

**NHSBT Board****Board Assurance Framework**25<sup>th</sup> January 2022**Status: Official****1. Summary and Purpose of Paper**

The Board Assurance Framework (BAF) brings together the information on the risks to delivery of NHSBT's corporate strategic priorities. The BAF has been in development since November, has had contribution from all Executive Directors and has been reviewed at the Risk Management Committee (RMC), the Executive Team (ET) and by the Audit, Risk and Governance Committee (ARGC). The paper summarises how we will transition from the current strategic risks to those now aligned with our corporate strategy.

This paper brings the final working version of the BAF to the Board for approval.

**2. Action Requested**

The Board is asked to:

- Note the development of new strategic risks that align with the organisation's strategic priorities and review the content and scoring of these risks.
- To approve the Board Assurance Framework and its constituent strategic risks.
- To approve the treatment of the existing strategic risks.
- To note and comment upon the next steps in bringing the Board Assurance Framework as a regular paper to Board

**3. Background**

The BAF brings together in one place all the relevant information on the risks to delivery of NHSBT's corporate strategic priorities. It provides the Executive and Board with a tool to focus on risk in the context of the issues that are most relevant at the strategic decision-making level, and an ability to bring together the assurance on which the Executive and Board rely to deliver their strategic priorities and objectives. The strategic oversight of risk, as provided by a BAF is also an expectation of the CQC, and evidence that it is used will be required in any future Well Led inspection.

The NHSBT Executive Team held a workshop to begin development of the BAF on 3rd November, using as prompts the strategic priorities agreed by an NHSBT Board workshop the previous day. Since then, the strategic risks have been presented to the RMC, the ARGC and the ET and there have been meetings with the Executive Director risk owners for each risk. There has been opportunity for risk owners and other directors to comment and contribute to both the BAF format and the strategic risks throughout the process.

The process from initiation to this point has been undertaken in isolation from the organisation's risk management system. This has allowed a fresh view of the risks, independent from existing influences and thinking. NHSBT uses a system of parent and child risks that enable the bottom-up flow of risk, from front-line to Board, therefore following approval at Board appropriate links with existing risks will be established.

## 4. Strategic Risks

The proposed strategic risks are laid out in Appendix 1 and in brief are:

| Risk | Risk Title                     | Risk Owner   |
|------|--------------------------------|--|
| 1    | Patient and Donor Harm         | Gail Mifflin, Chief Medical Officer and Director of Clinical Services  |
| 2A   | Disruptive Event (Internal)    | Ian Bateman, Director of Quality   |
| 2B   | Disruptive Event (External)    | Ian Bateman, Director of Quality   |
| 3    | Change Programme               | Wendy Clarke, Chief Digital and Information Officer  |
| 4    | Volume and mix of donors       | David Rose, Director of Donor Experience   |
| 5A   | Finance and Commissioning      | Rob Bradburn, Director of Finance  |
| 5B   | Financial support for strategy | TBA  |
| 6    | Access to Data                 | Gail Mifflin, Chief Medical Officer and Director of Clinical Services and<br>Wendy Clarke, Chief Digital and Information Officer |
| 7    | Workforce                      | Deborah McKenzie, Chief People Officer   |
| 8    | Leadership                     | Deborah McKenzie, Chief People Officer   |
| 9    | Regulatory Compliance          | Ian Bateman, Director of Quality   |

Full risk descriptions are in the appendix.

Risk 5B, Financial Support for Strategy, was arrived at following discussion on risk 5A (previously Risk 5) and it was agreed at the Executive Team meeting of 12<sup>th</sup> January that these two aspects of risk should be separated. This robust discussion should be considered beneficial and the fact that this is now being actively considered and discussed is a reflection that the BAF is a living document, subject to change and development at any time. This risk is, therefore, presented as incomplete with work ongoing.

Appendix 2 outlines the proposed strategic risks against the existing strategic risks and proposes how they are to be treated following approval of the new risks. In summary, the proposal is:

| Risk     | Title  | Proposed Treatment   |
|----------|--|--|
| NHSBT-01 | Safety and Quality of Clinical Care                    | Replaced by Risk 01  |
| NHSBT-02 | Staff Establishment and Recruitment                    | Replaced by Risk 07  |
| NHSBT-03 | Failure of the provision of blood and blood components | No link in corporate strategy – to be linked into the new Blood Service Strategy. There is some alignment with Risks 2A and 2B, but NHSBT-03 covers more than disruptive problems in the blood supply chain. |
| NHSBT-04 | Strategic Development Capacity                         | For review and possibly linked to a Service or Support Strategy  |
| NHSBT-05 | Functionality of Critical ICT systems & Technology     | Replaced by Risk 2A (this is a specific cause)   |
| NHSBT-06 | Supplier of critical product will fail to provide      | Replaced by Risk 2B (this is a specific cause)   |
| NHSBT-07 | Confidentiality, Accessibility and Integrity of Data   | For review and possibly linked to a Service or Support Strategy  |
| NHSBT-08 | Loss of a Key Facility                                 | Replaced by Risk 2A (this is a specific cause)   |

| Risk     | Title   | Proposed Treatment   |
|----------|---|--|
| NHSBT-09 | The reputation of NHSBT is adversely affected | Replaced by Risk 4 (reputation in this risk was seen as a cause of lack of donor confidence) |
| NHSBT-10 | Grant in Aid (GIA) Funding                    | Replaced by Risk 5 (a specific example of funding)   |
| New      | Regulatory Compliance                         | New Risk 9.  |

### 5. Next Steps

Following approval from Board, the risks outlined in the BAF will be entered into the organisation's risk management IT system and links will be made between existing risks and these strategic risks. Reports will be created using Power BI, a business reporting tool, which will be connected to the organisation's risk management IT system using an API. Andrew Weal is working with DDTS to address the installation of the API.

