

Ninety-fifth meeting of the Human Tissue Authority Board

Date: 11 February 2021

Time: 10.00 – 12.00

Venue: Zoom

Protective Marking: OFFICIAL

Agenda

1. Welcome and apologies
2. Declarations of interest
3. Minutes of 5 November 2020 meeting (HTA 01/21) **(for approval)**
4. Matters arising from 5 November 2020 meeting (HTA 02/21) **(for information)**

Regular reporting

5. Chair's Report (Oral) **(for information)**
6. Chief Executive's Report (HTA 03/21) **(for information)**

Annex A, Strategic risk register (HTA 03a/21)

Annex B, Board Supplementary Data Annex (03b/21)
7. UK Transition Update (Oral) **(for information)**

Change Programme

8. HTA Development Programme (HTA 04/21) **(for information)**
9. Virtual Regulatory Assessment (HTA 05/21) **(for information)**

Committees and Working Groups

10. Audit and Risk Assurance Committee Update (Oral) **(for information)**
11. Corporate Governance Audit Recommendations (HTA 06/21) **(for decision)**
 - Annex A, Corporate Governance Final Terms of Reference
 - Annex B, HTA Corporate Governance Final Report
 - Annex C, 'The Good Governance for Public Services' publication

Any Other Business

12. Any other Business **(for information)**

HTA Board Meeting

Matters Arising from the November 2020 meeting

Meeting	Action	Owner/Update
November 2020	Action 1: SMT to bring recommendations to ARAC and Board following the outcomes of the Corporate Governance Audit.	Owner- AMS This is tabled in the agenda.
November 2020	Action 2: A paper on Virtual Regulatory Assessments to be presented at the next Board meeting, specifically taking into consideration how the standards relating to premises, facilities and equipment are being met through this model.	Owner- ANH This is tabled in the agenda.

November 2020	Action 3: Board Members to be talked through an example of a Virtual Regulatory Assessment at an appropriate time to inform their understanding of this model of assessment.	Owner- ANH This item to be dealt with under action 2.
November 2020	Action 4: A workshop to be arranged for Board Members to provide greater insight into the Development Programme.	Owner- LD A workshop took place in December 2020.
November 2020	Action 5: A paper to be brought to the November 2021 meeting focussing on a review of the new system after a year of operation.	Owner- JP This is on the forward plan for the November 2021 meeting.

Human Tissue Authority Board meeting

Date: 11 February 2021

Paper reference: HTA 03/21

Agenda item: 6

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CEO

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Chief Executive's Report

Purpose of paper

1. This paper gives an overview of performance at the end of quarter three.
2. It provides the Board with an account of core regulatory business, the progress of development projects, a summary of the financial position at the end of the quarter three and a summary of people, resource and other key operational issues arising since the Board last met in November 2020.
3. Work continues to ensure that we balance our regulatory responsibilities and development goals whilst responding to a fast-changing environment in an agile way, particularly in the face of another national lockdown imposed in December.

General overview and strategic risks

4. During quarter three, the HTA has made significant progress on preparedness to undertake safe site visits; virtual regulatory assessments (VRAs); plans for the office move; the HTA website redevelopment work and UK transition.
5. In its assessment of risk in January, the senior management team concluded that five of the six risks were stable. The Board is asked to note the upward pressure on risk four, *failure to utilise our capabilities effectively*.
6. The Strategic Risk Register is included as Annex A to this paper.

Quarter three regulatory overview

7. Although the decision has been taken not to return to regular site visit inspections until at least quarter one of 2021/22, work has continued during quarter three to consider how the HTA will undertake safe site visits when this is appropriate. Following sign-off of the blueprint for safe site visits by SMT in October, the focus since November has been on scoping requirements for personal protective equipment (PPE) and securing the supply.
8. We have been successful in procuring PPE from the Department of Health and Social Care's (DHSC's) PPE Operational Strategy Team. All Heads of Regulation and all Regulation Managers will shortly be receiving a supply of PPE to their home address. This means we will have the capability to undertake a site visit when required as dictated by regulatory risk.
9. The next step is to begin phase two of the project, which will focus more specifically on effective planning for a return to site visits within the context of COVID-19. This will include more focussed consideration of what a site visit should entail. During quarter three we have been liaising with other regulators to learn from their experiences.
10. A substantial amount of process development and operational work has taken place on (Virtual Regulatory Assessments) VRAs during quarter three, involving almost all Regulation Managers. Following a risk-profiling exercise, 10 pilot VRAs were undertaken in our Human Application (HA) sector, adopting a 'test and learn' approach. Performance data and feedback was collected during the piloting, for

real-time assessment and post-piloting evaluation. In parallel, advanced development of VRA processes and supporting documentation has taken place for other sectors. The teams responsible for non-HA sectors have been able to learn from the HA pilots to consider modified sector-specific approaches. An additional benefit of the VRA development work is that it has generated thinking about the full range of assessment interactions open to the HTA, including what site-based assessments could involve in the future.

11. No licence revocations took place in quarter three, but 14 new licence applications were received, which is much higher than the 2019/20 average of 5.75 applications per quarter. In the Post-Mortem (PM) sector, five applications were from funeral director organisations (see further information in paragraph 15), one application was for an emergency mortuary and one application was for a standard PM licence. Three applications were also received in the Research sector, one in the Anatomy sector and one in the Organ Donation and Transplantation sector.
12. We have a thorough licence application assessment process, which includes provision for a visit, and provides an early assurance to us that the establishments we license have sound regulatory foundations. No licence application assessment visits have taken place this business year, meaning that licences have been assessed and approved using a virtual approach.
13. In quarter three, a significant amount of work was carried out in relation to European Union (EU) Exit and the end of the Transition Period, including stakeholder engagement regarding imports into Northern Ireland from Great Britain, amendments to governance documents, website content and licensing documents, and the development of a streamlined licence application process and fees model for establishments in Northern Ireland. Related enquiries and licence applications were prioritised. Three licence variations and two applications relating to the end of the Transition Period were received. Limited Northern Ireland-related stakeholder engagement work will continue in quarter four, but the focus has now shifted to ensuring that establishments can operate in the new trading environment.
14. Work is ongoing in the Human Application sector to try and resolve a number of new and ongoing issues relating to the work carried out by private tissue banks. Of particular regulatory interest, are new procurement practices that have been

introduced in response to the pandemic, and issues relating to the validation of existing services.

15. Members were updated in November about a streamlined regulatory model that had been developed for the licensing of funeral directors to allow material for testing to be removed at their premises. This work has been to support Public Health England's COVID-19 surveillance programme. Two licences were issued in quarter three. This has been a significant piece of work, working in collaboration with other bodies as part of the national effort.
16. At the Board meeting in November, Members agreed with the proposal to roll out the recommendation for the new process of considering living organ donation cases. These changes have now been made permanent and during quarter three a quality assurance mechanism has been developed to ensure that the system continues to operate effectively. Members will wish to note that, as a result of the pandemic, living donation cases remain at historically low volumes with case numbers continuing to reduce in January.
17. A further Anatomy sector meeting was held via Microsoft Teams in November, the fourth since April. With this being a small and well-connected sector, meeting in this way has been an effective means of understanding and responding to the issues people are dealing with as a result of the COVID-19 outbreak, and in the planning for a return to activities. The discussions have fed into the guidance we provide on our website and further sector meetings are scheduled.
18. During quarter three, we continued to work with the police on the case we referred to them in quarter one.
19. More detailed information on regulatory activity can be found in Annex B to this paper.

Quarter three - Development Programme overview

20. Good progress has been made on the projects within the Development Programme. More detail on the Programme is provided in paper (HTA 04/21).

Quarter three - other change projects

Office Move

21. The HTA formally moved to its new offices at 2 Redman Place, London E20 1JQ on 15 January 2021. All stakeholders were informed of this change at the start of 2021 and all external facing communication channels and official documentation has been amended to reflect our new location.
22. The office opened formally on 18 January 2021; however, HTA staff are not attending the office except for specific tasks relating to the relocation of HTA IT infrastructure. The office has been subject to a rigorous health and safety assessment and has been assessed as compliant with current COVID-19 operating guidance for offices. HTA staff who can demonstrate a specific business need, or have expressed particular health and safety or wellbeing concerns with their current homeworking arrangements, will now be able to access our offices subject to Director sign off. At this time no staff have requested to attend the office for business as usual activity.
23. Although the office is open, and the HTA has completed its logistical relocation, further tasks remain to be completed before the project closes. In relation to Redman Place further work is required to complete IT interoperability between all five organisations including desk usage, printing and audio-visual solutions for meeting rooms. Over the coming weeks the HTA will dispose of IT equipment left at 151 Buckingham Palace Road ahead of returning the office to the Government Property Agency at the end of February 2021.
24. Given the ongoing restrictions across the country we believe it unlikely that the HTA will consider any return to office working until April 2021 at the earliest.

Finance

Table one Financial position for Q3 2020/21

Human Tissue Authority Summary Management Accounts For the Nine months ending 31 December 2020					
	Actual	Budget	Variance		Forecast
	£	£	£	%	£
INCOME					
Grant in Aid	573,000	482,995	90,005	18.63	771,000
Non-cash cover	154,245	154,245	0	0	205,660
Licence Fee income	3,984,790	3,937,480	47,310	1.20	3,984,790
Devolved Governments	133,572	138,448	(4,876)	(3.52)	133,572
Rental Income	275,842	277,500	(1,658)	(0.60)	368,342
Other Income	36,657	35,213	1,444	4.10	48,394
TOTAL INCOME	5,158,105	5,025,880	132,225	2.63	5,511,758
OPERATING COSTS					
Staff costs (salaries etc)	2,406,197	2,431,284	(25,087)	(1.03)	3,225,649
Other staff costs (excl. inspections)	80,131	73,640	6,491	8.81	120,644
Board Costs	107,515	139,309	(31,794)	(22.82)	141,778
Inspection Costs	(318)	42,250	(42,568)	(100.75)	1,682
LODT costs	893	0	893	0	1,707
Communication Costs	14,199	8,862	5,337	60.23	15,909
IT and Telecoms	326,602	241,855	84,747	35.04	471,562
Office and Administration Costs	10,236	14,486	(4,250)	(29.34)	14,623
Other costs	47,982	47,880	102	0.21	134,132
Legal and Professional	96,695	69,750	26,945	38.63	126,195
Accommodation costs	624,096	610,125	13,971	2.29	827,471
Non-cash costs	89,512	154,245	(64,733)	(41.97)	233,781
Contingency (Dev Prog)	0	0	0	0	196,624
Total operating costs	3,803,741	3,833,685	(29,944)	(0.78)	5,511,757
Net Income/(expenditure)	1,354,365	1,192,195	162,169	13.60	0

HTA meeting papers are not policy documents.

