

HTA Board meeting, 5 December 2024

| | |
|---------------------------------------|---|
| Agenda item | 2.4 HTA Performance Report |
| Purpose: for information or decision? | Information |
| Decision making to date? | N/A |
| Recommendation | The HTA Board is asked to note and comment by exception on the performance recorded and the context provided |
| Which strategic risks are relevant? | Risk 1: Regulation Risk 2: Sector Risk 3: Staff Risk 4: Financial Risk 5: Digital |
| Strategic objective | Efficient and Effective |
| Core operations / Change activity | Core operations |
| Business Plan item | Senior Management Team – strategic direction and leadership of operational delivery across the organisation (including risk management and seeking opportunities for ALB collaboration) |
| Committee oversight? | Board only |
| Finance and resource implications | Various due to the range of items covered |
| Timescales | Various due to the range of items covered |
| Communication(s) (internal/external | N/A |
| Identified legislative implications | N/A |

HTA Performance Report

Purpose of paper

1. This paper informs the Board of the HTA's performance in Quarter 2 (Q2) of 24/25 against our objectives and operational delivery targets.
2. In addition, it provides an early indication of the initial performance in Quarter 3 (Q3) of 24/25.
3. Core operational areas from our Business Plan with formal Key Performance Indicators (KPIs) have been included as topics within this paper, in the order and nomenclature from that document, so as to allow the Board easy read across. We have also included some additional operational areas where the Board will be interested to note wider non-KPI performance and which may have associated KPIs in future Business Plans. **Annex A** provides the KPI and Project Data Overview for Q2 (final) and **Annex B** gives the KPI and Project Data Overview for Q3 (latest).
4. The current Strategic Risk Register is provided for information at **Annex C**.

Action required

5. The HTA Board is asked to **note** and comment on the performance recorded and the context provided.

Regulation

6. All of the Regulation KPIs are green with one exception. That is the KPI to reach a decision on 90% of appropriately completed new licence applications by 90 days. This was at 50% in Quarter 2 and 75% for the business year to date at 30 September 2024. There were two new licence applications whose 90 day period fell in Quarter 2, one of which was completed on time. 8 out of 10 were completed on time in Quarter 1. Cumulatively, this means that 9 out of 12 (75%) were completed on time over the first two quarters, hence the year to date percentage is 75%. Going forward, the HTA proposes to adopt a rolling annual basis for this measure next year to provide a more meaningful measure that is less skewed by the inherent volatility arising from highly variable small numbers per quarter.
7. Of the Regulation-led projects, none are rated red and all are on track but with some delays.

Communications

8. Following the successful in-person event, the Comms team has conducted a comprehensive analysis of the feedback and roundtable discussions. We are actively engaging with stakeholders to shape and optimise activities for the coming business year. Online forums continue to be delivered and will extend into Q4 in 2025.
9. Social media performance continues to exceed expectations, with LinkedIn emerging as our strongest platform for stakeholder engagement. Website metrics are surpassing internal targets, supported by ongoing Search Engine Optimisation efforts.

Information Technology

10. The performance against KPIs has remained consistent with expected levels. Both of the IT related KPIs are green. There have been no significant outages of IT systems and our Microsoft Exposure Score has started to come down, showing a positive change in our Cyber Security Posture, with additional improvements being reviewed to reduce our exposure score further.
11. Our Regulatory Insight Model and Index work has progressed significantly over the period, with successful testing of pulling data directly from our Customer Relationship Management (Dynamics) application and presented this using a reporting platform called PowerBI. This is an important shift forward for the HTA and we look forward to demonstrating this work to Board Members later in the afternoon.

Corporate Services

12. The KPI for responding to Freedom of Information requests continues to be met and, with a renewed focus, the enquiries KPI has improved in Q2 and is now also being met. We are pleased to note the positive trajectory against the enquiries KPI.

Finance

13. The table below is a summary of our financial position as of 30 September 2024(Q2) and our forecast for the year ending at 31 March 2025. An update by the components of our year to date net surplus are detailed below.

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| | Cumulative YTD | | | | 2024/25 | | | |
|---------------------------------------|------------------|------------------|------------------|----------------|------------------|------------------|------------------|--------------|
| | Actual | Budget | Variance | | Forecast Outturn | Annual Budget | Variance | |
| | £ | £ | £ | % | £ | £ | £ | % |
| INCOME | | | | | | | | |
| Grant in Aid including RDEL | 259,957 | 316,957 | (57,000) | -17.98% | 489,275 | 633,913 | (144,638) | -23% |
| Licence Fees | 5,376,033 | 5,309,239 | 66,794 | 1.26% | 5,376,033 | 5,309,239 | 66,794 | 1% |
| Other | 27,543 | 25,941 | 1,602 | 6.17% | 53,484 | 51,882 | 1,602 | 3% |
| Total Income | 5,663,532 | 5,652,137 | 11,396 | 0.20% | 5,918,792 | 5,995,034 | (76,242) | -1% |
| Staff Costs | | | | | | | | |
| Salaries and Wages | 1,973,175 | 2,149,502 | (176,327) | -8.20% | 4,195,793 | 4,299,004 | (103,211) | -2.4% |
| Authority Allowances | 61,683 | 69,533 | 7,850 | 11.29% | 125,304 | 139,066 | (13,762) | -9.9% |
| Total staff costs | 2,034,858 | 2,219,035 | (184,177) | -8.30% | 4,321,097 | 4,438,070 | (116,973) | -2.6% |
| Non-salary staff costs | | | | | | | | |
| Travel and subsistence | 90,911 | 83,048 | 7,863 | 9.47% | 175,656 | 173,500 | 2,156 | 1.2% |
| Other Staff costs ¹ | 22,437 | 36,475 | (14,038) | -38.49% | 58,223 | 70,150 | (11,927) | -17.0% |
| Recruitment | 17,085 | 22,500 | (5,415) | -24.07% | 34,085 | 30,000 | 4,085 | 13.6% |
| Training costs | 5,178 | 20,500 | (15,322) | -74.74% | 24,250 | 31,000 | (6,750) | -21.8% |
| | 135,611 | 162,523 | (26,912) | -16.56% | 292,214 | 304,650 | (12,436) | -4.1% |
| Other Operating costs | | | | | | | | |
| Telecommunication | 5,072 | 5,000 | 72 | 1.44% | 9,975 | 10,000 | (25) | -0.2% |
| ICT Development ² | 149,590 | 204,500 | (54,910) | -26.85% | 347,090 | 409,000 | (61,910) | -15.1% |
| Legal and Professional (Legal, audit) | 63,715 | 83,250 | (19,535) | -23.47% | 170,188 | 166,501 | 3,687 | 2.2% |
| Communications costs | 51,455 | 55,373 | (3,918) | -7.07% | 61,530 | 60,500 | 1,030 | 1.7% |
| Living Organ Donation costs | 172 | 0 | 172 | #DIV/0! | 172 | 9,000 | (8,828) | -98.1% |
| Shared Service/NHSBT/Projects | 73,850 | 147,250 | (73,400) | -49.85% | 297,600 | 294,500 | 3,100 | 1.1% |
| Administration costs | 8,555 | 8,250 | 305 | 3.70% | 11,963 | 11,500 | 463 | 4.0% |
| Accommodation costs | 101,488 | 79,089 | 22,398 | 28.32% | 159,280 | 165,000 | (5,720) | -3.5% |
| Non-cash costs | 62,664 | 63,157 | (492) | -0.78% | 129,077 | 126,313 | 2,764 | 2.2% |
| | 516,561 | 645,869 | (129,308) | -20.02% | 1,186,876 | 1,252,314 | (65,438) | -5.2% |
| Total expenditure | 2,687,030 | 3,027,427 | (340,397) | -11.24% | 5,800,186 | 5,995,034 | (194,848) | -3.3% |
| Net surplus/(deficit) | 2,976,503 | 2,624,710 | 351,793 | 13.40% | 118,606 | 0 | 118,606 | |

¹Other Staff costs (all-staff days, subscriptions, conferences, welfare)

²ICT Development (including IT Subscriptions, Maintenance, Consultancy)

14. Income - year to date is represented by grant in aid of £200k which is £57k less than budgeted. The remainder will be drawn down by year end. The balance of £59k is non-cash income which covers the depreciation/amortisation of our assets. Our licence fee income is above budget by £67k the bulk of which relates to application fees (£41k) which are difficult to budget for and income from HA licences (£43k); these are offset by reductions in three of the six sectors.
15. Expenditure – year to date, expenditure is under budget by £340k. Below are explanations for the significant variances to budget.
16. Staff costs were underspent by £184k which relates mainly to on-costs (PAYE and pensions). The budget was set assuming all staff would be in the scheme, the reality is that at least 10 members of staff have opted out. There

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were posts at manager level that were unfilled for a period which has also impacted this variance.