The flow of scoring from child risk to strategic risk is unlikely to match the expectation of risk score set out in the BAF as presented. The resolution of this mismatch will initiate a top-down view, as risk owners for these strategic risks discuss their risk scoring with risk owners of the child risks. This process enables not only a proper flow of risk both up and down the organisation, but also enables a consistency in approach and scoring between the constituent parts of NHSBT.

There are further improvements planned for the BAF, such as adding a performance narrative and commentary at the front, for example a heatmap of child risks outlining each risk in relation to the organisation's risk appetite and including the significant child risks to enable context to be understood. These improvements will be delivered following approval, enabled by the addition of risks to the organisation's risk management system and the review and development of the new organisational risk appetite, which will be reviewed and agreed with the Board in March.

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**Responsible Director: Ian Bateman, Director of Quality**  
**January 2022**

## Appendix 1: Board Assurance Framework - Summary page

| No. | Risk description   | Current risk score | Change since last review |
|-----|--|--------------------|--------------------------|
| 01  | There is a risk that harm occurs to a donor or patient, caused by one of the following<br>(i) Failure of NHSBT processes to mitigate a known risk (a serious incident)<br>(ii) Failure to scan for emerging infections<br>(iii) A known complication of transfusion or transplantation that we cannot currently mitigate<br>(iv) Complications occurring in the wider health system where NHSBT is responsible for advice and education<br>resulting in a loss of confidence and goodwill from our organisational stakeholders and the wider public. | 8                  |                          |
| 02A | There is a risk of interruption to the effective operation of one or more of NHSBTs business function(s), caused by disruption to one or more essential (internal) resources, including equipment, IT, staff, loss of access to data and estate / facilities, resulting in delay or failure to continued supply of safe and effective products and services.   | 12                 |                          |
| 02B | There is a risk NHSBT fails to meet the demand for essential products and services, caused by disruption and/or variability of external factors, such as donor behaviour, fluctuations in hospital demand, third party supplier shortages, adverse weather, resulting in NHSBT being unable to continue to deliver safe and effective products and services.   | 16                 |                          |
| 03  | There is a risk that the scale and pace of the NHSBT change programme will adversely impact our core functions or our ability to deliver our strategy caused by poor prioritisation, forecasting, change control and risk evaluation resulting in an impact on the provision of products and services  | 8                  |                          |
| 04  | There is a risk that we do not attract the right number and diversity of donors due to failure to engage the public effectively, resulting in the worsening of the supply demand gap for our products  | 16                 |                          |
| 05A | There is a risk that a sudden and unexpected change in government finances, health policy and associated commissioning arrangements for our services results in a significant shortfall in income  | 10                 |                          |
| 05B | There is a risk that failure to gain support from UK Health Departments, our commissioners and partners for our strategic priorities, and associated funding, results in constrained strategic objectives that do not deliver the increase in lives saved and improved that we seek  | 16                 |                          |
| 06  | There is a risk that NHSBT will be unaware and fail to monitor clinical outcomes in patients receiving our products and services caused by an inability to access data sets in a timely manner due to incompatibility of information systems and lack of engagement with Trusts and other bodies holding significant datasets, preventing us from identifying and driving forward opportunities for improvement  | 12                 |                          |
| 07  | There is a risk that a lack of capacity, capability and / or flexibility in our workforce, caused by challenges in our attraction, recruitment and retention strategies, prevent us from delivering our strategic priorities or core functions.  | 16                 |                          |
| 08  | There is a risk that our leaders and managers lack the skills and capabilities required in today's NHS to create a high-performing, inclusive environment, and to deliver our strategic priorities   | 9                  |                          |
| 09  | There is a risk that the organisation will become non-compliant with current or emerging regulations which could result in NHSBT being subject to significant regulatory action and/or licences being revoked. This would impact on the ability of NHSBT to provide critical services and products and/or have a serious impact on patient safety. It also has the potential to significantly, and detrimentally, affect the reputation of the organisation  | 12                 |                          |

|          |    |  |
|----------|----|--|
| BAF Risk | 01 | There is a risk that harm occurs to a donor or patient, caused by one of the following<br>(i) Failure of NHSBT processes to mitigate a known risk (a serious incident)<br>(ii) Failure to scan for emerging infections<br>(iii) A known complication of transfusion or transplantation that we cannot currently mitigate<br>(iv) Complications occurring in the wider health system where NHSBT is responsible for advice and education<br>resulting in a loss of confidence and goodwill from our organisational stakeholders and the wider public. |
|----------|----|--|

|   |
|---|
| Linked Strategic Priority   |
| Modernise our operations to improve safety, resilience and efficiency |

|                              |                       |
|------------------------------|-----------------------|
| Lead Executives              | Chief Medical Officer |
| Board or Executive Committee | CARE                  |

|                | Impact   | Likelihood | Total    |
|----------------|----------|------------|----------|
| Inherent       | X        | X          | X        |
| <b>Current</b> | <b>4</b> | <b>2</b>   | <b>8</b> |
| Target         | X        | X          | X        |

| Current score | Change since last review | Trend |
|---------------|--------------------------|-------|
| <b>8</b>      | ↔                        |       |

| Controls  |
|---|
| C1. Quality Management System including MPD772 management of serious incidents                  |
| C2. Investigation and learning from reported incidents/events                                   |
| C3. Learning from Excellence Group (OTDT)   |
| C4. JPAC and SaBTO Safety Policy Committees including Donor Organ Risk Assessment Group (SaBTO) |
| C5. Donor Vigilance Annual Report (Joint NHSBT / UKHSA Epidemiology Team)                       |
| C6. Emerging Infections Surveillance Process  |
| C7. Haemovigilance and Biovigilance Systems   |
| C8. Education and training programmes in transfusion and solid organ transplantation            |
| C9. 24-hour advice available from NHSBT Consultant on call rotas and Laboratories               |