Draft policies may be subject to revision following the HTA Board meeting

25. Table one above provides the summary position at the end of quarter three of the 2020/21 business year. A year-to-date net surplus of £1.4m against the budget of £1.2m.

26. A breakdown of income and expenditures is provided below.

Income

27. Table two provides a breakdown of our income to date. Variances are as follows:

- a. Grant in aid (GIA) – we have drawn down a higher than projected proportion of GIA at the end of quarter three, however, the balance to be drawn down in February will bring us back in line with the full year budget.
- b. Licence fees – all have been billed in September. The main cause of a surplus against budget is the inclusion of application fees which we do not budget for as these are difficult to assess. Offsetting additional application fees are licence fee shortfalls, particularly within the Post-mortem and Human Application sectors where licences have either been revoked or amended, thus reducing income.
- c. The variance within other income is due to an inflationary increase within budget not billed to the Devolved Governments in line with our response to COVID-19 early in the year.

Table two Income summary

Human Tissue Authority Income Summary For the Nine Months Ending 31 December 2020				
	Actuals	Budget	Variance	
	£	£'	£	%
Grant in Aid	573,000	483,000	90,000	18.63
Non-cash	154,240	154,240	0	0
Sub-Total	727,240	637,240	90,000	14.12
Licence Fees				

Application Fees	62,650	0	62,650	0
Anatomy	104,780	102,230	2,550	2.49
Post-mortem	1,281,473	1,301,095	(19,622)	(1.51)
Public Display	20,908	22,990	(2,082)	(9.06)
Research	723,263	717,705	5,558	0.77
Human Application	1,477,130	1,483,100	(5,970)	(0.40)
ODT	314,585	310,360	4,225	1.36
Sub-Total	3,984,790	3,937,480	47,310	1.20
Other				
Rental income	275,842	277,500	(1,658)	(0.60)
Secondees	36,657	35,213	1,444	4.10
Devolved Assemblies	133,572	138,448	(4,876)	(3.52)
Sub-Total	446,071	451,160	(5,090)	(1.13)
Total Income	5,158,100	5,025,880	132,220	2.63

Expenditure (by exception)

28. **Staff costs (salaries)** – are under budget by £25k as a result of vacancies being carried for a period of time. This is a reduction from the quarter two position as we have utilised agency staff as interim cover and for project work.
29. **Board costs** – Board costs are down against budget as there are no travel or venue costs incurred due to the on-going restrictions preventing any travel.
30. **Inspection costs** – remain low as no site visits are being conducted during the lockdown period.
31. **IT and Telecom costs** – year-to-date spend is over budget due to increased expenditure relating to Office 365 (£25k) subscription costs (overlapping contracts); additional support costs not previously anticipated (£19k); maintenance costs (£17k) not budgeted for; and Information Technology Development Consultancy (£33k) costs, some of which relate to the Development Programme but not budgeted for at the start of the year. There are underspends within other areas such as consumables, photocopying and telephony totalling £10k.

32. **Legal and professional costs** – consist of audit fees for internal and external audits which are on budget, the balance relates to legal fees where we are over budget (£8k) and consultancy (£19k) for risk work that traversed two financial years.
33. **Accommodation costs** – the overspend of (£14k) is represented by additional Building Services cost at 151 Buckingham Palace Road. These were not budgeted for.
34. **Non-cash costs** – are under budget (£65k), which is the result of a reversal of provision for additional staff travel costs post the office move. The reversal was made after establishing the number of staff who have chosen to become home-workers rather than be office-based.

Forecast outturn

35. In January we undertook a further review of costs and consulted with teams about changes in their plans in the last quarter. The forecast reflects the changes as far they are known.
36. We are forecasting a balanced position including a contingency from which any work relating to the Development Programme will be funded, overseen by the SMT.

Other key performance indicators

Debtors

37. The value of debtors outstanding as at 31 December 2020 was **£663k** represented by **113** accounts. The table below is a breakdown by sector.

Table three Debtors by sector

Sector	Number of establishments	Value of debt £	%age
NHS	62	£473,892	71
Local Government Bodies	3	£ 19,200	3
Non-Government Bodies¹	48	£169,598	25
Total	113	£662,690	100

38. Of the 62 NHS accounts, 16 (£58k) relate to 2019/20. These accounts are being pursued through the Agreement of Balances (AoB) exercise, in which all organisations within the DHSC group participate. We are making slow but steady progress in this work. Within the Non-Government category, there are 13 (£28k) accounts that also relate to 2019/20.

Financial risks and mitigations

Risk	Mitigating actions and controls
Risk that we cannot maintain continuity of payments and salaries	Regular review of cashflow and maintenance of agreed level of reserves.
Establishments change their profile resulting in a reduction in hubs and satellites, and licensed activities, leading to a reduction in fee income	Periodic review of current licences and expected income. Budgets are adjusted accordingly.
An overspend or significant underspend may lead to a lack of stakeholder confidence in HTA's ability to manage resources effectively.	Monthly review of financial position and quarterly re-forecasting. Review of activities that can be deferred.
Unexpected increases in regulatory responsibilities	Prioritisation when work requirements change. DHSC funding if appropriate.
Management fail to set licence fees at a level that recovers sufficient income	Financial projections and cash flow forecasting and monitoring.

¹ Includes Universities and private organisations

People

COVID-19 response

39. In September schools reopened and children returned to classroom learning. Most establishments were permitted to reopen, and the lockdown restrictions were relaxed. In light of this, the HTA withdrew the Additional Flexible Support that had been made available to staff during the initial response and which only two members of staff had taken advantage of. We reverted to our standard Flexible Working policy.
40. The HTA recognised the impact that living with (the implications of) COVID could have on general wellbeing of staff. All managers have been encouraged to regularly review staff wellbeing within their teams and to report any concerns to HR, Heads and SMT.

Wellbeing

41. Wellbeing measures have largely focused on our response to the impact of COVID. Staff were encouraged to consider their own resilience in preparation for the winter months with shorter days and inclement weather conditions. There was an expectation that a strengthening of lockdown restrictions could again be implemented in the new year and staff were advised to plan ahead in preparation for that.
42. During quarter three our monthly wellbeing themes were Resilience, Renewal and Gratitude. Material related to themes was updated on a regular basis in order to provide support and additional resources to staff.

Training

43. Online Training has been made available to staff which include, Strategy and Decision Making, Remote Auditing and a session on Stem Cell development.
44. Fiona Reed Associates continue to work with Heads and SMT to strengthen leadership capability. There are currently five members of staff who have accessed individual coaching to support their leadership practice.

Recruitment and Retention

45. During quarter three, two members of staff resigned with a leave date of 31 December 2020. A recruitment process was initiated to backfill these roles (Head of Development and Policy Manager). An internal candidate successfully applied for the Policy Manager role and began in January 2021.
46. An interim Communications Lead to support the Development programme and interim Head of Business Planning and Reporting to support the tracking and delivery of the business plan were also recruited in quarter three, although the latter decided to terminate their contract early at the end of January.

Remote Working Contracts

47. The Remote Working consultation conducted with HTA staff in January 2020 was focused on Regulation Managers as the only cohort eligible for Remote Working at that time. Due to the pandemic, enforced home working has demonstrated that all roles can be effectively conducted from home, and therefore the option for remote working was made available to all staff.
48. During September and October, a series of question and answer sessions and presentations were conducted to explain the option available and reiterate the current, comprehensive HTA Flexible Working policy.
49. Approximately half the HTA staff have requested and agreed a remote working agreement that officially came into effect as of 1 January 2021. The HTA remains a work from home organisation until the current lockdown restrictions are lifted and a resumption of office-based working is considered safe and appropriate.

Pulse Survey

50. A pulse survey was conducted in October. The general feedback was that staff do not feel as well informed of expectations of them or the goals for the HTA as they did in July. Further explanation and communication has been planned and Heads encouraged to disseminate information to mitigate this.

Change

51. The (interim) Change Manager conducted a series of sessions across the HTA to increase the awareness of the process and impact of change. She has also supported raising awareness, and communication of the goals of projects connected to the Development Programme, e.g. Office 365 roll out, Microsoft Teams deployment, VRA's and Electronic Document and Records Management System (EDRMS).
52. She leads the Staff Engagement Team where new initiatives and ways of working are shared with staff for information and feedback. This has been particularly helpful with the Office move project.

Competency Framework

53. This framework was launched in quarter three with a "How to Use" Guide. Staff have been encouraged to familiarise themselves with the framework in preparation for its inclusion in PDP discussions for 2021/22.

Diversity and Inclusion

54. A second listening event was held during quarter three. There was limited attendance but a good contribution. The general sentiment was that the HTA is providing a culture of diversity and inclusion with no tangible improvement suggested. For next session in quarter four we will invite a speaker from Race at Work.

Social Committee

55. The Social Committee delivered a number of events to celebrate World Food Day, Halloween, Festival of Light and Christmas jumper day. These sessions have been conducted both at lunch time and after work and appear to have had a positive impact on staff morale.