17. Other Costs – underspend includes staff away day costs which are currently under budget by £9k due to profiling (cost expected in November). The balance relates to subscriptions and staff welfare costs (cost of home-office equipment).
18. Training costs – underspent by Q2 by £15k which is mainly within corporate training, through further spend is planned for Q4.
19. ICT Development – underspent by £54k represented by maintenance costs £34k and General IT consultancy £20k. The underspend against maintenance costs is a profiling issue with the underspend in consultancy due to a change in plans with no costs expected.
20. Legal and Professional – are also costing less than anticipated with the majority within legal fees. It is expected that legal costs may increase during the remainder of the financial year due to activity within the living organ donation sphere.
21. Shared Services and projects – the significant underspend is due to costs related to the CRM upgrade being categorised as revenue (RDEL) during budget setting but will now likely be capitalised (CDEL) on completion (February or March 2025). The total budget allocated is £115k.
22. Accommodation costs – are over budget by £22k which is represented by rent costs that will eventually be capitalised which is necessary under the accounting standard IFRS 16 – accounting for leases.
23. Forecast – we are forecasting a surplus of £118k before any accounting adjustments such as IFRS 16 and the recategorization of CRM costs from revenue to capital and any write-off out uncollectable debt.
24. Position as of October 2024 – as of month 7, our income is over budget by £51k which largely due to application fees. Expenditure (including staff costs) are under budget by £302k which is not a significant change from Q2.
25. Debtors at 30 September 2024 – our debtors at the end of September 2024 were £3,597k represented by 536 transactions compared to the same period last year which stood at £2,871k with 499 transactions. This sum is due to the billing run that took place the last week of September and largely is not longstanding debt. A breakdown of total debts by sector compared to 2023/24 is below.

| Sector | 2024/25 | | | 2023/24 | | |
|-----------------------|------------|-------------------|-----|------------|-------------------|-----|
| | No. of est | Value | % | No. of est | Value | % |
| NHS | 234 | £2,107,540 | 59% | 219 | £1,605,297 | 56% |
| Government bodies | 30 | £243,975 | 7% | 31 | £240,411 | 9% |
| Non-Government bodies | 272 | £1,245,731 | 34% | 249 | £1,026,160 | 35% |
| Total | 536 | £3,597,246 | | 499 | £2,871,868 | |

26. Of the 2024/25 debts the following relate to pre-March 2024.

34 totalling £190,364 represented by – 17 NHS establishments £77,140 and 17 Non-NHS (non-Government) £113,224

Within the non-NHS is one establishment that we know has gone into liquidation with a total debt of £38,225. This debt will be need to written off against a provision created at the end of 2023/24.

Audit and Risk

27. The latest version of the HTA’s Strategic Risk Register is provided at **Annex C**. This document is reviewed each month by the Senior Management Team, most recently at the Portfolio SMT meeting on 19 November and narrative including actions to mitigate the identified risk has been updated.

28. The risk ratings for the five strategic risks remain unchanged since the last Board meeting with the exception of Risk 4 (There is a risk that the HTA has insufficient or ineffective management of its financial resources) which has returned to being at tolerance with the appointment of two new colleagues to assist within the finance team.

Human Resources

29. Sickness absence for the quarter ended 30 September remains within our target of 3% at 1.8% and reduced to 1.7% in October.

30. Our attrition rate is still under review. We have included the percentage calculated using the current methodology as we cut over to our HR provider. In Annex A we are reporting attrition at around 30% which remains above the KPI of 20% and is consistent across the financial year to date.

Health and Safety

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31. As part of the HTA's management of health and safety, performance monitoring in this area will commence from Q3.
32. The reporting cycle to the Board, as approved by ARAC at the 17 October meeting will include sub-headings that will cover the following topics: incident reporting (number of accidents, incidents and near misses with commentary), health and safety training (compliance rates), risks (as identified through the risk assessment process) and continuous improvement (relevant information and updates from the Health Safety Executive and changes based on lessons learned analysis of events).
33. We anticipate establishing formal KPIs for health and safety as part of Business Planning for 25/26.

Quarter 3 early insights

34. Details of early Q3 performance are given at **Annex B**:
35. Current overall Business Plan **RAG** rating is **Green**:
 - Core operations: All of our KPIs are either currently being achieved or else the position should be made up by year-end, with two exceptions, which are: spend within forecast and attrition rate. In both these cases performance is consistent with previous years. That said, we continue to work to improve these two indices.
 - Change activities: *must-do* projects are all currently on track to deliver / complete as expected by year-end. We have moved the work to replace our finance system back to 25/26 due to the dependency with our CRM updates that will not complete until the end of this financial year in March. We have brought online mid-year a project to engage with Substances of Human Origin legislation, as previously discussed with the Board.

Recommendation

36. The HTA Board is asked to **note** and comment on the performance recorded and the context provided.

**Annex A – Quarterly Board Data Overview, 24/25 Quarter 2 Final Position
Core Operations**

Business Plan KPIs

| | | |
|----------------------|---------------------|-----------------------|
| 8 On Track | 0 At Risk | 3 Off Track |
|----------------------|---------------------|-----------------------|

| | | Apr | May | Jun | Jul | Aug | Sep | 24/24 YTD |
|-------------------------------|--|--------------------|-------------------|------|--------------------|------|------|-----------|
| Approach to Regulation | | | | | | | | |
| Regulation | 222 compliance assessments across all sectors [reported quarterly against planned allocation] | Reported Quarterly | | 67 | Reported Quarterly | | 55 | 122 |
| | 99% of panel and non-panel cases actioned within 10 and 5 working days respectively [reported monthly] | 100% | 100% | 100% | 100% | 100% | 100% | 100% |
| | Support healthcare provision and life-sciences by decisions being reached on 90% of completed new licence applications within 90 days of the application fee being paid [reported quarterly] | Reported Quarterly | | 80% | Reported Quarterly | | 50% | 75% |
| Trust and Confidence | | | | | | | | |
| DTD | Publish two datasets per year [reported annually] | Reported Annually | | | | | | |
| | Publish quarterly incidents data [reported annually] | 100% | Reported Annually | | | | | 100% |
| Use of Information | | | | | | | | |
| DTD | Server downtime less than 3% (within working hours and excluding planned testing) [reported monthly] | 0% | 0.1% | 1.9% | 0% | 0% | 0% | 0.3% |
| | 100% of RTANCA (NHS cyber security alert) notifications actioned / replied to within 48 hours [reported monthly] | 100% | 100% | 100% | 100% | 100% | 100% | 100% |

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Business Plan KPIs

| | | |
|----------------------|---------------------|-----------------------|
| 8 On Track | 0 At Risk | 3 Off Track |
|----------------------|---------------------|-----------------------|

| | | Apr | May | Jun | Jul | Aug | Sep | 24/24 YTD | |
|--------------------------------|---|--------------------|-------|--------|--------------------|-------|-------|-----------|--|
| Efficient and Effective | | | | | | | | | |
| Perf & Corp Gov | 95% of enquiries are answered within 10 working days [reported monthly] | 99% | 89.6% | 91.8 % | 96.0% | 97.3% | 96.5% | 95% | |
| | 100% of FOIs responded to within 20 working days [reported quarterly] | Reported Quarterly | | 100% | 100% | 100% | 100% | 100% | |
| Resources | Actual spend within 1% of forecast [reported quarterly] | Reported Quarterly | | 4% | Reported Quarterly | | 11% | 11% | |
| | Debt no more than 3% of income at year end [reported annually] | Reported Annually | | | | | | | |
| | Unqualified external audit opinion received [reported annually] | Reported Annually | | | | | | | |
| | Attrition rate no more than 20% [reported monthly] | 31.4% | 33.3% | 29.7% | 34.5% | 33.9% | 30.4% | 30.4% | |
| | Staff sickness no more than 3% [reported monthly] | 2% | 2.2% | 2.4% | 2.1% | 2.4% | 1.8% | 1.8% | |