| Assurances  |
|---|
| A1. Management Quality Review and MHRA Audit Reports                    |
| A2. Annual Safe Supplies Report (Joint NHSBT / UKHSA Epidemiology Team) |
| A3. UK Blood Services Horizon Scanning Reports (JPAC)                   |
| A3a. Internal Audit on Horizon Scanning Processes (GIAA 2021)           |
| A4. ABO Horizon Scanning report   |
| A4. Annual SHOT Report  |
| A5. Annual solid organ transplantation Biovigilance Report (SaBTO)      |
| A6. Hospital customer services surveys and reports                      |

| Gaps in control  |
|--|
| GC1. Processes span whole of NHS including UKHSA and Trusts. Gaps are not always easy to see         |
| GC2. The detection of new infections is inherently difficult with usual involvement of other species |

| Gaps in assurance  |
|--|
| GA1. No annual stem cell transplantation biovigilance report |

| Actions to address gaps in control or assurance   | Due date                 |
|---|--------------------------|
| GC1. Establish data system for improved knowledge of patient outcomes for stem cell transplantation       | April 22- UK SCSF report |
| C2. Introduction of Automated results transfer project  | June 2022                |
| C3. CRM and outcomes database for NHSBT TAS treated patients  | 22/23                    |
| C4. Implementation of new NHSE PSIRF framework as rolled out  | Oct 2022                 |
| C5. NHSBT Education strategy defined  | 22/23                    |
| C6. Review of Consultant on call rotas as part of operating model review to ensure remain fit for purpose | Q1 2022                  |

| Linked BAF or high-level operational risks           | Current score |
|--|---------------|
| Risk no. To be completed following approval at Board |               |

|          |     |  |
|----------|-----|--|
| BAF Risk | 02A | There is a risk of interruption to the effective operation of one or more of NHSBTs business function(s), caused by disruption to one or more essential (internal) resources, including equipment, IT, staff, loss of access to data and estate / facilities, resulting in delay or failure to continued supply of safe and effective products and services. |
|----------|-----|--|

|   |
|---|
| <b>Linked Strategic Priority</b>  |
| Modernise our operations to improve safety, resilience and efficiency<br>Staffing and recruitment |

|                                     |                           |
|-------------------------------------|---------------------------|
| <b>Lead Executive</b>               | Director of Quality       |
| <b>Board or Executive Committee</b> | Risk Management Committee |

|                | Impact   | Likelihood | Total     |
|----------------|----------|------------|-----------|
| Inherent       | X        | X          | X         |
| <b>Current</b> | <b>4</b> | <b>3</b>   | <b>12</b> |
| Target         | X        | X          | X         |

| Current score | Change since last review | Trend |
|---------------|--------------------------|-------|
| <b>12</b>     |                          |       |

|   |
|---|
| <b>Controls</b>   |
| <ul style="list-style-type: none"> <li>C1. Business Continuity Management System and BC Plans</li> <li>C2. Supply contingency and risk arrangements</li> <li>C3. Resilience in IT arrangements</li> <li>C4. Operational Development Group</li> <li>C5. National Fire Safety Group</li> <li>C6. Electrical Group</li> <li>C7. National Water Safety Group</li> <li>C8. Security Governance Board</li> <li>C9. IPC</li> <li>C10. Asbestos Group</li> <li>C11. Estates Internal Cryogenic Group</li> <li>C12. Estates Risk Management Group</li> <li>C13. Estates Training Group</li> <li>C14. Hazop Group</li> <li>C15. Clean Room Advisory Group</li> <li>C16. Software development lifecycle</li> <li>C17. Change control process</li> <li>C18. IT Monitoring capabilities</li> <li>C19. Test Assurance Process</li> <li>C20. Firewalls and other IT security measures</li> </ul> |

|   |
|---|
| <b>Assurances</b>   |
| <ul style="list-style-type: none"> <li>A1. ISO22301 certification and audit</li> <li>A2. Internal and External Audit programme</li> <li>A3. BC Exercise programme</li> <li>A4. Statutory Compliance Dashboard</li> <li>A5. BC report to RMC?</li> </ul> |

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| <b>Gaps in control</b>   |
| <ul style="list-style-type: none"> <li>GC1. BC Plan for Pulse Failure</li> <li>GC2. BC Plan for Microbiology Services</li> </ul> |

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| <b>Gaps in assurance</b>  |
| <ul style="list-style-type: none"> <li>GA1. BC Exercise plan paused due to Covid</li> </ul> |

| Actions to address gaps in control or assurance                        | Due date   |
|--|------------|
| GC1. BCP review and Single point of failure identification             | Q2 2022/23 |
| GA2. Exercise programme to improve coverage and identify gaps in plans | Q1 2022/23 |
| GA3. Data Centre migration project                                     | Q3 2022/23 |

|  |               |
|--|---------------|
| <b>Linked BAF or high-level operational risks</b>      | Current score |
| Risk no.   To be completed following approval at Board |               |

|          |     |  |
|----------|-----|--|
| BAF Risk | 02B | There is a risk NHSBT fails to meet the demand for essential products and services, caused by disruption and/or variability of external factors, such as donor behaviour, fluctuations in hospital demand, third party supplier shortages, adverse weather, resulting in NHSBT being unable to continue to deliver safe and effective products and services. |
|----------|-----|--|

|   |
|---|
| <b>Linked Strategic Priority</b>                                      |
| Modernise our operations to improve safety, resilience and efficiency |

|                                     |                                 |              |
|-------------------------------------|---------------------------------|--------------|
| <b>Lead Executive</b>               | Director of Quality             |              |
| <b>Board or Executive Committee</b> | Risk Management Committee       |              |
| <b>Current score</b>                | <b>Change since last review</b> | <b>Trend</b> |
| <b>16</b>                           |                                 |              |

|                | Impact   | Likelihood | Total     |
|----------------|----------|------------|-----------|
| Inherent       | X        | X          | X         |
| <b>Current</b> | <b>4</b> | <b>4</b>   | <b>16</b> |
| Target         | X        | X          | X         |