Other issues

Quarter two Accountability

56. We continue to meet our accountability requirements to the DHSC differently in the short term. DHSC colleagues have agreed to scrutinise Board papers as part of their accountability review and follow up with supplementary questions where required.
57. The HTA's sponsor wrote, in November 2020, to confirm there were no concerns with our performance in quarter two and gave positive feedback on our pandemic response.

Internal Audit

58. Internal Audit presented their paper to the Audit and Risk Assurance Committee on 28 January and issued the final report for the Corporate Governance and Committee Effectiveness audit. Internal Audit presented the audits which are on the 2021/22 audit plan, which are due to take place in quarters one and two of the next business year.

Freedom of Information requests

59. During quarter three, the HTA received four requests for information under the Freedom of Information Act (FOIA). We publish FOIA responses on our [website](#).

Complaints

60. In quarter three, two complaints were received by the HTA. The complaints relate to allegations of failure of the HTA to execute statutory functions.

HTA Strategic Risk Register January

January update

Overall our risks are generally stable, however there are pressures associated with leading, planning and managing in the face of a fast changing operating environment. We are confident that we have sufficient mitigating actions against each risk in place but acknowledge that pressures are changing constantly. Our activities need time to embed which also brings additional challenges during this period. The challenge of balancing the use of our people, data and technology capabilities during quarter four, is reflected in this risk, particularly risks 4 and 6. Changes within our technology structures over the last quarter of the year also bring with it challenges around resource utilisation.

Overview: Risks reflect the strategy for 2019 - 2022. Our highest scored risks are: **failure to regulate appropriately** – which is the result of the continuing absence of site visit inspection as part of our regulatory toolkit during this initial phase of the pandemic. We are currently developing and piloting a virtual regulatory assessment model with a view to extending this as a core regulatory tool in Q1 2021; **failure to manage expectations of regulation**, which reflects the fast-pace of change within the sectors we regulate, the low likelihood of legislative change in the foreseeable future and the ongoing temporary removal of routine site visit inspections as a regulatory tool; **failure to utilise our capabilities effectively**, which reflects the fact that business plans are being redeveloped at pace to adjust to the current limitations on activities as a response to changing Covid-related government restrictions whilst also seeking to take advantage of this opportunity to quickly take forward long-planned strategic change through the development programme. The organisation has adapted well to this new working environment and is developing new regulatory tools to supplement our existing non-site visit activity, that will allow continued oversight of our sectors. SMT believes there is currently some upward pressure on this risk.

Other notable risks: Horizon scanning for emerging issues and liaison with DHSC remain a key focus. Progress on other development activity has continued using the additional funds available this year from the cessation of site visits and a recruitment freeze that are being invested for optimum benefit this business year. In particular, this includes work to support our office move and to build a foundation for future strategic development. Work is continuing on these development priorities.

Risk	Oct 2020	Nov 2020	Dec 2020	Jan 2021	Comments
1 - Failure to regulate appropriately (Risk to Delivery a-d & f and Development a-d)		→ 10		→ 10	Whilst we have a good regulatory framework for normal times, with a strong assured position on our key regulatory processes from an Internal Audit review within the past 18 months. We coped well with the novel challenges and intensity of increased activity in the PM sector during the peak of the pandemic but continue to face new challenges arising from this new context, particularly the suspension of one key regulatory process, site visits, across all sectors since mid-March. Activity in the PM sector is now stable, although there continues to be some demand for emergency licences and for licences for funeral directors' premises. We continue to use all other regulatory tools and processes. Virtual regulatory assessments were piloted during quarter three in the HA sector and will be continued in quarter four and extended to Act sectors with a view to scaling up the use of this tool in the new business year. Our inability to meet our legal obligation to undertake biennial site visits in the HA sector since mid-March 2020 is being managed as an issue, of which the Board and DHSC sponsors are aware. The continuing absence of site visit inspections by the HTA may result in an increase in this risk, or perception of this risk by external stakeholders, although this may vary by sector. Planning for undertaking site visits safely (including access to PPE) has been undertaken. In light of the renewed restrictions put in place by the government in January 2021 and the pressures on the health and care system, site visits will only be undertaken if absolutely necessary during quarter four. SMT believe this risk is stable in January 2021.
2 - Failure to manage an incident (Delivery, Development and Deployment)		→ 6		→ 6	The HTA response to managing the impact of the pandemic using these existing plans has been a significant stress test of their adequacy. They have not so far proved wanting. At present the greatest concern is the emergence of another significant incident in parallel that results in compound management stretch. SMT believe this risk is stable in January 2021.
3 - Failure to manage expectations of regulation (Risk to Delivery e and Development c)		→ 12		→ 12	We continue to communicate our remit and advise where appropriate. There is ongoing dialogue with DHSC and stakeholders about emerging issues and we provide clear lines to the media when necessary. Communicating on an issue which is not within remit but which may adversely impact on public confidence is challenging. Looking forward, the Development programme has included a specific workstream to strengthen horizon scanning on emerging changes to policy or activities where the HTA may be required to act or offer an authoritative voice. This proactive approach should identify perimeter issues. The transition period for leaving the EU came to an end in January 2021, and while there had been some uncertainty in what could be communicated to stakeholders who import and export material across the EU, the HTA was able to provide advice when requested. The HTA has been involved in ongoing dialogue with Members of the House of Lords concerning the consent provisions for material imported for the purposes of public display, where there are some concerns about the adequacy of the provisions of the legislation as it currently stands. There has also been dialogue with a private sector body regarding the licensing requirements for removing cells from the deceased on funeral directors' premises. All of these matters are being actively managed, and there has at this stage been no detrimental impact on the HTA's reputation. SMT believe this risk is stable in January 2021.
4 - Failure to utilise our capabilities effectively (Delivery a-e) (Development a-d) (Deployment a, c and d)		↑ 16		↑ 16	Recruitment to permanent roles was put on hold in quarter one while development work was ongoing to ensure more flexible access to the necessary capabilities associated with change. As of January 2021, the HTA is employing seven staff on temporary contracts. The recent loss of two Regulation Managers in the PM sector (one to another role internally) will be addressed during quarter four. In addition SMT discussed short and medium term staffing needs in January 2021 and have commissioned a plan for recruitment. The new restrictions generally and in particular the limitations on access to education and childcare, will almost certainly limit the HTAs people capability. Planning is being undertaken to develop new flexible arrangements to maximise staff availability. ARAC has supported the temporary deprioritisation of the response to the records management internal audit. As a result, the HTA will be tolerating a degree of risk in the medium term. The scoping of development of our EDRMS forms part of development plans for 2020/21 building on the preparatory work completed in quarter 4. The sequencing of this work will need to take into account interdependencies across the development programme. As of January, the HTA continues to operate in an uncertain environment. During the initial peak of the pandemic we agreed to plan over a shorter time horizon quarter by quarter, but are now returning to longer term planning for the 2021/22 reporting year. SMT believe that there is upward pressure on this risk in January 2021.
5 - Insufficient, or ineffective management of, financial resources (Deployment b)		→ 8		→ 8	The ability to maintain the organisation and ensure continuity of payments and salaries processing has not been impacted by the pandemic, although contingencies for processing remain in place. Although the decision to defer invoicing for the HA sector until September did represent an explicit risk payments received to date are not materially different to previous years and as a whole we are confident we will recover payments broadly as usual this financial year. Planning for 2021/22 is now underway, informal discussions with DHSC indicate static GIA funding for the new financial year with scope to access reserves for investment unlikely. With anticipated cost reductions from our estate, and the impact of ongoing restrictions on normal site visit and meetings/events likely to continue to reduce expenditure, we anticipate some funds being available for continuation of our development activities. Further SMT discussions on priorities and other options to divert funds to this area will take place as we finalise our 2021/22 budget. The medium term impact of the pandemic on our licensed centres remains difficult to predict, we will continue to programme expenditure in a way that allows cover for any emerging drop in income and consider emerging trends as we start the 2022/23 fees work in May/June 2021.
6 - Failure to achieve the benefits of the HTA Development Programme (Development objectives a-d)		↑ 9		→ 9	The removal of costs associated with site visit inspection along with the pause in recruitment has provided some headroom for development investment within the existing budget for 2020/21 and will continue to do so in 2021/22. The office move project is nearing completion with 151BPR vacated and the new premises ready for occupation on 18 January. There has been more uncertainty about the timing of the office move the successful delivery of a number of projects to the end of the 2019/20 business year (HTA Intranet, Office 365 upgrade, adoption of remote working, future EDRMS requirements and data and intelligence review) has led to a downgrading of the impact and likelihood score for this risk - now 3/3. There is still more to do, but the work to date represents a significant proportion of the "must do" element of this programme. SMT believe this risk is stable in September 2020.

Strategic Objectives

Delivery objectives

- Deliver a right touch programme of licensing, inspection and incident reporting, targeting our resources where there is most risk to public confidence and patient safety.
- Deliver effective regulation of living donation.
- Provide high quality advice and guidance in a timely way to support professionals, Government and the public in matters within our remit.
- Be consistent and transparent in our decision-making and regulatory action, supporting those licence holders who are committed to achieving high quality and dealing firmly and fairly with those who do not comply with our standards.
- Inform and involve people with a professional or personal interest in the areas we regulate in matters that are important to them and influence them in matters that are important to us.

Development objectives

- Use data and information to provide real-time analysis, giving us a more responsive, sharper focus for our regulatory work and allowing us to target resources effectively.
- Make continuous improvements to systems and processes to minimise waste or duplicated effort, or address areas of risk.
- Provide an agile response to innovation and change in the sectors we regulate, making it clear how to comply with new and existing regulatory requirements.
- Begin work on implementing a future operating model, which builds our agility, resilience and sustainability as an organisation.