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Project Summary Status – Overall RAG Heatmap for *Board Review*

| Project | | Sponsor | Jul 24 | Aug 24 | Sep 24 | Commentary for Board Review |
|------------|---|----------------|--------|--------|--------|---|
| Activities | Fuller Independent Inquiry <i>[Must do]</i> | Nicky Harrison | A | A | A | Live work packages - continue to maintain, respond and support as required <i>[Expected to run into 25/26]</i> |
| | Innovation in inspection <i>[Should do]</i> | Nicky Harrison | G | A | A | Workstream 'Security Standards' focused on PM sector, in-play: rolling out activities aligned to outlined security enforcement strategy and piloting evidence -based assurance programme. Owing to pressures from other Projects (FII for example) delays in developing new approaches to CAPAs; limited progress <i>[Expected to run into 25/26]</i> |
| | Substances of Human Origin <i>[Must do]</i> | Louise Dineley | W | W | W | Not formally started – although first conversations are being held <i>[Start Date Oct 24, as originally planned]</i> |
| | Public Bodies Review <i>[Must do** if notified]</i> | Louise Dineley | W | W | W | Not started <i>[Start Date N/A]</i> |
| | Facilitate an in-person event <i>[Must do]</i> | Louise Dineley | G | G | G | Event has been delivered, closure in progress <i>[Expected to complete in 24/25]</i> |
| | Establish an Insight Network <i>[Could do]</i> | Louise Dineley | A | A | A | A proposal for the horizon scanning process has been created. This has been presented at a high level to BDT in October to gather insight into interaction and impacts on teams <i>[Expected to complete in 24/25]</i> |
| | Publish a 2023/24 review <i>[Must do]</i> | Louise Dineley | G | G | C | Project completed |
| | Data and Technology strategy <i>[Must do]</i> | Louise Dineley | C | C | C | Project completed |

Project Summary Status – Overall RAG Heatmap for *Board Review*

| Project | | Sponsor | Jul 24 | Aug 24 | Sep 24 | Commentary for Board Review |
|------------|---|----------------|--------|--------|--------|--|
| | Complete backlog updates to CRM <i>[Must do]</i> | Louise Dineley | G | G | G | BCC provided with Purchase Order and work has started <i>[Expected to complete in 24/25]</i> |
| Activities | Regulatory Insight Model and Index <i>[Must do]</i> | Louise Dineley | R | A | A | The RIMI design and development phase has recommenced. Research has been undertaken to assess the feasibility of using existing systems including using original proof of concept and / or the data indicators to develop and refine a basic mvp RIMI tool <i>[Expected to run into 25/26]</i> |
| | Review records management <i>[Should do]</i> | Louise Dineley | W | W | W | Not started <i>[Start Date Jul 24, slipped – Change Control required]</i> |
| | Replace our current finance system <i>[Should do]</i> | Tom Skrinar | W | W | W | Not started <i>[Start Date Sep 24, as originally planned – Change Control required]</i> |
| | Outsource Human Resources <i>[Must do]</i> | Tom Skrinar | G | G | G | HR was effectively outsourced as per the SLA between HTA and CQC as at April 2024. The relationship is now BAU, but there remains some work to drive improvements in the HR service and close / complete the Project governance <i>[Expected to complete in 24/25]</i> |
| | Develop a People strategy <i>[Must do]</i> | Tom Skrinar | G | G | G | Engagement with staff in progress <i>[Expected to complete in 24/25]</i> |
| All | Project delivery | All SMT | A | G | G | Broadly on track to deliver all <i>must do</i> items as planned |

Annex B – Quarterly Board Data Overview, 24/25 Quarter 3 Latest Position

Core Operations

| | | | | | | | | | | 8 On Track | 0 At Risk | 3 Off Track |
|-------------------------------|--|--------------------|-------------------|------|--------------------|------|------|--------------------|-----------|----------------------|---------------------|-----------------------|
| | | Apr | May | Jun | Jul | Aug | Sep | Oct | 24/24 YTD | | | |
| Business Plan KPIs | | | | | | | | | | | | |
| Approach to Regulation | | | | | | | | | | | | |
| Regulation | 222 compliance assessments across all sectors [reported quarterly against planned allocation] | Reported Quarterly | | 67 | Reported Quarterly | | 55 | Reported Quarterly | 122 | | | |
| | 99% of panel and non-panel cases actioned within 10 and 5 working days respectively [reported monthly] | 100% | 100% | 100% | 100% | 100% | 100% | 99% | 100% | | | |
| | Support healthcare provision and life-sciences by decisions being reached on 90% of completed new licence applications within 90 days of the application fee being paid [reported quarterly] | Reported Quarterly | | 80% | Reported Quarterly | | 50% | Reported Quarterly | 75% | | | |
| Trust and Confidence | | | | | | | | | | | | |
| DTD | Publish two datasets per year [reported annually] | Reported Annually | | | | | | | | | | |
| | Publish quarterly incidents data [reported annually] | 100% | Reported Annually | | | | | | | | 100% | |
| Use of Information | | | | | | | | | | | | |
| DTD | Server downtime less than 3% (within working hours and excluding planned testing) [reported monthly] | 0% | 0.1% | 1.9% | 0% | 0% | 0% | 0% | 0.3% | | | |
| | 100% of RTANCA (NHS cyber security alert) notifications actioned / replied to within 48 hours [reported monthly] | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | | | |

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Business Plan KPIs

| | | |
|----------------------|---------------------|-----------------------|
| 8 On Track | 0 At Risk | 3 Off Track |
|----------------------|---------------------|-----------------------|

| | | Apr | May | Jun | Jul | Aug | Sep | Oct | 24/24 YTD |
|--------------------------------|---|--------------------|-------|--------|--------------------|-------|-------|--------------------|-----------|
| Efficient and Effective | | | | | | | | | |
| Perf & Corp Gov | 95% of enquiries are answered within 10 working days [reported monthly] | 99% | 89.6% | 91.8 % | 96.0% | 97.3% | 96.5% | 97.4% | 95.36% |
| | 100% of FOIs responded to within 20 working days [reported quarterly] | Reported Quarterly | | 100% | Reported Quarterly | | 100% | Reported Quarterly | 100.00% |
| Resources | Actual spend within 1% of forecast [reported quarterly] | Reported Quarterly | | 4% | Reported Quarterly | | 11% | Reported Quarterly | 11% |
| | Debt no more than 3% of income at year end [reported annually] | Reported Annually | | | | | | | |
| | Unqualified external audit opinion received [reported annually] | Reported Annually | | | | | | | |
| | Attrition rate no more than 20% [reported monthly] | 31.4% | 33.3% | 29.7% | 34.5% | 33.9% | 30.4% | 28.6% | 28.6% |
| | Staff sickness no more than 3% [reported monthly] | 2% | 2.2% | 2.4% | 2.1% | 2.4% | 1.8% | 1.7% | 1.7% |

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Project Summary Status – Overall RAG Heatmap for *Board Review*

| Project | | Sponsor | Aug 24 | Sep 24 | Oct 24 | Commentary for Board Review |
|------------|---|----------------|--------|--------|--------|---|
| Activities | Fuller Independent Inquiry <i>[Must do]</i> | Nicky Harrison | A | A | A | Live work packages - continue to maintain, respond and support as required <i>[Project expected to complete in 24/25, but work will continue into 25/26 as part of core operations]</i> |
| | Innovation in inspection <i>[Should do]</i> | Nicky Harrison | A | A | A | Workstream 'Security Standards' focused on PM sector, in-play: rolling out activities aligned to outlined security enforcement strategy and piloting evidence -based assurance programme <i>[Project expected to run into 25/26]</i> |
| | Substances of Human Origin <i>[Must do]</i> | Louise Dineley | W | W | W | Not formally started – although first conversations are being held and Business Case is drafted <i>[Project expected to run into 25/26]</i> |
| | Public Bodies Review <i>[Must do** if notified]</i> | Louise Dineley | W | W | W | Not started <i>[Start Date N/A]</i> |
| | Facilitate an in-person event <i>[Must do]</i> | Louise Dineley | G | G | C | Project completed |
| | Establish an Insight Network <i>[Could do]</i> | Louise Dineley | A | A | G | A proposal for the horizon scanning process and options for gathering expert insight have been finalised. A paper outlining this proposal and options for SMT's agreement is planned for the 21 November SMT meeting <i>[Project expected to complete in 24/25]</i> |
| | Publish a 2023/24 review <i>[Must do]</i> | Louise Dineley | G | C | C | Project completed |
| | Data and Technology strategy <i>[Must do]</i> | Louise Dineley | C | C | C | Project completed |