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|--|
| <b>Controls</b>  |
| C1. Business Continuity Management System<br>C2. Supply contingency and risk arrangements<br>C3. Demand management process<br>C4. Donor demographic data analysis and action<br>C5. Donor Marketing activities<br>C6. Customer Services intelligence gathering |

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| <b>Assurances</b>  |
| A1. ISO22301 certification and audit<br>A2. Supply report to RMC<br>A3. Internal and External Audit programme<br>A4. BC Exercise programme<br>A5. BC report to RMC |

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|------------------------|
| <i>Gaps in control</i> |
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| <i>Gaps in assurance</i>                       |
| GA1. BC Exercise Programme paused due to Covid |

| Actions to address gaps in control or assurance            | Due date   |
|--|------------|
| GC1. Exercise programme development                        | Q1 2022/23 |
| GC2. Actions to address RO demand gap                      |            |
| GC3. Appointment Grid Trial and new Donor Appeal           |            |
| GC4. Review of supplier resilience and border arrangements |            |

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|--|----------------------|
| <b>Linked BAF or high-level operational risks</b>      | <b>Current score</b> |
| Risk no.   To be completed following approval at Board |                      |

|          |    |   |
|----------|----|---|
| BAF Risk | 03 | There is a risk that the scale and pace of the NHSBT change programme will adversely impact our core functions or our ability to deliver our strategy caused by poor prioritisation, forecasting, change control and risk evaluation resulting in an impact on the provision of products and services |
|----------|----|---|

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| <b>Linked Strategic Priority</b>   |
| Grow and diversify our donor base<br>Modernise our operations<br>Collaborate with partners |

|                              |  |
|------------------------------|--|
| Lead Executive               | Chief Digital and Information Officer                      |
| Board or Executive Committee | Executive Committee supported by portfolio oversight group |

|                | Impact   | Likelihood | Total    |
|----------------|----------|------------|----------|
| Inherent       | X        | X          | X        |
| <b>Current</b> | <b>4</b> | <b>2</b>   | <b>8</b> |
| Target         | X        | X          | X        |

| Current score | Change since last review | Trend |
|---------------|--------------------------|-------|
| <b>8</b>      |                          |       |

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| <b>Controls</b>  |
| C1. Portfolio prioritisation and regular review<br>C2. Appropriate assignment of qualified SROs and PPM staff<br>C3. Business cases include optimism bias, contingency and are approved at appropriate levels<br>C4. Scale of change investment fund<br>C5. Change control system operated by QA<br>C6. Change control system operated by IT |

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| <b>Assurances</b>  |
| A1. MHRA licences and audit reports<br>A2. Programme and project status reporting<br>A3. Programme/Project internal assurance reviews<br>A4. Independent Gateway reviews<br>A5. NHSBT performance reporting<br>A6. Business plan quarterly reviews<br>A7. GIAA Audit |

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| <i>Gaps in control</i>   |
| GC1. Qualified SROs and PPM staff<br>GC2. Understanding of delivery capacity and change dependencies |

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| <i>Gaps in assurance</i>                                     |
| GA1. Portfolio level MI on changes to time, cost and quality |

| Actions to address gaps in control or assurance  | Due date |
|--|----------|
| GC1. SRO and PPM continuous learning plan  |          |
| GA2. Mature and embed Portfolio Oversight Group performance and management information |          |
| GA3. Improve scheduling, demand and capacity planning at portfolio level               |          |

|   |   |                      |
|---|---|----------------------|
| <b>Linked BAF or high-level operational risks</b> |   | <b>Current score</b> |
| Risk no.  | To be completed following approval at Board |                      |

|          |    |  |
|----------|----|--|
| BAF Risk | 04 | There is a risk that we do not attract the right number and diversity of donors due to failure to engage the public effectively, resulting in the worsening of the supply demand gap for our products. |
|----------|----|--|

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|--|
| Linked Strategic Priority  |
| Grow and diversify our donor base to meet clinical demand and reduce health inequalities |

|                              |                                      |
|------------------------------|--------------------------------------|
| Lead Executive               | Director of Donor Experience         |
| Board or Executive Committee | BOLT, OTDT SMT, Plasma Board, DX QPR |

|                | Impact   | Likelihood | Total     |
|----------------|----------|------------|-----------|
| Inherent       | 4        | 5          | 20        |
| <b>Current</b> | <b>4</b> | <b>4</b>   | <b>16</b> |
| Target         | 3        | 2          | 6         |

| Current score | Change since last review | Trend |
|---------------|--------------------------|-------|
| <b>16</b>     | ↔                        |       |

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|--|
| <b>Controls</b>  |
| C1. Blood stock oversight activity<br>C2. GCS PASS and Business Case<br>C3. Agency Procurement Process (Media)<br>C4. Quarterly survey |

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|---|
| <b>Assurances</b>   |
| A1. Consensus Review at BOLT<br>A2. Quarterly Reporting / DHSC and Cab Office PASS Form<br>A3. Cab Office Contract Management of Media Buying<br>A4. Donor Metrics (satisfaction, sentiment, propensity to donate etc.) |

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| <i>Gaps in control</i>   |
| GC1. Stem cell strategy<br>GC2. Ro Strategy<br>GC3. Visibility at Exec level<br>GC4: Cross-DX Marketing and Campaigns Governance |

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| <i>Gaps in assurance</i>   |
| GA1. National Stem cell operational reporting<br>GA2. Black donor metrics<br>GA3. Campaign and communication content<br>GA4: Consistent and regular Donor feedback |

| Actions to address gaps in control or assurance                                 | Due date   |
|---|------------|
| GC1&2: Development of dedicated plans and strategy for controls                 | By Apr2022 |
| GC3&GA3. Marketing plan visibility and Quarterly updates to the ET              | By Apr2022 |
| GC4: New Cross-DX Marketing and Communication Governance framework              | By Apr2022 |
| GA1&GA2: Updated KPIs and metrics aligned to plans and strategy                 | By Jul2022 |
| GA4: Quarterly 'hot topic' reporting to ET and Board, from 'voice of the donor' | By Apr2022 |