Deployment objectives

- Manage and develop our people in line with the HTA's People Strategy
- Ensure the continued financial viability of the HTA while charging fair and transparent licence fees and providing value for money
- Provide a suitable working environment and effective business technology, with due regard for data protection and information security
- Begin work on implementing a future operating model, which builds our agility, resilience and sustainability as an organisation

Risks are assessed by using the grid below

Risk scoring matrix						
Impact	5. Very high	5	10	15	20	25
	4. High	4	8	12	16	20
	3. Medium	3	6	9	12	15
	2. Low	2	4	6	8	10
	1. Very Low	1	2	3	4	5
Risk Score = Impact x Likelihood		1. Rare (<10%)	2. Unlikely (11%-33%)	3. Possible (34%-67%)	4. Likely (68%-89%)	5. Almost Certain (>90%)
Likelihood						

Lines of defence are:

- 1 - Embedded in the business operation
- 2 - Corporate oversight functions
- 3 - Independent of the HTA

Lines of defence

1. Management control and internal controls (frontline)
2. Risk Management functions (senior management)
3. Internal Audit (board/audit committee)

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT		PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL		ACTIONS TO IMPROVE MITIGATION	LINE OF DEFENCE			TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION									
			I	L			I	L		1	2	3												
1	<p>Failure to regulate in a manner that maintains public safety and confidence and is appropriate</p> <p><i>(Risk to Delivery objectives a-d & f Development objectives a-d)</i></p> <p>Risk Owner: Allan Marriott-Smith</p>	<p>Causes</p> <ul style="list-style-type: none"> Failure to identify 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, including insufficient expertise, due to staff attrition, inadequate contingency planning, difficulty in recruiting (including Independent Assessors (IAs)). Inadequate adherence to agreed policies and procedures in particular in relation to decision making Poor quality or out of date policies and procedures Failure to identify new and emerging issues within HTA remit Failure to properly account for Better Regulation Insufficient funding in regulated sectors Failure to deal with regulatory consequences of the Transition Period and the period after 31 December 2020. Failure to properly manage the business impact of the coronavirus pandemic. <p>Effects</p> <ul style="list-style-type: none"> Loss of public confidence Compromises to patient safety Loss of respect from regulated sectors potentially leading to challenge to decisions and non-compliance Reputational damage 	5	4	Ongoing	<p>Regulatory model</p> <p>Fortnightly Transition Period oversight meetings from February 2020 with+H4:Q16+H4:Q15</p> <p>Regulatory decision making framework</p> <p>Annual scheduled review of Strategy</p> <p>The HTA has produced a detailed business plan for the remainder of the year. These plans are approved by SMT and balance core regulatory functions, development priorities and resource deployment considerations.</p> <p>Well established processes support our core regulatory business.</p> <p>Quality management systems</p> <p>HTA quality management system contains decision making framework, policies and Standard Operating Procedures to achieve adherence to the regulatory model</p> <p>People</p> <p>Adherence to the HTA People Strategy which has been substantially amended and approved by the Board</p> <p>Training and development of professional competence</p> <p>Specialist expertise identified at recruitment to ensure we maintain a broad range of knowledge across all sectors and in developing areas</p> <p>Transition period</p> <p>Close liaison with DHSC to ensure communications are in line with government policy and that appropriate arrangements are made to support DHSC and stakeholders during the transition period.</p> <p>HA Guide, ODT Framework and other external guidance being updated inline with new legislation to ensure we can regulate accordingly.</p> <p>Regulatory model</p> <p>Development work being undertaken to become a more data-driven risk based regulator as part of the HTA Development Programme.</p> <p>Other</p> <p>Strengthening horizon scanning arrangements</p>	5	2	<p>In the current absence of site visit inspection, work will be undertaken to develop a risk assessment and a virtual regulatory assessment proposal..</p> <p>Internal audit conducted on Key Regulatory Processes, receiving substantial assurance and noting good areas of best practice</p> <p>As vacancies arise, SMT take the opportunity to review business requirements and target building capability and filling skills gaps.</p> <p>Fortnightly Transition Period oversight meetings from February 2020 with a standing item on the SMT agenda. Continued close liaison with DHSC policy and communications teams, through fortnightly catch-ups of DHSC with ALBs. High level resource planning done for 2020/21 business plan in preparation for anticipated changes at the end of Transition Period.</p> <p>Strengthening horizon scanning arrangements</p>	X			X			X			X			<p>Preventative</p> <p>Preventative</p> <p>Preventative</p> <p>Preventative</p> <p>Detective</p> <p>Preventative/Monitoring</p> <p>Preventative</p> <p>Preventative/Monitoring</p> <p>Preventive / Detective / Monitoring</p> <p>Preventative</p> <p>Preventative</p>	<p>Board developed and approved the current HTA Strategy and is aware of the risk associated with current impossibility of site visit inspections.</p> <p>Reports of key decisions in Board Reporting.</p> <p>Outputs from annual strategy review translate into revised annual Strategy</p> <p>Business plan for 2020/21 has been produced and approved for publication by the sponsor Department.</p> <p>Internal audit conducted on Key Regulatory Processes, receiving substantial assurance and noting good areas of best practice</p> <p>Identified staff member temporarily responsible for QMS, automated review reminders, management oversight of progress on updates</p> <p>Management information and assessment presented to the Board quarterly.</p> <p>Annual PDPs, Corporate Training Programme (led by Head of HR), RM Training programme, Career Investment Scheme proposals to SMT</p> <p>SMT assessment of skills requirements and gaps as vacancies occur, Recruitment policy</p> <p>Weekly reporting by ANH to SMT under standing item on SMT agenda. Short fortnightly Heads meetings give an overview of any enquiries and feedback steers and guidance from DHSC. These are reported to SMT.</p>	<p>HTA Strategy published in November 2020 and pilot virtual regulatory assessment in the HA sector commenced in quarter three 2020/21 and will be expanded in quarter four. The Board will receive an update on progress in February 2021. .</p> <p>Satisfactory Report made in November 2020. Lessons learned from Regulatory Decision Meetings (RDMs) held January 2020 and used to inform update to Regulatory Decision Making SOP. Regulatory Decision Making SOP updated February 2020.</p> <p>Annual strategic planning away day completed in January 2020.</p> <p>Quarterly reporting to Board and DHSC in November 2020 reflected progress against business plans.</p> <p>Final report received April 2019 and showed substantial assurance. Two low priority recommendations have been followed-up with actions during 2019/20, namely review of SOPs for key regulatory processes (completed) and training on core legislative framework, HT Act which was delivered in March 2020.</p> <p>Limitations in QMS still remain. Scheduled reviews have now been re-instated following the departure of the quality manager with a schedule of activity in place. QMS includes evidence of degree to which the documents are current.</p> <p>Quarterly report made at November 2020 Board meeting. Mid-year PDP reviews were completed in October 2020.</p> <p>Evidence of corporate training programme, Regulation-led (RM-Training Programme) e.g. quarterly Regulation Training Mornings (most recent being 1/6/20) and 'Lunch and Learn' programme.</p> <p>Staffing levels and risks reported quarterly to the Board. Recent vacancies have been used to introduce new skills to the HTA e.g. recruitment of a data analyst in January 2020, recruitment of a project manager and inward secondments to support intranet development activity and management of FOIs.</p> <p>Minutes of weekly SMT meetings.</p>

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT		PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL		ACTIONS TO IMPROVE MITIGATION	LINE OF DEFENCE			TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION
			I	L			I	L		1	2	3			
2	<p>Inability to manage an incident impacting on the delivery of HTA strategic objectives. This might be an incident:</p> <ul style="list-style-type: none"> relating to an activity we regulate (such as retention of tissue or serious injury or death to a person resulting from a treatment involving processes regulated by the HTA) caused by deficiency in the HTA's regulation or operation where we need to regulate, such as with emergency mortuaries that causes business continuity issues <p>(Risk to all Delivery Development and Deployment objectives)</p> <p>Risk owner: Nicky Harrison</p>	<p>Cause</p> <ul style="list-style-type: none"> Insufficient capacity and/or capability (for instance, staff availability, multiple incidents or ineffective knowledge management) Failure to recognise the potential risk caused by an incident (for instance poor decision making, lack of understanding of sector, poor horizon scanning) Failure to work effectively with partners/other organisations Breach of data security IT failure or attack incident affecting access to HTA office External factors such as terrorist incident, large scale infrastructure failure or pandemic <p>Effect</p> <ul style="list-style-type: none"> Loss of public confidence Reputational damage Legal action against the HTA Intervention by sponsor 	5	3	Future, should event occur	<p>Critical incident response plan, SOPs and guidance in place, regularly reviewed, including by annual training, and communicated to staff</p> <p>All specific roles identified in the Critical Incident Response Plan are filled.</p> <p>Media handling policy and guidance in place and Critical Incident Response Plan includes requirement to involve Comms team. Comms Team have embedded media handling and development of lines to take into business as usual.</p> <p>Availability of legal advice</p> <p>Fit for purpose Police Referrals Policy</p> <p>Onward delegation scheme and decision making framework agreed by the Board</p> <p>Regulatory decision making framework</p> <p>IT security controls and information risk management</p> <p>Critical incident response plan regularly reviewed and tested</p> <p>Evaluate test exercise of incident and feedback to all staff.</p> <p>Ensure DIs (or equivalent in ODT sector) are aware of and follow the incident reporting procedure for incidents reportable to the HTA.</p> <p>Management of Transition Period to 31 December 2020 following the UK's departure from the EU. Continuing engagement with DHSC to manage follow-up activity during the 6-month grace period for GB import / export licensing.</p>	3	2		X	X		Preventative	Policies etc. reviewed annually, training specification and notes after incident reviews	Subject to internal audit reported to ARAC in February 2020 Version 19 of CIRP published July 2019. CIRP deployed in March 2020 to manage coronavirus pandemic.
										1	2	3	Preventative	Evidence of regular review and updating of the CIRP and no specific CIRP roles left vacant.	CIRP reviewed and updated to version 19 in July 2019. Further minor changes proposed February 2020 updated roles following staff changes.
										X			Preventative	Policy reviewed as scheduled. Reports on media issues and activity in Delivery Report. Evidence of active Comms Team participation in issues with potential for media or public interest.	Media issues are included in the quarterly Board reporting as they arise and as relevant.
										X			Preventative	Lawyers specified in Critical Incident Response Plan, SMT updates	In place
										X			Preventative	Annual review of policy (minimum), usage recorded in SMT minutes	Police referral process used regularly by SMT and captured in SMT minutes.
										X	X		Preventative	Standing Orders and Board minutes	Standing Orders published May 2017, due to be updated at November Board meeting.
										X			Preventative	Reports to Board of key decisions in Delivery Report	RDMs summarised in quarterly reporting to the Board. Regulatory Decision Making SOP reviewed and updated February 2020.
										X	X		All	SIRO annual review and report Internal audit reports	Cyber security review - standing agenda item at ARAC - last discussed June 2020.
										X	X		Preventative	Critical Incident Response Plan and notes of test, reported to SMT Use of CIRP reported to SMT.	CIRP used to manage response to coronavirus pandemic in March 2020.
										X			Preventative	SMT content that activation and use of CIRP during first wave and first lockdown superseded the need for a test.	
										X			Preventative / Detective / Monitoring	Inspections (and audits for ODT) include assessment of licensed establishments' knowledge and use of the relevant HTA incident reporting process.	Findings at inspection. Monitoring establishments' reporting of incidents through the HTARI, HA SAEARs and ODT SAEARs groups.
													Preventative / Detective / Monitoring	Engagement with DHSC on planning for the end of the transition period. Director-level oversight as SRO (Director of Regulation), fortnightly oversight meetings with relevant Heads, regular reporting to SMT.	Regular reports to SMT - standing item on SMT agenda from February 2020.