Project Summary Status – Overall RAG Heatmap for *Board Review*

| Project | | Sponsor | Aug 24 | Sep 24 | Oct 24 | Commentary for Board Review |
|------------|---|----------------|--------|--------|--------|--|
| Activities | Complete backlog updates to CRM <i>[Must do]</i> | Louise Dineley | G | G | G | BCC have been asked to provide a concise breakdown of the works required. Project Initiation Document approved. BCC provided with Purchase Order and work has started. <i>[Project expected to complete in 24/25]</i> |
| | Regulatory Insight Model and Index <i>[Must do]</i> | Louise Dineley | A | A | A | The 23 Oct RIMI workshop was successful. Consequently, the Project Plan and Resource requirements have been reviewed and work is in progress to deliver the RIMI pilot from Jan 25 – Mar 24 <i>[Project expected to complete in 24/25, but work will continue into 25/26 as part of core operations]</i> |
| | Review records management <i>[Should do]</i> | Louise Dineley | W | W | W | Not started <i>[Start Date Jan 24, slipped – Project expected to complete in 24/25, but work will continue into 25/26 as part of core operations]</i> |
| | Replace our current finance system <i>[Should do]</i> | Tom Skrinar | W | W | W | Not started <i>[Removed from 24/25 – Project expected to be progressed in 25/26]</i> |
| | Outsource Human Resources <i>[Must do]</i> | Tom Skrinar | G | G | G | HR was effectively outsourced as per the SLA between HTA and CQC as at April 2024. The relationship is now BAU, but there remains some work to drive improvements in the HR service and close / complete the Project governance <i>[Project expected to complete in 24/25]</i> |
| | Develop a People strategy <i>[Must do]</i> | Tom Skrinar | G | G | G | Delivered themed workshops for the People Strategy strands <i>[Project expected to complete in 24/25]</i> |
| All | Project delivery | All SMT | G | G | G | Broadly on track to deliver all <i>must do</i> items as planned |

HTA 19-24 ANNEX B

| Category | Red | Amber | Green |
|----------|----------------------------------|-----------------------------------|-------------------------|
| KPI | Performance is >10% below target | Performance is = 1%-10% of target | Performance is = target |

| Category | Red | Amber | Green | Blue | White |
|----------|--|---|---|------------------|------------------|
| Project | There is significant risk that the overall Activity will be delivered late or will fail to deliver everything within scope against the agreed baseline plan. | There is a risk that one or more milestones may be late, or that the full scope will not be delivered. However, there is a good possibility of implementing mitigations to bring the plan back on track to meet the schedule and delivery as planned. | Overall Activity is on track to be delivered against the baseline plan and there is no, or minimal risk of milestones being delivered late. | Project complete | Project not live |

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Annex C – Strategic Risk Register, 24/25 Current

1 Regulation risk

| | | | | | | | | | | |
|--------------------------------------|--|--|------------|-----------------------------|------------------------|------------|--------------------------------|-----------------------------|-----------------------|--|
| Updated by | | Nicolette Harrison | | | | | Updated date | | 20/11/2024 | |
| Risk name | | Risk 1: Notable regulation failure leading to public harm and/or loss of public/professional confidence in the HTA | | | | | | | | |
| Risk levels | Inherent risk levels | | | Residual risk levels | | | Optimal risk level | Tolerable risk level | Risk tolerance | |
| | Likelihood | Impact | Risk level | Likelihood | Impact | Risk level | | | | |
| | 3 | 5 | 15 | 2 | 4 | 8 | 5 | 8 | At tolerance | |
| Risk owner | Nicolette Harrison | | | Link to strategy | Approach to regulation | | Trend since last update | | ↔ | |
| Cause | <ul style="list-style-type: none"> - Failure to identify notable regulatory non-compliance - Regulation is not transparent, accountable, proportionate, consistent and targeted - Regulation is not sufficiently agile to respond to changes in sectors - Insufficient capacity and/or capability. This includes insufficient expertise, reductions in staffing from attrition, inadequate contingency planning, recruitment difficulties (including Independent Assessors [IAs]), inadequate adherence to agreed policies and procedures (especially in relation to decision-making)) - Poor quality or out of date policies and procedures - Failure to fully follow-up on identified risks and issues - Inability to access relevant technical expertise; for example, to support the assessment of regulated activities or premises | | | | | | | | | |
| Effect | <ul style="list-style-type: none"> - Patient safety compromised - Loss of public confidence - Loss of professional confidence - Loss of trust and respect from people in regulated sectors, potentially leading to greater non-compliance and challenging of decisions - Reputational damage - Technical regulatory decisions re process or risk management that turn out to be incorrect | | | | | | | | | |
| Existing controls | <ul style="list-style-type: none"> - Regulatory model that provides a range of proactive and targeted regulatory assessments - Well-established processes supporting our core business; Regulatory decision-making framework including police referral policy and process - Range of assessment models to support sector-specific inspection approaches that can be adapted quickly according to risk - Training and development: Structured induction for new staff; Directorate training / away days; Regulation budget includes provision for conference attendance and staff training - Specialist expertise identified and recruited to ensure a broad range of knowledge across sectors and developing areas - In exceptional circumstances, scope for limited reallocation of resource to priority areas - Access to specialist legal advice for novel or complex matters | | | | | | | | | |
| Actions to improve mitigation | <p>Although this risk is currently at a tolerable level, the following actions have been identified as ways of bringing the residual risk level closer to optimal.</p> <ol style="list-style-type: none"> 1. Invest resource in cross-organisational work to develop operational policy positions on new or complex areas eg new SoHO Regulations 2. Develop and implement a programme of continuing professional development for Regulation staff, commencing with the completion of a Training Needs Analysis (TNA) 3. Establish HTA Insight Network to facilitate horizon scanning 4. Identify and establish HTA access to suitable expert groups to assist with advice on complex PPD authorisations and SAEARs/HTARI cases 5. HTA to reconvene internal Quality Forum meetings and associated processes for governance document review 6. Undertake a critical evaluation of the activities aimed at strengthening the Living Organ Donation approval process over the past couple of years to assess their effectiveness and impact. <p>Action 1: 0.5 x RM supporting policy team work on SoHO Regs-related work until 31 March 2025, in first instance. Business Case and PID agreed by PSMT in October and November respectively. Discussions ongoing as part of 25/26 business planning process to agree resource requirements for the future. Project plan identifies key activities and phasing of work over the next 2 years. [Update 22/11/24: Ongoing]</p> <p>Action 2: Training Needs Analysis for Regulation Directorate complete; Implementation plan to be in place by e/o Dec '24 [Update 20/11/24: Ongoing]</p> <p>Action 3: Horizon scanning and the development of an Insight Network proposals agreed by SMT on 21/11/2024. Approach to be embedded in the remainder of 2024/25. [Update 22/11/24 - Ongoing]</p> <p>Action 4: Discussions ongoing with DHSC regarding potential for HTA to access EU Expert Advisory Groups to be set up under the new EU SoHO Regs. No further activity pending outcome of the discussions with DHSC SoHO Team - next meeting planned for 18/12/24. [Update 20/11/24: Ongoing]</p> <p>Action 5: Corporate Services Manager role now filled and Quality and Corporate Governance Forum meetings have resumed but further action required to address backlogs in the</p> | | | | | | | | | |
| Owners / Status | Nicolette Harrison | | | | | | | | | |