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|--|---------------|
| Linked BAF or high-level operational risks             | Current score |
| Risk no.   To be completed following approval at Board |               |

|          |     |   |
|----------|-----|---|
| BAF Risk | 05A | There is a risk that a sudden and unexpected change in government finances, health policy and associated commissioning arrangements for our services results in a significant shortfall in income |
|----------|-----|---|

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|---|
| <b>Linked Strategic Priority</b>  |
| Develop and scale new services to provide additional support to the NHS |

|                                     |                         |
|-------------------------------------|-------------------------|
| <b>Lead Executive</b>               | Director of Finance     |
| <b>Board or Executive Committee</b> | Finance and Performance |

|                | Impact   | Likelihood | Total     |
|----------------|----------|------------|-----------|
| Inherent       | X        | X          | X         |
| <b>Current</b> | <b>5</b> | <b>2</b>   | <b>10</b> |
| Target         | X        | X          | X         |

| Current score | Change since last review | Trend |
|---------------|--------------------------|-------|
| <b>10</b>     |                          |       |

|  |
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| <b>Controls</b>  |
| C1. National Commissioning Group<br>C2. Annual accountability and budget setting<br>C3. Business Planning and Performance Management |

|   |
|---|
| <b>Assurances</b>   |
| A1. NCG Outcome letters to NHS Trusts<br>A2. Business plans<br>A3. Performance Reports<br>Audit performance reporting |

|                                |
|--------------------------------|
| <i>Gaps in control</i>         |
| GC1. Example of gap in control |

|                                  |
|----------------------------------|
| <i>Gaps in assurance</i>         |
| GA2. Example of gap in assurance |

| Actions to address gaps in control or assurance | Due date |
|---|----------|
| GC1. Diversifying income sources                |          |
|   |          |
|   |          |

| Linked BAF or high-level operational risks |   | Current score |
|--|---|---------------|
| Risk no.                                   | To be completed following approval at Board |               |

|          |     |   |
|----------|-----|---|
| BAF Risk | 05B | There is a risk that failure to gain support from UK Health Departments, our commissioners and partners for our strategic priorities, and associated funding, results in constrained strategic objectives that do not deliver the increase in lives saved and improved that we seek |
|----------|-----|---|

|   |
|---|
| Linked Strategic Priority   |
| Develop and scale new services to provide additional support to the NHS |

|                              |                         |
|------------------------------|-------------------------|
| Lead Executive               | TBA                     |
| Board or Executive Committee | Finance and Performance |

|                | Impact   | Likelihood | Total     |
|----------------|----------|------------|-----------|
| Inherent       | X        | X          | X         |
| <b>Current</b> | <b>4</b> | <b>4</b>   | <b>16</b> |
| Target         | X        | X          | X         |

| Current score | Change since last review | Trend |
|---------------|--------------------------|-------|
| <b>16</b>     |                          |       |

|          |
|----------|
| Controls |
| C1. TBA  |

|            |
|------------|
| Assurances |
| A1. TBA    |

|                                |
|--------------------------------|
| <i>Gaps in control</i>         |
| GC1. Example of gap in control |

|                                  |
|----------------------------------|
| <i>Gaps in assurance</i>         |
| GA2. Example of gap in assurance |

| Actions to address gaps in control or assurance | Due date |
|---|----------|
| GC1. TBA  |          |
|   |          |
|   |          |

| Linked BAF or high-level operational risks             | Current score |
|--|---------------|
| Risk no.   To be completed following approval at Board |               |

|          |    |   |
|----------|----|---|
| BAF Risk | 06 | There is a risk that NHSBT will be unaware and fail to monitor clinical outcomes in patients receiving our products and services caused by an inability to access data sets in a timely manner due to incompatibility of information systems and lack of engagement with Trusts and other bodies holding significant datasets, preventing us from identifying and driving forward opportunities for improvement |
|----------|----|---|

|                                      |
|--------------------------------------|
| Linked Strategic Priority            |
| Innovate to improve patient outcomes |

|                              |  |
|------------------------------|--|
| Lead Executive               | Chief Medical Officer and Director of Clinical Services<br>Chief Digital and Information Officer |
| Board or Executive Committee | RMC or CARE (TBC)  |

|                | Impact   | Likelihood | Total     |
|----------------|----------|------------|-----------|
| Inherent       |          |            |           |
| <b>Current</b> | <b>4</b> | <b>3</b>   | <b>12</b> |
| Target         |          |            |           |

| Current score | Change since last review | Trend |
|---------------|--------------------------|-------|
| <b>12</b>     |                          |       |

| Controls   |
|--|
| <p>C1. Established processes between solid organ transplant centres and NHSBT</p> <p>C2. Funded transformation plans to establish pilot in multi-transfused patients</p> <p>C3. Priority with UK Stem Cell Strategic Forum deliverables (in publication)</p> <p>C4. NHSBT's membership of the Data Alliance Partnership</p> <p>C5. IT Security and Governance</p> <p>C6. Industrialising our Data Supply Chain</p> |

| Assurances  |
|---|
| <p>A1. ODT Annual Reports</p> <p>A2. National Comparative Audit Reports</p> <p>A3. SHOT Annual Report</p> <p>A4. EBMT and BSBMTCT Annual Reports</p> <p>A5. NHSBT Internal Clinical Audit Reports</p> |

| Gaps in control  |
|--|
| <p>GC1. No systemised mechanism to capture and understand outcomes in the patients we serve</p> <p>GC2. No data sharing SLA in place between NHSBT and Trusts / other agencies</p> |

| Gaps in assurance   |
|---|
| <p>GA2. Outcome of transfusion recipients</p> <p>GA2. Full and timely outcomes of Stem Cell recipients</p> <p>GA3. Outcomes in NHSBT TAS patients</p> <p>GA4. Limited patient related outcome or experience measures (PROMs and PREMs) in any directorate</p> |