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT		PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL RISK		ACTIONS TO IMPROVE MITIGATION	LINE OF DEFENCE			TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION
			I	L			I	L		1	2	3			
3	<p>Failure to manage public and professional expectations of human tissue regulation in particular stemming from limitations in current legislation or misperception of HTA regulatory reach</p> <p>(Risk to Delivery objective e, and Development c)</p> <p>Risk Owner: Louise Dineley</p>	<p>Cause</p> <p>External factors</p> <ul style="list-style-type: none"> No scheduled review of Human Tissue Act and associated regulations, or Quality and Safety Regulations (other than for EU Exit) Rapidly advancing life sciences Potential move away from the UK as base for some regulated establishments/sectors due to EU Exit and changes in exchange rates Introduction of deemed consent for Organ donation in England Uncertainty posed by EU Exit, and misperceptions stemming from a 'no-deal' scenario <p>Matters which certain stakeholder groups believe require review</p> <ul style="list-style-type: none"> Scope of relevant material e.g. waste products Licensing requirements e.g. transplantation research Regulation relating to child bone marrow donors Issues raised by emergence of social media e.g. non-related donors Strengthening of civil sanctions for non-compliance <p>Matters which stakeholders/public may expect to be inside regulatory scope</p> <ul style="list-style-type: none"> Efficacy of clinical treatment from banked tissue and treatments carried out in a single surgical procedure Police holdings Products of conception and fetal remains Data generated from human tissue Funeral directors Forensic research facilities Cryonics Body stores / Taphonomy Imported material Clinical waste Other Inadequate stakeholder management <p>Effect</p> <ul style="list-style-type: none"> Diminished professional confidence in the adequacy of the legislation Reduced public confidence in regulation of matters relating to human tissue Reputational damage 	5	4	Ongoing	<p>Horizon scanning process in place that creates and maintains an up to date log of issues known to the HTA with respect to the legislation (updates, amendments or emerging issues) to inform DH and manage messages</p> <p>Active management of professional stakeholders through a variety of channels including advice about relevant materials in and out of scope</p> <p>Active management of issues raised by the media – including the development of the HTA position on issues</p> <p>Regular reporting to DHSC sponsorship and policy team on matters which risk public and professional confidence</p> <p>Action where we believe it will support public confidence</p> <p>Clear view of use of s.15 duty to report issues directly to Ministers in England, Wales and Northern Ireland as new issues emerge</p> <p>No further changes to HTA's Standards since significant changes launched April 2017. Significant activity to update Codes of Practice for Organ Donation and Transplantation (and consent) to support the introduction of deemed consent (May 2020).</p> <p>Extensive Professional Evaluation Survey undertaken in Q4 2019/20, reported to Board in July 2020 and used to inform further developments.</p> <p>Proactive horizon scanning and development of policy in emerging/complex areas. Further strengthening building on existing system.</p> <p>Communications work package set up as part of UK Transition project to ensure we are managing our licensed establishments' expectations of what is required at the end of the transition period. As part of this WP we will also attempt to reach out to unknown end users to make them aware of their new regulatory licensing requirements and timelines.</p>	4	3	<p>Horizon scanning process in place that creates and maintains an up to date log of issues known to the HTA with respect to the legislation (updates, amendments or emerging issues) to inform DH and manage messages</p> <p>Comms & Engagement strategy under development to strengthen the HTA's approach and impact of stakeholder engagement. Updated C&E Strategy planned for Q4.</p> <p>Further work planned in 2021/22 to review and update codes of practice. Focus will be on factual update.</p>	1	2	3	<p>Monitoring</p> <p>Preventative/Detective</p> <p>Preventative/Detective</p> <p>Monitoring</p> <p>Preventative</p> <p>Preventative</p> <p>Preventative</p> <p>Preventative</p>	<p>Ongoing log</p> <p>Stakeholder Group meeting minutes Authority minutes (including Public Authority Meeting) TAG and HWG meetings</p> <p>Quarterly reports to Board on communication (including media) activities</p> <p>Quarterly Accountability meetings with DH</p> <p>Updated guidance in response to the coronavirus emergency published on the website, further sector specific guidance also published. These publications reflect the importance of ongoing publications and updates to specific conditions.</p> <p>Duty and its uses understood by SMT and Chair</p> <p>Updated guidance published. Updated Codes of Practice to support deemed consent published.</p> <p>Evidence from Professional Evaluation used as an evidence and information source to inform and drive improvements</p> <p>Horizon scanning improvement is one of the six strands of the development programme</p>	<p>Log in place and stable.</p> <p>Last stakeholder group meeting in October 2019 Public Authority Meeting in May 2019; Histopathology Working Group February 2020; Transplant Advisory Group October 2019</p> <p>Last report July 2020</p> <p>Last assured position from DHSC on 31 July 2020</p> <p>Update to the Board and DHSC at Board meeting May 2020.</p> <p>Advice and guidance continues to be provided, for example on the Private Members Bill - Organ Tourism and Cadavers on Display, 2020.</p> <p>Supplementary guidance on PM standard on traceability issued Feb 2019. Further guidance developed on PM Standards in consultation with HWG, eg on three points of identification, long-term storage of bodies and dealing with consent for testing for infection of deceased in cases of sharps injuries. Updated Code of Practice for Organ Donation and Transplantation laid in Parliament February 2020.</p> <p>Evidence from Professional Evaluation presented to the Board in July.</p> <p>Update on this work presented at July Board meeting</p>

						<i>Regular meetings with DHSC policy team and attendance at other departmental meetings (ALB delivery partners) to inform planning for key pressures such as ongoing response to Covid-19; winter pressures, Transition Period and the period after 31 December 2020 and the progress of the MMD Bill.</i>	x			<i>Preventative</i>	Development programme workstream 20/21. Stengthening of Horizon scanning has identified 4 areas to progress. Regular reporting to SMT and through formal routes.	
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REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT		PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL		ACTIONS TO IMPROVE MITIGATION	LINE OF DEFENCE			TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION
			I	L			I	L		1	2	3			
4	<p>Failure to utilise people, data and business technology capabilities effectively</p> <p>(Risk to Delivery objectives a-e, Development a-d Deployment a, c and d)</p> <p>Risk Owner: Louise Dineley</p>	<ul style="list-style-type: none"> Cause Lack of knowledge about individuals' expertise Poor job and organisational design resulting in skills being under used Poor line management practices Poor project management practices Poor leadership from SMT and Head Loss of productivity as a result of the effects of changes to ways of working Data holdings poorly managed and under-exploited Inadequate business technology or training in the technology available Lack of ring-fenced resource for 'no-deal' EU Exit Effect Poor deployment of staff leading to inefficient working Disaffected staff Increased turnover leading to loss of staff Knowledge and insight that can be obtained from data holdings results in poor quality regulation or opportunities for improvement being missed Poor use of technology resulting in inefficient ways of working Inadequate balance between serving Delivery and Development objectives 	4	4		<p>People capability</p>	4	4		1	2	3			
						<p>People Strategy for the period 2019 to 2021 is in effect</p>			X	X		Preventative/Monitoring	Board approval of the Strategy	Board approved the Strategy at its meeting in February 2019 and is provided with regular updates on all facets of its progress in quarterly board reporting. Most recently in July 2020.	
						<p>Full suite of people policies and procedures (including performance management)</p>			X			Preventative/Monitoring	Full suite of policies in place and available on Wave	https://intranet.hta.gov.uk/pages/policies_forms	
						<p>External assessment of utilisation of capabilities</p>					X	Monitoring/Detective	Internal audit 'Utilisation of capability' provided moderate assurance in July 2019	ARAC received the audit report and monitors progress against recommendations - most recently June 2020	
						<p>Adherence to the HTA Workforce Capability Development Framework</p>			X			Preventative	SMT approved the Framework in September 2020 - as a response to internal audit recommendations	ARAC to receive update on the Framework at its meeting in October 2020	
						<p>Investment in the development of the HTA leadership team</p>			X			Preventative	External consultants engaged to assess team and individual development needs and design appropriate interventions	Interventions have commenced including full leadership team workshop in September 2020	
						<p>Handover process is formalised via a checklist to ensure corporate knowledge is retained</p>			X			Preventative/Monitoring	Handover checklist is in place and in operation.		
						<p>More formal assessment of future capability needs and how these should be met including through better knowledge of internal skills</p>			X	X		Preventative/Monitoring	Director and Head of HR assessing capability needs as part of future operating model HTA Workforce Capability Development Framework sets out how capability needs will be met Head of HR has implemented a register of skills within the HTA	SMT will be agreeing its approach to filling specific immediate capability needs in October Development Programme is picking up medium to long term capability needs.	
						<p>Establish a formal role within SMT terms of reference to look holistically at people and capability issues across the organisation focussing on short and long term impacts and deliverables.</p>				X		Preventative/Monitoring	SMT terms of reference and SMT minutes	SMT ToRs review is in process supported by external advisers. Due to be in place by end October 2020	
						<p>Data capability</p>									
						<p>Data relating to establishments securely stored with the Customer Relationship Management System (CRM)</p>			X		X	Preventative/Monitoring	Upgrades to CRM, closely managed changes to CMR development. Internal audit of personal data security.	CRM upgrade completed successfully in March 2019	
						<p>Appropriate procedures to manage personal data including GDPR compliance.</p>			X		X	Preventative/Monitoring	Internal audit on GDPR compliance provided moderate assurance.	Internal audit report in March 2019. Part of ongoing Cyber and data security and SIRO reporting.	
						<p>Business technology capability</p>									
						<p>Staff training in key business systems</p>			X			Preventative	Systems training forms part of the induction process for new starters	Ongoing records of all new starters trained in key business systems. New remote induction programme was launched in Summer 2020.	
						<p>IT systems protected and assurances received from 3rd party suppliers that protection is up to date</p>			X	X	X	Preventative/Monitoring	Quarterly assurance reports from suppliers. MontAMSy operational cyber risk assessments. Annual SIRO report	Annual SIRO report presented to ARAC June 2020	
						<p>Business technology</p>									
<p>Identify refresher training and targeted software specific training needs.</p>	X			Preventative	Evidence of targeted training in last quarter. Further strengthening of core training requirements included in updated induction programme.										