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HTA 19-24 ANNEX C

2 Sector risk

| | | | | | | | | | |
|--------------------------------------|--|--------|------------|-----------------------------|--------------------|---------------------|---------------------------|--------------------------------|-----------------------|
| Updated by | Nicolette Harrison | | | | | Updated date | 20/11/2024 | | |
| Risk name | Risk 2: Misperception of the HTA's role and reach or poor external relationships leading to gaps in sectoral risk management | | | | | | | | |
| Risk levels | Inherent risk levels | | | Residual risk levels | | | Optimal risk level | Tolerable risk level | Risk tolerance |
| | Likelihood | Impact | Risk level | Likelihood | Impact | Risk level | | | |
| | 3 | 5 | 15 | 2 | 4 | 8 | 4 | 8 | At tolerance |
| Risk owner | Nicolette Harrison | | | Link to strategy | Trust & confidence | | | Trend since last update | ↔ |
| Cause | <ul style="list-style-type: none"> - Complex regulatory landscape creates potential for confusion (for the public and sectors) about regulatory remits of different regulators; real or perceived regulatory gaps - Issues managing intersections in remits between different regulators - HTA's formal regulatory framework, including legislation, may not keep pace with sector developments and so may not be able to effectively manage emerging risks - Lack of clarity about changes in responsibilities e.g. following any legislative changes - Lack of HTA insight into broader pressures and issues affecting our sectors that may be indicators of new or emerging risks - Lack of suitable engagement or information or intelligence-sharing mechanisms between the HTA and other regulators, relevant agencies or law enforcement impedes the HTA's ability to share and escalate concerns or to refer concerns or issues to other more appropriate agencies, where relevant | | | | | | | | |
| Effect | <ul style="list-style-type: none"> - Diminished professional confidence in the adequacy of the legislation and/or the regulatory framework operated by HTA - Reduced public confidence in regulation of matters relating to human tissue - Reputational damage | | | | | | | | |
| Existing controls | <ul style="list-style-type: none"> - Horizon scanning process; Communications and Engagement Strategy; Formal and informal engagement with, and feedback from, our sectors and stakeholders - Effective management of HTA's public profile to maintain awareness and professionalism and deal with media enquiries, including developing HTA lines and positions - Active management of professional stakeholders, in our sectors, other bodies, other Government Departments and Devolved Administrations, including providing advice - Regular engagement with DHSC sponsorship team and Substances of Human Origin (SoHO) team on matters which might impact public and professional confidence - Identifying and taking action on issues where we believe these will support public and professional confidence - HTA representation on relevant multi-agency groups and forums, including particularly those dealing with new and emerging issues or innovative practice - Maintaining and utilising existing Memoranda of Understanding (MOUs) and Information Sharing Agreements with other relevant bodies e.g. other regulators - Maintaining, utilising and periodically updating relevant HTA policies and processes (e.g. the Police Referral and Warrants Policy) | | | | | | | | |
| Actions to improve mitigation | <p>Although this risk is currently at a tolerable level, the following actions have been identified as ways of bringing the residual risk level closer to optimal.</p> <ol style="list-style-type: none"> 1. Undertake a programme of wider awareness-raising activities following the sentencing of private healthcare group for licensing breach in 2023/24 2. Review and update existing Memoranda of Understanding (MOUs) and Information Sharing Agreements (ISAs), especially with CQC and other health regulators 3. Join the NHSE-led 'Mortuary Oversight Group' as an observer 4. Join the Health and Social Care Regulators Forum and Emerging Concerns Protocol 5. Revise the HTA's horizon scanning processes to ensure they are fit for purpose and proportionate 6. Publish an HTA Annual Review of 2023/24 and share related information as part of a stakeholder event <p>Action 1: Meeting between Regs and Comms 12/11/24 refreshed scope and objectives of proposed sector-focused Comms activity, with target of agreeing next steps and activities by 31 Dec 2024 [Update 20/11/24: Ongoing]</p> <p>Action 2: Update to MoU with CQC and UKAS in progress and initial discussions with NHSE re potential MOU focused on PM sector. [Update 20/11/24: Ongoing]</p> <p>Action 3: HTA an established observer member of NHSE Mortuary Oversight Group and from Quarter 3, participating in its Data Workstream. [Update 20/11/24: Complete]</p> <p>Action 4: HTA now established as member of the Health and Social Care Regulators Forum and its Emerging Concerns Protocol. [Update 20/11/24: Action complete]</p> <p>Action 5: Horizon scanning process approved by SMT on 21/11/24. [Update 22/11/24: Ongoing]</p> <p>Action 6: HTA Annual Review 23/24 published in July 24. Face-to-face stakeholder event held in Sept 24. [Update 20/11/24: Action complete]</p> | | | | | | | | |
| Owners / Status | Nicolette Harrison | | | | | | | | |

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HTA 19-24 ANNEX C
3 Staff risk

| | | | | | | | | | | |
|--------------------------------------|---|---|-------------------|-----------------------------|-----------------------|-------------------|--------------------------------|-----------------------------|------------------------|--|
| Updated by | | Tom Skrinar | | | | | Updated date | | 17/09/2024 | |
| Risk name | | Risk 3: Inability to progress core activities due to insufficient staff capacity and capability to deliver organisational goals | | | | | | | | |
| Risk levels | Inherent risk levels | | | Residual risk levels | | | Optimal risk level | Tolerable risk level | Risk tolerance | |
| | Likelihood | Impact | Risk level | Likelihood | Impact | Risk level | | | | |
| | 4 | 5 | 20 | 4 | 4 | 16 | 9 | 9 | Above tolerance | |
| Risk owner | Tom Skrinar | | | Link to strategy | Efficient & effective | | Trend since last update | | ↔ | |
| Cause | <ul style="list-style-type: none"> - General high staff turnover putting recruitment pressure on managers and capacity pressures on broader teams to cover gaps - Turnover of staff in key roles that are 'single points of failure', leading to gaps in essential capability - Poor leadership and line management practices, including unclear objectives. Also poor job design and recruitment techniques and/or poor support from HR. - Poor prioritisation or insufficiency of resources - Poor H&S and risk assessment and monitoring of staff safety - Insufficient focus on staff culture or health and well-being due to lack of resource or SMT/CEO focus to organise and support effectively | | | | | | | | | |
| Effect | <ul style="list-style-type: none"> - Lack of key expertise leading to organisational inability to deliver key objectives or to effectively manage risk - Insufficient staff capacity to manage the extent of the HTA's core duties and corporate responsibilities. - Poor deployment of staff leading to inefficient working and increasingly pressured staff leading to further loss of staff - Reduction in staff resilience, or inability to protect staff in the workplace, leading to sickness absence and staff loss. Poor advice from HR not resolving issues. - Poor culture and engagement and general lack of motivation amongst staff; HTA becomes a less attractive place to work. | | | | | | | | | |
| Existing controls | <ul style="list-style-type: none"> - Recruitment to vacancies and skills gaps ongoing, with use of agencies where needed. Good engagement with HR on JDs and recruitment approach. - Prioritisation of organisational tasks and objectives to ensure pinch points are recognised and staff not overloaded, including reducing workloads where necessary - Creation by teams of SOPs and clear role descriptions for quick induction of staff on recruitment or whilst covering roles due to absence. Cross-team training. - Development of a staff forum to support networking and a focus on social / organisation culture and to have a stronger staff voice in the organisation. [Q2 2024] - Staff survey and review of HR MI to ensure there is a clearer senior understanding of staffs' feelings and situations [Q2 2024] | | | | | | | | | |
| Actions to improve mitigation | <ul style="list-style-type: none"> - People Strategy for the period 2025 - 2028, starting with the staff survey, that focusses on valuing and supporting employees to deliver effectively [Q3 2024] - Monitoring of the implementation of the People Strategy tracking measurable actions [from Q1 2025] - Revision of people policies and procedures that protect staff, including Health and Safety, risk assessments and sickness management [throughout 2024/25] - Development of the HTA leadership team and managers, and improvements to how we manage performance. [Ongoing] - Strengthen L&D and induction processes to ensure staff are equipped to succeed in their roles [included in People Strategy] - Leavers / handover process formalised via a checklist to ensure corporate knowledge is retained and encourage staff to complete exit interviews [throughout 2024/25] | | | | | | | | | |
| Owners | Tom Skrinar, SMT, BDT | | | | | | | | | |