| Actions to address gaps in control or assurance   | Due date |
|---|----------|
| GA1. Data mapping information flows in stem cell transplantation                                |          |
| GA2. Setting up database for clinical outcomes in TAS   |          |
| GA3. TAS setting up CRM   |          |
| GA4. The full adoption, endorsement, and funding of the data strategy to give greater influence |          |
| GA5. Developing standard APIs to NHS Digital Guidance   |          |

| Linked BAF or high-level operational risks             | Current score |
|--|---------------|
| Risk no.   To be completed following approval at Board |               |

|          |    |   |
|----------|----|---|
| BAF Risk | 07 | There is a risk that a lack of capacity, capability and / or flexibility in our workforce, caused by challenges in our attraction, recruitment and retention strategies, prevent us from delivering our strategic priorities or core functions. |
|----------|----|---|

|   |
|---|
| <b>Linked Strategic Priority</b>  |
| Invest in people and culture to ensure a high performing and inclusive organisation |

|                                     |   |
|-------------------------------------|---|
| <b>Lead Executive</b>               | Chief People Officer                    |
| <b>Board or Executive Committee</b> | Nominations and Remunerations Committee |

|                | Impact   | Likelihood | Total     |
|----------------|----------|------------|-----------|
| Inherent       | X        | X          | X         |
| <b>Current</b> | <b>4</b> | <b>4</b>   | <b>16</b> |
| Target         | X        | X          | X         |

| Current score | Change since last review | Trend |
|---------------|--------------------------|-------|
| <b>16</b>     |                          |       |

|   |
|---|
| <b>Controls</b>   |
| C1. Recruitment process<br>C2. Organisational Development<br>C3. Strategic advice from People and Culture Teams<br>C4. HR Policies in place |

|   |
|---|
| <b>Assurances</b>   |
| A1. People Tracker in Performance Report<br>A2. Directorate People Scorecards<br>A3. Audit of Recruitment (GIAA)<br>A4. Staff Partnership Council reports |

|                                |
|--------------------------------|
| <i>Gaps in control</i>         |
| GC1. Example of gap in control |

|  |
|--|
| <i>Gaps in assurance</i>                 |
| GA2. Audit of People Data for validation |

| Actions to address gaps in control or assurance                | Due date   |
|--|--|
| GC1. Workforce planning and succession planning                | High Level Approach – Q3 22/23<br>Socialisation & Agreement Q4 22/23<br>Mobilise Year 1 version 23/24<br>Refine Q1 24/25 onwards |
| GA2. Applicant tracker system for recruitment (PETS Project)   | April 2022   |
| GA3. Attraction Strategy (completed and expanded to all roles) | March 2023   |
| GA4. Refresh of people development strategy                    | End Q4 2022/23   |
| GA5. Establish the Academy                                     | End Q4 2021/22   |
| GA6. People Strategy   | End Q3 2022/23   |
| GA7. Education and Training Strategy                           | End Q3 2022/3  |

| Linked BAF or high-level operational risks           | Current score |
|--|---------------|
| Risk no. To be completed following approval at Board |               |

|          |    |  |
|----------|----|--|
| BAF Risk | 08 | There is a risk that our leaders and managers lack the skills and capabilities required in today's NHS to create a high-performing, inclusive environment, and to deliver our strategic priorities |
|----------|----|--|

|   |
|---|
| Linked Strategic Priority   |
| Invest in people and culture to ensure a high performing and inclusive organisation |

|                              |   |
|------------------------------|---|
| Lead Executive               | Chief People Officer                    |
| Board or Executive Committee | Nominations and Remunerations Committee |

|                | Impact   | Likelihood | Total    |
|----------------|----------|------------|----------|
| Inherent       | X        | X          | X        |
| <b>Current</b> | <b>3</b> | <b>3</b>   | <b>9</b> |
| Target         | X        | X          | X        |

| Current score | Change since last review | Trend |
|---------------|--------------------------|-------|
| <b>9</b>      |                          |       |

| Controls   |
|--|
| <ul style="list-style-type: none"> <li>C1. D&amp;I Embedded in Policy</li> <li>C2. PDPR Processes (inc. Training Gateway review)</li> <li>C3. Clear expectations included in PDPR</li> <li>C4. Development Policy</li> <li>C5. Tracking professional development / revalidation</li> <li>C6. Freedom to Speak Up Guardian</li> <li>C7. Workforce Race Equality Standard Plan</li> <li>C8. Workforce Disability Equality Standard Plan</li> </ul> |

| Assurances   |
|--|
| <ul style="list-style-type: none"> <li>A1. Training reporting</li> <li>A2. D&amp;I Programme Board and EDI Consultative Council</li> <li>A3. Reports on workforce profile characteristics</li> <li>A4. Code of Conduct</li> <li>A5. Staff Survey</li> <li>A6. Staff Network</li> </ul> |

| Gaps in control                |
|--------------------------------|
| GC1. Example of gap in control |

| Gaps in assurance  |
|--|
| <ul style="list-style-type: none"> <li>GA1. Comprehensive Training Reporting</li> <li>GA2. Audit of PDPR Process</li> <li>GA3. Gaps in staff network coverage</li> </ul> |

| Actions to address gaps in control or assurance                                   | Due date       |
|---|----------------|
| GC1. Introduction of career conversations   | End Q4 2022/23 |
| GA2. New resolution framework (most inclusive and fair way of resolving problems) | Jan 2023       |
| GA3. People Strategy  | End Q3 2022/23 |
| GA4. Education and Training Strategy  | End Q3 2022/3  |
| GA5. Cultural Audit   | End Q4 2022/3  |
| GA6. Leadership Development Programme   | End Q4 2022/3  |

| Linked BAF or high-level operational risks             | Current score |
|--|---------------|
| Risk no.   To be completed following approval at Board |               |