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT RISK PRIORITY		PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL RISK PRIORITY		ACTIONS TO IMPROVE MITIGATION	LINE OF DEFENCE			TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION												
			I	L			I	L		1	2	3															
5	<p>Insufficient, or ineffective management of, financial resources</p> <p>(Risk to Deployment objective b</p> <p>Risk Owner: Richard Sydee</p>	<p>Cause</p> <ul style="list-style-type: none"> Fee payers unable to pay licence fees - The number of licenced establishments changes, leading to reduced fee income Management fail to set licence fees at a level that recover sufficient income to meet resource requirements Failure to estimate resource required to meet our regulatory activity Poor budget and/or cash-flow management Unexpected increases in regulatory responsibilities Unforeseeable price increases / reductions in GIA Fraudulent activity detected too late <p>Effect</p> <ul style="list-style-type: none"> Payments to suppliers and/or staff delayed Compensatory reductions in staff and other expenditure budgets Increased licence fees Requests for further public funding Draw on reserves Failure to adhere to Cabinet Office Functional Standards <p>Leading to:</p> <ul style="list-style-type: none"> Inability to deliver operations and carry out statutory remit Reputational damage and non payment of fees 	5	4	Ongoing		2	4		1	2	3	All	Budgetary control policy reviewed annually and agreed by SMT	Revised version reviewed by SMT in November 2020.												
																Budget management framework to control and review spend and take early action	X	X									
																Financial projections, cash flow forecasting and monitoring	X							Monitoring	Monthly finance reports to SMT and quarterly to Authority. Quarterly reports to DH	Last quarterly report to Board in November 2020	
																Licence fee modelling								Preventative	Annual update to fees model	No change to fees agreed by the Board November 2020 meeting	
																Rigorous debt recovery procedure	X							Preventative	Monthly finance reports to SMT and quarterly to Authority	Level of outstanding debt is being reduced. Older debt are being collected. Although we maintain a tight grip on our position, the overall environment is more uncertain than normal.	
																Reserves policy and levels reserves	X							Monitoring	Reserves policy reviewed annually and agreed by ARAC	Last agreed by ARAC October 2020	
																Delegation letters set out responsibilities	X	X						Preventative	Delegation letters issued annually	Issued in May 2020	
																Fees model provides cost/income information for planning	X							Preventative	Annual review of fees model, reported to SMT and Authority	Update agreed by the Board November 2019. No review or change in fees and agreed at November Board meeting.	
																Annual external audit								X	Detective	NAO report annually	Last report in June 2020 - clean opinion
																Monitoring of income and expenditure (RS) Ongoing								X	Detective	Monthly finance reports to SMT and quarterly to Authority. Quarterly reports to DH	Last quarterly report November 2020
Horizon scanning for changes to DH Grant-in-aid levels and arrangements (RS) Ongoing	X	X							Detective	Quarterly Finance Directors and Accountability meetings	FD from NHS Resolution, HRA, NICE and CQC maintain contact over common issues weekly. Quarterly meetings with DHSC which cover finance and non-finance issues/risks.																
Action plan to move from rudimentary to Basic level of maturity on the GovS 013 Functional Standards	X	X							Preventative	Counter fraud Strategy and Action Plan developed and presented to ARAC Oct-19. Annual training of staff completed n Q4	Cabinet Office - CDR submissions Counter-fraud activities now part of BAU.																

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT		PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL		ACTIONS TO IMPROVE MITIGATION	LINE OF DEFENCE			TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION
			I	L			I	L		1	2	3			
6	<p>Failure to achieve the benefits of the HTA Development Programme</p> <p>(Development objectives a-d)</p> <p>Risk owner</p> <p>Louise Dineley</p>	<p>Causes</p> <ul style="list-style-type: none"> Uncertainty of funding Programme and project benefits poorly defined and understood Inadequate programme and project governance arrangements Poorly specified programme and projects Insufficient programme, project and change management skills Inadequate leadership of change Inability to access the necessary skills required at a affordable cost Lack of staff buy-in to change Management and Head stretch of delivering transformation alongside business as usual and other development activity Insufficient agility in (re)deploying people to change projects Poorly specified procurement and inadequate contract management Realisation of single points of failure for DDAT and People Strategy <p>Effects</p> <ul style="list-style-type: none"> Wasted public money Failure to achieve the central strategic intent of the Authority Distracts senior management from operations at a time when demands have increased Reputational damage Unaffordable cost over run Staff demotivation Data remains under-utilised Technology inadequate to meet future needs (cost, functionality) Limited ability to achieve improvements in efficiency and effectiveness Pace of change is inadequate and impacts negatively on other work 	5	4			3	3	<p>Change Manager appointed in August 2020 to support the development of capacity & capability across the organisation</p> <p>HTA approach to the management of change projects (<i>underpinned by project management methodologies</i>)</p> <p>A number of trained project managers among HTA staff</p> <p>Experience of procurement and contract management</p> <p>Existing mechanisms for engaging staff</p> <p>Well established corporate governance arrangements and financial controls</p> <p>Agreement to a phased delivery approach to avoid all or nothing investment and align with available funding</p> <p>Embed Benefits Realisation Management methodology within programme</p> <p>Introduce a Programme Management function</p> <p>Board approval to proceed at key Gateway decision points</p> <p>Training plan to encompass project and change management and HTA approach</p> <p>Strengthened planning supports a single message and focus on an agreed set of priorities</p> <p>SROs identified for Programme and individual projects</p> <p>Schedule a regular programme of staff engagement events</p> <p>Establish an external stakeholder communications and engagement plan</p> <p>Recruitment of new Board Member(s) with digital and organisational change experience</p> <p>Programme to become a focus for appropriate internal audit</p> <p>Appointment of external critical friend to counter potential optimism bias</p>	X			Preventative	Recruitment of an HTA Programme Director	The Director of Data, Technology and Development appointed in October 2019 will act as Programme Director.
									X			Preventative	Dedicated permanent project manager appointed	PM in place an operating effectively	
									X			Preventative			
									X			Preventative			
									X			Preventative			
										X		Monitoring	Internal audit of key controls	Assurance provided by Internal Audit of adequacy of key financial controls	
									X			Preventative	Programme plan in place	Update reported to July Board meeting	
									X			Preventative			
									X			Preventative		New PM appointed, procedures and PMO established. Ongoing focus to embed skills and build wider capability across the business	
										X		Monitoring			
									X			Preventative		Change management training activity is now in progress following the appointment of the HTA Change Manager. Mandatory all staff sessions were undertaken in quarter 3. Further osu planned in Q4	
									X			Preventative		Plan in place, work ongoing in 2020/21.	
									X			Preventative		Updating of the Business plan in Q4	
									X			Preventative		Reset and relaunch event planned in Q4 providing focus to developments over the next 15 months. Review of stakeholder engagement also extends to inviting a wider contribution to future development plans.	
									X			Preventative		Work progressing Q4	
										X		Monitoring/ Detective		This was not achieved as part of the recent recruitment round, but will be a focus for the next round in 2021.	
											X	Monitoring/ Detective			
											X	Preventative			

Human Tissue Authority

Board meeting

Date: 11 February 2021

Paper reference: HTA 03b/21 (Board Supplementary Data Annex)

