of Group.	5.2.32	The Committee received the terms of reference for the CQSGG (May 2024) for approval. The Committee receives the Integrated Report from CQSGG at each meeting. The CQSGG terms of reference (paragraph 20) state that CQSGG will provide the CGC with an annual (assurance) report of work undertaken, providing assurance that clinical governance mechanisms are in place and effective and highlighting key concerns. The CQSGG has not yet operated for a full year and therefore annual assurance reporting will commence following the 2025/26 year.
The Committee will consider any other relevant matters where requested to do so by the Board.	5.2.33	The Committee has received reports related to the IBI since its publication in May 2024.
Monitor progress with managing principle risks: P-01 – Harm to a donor or patient P-06 – Failure to monitor clinical outcomes And undertake a deep dive into each at least annually.	6	Annual deep dives have been undertaken (September and November 2024).