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HTA 19-24 ANNEX C

4 Financial risk

| Updated by | | Tom Skrinar | | | | | Updated date | | 17/09/2024 | |
|-------------------------------|--|--|------------|----------------------|-----------------------|------------|--------------------|-------------------------|----------------|--|
| Risk name | | Risk 4: There is a risk that the HTA has insufficient or ineffective management of its financial resources | | | | | | | | |
| Risk levels | Inherent risk levels | | | Residual risk levels | | | Optimal risk level | Tolerable risk level | Risk tolerance | |
| | Likelihood | Impact | Risk level | Likelihood | Impact | Risk level | | | | |
| | 4 | 4 | 16 | 3 | 3 | 9 | 6 | 9 | At tolerance | |
| Risk owner | Tom Skrinar | | | Link to strategy | Efficient & effective | | | Trend since last update | ↑ | |
| Cause | <ul style="list-style-type: none"> - Under-recovery of income / poor debt recovery (including regulated establishment inability to pay) or inability to forecast variable income accurately - Failure in setting a robust operating budget or to effectively prioritise work and / or manage costs / efficiencies - Unexpected significant cost pressures (e.g. legal, urgent infrastructure investment, etc) or budget change requests from DHSC or HMT arising in year - Inability to robustly control expenditure / manage operating budgets or failure to adhere to HMT and Cabinet Office Standards (finance and commercial) - System of control unable to prevent fraud / error or adapt to new risks - Insufficient finance resource to manage transactions or support sound financial management / finance system no longer fit for purpose | | | | | | | | | |
| Effect | <ul style="list-style-type: none"> - Late or non-payment of HTA debt leading to reputational damage / pressures on suppliers / staff - Resources lost due to fraud, error or avoidable fees/charges - Inability to stay within budget leading to leading to the need to stop work or to lose the confidence of DHSC. - Inability to manage costs over the longer term leading to unreasonable increases in licence fees or requests for further public funding. - Reputational risk to the Accounting Officer, increased scrutiny (including the PAC) and difficulties in gaining business case approval | | | | | | | | | |
| Existing controls | <ul style="list-style-type: none"> - Budget management framework to control and review spend and take early action when diverging from budget. - Close engagement with DHSC sponsors and finance, with timely openness about financial position and pressures to allow amendments to budget/access reserves. - Financial projections, cash flow forecasting and monitoring, good communications between finance and operational teams allows robust financial management. - Robust licence fee modelling and rigorous debt recovery procedure ensures income comes in as expected. - Annual external audit and internal audits of financial processes and control environment to identify weaknesses in procedure. - Horizon scanning for changes to DHSC funding and networking with DHSC and ALB FDs regarding Spending Reviews, etc to ensure we can engage effectively | | | | | | | | | |
| Actions to improve mitigation | <ul style="list-style-type: none"> - Improved internal financial monitoring and management and teach-ins for SMT, including a focus on resource use. [Q3 2024] - Action plan to move from rudimentary to basic level of maturity on the GovS:013 Counter Fraud Functional Standards [throughout 2024/25] - Develop plans to improve structure, systems and processes across HTA and HFEA finance teams to improve efficiency and staff development [throughout 2024/25] - Focus on financial and commercial skills and awareness of HTA managers. [throughout 2024/25] | | | | | | | | | |
| Owners | Tom Skrinar, Colin Sullivan (AO), SMT | | | | | | | | | |

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HTA 19-24 ANNEX C

5 Digital risk

| | | | | | | | | | |
|--------------------------------------|--|--------|------------|-----------------------------|---------------------------|---------------------|---------------------------|--------------------------------|------------------------|
| Updated by | Louise Dineley | | | | | Updated date | 22/11/2024 | | |
| Risk name | Risk 5: Failure to make use of available data, digital and technology to ensure systems are kept up to date and support the delivery of business activities. | | | | | | | | |
| Risk levels | Inherent risk levels | | | Residual risk levels | | | Optimal risk level | Tolerable risk level | Risk tolerance |
| | Likelihood | Impact | Risk level | Likelihood | Impact | Risk level | | | |
| | 5 | 4 | 20 | 3 | 4 | 12 | 9 | 9 | Above tolerance |
| Risk owner | Louise Dineley | | | Link to strategy | Use of Information | | | Trend since last update | ↔ |
| Cause | <ul style="list-style-type: none"> - Core systems identified as either approaching or out of support in the event of an incident - Data management is inconsistent across the business limiting opportunities to optimise and make use of information and intelligence. - Ageing business technology systems that have evolved rather than be designed limit alignment to business needs and / or opportunities for digital developments. - Staff confidence and capability in data and digital services can limit developments - Cyber Security changes in compliance requirements and standards not aligned to business capabilities - Knowledge and intellectual property of HTA systems is held by third party supplier - Inconsistency in data and information management practices is a limiting factor in our ability to make better use of information held. | | | | | | | | |
| Effect | <ul style="list-style-type: none"> - IT breach and/or loss of sensitive data - Increased risk of system and process vulnerabilities being exploited by third parties resulting in restricted access or system failure - Loss of core IT systems required by HTA staff to deliver their work - Options that make use of existing technology and digital developments need to be adopted to address inefficient ways of working and reduce manual work-arounds - Knowledge and insight that can be obtained from data holdings results in poor quality regulation or opportunities for improvement being missed - Reliance on manual processes and single points of contact to bridge digital gaps - Large volume of data and records held beyond designated retention schedules impacting on storage, records management, data quality and information governance - Digital ambition such as the use or consideration of AI in regulated activities is constrained and / or not understood to determine compliance with standards - Limited internal resourcing capacity risks maintaining a reliance on third party supplier support | | | | | | | | |
| Existing controls | <ul style="list-style-type: none"> - Policies, processes and practices covering all aspects of system security and data management have been reviewed, revised and or updated on a 12 month schedule. - Data relating to establishments securely stored with the Customer Relationship Management System (CRM) - Appropriate procedures to manage personal data including GDPR compliance. - Staff training in key business systems and mandatory annual training on policies and required controls - Training and development of professional competence part of annual PDPs and performance reviews - IT systems protected and assurances received from 3rd party suppliers that protection is up to date - System performance analytics available and reported monthly - Business Planning to map out anticipated Information Technology and Data work and Portfolio Management to track / support / report delivery for example 2024/25 Business plans and identified projects covering updates and data development (including AI) - Ongoing knowledge gathering and transfer from third party suppliers and wider health system partners - Compliance with DSPT 2024 assessment and forward look to Cyber Essentials Plus. | | | | | | | | |
| Actions to improve mitigation | <ul style="list-style-type: none"> - Agreed Digital and IT Strategy 2024-27 sets the direction of travel through a defined vision, mission and priorities. - Plans in place to communicate and embed the strategy from early Q2 2024/25. These priorities will inform projects delivered through the annual business planning process to drive change, improvement and identify opportunities to strengthen and or / exploit the use of current systems and data holdings. - Priorities identified for 2024/25 aim to establish a strong foundation through supported systems, resourcing and developments to strengthen future digital capacity and capability. These include: CRM update (phase 2) - Q4 2024/25. Status: On track; Pilot of AI - Q3 2024/25. Status: On track RIMI - initial build to agreed indicators Q4 2024/25. Status : On track for a mvp; Data publications - Q2 2024/25 and Q4 2024/25. Status: Q2 completed. - The increased and continued threat posed through cyber security is key under continual review with formal assurance reported on a quarterly basis. Reports to ARAC - Mitigation of the risk through controls and actions is dependent on an ongoing commitment and prioritisation of resources relative to the risk. It is anticipated that the risk will move to within tolerance on commencement and progress of the CRM update in Q3 that is underway. B15 | | | | | | | | |
| Owners | Louise Dineley 08/10/2024 | | | | | | | | |

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Tolerance movement

This dashboard provides a trend in changes in risk and tolerance

| Team | Tolerance (June-24) | Oct-24 | Nov-24 |
|------------|---------------------|--------|--------|
| Regulation | 8 | ↔ | ↔ |
| Sector | 8 | ↔ | ↔ |
| Staff | 9 | ↔ | ↔ |
| Financial | 9 | ↑ | ↔ |
| Digital | 9 | ↔ | ↔ |

| Risk Scoring Matrix | | | | | | |
|---|--------------------------|---------------------------------|----------------------------------|-------------------------------------|---|-----------------|
| IMPACT | 5. Very High | 5 Medium | 10 Medium | 15 High | 20 Very High | 25 Very High |
| | 4. High | 4 Low | 8 Medium | 12 High | 16 High | 20 Very High |
| | 3. Medium | 3 Low | 6 Medium | 9 Medium | 12 High | 15 High |
| | 2. Low | 2 Very Low | 4 Low | 6 Medium | 8 Medium | 10 Medium |
| | 1. Very Low | 1 Very Low | 2 Very Low | 3 Low | 4 Low | 5 Medium |
| Likelihood | | | | | | |
| Risk score = Impact x Likelihood | 1. Rare (≤3%) | 2. Unlikely (3%-10%) | 3. Possible (10%-50%) | 4. Likely (50%- 90%) | 5. Almost certain (≥90%) | |