Agenda item: 6

Author: Allan Marriott-Smith
CEO

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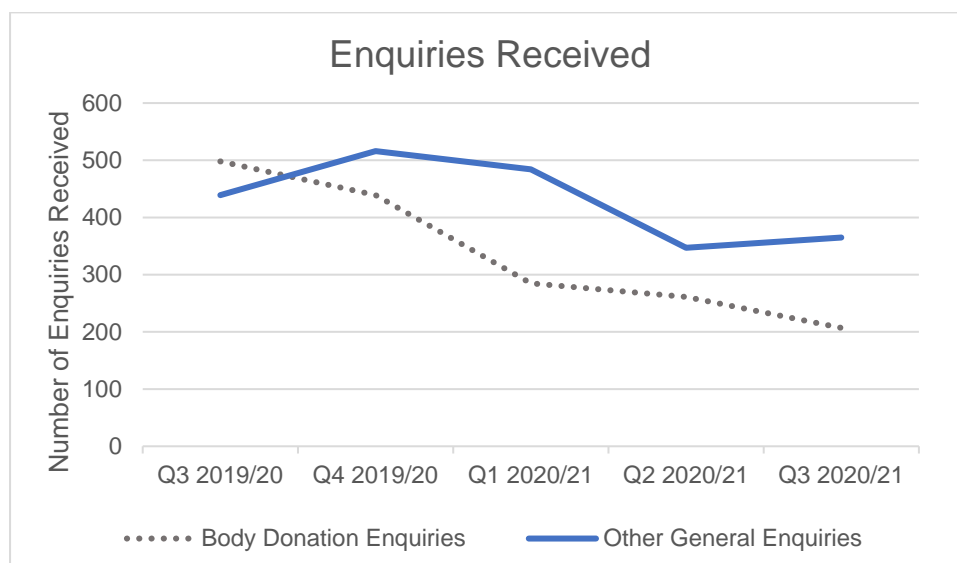
Purpose of Report

1. This report sets out a high-level overview of activity in quarter three 2020/21.

Enquiries

2. Figure 1 below displays the total number of body donation enquiries and other general enquiries received. In quarter three, 365 General Enquiries and 207 Body Donation Enquiries were received.

Figure 1: Number of body donation and other general enquiries received each quarter



3. Table 1 displays the number of general enquiries received for each sector (excluding body donation enquiries).

Table 1: General Enquiries Received by sector (excluding Body Donation Enquiries)

Sector	Q3 2019/20	Q4 2019/20	Q1 2020/21	Q2 2020/21	Q3 2020/21	2018/19 Total	2019/20 Total
Anatomy	43	21	20	19	13	160	136
Human Application	78	103	100	86	147	282	316
Organ Donation and Transplantation	8	6	12	14	10	30	38
Post Mortem	88	147	196	116	93	178	379
Public Display	5	8	1	6	2	21	22
Research	75	53	74	62	73	139	248
Removal	1	0	6	1	0	1	4
No Sector Assigned	141	178	75	43	27	908	679
Total	439	516	484	347	365	1,719	1,822

Licensing

4. Table 2 displays the number of new licence applications, new licences offered, satellite additions and revocations in quarter three.

Table 2: New licence applications, new licences offered, satellite additions and revocations in quarter three

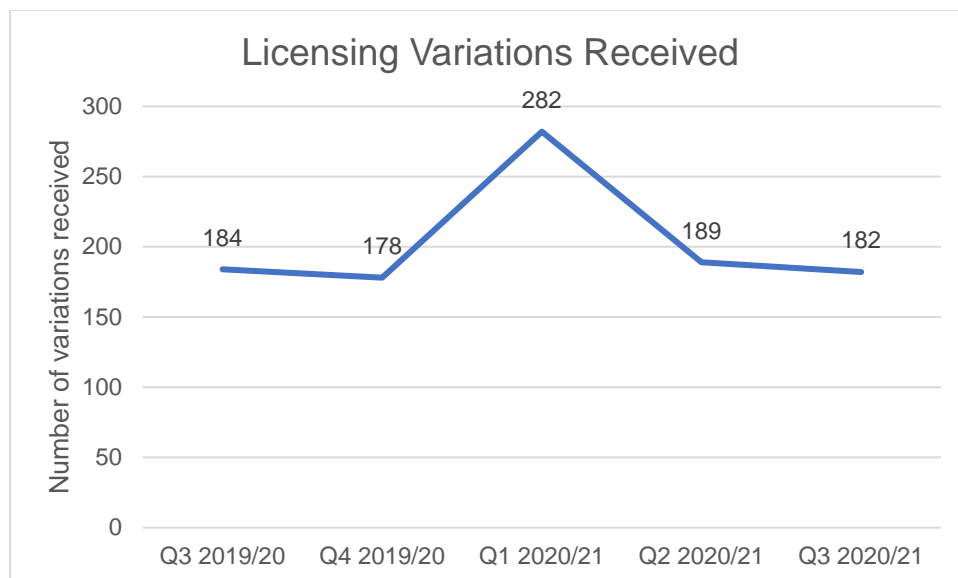
Sector	New Licence Application	No. of Licence Applications with Decision Made	Satellite Additions	Revocations	Satellite Revocations
Anatomy	1	1	0	0	0
Human Application	2	2	1	0	3

Organ Donation and Transplantation (ODT)	1	0	0	0	0
Post Mortem	7	4	1	0	1
Public Display	0	0	0	0	0
Research	3	3	2	0	0
Total	14	10	4	0	4

5. Fourteen new licence applications were received in quarter three 2020/21. In the post mortem sector, five applications were from funeral director organisations, one application was for an emergency mortuary and one application was for a standard Post Mortem licence. Two licence applications related to European Union Exit were received and granted in the Human Application sector. Three applications were also received in the Research sector, one in the Anatomy sector and one in the ODT sector.
6. In quarter three 2020/21, decisions were made on ten applications.
7. There were four satellite additions in quarter three (one in the Human Application sector, one in the Post Mortem sector and two in the Research sector).
8. No revocations took place in quarter three.
9. Four satellite revocations took place in quarter three (three were in the Human Application sector and one in the Post Mortem sector).

Licensing Variations

10. Figure 2 displays the total number of licensing variations received each quarter. A total of 182 licensing variations were received in quarter three. Volumes received has returned to the average number received before the COVID-19 period.
11. Licensing variations received by sector is displayed in Table 3.

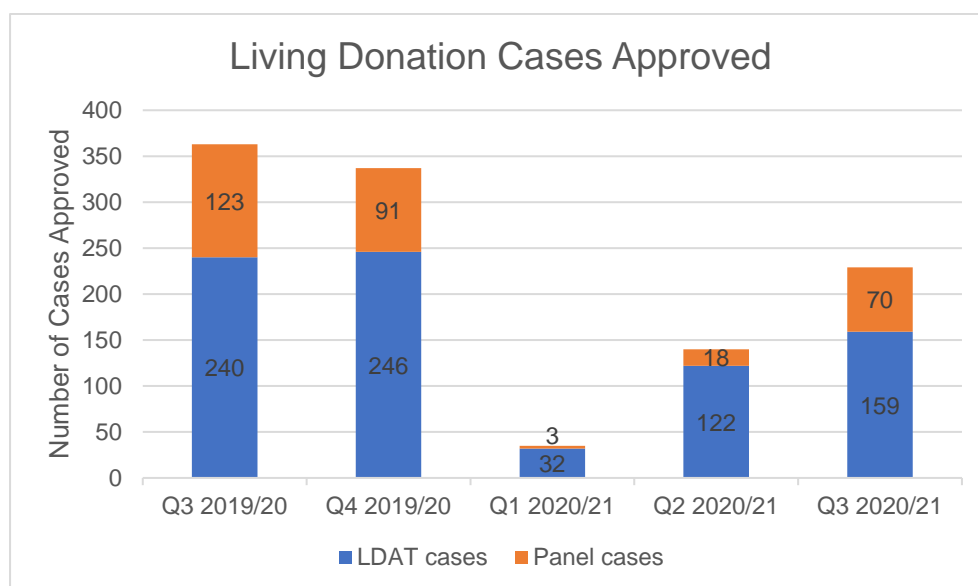
Figure 2: Number of licencing variations received each quarter**Table 3: Licensing variations received by sector**

Sector	Q3 2019/20	Q4 2019/20	Q1 2020/21	Q2 2020/21	Q3 2020/21	2018/19 Total	2019/20 Total
Anatomy	10	8	6	3	7	25	30
Human Application	54	83	127	102	87	260	118
Organ Donation and Transplantation	12	4	6	4	12	27	27
Post Mortem	55	40	89	39	41	158	205
Public Display	9	1	5	2	2	9	16
Research	42	42	49	39	33	155	165
Removal	2	0	0	0	0	0	2
Total	184	178	282	189	182	634	708

Living Donation

12. Figure 3 shows the total number of living donation cases approved by the Living Donation Assessment Team (LDAT) and the panel.
13. In quarter three, 159 cases were approved by the LDAT and 70 cases were approved by the panel. The total number of cases approved also includes those using the emergency out-of-hours processes.