|          |    |   |
|----------|----|---|
| BAF Risk | 09 | There is a risk that the organisation will become non-compliant with current or emerging regulations which could result in NHSBT being subject to significant regulatory action and/or licences being revoked. This would impact on the ability of NHSBT to provide critical services and products and/or have a serious impact on patient safety. It also has the potential to significantly, and detrimentally, affect the reputation of the organisation |
|----------|----|---|

| Linked Strategic Priority  |
|--|
| Modernise our operations to improve safety, resilience and efficiency<br>Innovate to improve patient outcomes<br>Collaborate with partners to develop and scale new services for the NHS |

|                              |                           |
|------------------------------|---------------------------|
| Lead Executive               | Director of Quality       |
| Board or Executive Committee | Risk Management Committee |

|                | Impact   | Likelihood | Total     |
|----------------|----------|------------|-----------|
| Inherent       | X        | X          | X         |
| <b>Current</b> | <b>4</b> | <b>3</b>   | <b>12</b> |
| Target         | X        | X          | X         |

| Current score | Change since last review | Trend |
|---------------|--------------------------|-------|
| <b>12</b>     |                          |       |

| Controls   |
|--|
| C1. Quality Management System<br>C2. Regulatory and Legislative Change Management<br>C3. Regulatory Affairs and Licencing<br>C4. Training, Education, Competency and Development |

| Assurances   |
|--|
| A1. Management Quality Review<br>A2. Regulatory Radar<br>A3. External Audit Reports from MHRA/HTA<br>A4. Internal Audit via GIAA |

| Gaps in control  |
|--|
| GC1. Lack of formal demand planning process for QA.<br>GC2. Lack of control over Data Integrity (non-conformance identified through MHRA Audit).<br>GC3. CQC Registration process is outside of QA scope (i.e. separate to licensing). |

| Gaps in assurance                                |
|--|
| GA1 – no prior audits of CQC Well Led compliance |

| Actions to address gaps in control or assurance                                | Due date                                 |
|--|--|
| GC1. Design of a demand planning process for QA.                               | TBC                                      |
| GC2. Data Integrity plan (CoreStream DI pilot for Clinical Services Q3 21/22). | Q1 22/23<br>(organisation wide roll out) |
| GC3: CQC registration to be included in the Regulatory Affairs team scope.     | Q4 21/22                                 |
| GC4. Well Led Project and GGI review   | January 2022                             |

| Linked high-level operational risks                    | Current score |
|--|---------------|
| Risk no.   To be completed following approval at Board |               |

## Appendix 2 – Comparison of “Old” and “New” Strategic lists

| New Strategic Risk description as in Current Paper   | Residual risk score | Existing Strategic Risk Description most closely aligning with New Risk   | Residual Risk Score | Comment on alignment   |
|--|---------------------|---|---------------------|--|
| <p><b>Risk 01</b><br/>There is a risk that harm occurs to a donor or patient, caused by one of the following</p> <ul style="list-style-type: none"> <li>(i) Failure of NHSBT processes to mitigate a known risk (a serious incident)</li> <li>(ii) Failure to scan for emerging infections</li> <li>(iii) A known complication of transfusion or transplantation that we cannot currently mitigate</li> <li>(iv) Complications occurring in the wider health system where NHSBT is responsible for advice and education resulting in a loss of confidence and goodwill from our organisational stakeholders and the wider public.</li> </ul> | <b>5</b>            | <p><b>NHSBT-01</b><br/>There is a risk that the quality or safety of NHSBT's products or services provided to donors, donor families or patients does not support or provide appropriate standards of care, and therefore puts donors or patients at risk of harm</p> | <b>12</b>           | <p>NHSBT-01 is more succinct, but the new risk is more specific. There is a clear misalignment on scoring.<br/>NHSBT-01 is clearly replaced by the new risk.</p> |
| <p><b>Risk 02A</b><br/>There is a risk of interruption to the effective operation of one or more of NHSBTs business function(s), caused by disruption to one or more essential (internal) resources, including equipment, IT, staff, loss of access to data and estate / facilities, resulting in delay or failure to continued supply of safe and effective products and services.</p>  | <b>12</b>           | <p><b>NHSBT-08</b><br/>There is a risk that the loss of a key facility will cause a failure to deliver key products or services to customers, causing delays to treatment or harm to patients.</p>  | <b>12</b>           | <p>The new risk is broader and more comprehensive. NHSBT-08 should be replaced in its entirety by the new risk.</p>  |
|  |                     | <p><b>NHSBT-05</b><br/>There is a risk that critical NHSBT business services are impacted because digital and technology solutions are not available or providing the right functionality.</p>  | <b>12</b>           | <p>This risk is essentially about potential IT failure and is, therefore, a specific cause for risk 2A</p>   |

| New Strategic Risk description as in Current Paper  | Residual risk score | Existing Strategic Risk Description most closely aligning with New Risk   | Residual Risk Score | Comment on alignment   |
|---|---------------------|---|---------------------|--|
| <p><b>Risk 02B</b><br/>There is a risk NHSBT fails to meet the demand for essential products and services, caused by disruption and/or variability of external factors, such as donor behaviour, fluctuations in hospital demand, third party supplier shortages, adverse weather, resulting in NHSBT being unable to continue to deliver safe and effective products and services.</p> | <b>9</b>            | <p><b>NHSBT-06</b><br/>There is a risk that a supplier of critical product will fail to provide at the expected level caused by supplier failure, poor performance, changes in regulation or poor contract / specification.</p> | <b>12</b>           | The new risk is broader and more comprehensive. NHSBT-06 should be replaced in its entirety by the new risk.   |
| <p><b>Risk 03</b><br/>There is a risk that the scale and pace of the NHSBT change programme will adversely impact our core functions or our ability to deliver our strategy caused by poor prioritisation, forecasting, change control and risk evaluation resulting in an impact on the provision of products and services</p>   | <b>8</b>            | No existing risk on this issue  |                     |  |
| <p><b>Risk 04</b><br/>There is a risk that we do not attract the right number and diversity of donors due to failure to engage the public effectively, resulting in the worsening of the supply demand gap for our products</p>   | <b>9</b>            | <p><b>NHSBT-09</b><br/>There is a risk that a significant event(s) impacts on the reputation of the organisation, such that NHSBT may lose the confidence and trust of the public, resulting in donors stop coming forward</p>  | <b>12</b>           | NHSBT-09 focusses on reputation, which is a function (potentially) of all risk and adverse events. The impact (“donors stop coming forward”) is covered more comprehensively in the new risk. Whilst they are not a one-for-one match, NHSBT-09 should be taken out of circulation and child risks reassigned (not all will be reassigned to the new risk) |