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HTA 19-24 ANNEX C

| | | | | | | | | | | |
|--------------------------------------|---|--|------------|----------------------|------------------------|------------|-------------------------|----------------------|----------------|---|
| Updated by | | Nicolette Harrison | | | | | Updated date | | 17/06/2024 | |
| Risk name | | Risk 1: Notable regulation failure leading to public harm and/or loss of public/professional confidence in the HTA | | | | | | | | |
| Risk levels | Inherent risk levels | | | Residual risk levels | | | Optimal risk level | Tolerable risk level | Risk tolerance | |
| | Likelihood | Impact | Risk level | Likelihood | Impact | Risk level | | | | |
| | 3 | 5 | 15 | 2 | 4 | 8 | | | | 5 |
| Risk owner | Nicolette Harrison | | | Link to strategy | Approach to regulation | | Trend since last update | | ↔ | |
| Cause | <ul style="list-style-type: none"> - Failure to identify notable regulatory non-compliance - Regulation is not transparent, accountable, proportionate, consistent and targeted - Regulation is not sufficiently agile to respond to changes in sectors - Insufficient capacity and/or capability. This includes insufficient expertise, reductions in staffing from attrition, inadequate contingency planning, recruitment difficulties (including Independent Assessors [IAs]), inadequate adherence to agreed policies and procedures (especially in relation to decision-making) - Poor quality or out of date policies and procedures - Failure to fully follow-up on identified risks and issues. - Inability to access relevant technical expertise; for example, to support the assessment of regulated activities or premises. | | | | | | | | | |
| Effect | <ul style="list-style-type: none"> - Compromise of patient safety - Loss of public confidence - Loss of professional confidence - Loss of trust and respect from people in regulated sectors, potentially leading to greater non-compliance and challenging of decisions B14 - Reputational damage - Technical regulatory decisions re process or risk management that turn out to be incorrect | | | | | | | | | |
| Existing controls | <ul style="list-style-type: none"> - Regulatory model that provides a range of proactive and targeted regulatory assessments - Well established processes supporting our core business; Regulatory decision-making framework including police referral policy and process - Training and development: Structured induction for new staff; Directorate Training Days; budget conference attendance; starting a Directorate Training Needs Analysis - Specialist expertise identified and recruited to ensure a broad range of knowledge across sectors and developing areas - In exceptional circumstances, scope for limited reallocation of resource to priority areas - Access to specialist legal advice for novel or complex matters | | | | | | | | | |
| Actions to improve mitigation | <ul style="list-style-type: none"> - Investing resource in cross-organisational work to develop considered operational policy positions on new or complex areas [Ongoing - mostly concept in initiation phase between Regulation Directorate and newly-expanded Policy Team in DTD Directorate] - Developing and implementing a programme of continuing professional development for Regulation Staff [ONGOING - Training Needs Analysis to be developed with support of CQC's HR shared service 'Learning Academy' over Quarter 2] - Access to expert advisory group(s) [ONGOING - HTA has some existing engagement in sub-sector specialist advisory panels for HA; exploring options to identify and access to other specialists on an <i>ad hoc</i> basis for specific novel or highly specialist topics] | | | | | | | | | |
| Owners | Nicolette Harrison | | | | | | | | | |

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HTA 19-24 ANNEX C

| | | | | | | | | | |
|--------------------------------------|--|--------|------------------|----------------------|--------|---------------------|-------------------------|----------------------|----------------|
| Updated by | Nicolette Harrison | | | | | Updated date | 17/06/2024 | | |
| Risk name | Risk 2: Misperception of the HTA's role and reach or poor external relationships leading to gaps in sectoral risk management | | | | | | | | |
| Risk levels | Inherent risk levels | | | Residual risk levels | | | Optimal risk level | Tolerable risk level | Risk tolerance |
| | Likelihood | Impact | Risk level | Likelihood | Impact | Risk level | | | |
| | 3 | 5 | 15 | 2 | 4 | 8 | 4 | 8 | At tolerance |
| Risk owner | Nicolette Harrison | | Link to strategy | Trust & confidence | | | Trend since last update | | ↔ |
| Cause | <ul style="list-style-type: none"> - Complex regulatory landscape creates potential for confusion (for the public and sectors) about regulatory remits of different regulators; real or perceived regulatory gaps - Issues managing intersections in remits between different regulators - HTA's formal regulatory framework, including legislation, may not keep pace with sector developments and so may not be able to effectively manage emerging risks - Lack of clarity about changes in responsibilities eg following any legislative changes - Lack of HTA insight into broader pressures and issues affecting our sectors that may be indicators of new or emerging risks - Lack of suitable engagement or information or intelligence-sharing mechanisms between the HTA and other regulators, relevant agencies or law enforcement impedes the HTA's ability to share and escalate concerns or to refer concerns or issues to other more appropriate agencies, where relevant | | | | | | | | |
| Effect | <ul style="list-style-type: none"> - Diminished professional confidence in the adequacy of the legislation and/or the regulatory framework operated by HTA - Reduced public confidence in regulation of matters relating to human tissue - Reputational damage | | | | | | | | |
| Existing controls | <ul style="list-style-type: none"> - Horizon scanning process; Communications and Engagement Strategy; Formal and informal engagement with, and feedback from, our sectors and stakeholders - Effective management of HTA's public profile to maintain awareness and professionalism and deal with media enquiries, including developing HTA lines and positions - Active management of professional stakeholders, in our sectors, other bodies, other Government Departments and Devolved Administrations, including providing advice - Regular engagement with DHSC sponsorship team and Substances of Human Origin (SoHO) team on matters which might impact public and professional confidence - Identifying and taking action on issues where we believe these will support public and professional confidence - HTA representation on relevant multi-agency groups and forums, including particularly those dealing with new and emerging issues or innovative practice - Maintaining and utilising existing Memoranda of Understanding (MOUs) and Information Sharing Agreements with other relevant bodies eg other regulators - Maintaining, utilising and periodically updating relevant HTA policies and processes (eg the Police Referral and Warrants Policy) | | | | | | | | |
| Actions to improve mitigation | <ol style="list-style-type: none"> 1) - Wider awareness-raising activities following conviction of private hospital for licensing breach in 2023/24 [ONGOING - paused during pre-election period] 2) - Reviewing and updating existing Memoranda of Understanding (MOUs) and Information Sharing Agreements (ISAs), especially with CQC and other health regulators [ONGOING - initiated revival of review of HTA/CQC MOU / ISA in Quarter 1; should be complete by end of Quarter 3] 3) - Joining (as an observer) the NHSE-led 'Mortuary Oversight Group' [ONGOING - Initiated Quarter 1 - should be complete by end of Quarter 2] 4) - Joining the Health and Social Care Regulators Forum and Emerging Concerns Protocol [ONGOING - exploration during Quarter 1; should be initiated during Quarter 2] 5) - Revision of the horizon scanning process planned for 2024-25 to ensure it is fit for purpose and proportionate [ONGOING throughout 2024/25] 6) - HTA Annual Review of 2023/24 published and shared in Stakeholder event [ONGOING - deferred to late Quarter 2 because of pre-election period] | | | | | | | | |
| Owners | Nicolette Harrison | | | | | | | | |

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HTA 19-24 ANNEX C

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|--------------------------------------|--|---|------------|----------------------|-----------------------|------------|-------------------------|----------------------|------------------------|--|
| Updated by | | Tom Skrinar | | | | | Updated date | | 14/06/2024 | |
| Risk name | | Risk 3: Inability to progress core activities due to insufficient staff capacity and capability to deliver organisational goals | | | | | | | | |
| Risk levels | Inherent risk levels | | | Residual risk levels | | | Optimal risk level | Tolerable risk level | Risk tolerance | |
| | Likelihood | Impact | Risk level | Likelihood | Impact | Risk level | | | | |
| | 4 | 5 | 20 | 4 | 4 | 16 | 9 | 9 | Above tolerance | |
| Risk owner | Tom Skrinar | | | Link to strategy | Efficient & effective | | Trend since last update | | ↔ | |
| Cause | <ul style="list-style-type: none"> - General high staff turnover putting recruitment pressure on managers and capacity pressures on broader teams to cover gaps - Turnover of staff in key roles that are 'single points of failure', leading to gaps in essential capability - Poor leadership and line management practices, including unclear objectives. Also poor job design and recruitment techniques and/or poor support from HR. - Poor prioritisation or insufficiency of resources - Poor H&S and risk assessment and monitoring of staff safety | | | | | | | | | |
| Effect | <ul style="list-style-type: none"> - Lack of key expertise leading to organisational inability to deliver key objectives or to effectively manage risk - Insufficient staff capacity to manage the extent of the HTA's core duties and corporate responsibilities. - Poor deployment of staff leading to inefficient working and increasingly pressured staff leading to further loss of staff - Reduction in staff resilience, or inability to protect staff in the workplace, leading to sickness absence and staff loss. Poor advice from HR not resolving issues. | | | | | | | | | |
| Existing controls | <ul style="list-style-type: none"> - Recruitment to identified vacancies and skills gaps ongoing. Succession planning, talent management and future skills needs to be developed further. - Prioritisation of resources (human and financial) against organisational tasks and objectives to ensure pinch points are recognised and staff not overloaded - Business Planning to map out anticipated Human Resources work and Portfolio Management to track / support / report delivery of such - Good governance cycles recording the proposals / decisions / actions related to specific Human Resources work - Business Continuity Plan (and Critical Incident Response Plan) arrangements / training / testing | | | | | | | | | |
| Actions to improve mitigation | <ul style="list-style-type: none"> - Staff survey and review of HR MI to ensure there is a clearer senior understanding of staffs' feelings and situations [Q2 2024] - People Strategy for the period 2025 - 2028, starting with the staff survey, that focusses on valuing and supporting employees to deliver [Q3 2024] - Revision of people policies and procedures that protect staff, including Health and Safety, risk assessments and sickness management [throughout 2024/25] - Development of the HTA leadership team and managers, and improvements to how we manage performance. [Ongoing] - Stengthen L&D and induction processes to ensure staff are equipped to succeed in their roles [alongside People Strategy] - Leavers / handover process formalised via a checklist to ensure corporate knowledge is retained [throughout 2024/25] - Development of a staff forum to support networking and a focus on social / organisation culture and to have a stronger staff voice in the organisation. [Q2 2024] | | | | | | | | | |
| Owners | Tom Skrinar | | | | | | | | | |