| New Strategic Risk description as in Current Paper  | Residual risk score | Existing Strategic Risk Description most closely aligning with New Risk  | Residual Risk Score | Comment on alignment  |
|---|---------------------|--|---------------------|---|
| <p><b>Risk 05</b><br/>There is a risk that the commissioning arrangements for our services change caused by a policy driver, resulting in a significant change in strategy driven by financial resource</p>   | 10                  | <p><b>NHSBT-10</b><br/>There is a risk that Grant in Aid (GIA) funding for organ donation may be adversely affected by political or policy decisions in Government.</p>  | 10                  | NHSBT-10 has long been a risk of concern and suggested for removal several times. The new risk covers the fundamental points in its consideration and NHSBT-10 should be removed. |
| <p><b>Risk 06</b><br/>There is a risk that NHSBT will be unaware and fail to monitor clinical outcomes in patients receiving our products and services caused by an inability to access data sets in a timely manner due to incompatibility of information systems and lack of engagement with Trusts and other bodies holding significant datasets, preventing us from identifying and driving forward opportunities for improvement</p> | 12                  | No existing risk on this issue (although see NHSBT-07 which references data, but from an internal data management perspective rather than an access to external data perspective)  |                     |   |
| <p><b>Risk 07</b><br/>There is a risk that a lack of capacity, capability and / or flexibility in our workforce, caused by challenges in our attraction, recruitment and retention strategies, prevent us from delivering our strategic priorities or core functions.</p>   | 16                  | <p><b>NHSBT-02</b><br/>There is a risk that NHSBT will not be able to recruit staff with sufficient skills, qualifications and experience to meet NHSBT's requirements, especially where there is a known shortage in a specific staff group or expertise required by the NHS.</p> | 12                  | NHSBT-02 has substantially the same intent as the new risk, but the new risk is better worded. NHSBT-02 should be completely replaced by the new risk                             |
| <p><b>Risk 08</b><br/>There is a risk that our leaders and managers lack the skills and capabilities required in today's NHS to create a high-performing, inclusive environment, and to deliver our strategic priorities</p>  | 9                   | No existing risk on this issue   |                     |   |

| New Strategic Risk description as in Current Paper  | Residual risk score | Existing Strategic Risk Description most closely aligning with New Risk   | Residual Risk Score | Comment on alignment  |
|---|---------------------|---|---------------------|---|
| <p><b>Risk 09</b><br/>There is a risk that the organisation will become non-compliant with current or emerging regulations which could result in NHSBT being subject to significant regulatory action and/or licences being revoked. This would impact on the ability of NHSBT to provide critical services and products and/or have a serious impact on patient safety. It also has the potential to significantly, and detrimentally, affect the reputation of the organisation</p> | <b>12</b>           | <p><b>Not yet registered</b><br/>There is a risk that the organisation will become non-compliant with current or future regulations which could result in NHSBT being subject to significant regulatory action and/or licences being revoked. This would impact on the ability of NHSBT to provide critical services and products and have a serious impact on patient safety. It also has the potential to significantly, and detrimentally, affect the reputation of the organisation</p> | <b>12</b>           | <p>The “Not yet registered” risk was on the pathway to being approved and had been accepted at ARGC. The strategic risk workshop gave an opportunity for this to have further scrutiny and minor changes were made. The “Not yet registered” risk will be replaced by the new strategic risk.</p>   |
| No new risk on this issue   |                     | <p><b>NHSBT-03</b><br/>There is a risk that NHSBT fails in the collection, analysis, processing, testing and supply of regulatory compliant and clinically appropriate blood components in sufficient quantity to meet demand, leading to patient harm</p>  | <b>12</b>           | <p>With operational issues being removed from the NHSBT strategic objectives, there is no specific link for NHSBT-03 in the strategy. There is a tenuous link with new strategic risks 2A and 2B, but this risk includes failures for reasons outside disruptions. This risk needs further review by the Director of Blood Supply. It is suggested that this risk (which links to the strategic intent as set out in NHSBT’s Establishment and Constitution Order) links to the blood service strategy when this is approved.</p> |

| New Strategic Risk description as in Current Paper | Residual risk score | Existing Strategic Risk Description most closely aligning with New Risk   | Residual Risk Score | Comment on alignment   |
|--|---------------------|---|---------------------|--|
| No new risk on this issue                          |                     | <p><b>NHSBT-04</b><br/>           There is a risk that NHSBT fails to react to changes in the wider healthcare environment, regulatory framework or developments in research and/or technology, caused by NHSBT failing to foresee, adapt appropriately or with sufficient agility, resulting in a failure to maintain position or make strategic change.</p> | 9                   | NHSBT-04 was linked to a perceived lack of strategic development capacity. This risk needs further review to ensure that it is either closed as a result of the recruitment of the strategy team or linked appropriately in service level and / or supporting strategies.  |
| No new risk on this issue                          |                     | <p><b>NHSBT-07</b><br/>           There is a risk that NHSBT may inappropriately release data, may lose access to data or may lack integrity in its data or data transfers caused by poor governance, poor process or actions of external agencies.</p>   | 12                  | This may have some alignment with new risk 06, but one is about access to external data and the other about management of internal data, so they are not sufficiently similar to make comparison. This risk needs further review to ensure that it is considered as an addition to the exiting risks, or whether it should be added as a risk to service or supporting strategies. |