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HTA 19-24 ANNEX C

| | | | | | | | | | | |
|--------------------------------------|--|--|------------|----------------------|-----------------------|------------|-------------------------|----------------------|----------------|--|
| Updated by | | Tom Skrinar | | | | | Updated date | | 14/06/2024 | |
| Risk name | | Risk 4: There is a risk that the HTA has insufficient or ineffective management of its financial resources | | | | | | | | |
| Risk levels | Inherent risk levels | | | Residual risk levels | | | Optimal risk level | Tolerable risk level | Risk tolerance | |
| | Likelihood | Impact | Risk level | Likelihood | Impact | Risk level | | | | |
| | 4 | 5 | 20 | 3 | 3 | 9 | 6 | 9 | At tolerance | |
| Risk owner | Tom Skrinar | | | Link to strategy | Efficient & effective | | Trend since last update | | ↔ | |
| Cause | <ul style="list-style-type: none"> - Under-recovery of income / poor debt recovery (including regulated establishment inability to pay) or inability to forecast variable income accurately - Failure in setting a robust operating budget or to effectively prioritise work and / or manage costs / efficiencies - Unexpected significant cost pressures (eg legal, urgent infrastructure investment, etc) or budget change requests from DHSC or HMT arising in year - Inability to robustly control expenditure / manage operating budgets or failure to adhere to HMT and Cabinet Office Standards (finance and commercial) - System of control unable to prevent fraud / error or adapt to new risks - Insufficient finance resource to manage transactions or support sound financial management / finance system no longer fit for purpose | | | | | | | | | |
| Effect | <ul style="list-style-type: none"> - Late or non-payment of HTA debt leading to reputational damage / pressures on suppliers / staff - Resources lost due to fraud, error or avoidable fees/charges - Inability to stay within budget leading to leading to the need to stop work or to lose the confidence of DHSC. - Inability to manage costs over the longer term leading to unreasonable increases in licence fees or requests for further public funding. - Reputational risk to the Accounting Officer, increased scrutiny (including the PAC) and difficulties in gaining business case approval | | | | | | | | | |
| Existing controls | <ul style="list-style-type: none"> - Budget management framework to control and review spend and take early action when diverging from budget. - Close engagement with DHSC sponsors and finance, with timely openness about financial position and pressures to allow amendments to budget/access reserves. - Financial projections, cash flow forecasting and monitoring, good communications between finance and operational teams allows robust financial management. - Robust licence fee modelling and rigorous debt recovery procedure ensures income comes in as expected. - Annual external audit and internal audits of financial processes and control environment to identify weaknesses in procedure. - Horizon scanning for changes to DHSC funding and networking with DHSC and ALB FDs regarding Spending Reviews, etc to ensure we can engage effectively | | | | | | | | | |
| Actions to improve mitigation | <ul style="list-style-type: none"> - Improved internal financial monitoring and management and teach-ins for SMT, including a focus on resource use. [Q3 2024] - Action plan to move from rudimentary to basic level of maturity on the GovS:013 Functional Standards [throughout 2024/25] - Develop plans to improve structure, systems and processes across HTA and HFEA finance teams to improve efficiency and staff development [throughout 2024/25] - Focus on financial and commercial skills and awareness of HTA managers. [throughout 2024/25] | | | | | | | | | |
| Owners | Tom Skrinar | | | | | | | | | |

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HTA 19-24 ANNEX C

| | | | | | | | | | | |
|--------------------------------------|--|--|-------------------|-----------------------------|--------------------|-------------------|--------------------------------|-----------------------------|-----------------------|--|
| Updated by | | Louise Dinely | | | | | Updated date | | 23/04/2024 | |
| Risk name | | Risk 5: Failure to make use of available data, digital and technology to ensure systems are kept up to date and support the delivery of business activities. | | | | | | | | |
| Risk levels | Inherent risk levels | | | Residual risk levels | | | Optimal risk level | Tolerable risk level | Risk tolerance | |
| | Likelihood | Impact | Risk level | Likelihood | Impact | Risk level | | | | |
| | 5 | 4 | 20 | 3 | 4 | 12 | 9 | 9 | Above tolerance | |
| Risk owner | Louise Dineley | | | Link to strategy | Use of Information | | Trend since last update | | ↔ | |
| Cause | <ul style="list-style-type: none"> - Core systems identified as either approaching or out of support in the event of an incident - Data management is inconsistent across the business limiting opportunities to optimise and make use of information and intelligence. - Ageing business technology systems that have evolved rather than be designed limit alignment to business needs and / or opportunities for digital developments. - Staff confidence and capability in data and digital services can limit developments - Cyber Security changes in compliance requirements and standards not aligned to business capabilities - Knowledge and intellectual property of HTA systems is held by third party supplier - Inconsistency in data and information management practices is a limiting factor in our ability to make better use of information held. | | | | | | | | | |
| Effect | <ul style="list-style-type: none"> - IT breach and/or loss of sensitive data - Increased risk of system and process vulnerabilities being exploited by third parties resulting in restricted access or system failure - Loss of core IT systems required by HTA staff to deliver their work - Options that make use of existing technology and digital developments need to be adopted to address inefficient ways of working and reduce manual work-arounds - Knowledge and insight that can be obtained from data holdings results in poor quality regulation or opportunities for improvement being missed - Reliance on manual processes and single points of contact to bridge digital gaps - Large volume of data and records held beyond designated retention schedules impacting on storage, records management, data quality and information governance - Digital ambition such as the use or consideration of AI in regulated activities is constrained and / or not understood to determine compliance with standards - Limited internal resourcing capacity risks maintaining a reliance on third party supplier support | | | | | | | | | |
| Existing controls | <ul style="list-style-type: none"> - Policies, processes and practices covering all aspects of system security and data management have been reviewed, revised and or updated on a 12 month schedule. - Data relating to establishments securely stored with the Customer Relationship Management System (CRM) - Appropriate procedures to manage personal data including GDPR compliance. - Staff training in key business systems and mandatory annual training on policies and required controls - Training and development of professional competence part of annual PDPs and performance reviews - IT systems protected and assurances received from 3rd party suppliers that protection is up to date - System performance analytics available and reported monthly - Business Planning to map out anticipated Information Technology and Data work and Portfolio Management to track / support / report delivery for example 2024/25 Business plans and identified projects covering updates and data development (including AI) - Ongoing knowledge gathering and transfer from third party suppliers and wider health system partners - Compliance with DSPT 2024 assessment and forward look to Cyber Essentials Plus. | | | | | | | | | |
| Actions to improve mitigation | <ul style="list-style-type: none"> - Agreed Digital and IT Strategy 2024-27 sets the direction of travel through a defined vision, mission and priorities. - Plans in place to communicate and embed the strategy from early Q2 2024/25. These priorities will inform projects delivered through the annual business planning process to drive change, improvement and identify opportunities to strengthen and or / exploit the use of current systems and data holdings. - Priorities identified for 2024/25 aim to establish a strong foundation through supported systems, resourcing and developments to strengthen future digital capacity and capability. These include: CRM update (phase) 2 - Q4 2024/25; Pilot of AI - Q3 2024/25; RIMI - initial build to agreed indicators Q4 2024/25; Data publications - Q2 2024/25 and Q4 2024/25. - The increased and continued threat posed through cyber security is kept under continual review with formal assurance reported on a quarterly basis. Reports to ARAC - Mitigation of the risk through controls and actions is dependent on an ongoing commitment and prioritisation of resources relative to the risk. It is anticipated that the risk will move to within tolerance on commencement of the CRM update scheduled for Q2 2024/25. | | | | | | | | | |
| Owners | Louise Dineley 14/06/2024 | | | | | | | | | |

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