Figure 3: Number of living donation cases approved per quarter



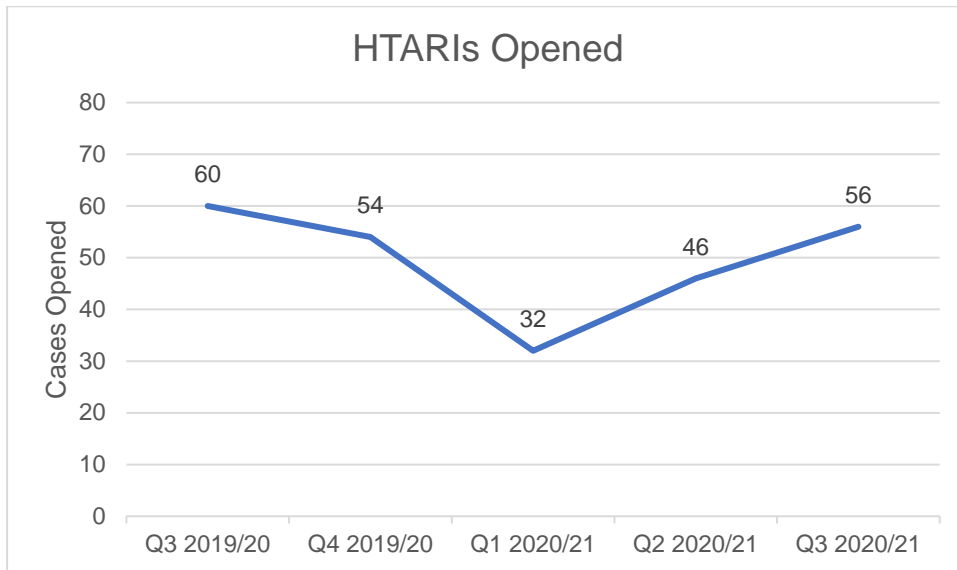
14. Table 4 below shows the total number of bone marrow and peripheral blood stem cell (PBSC) cases approved in quarter three compared to preceding quarters.

Table 4: Total number of bone marrow and PBSC cases approved

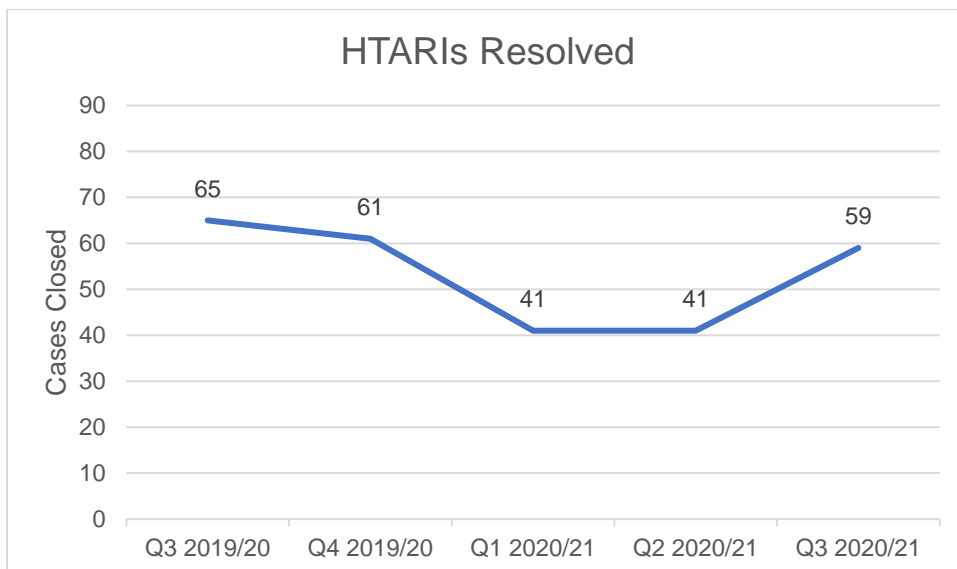
	Q3 2019/20	Q4 2019/20	Q1 2020/21	Q2 2020/21	Q3 2020/21	2018/19 Total	2019/20 Total
Approvals	15	17	16	15	17	71	66

Incidents – HTARIs

15. Figure 4 displays the number of reported HTA Reportable Incidents (HTARIs) in quarter three compared to preceding quarters. This also includes any near misses and incidents that may, on investigation, be found not to be reportable incidents. In quarter three, 56 HTARI cases were opened, compared to 46 cases opened in quarter two.

Figure 4: HTARI cases opened during quarter in the Post Mortem sector

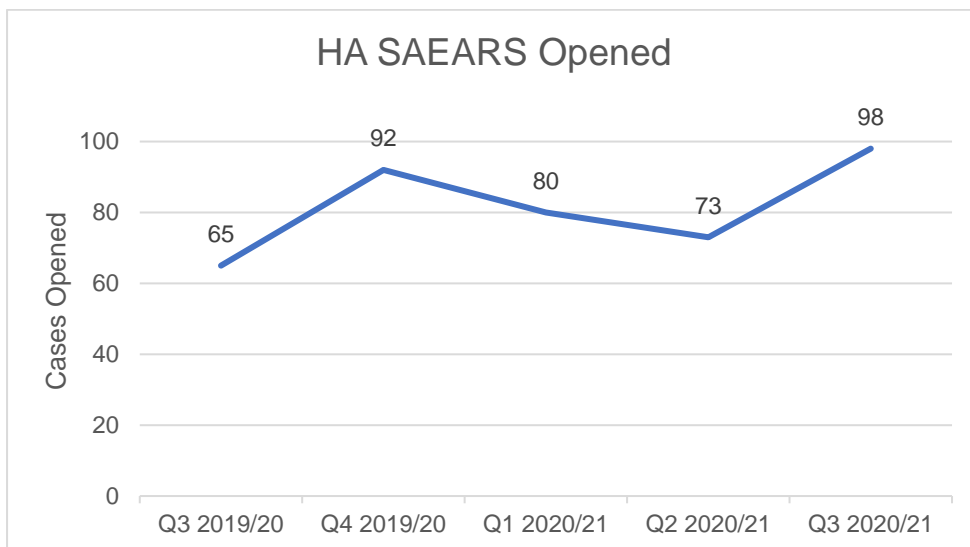
16. Figure 5 displays the number of HTARIs resolved in quarter three compared to the preceding quarters. 59 HTARIs were resolved in quarter three, compared to 41 resolved in quarter two.

Figure 5: HTARI cases resolved during quarter in the Post Mortem sector

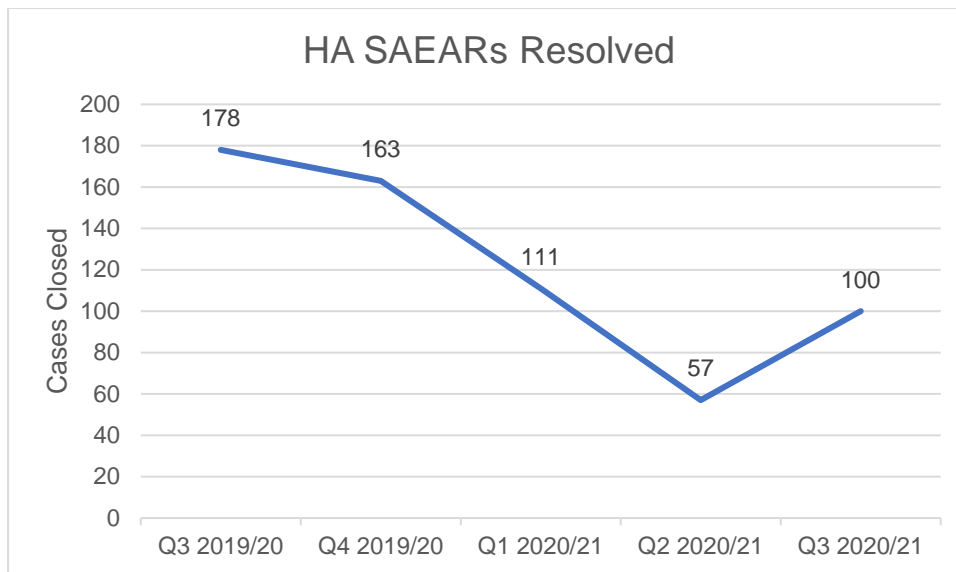
Incidents – Human Application Serious Adverse Events and Reactions (HA SAEARs)

17. Figure 6 below displays the number of reported HA SAEARs in quarter three compared to preceding quarters. This also includes any near misses and incidents that may, on investigation, be found not to fit the criteria of a SAEAR. In quarter three, 98 HA SAEARs cases were opened, compared to 73 cases opened in quarter two.

Figure 6: SAEARs opened during quarter in the Human Application sector

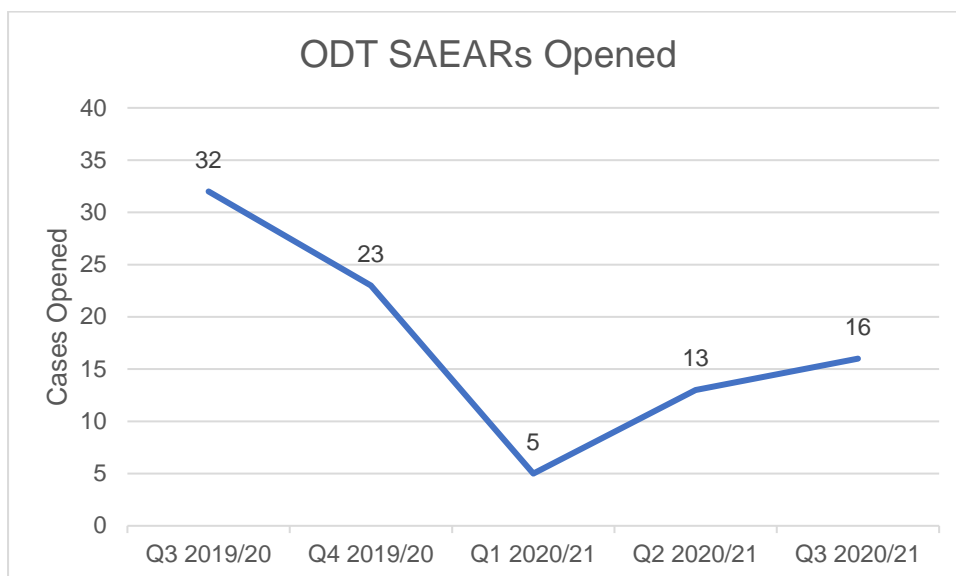


18. Figure 7 displays the number of HA SAEARs resolved in quarter three compared to preceding quarters. 100 HA SAEARs cases were resolved in quarter three, compared to 57 cases resolved in quarter two.

Figure 7: SAEARs resolved during quarter in the Human Application sector

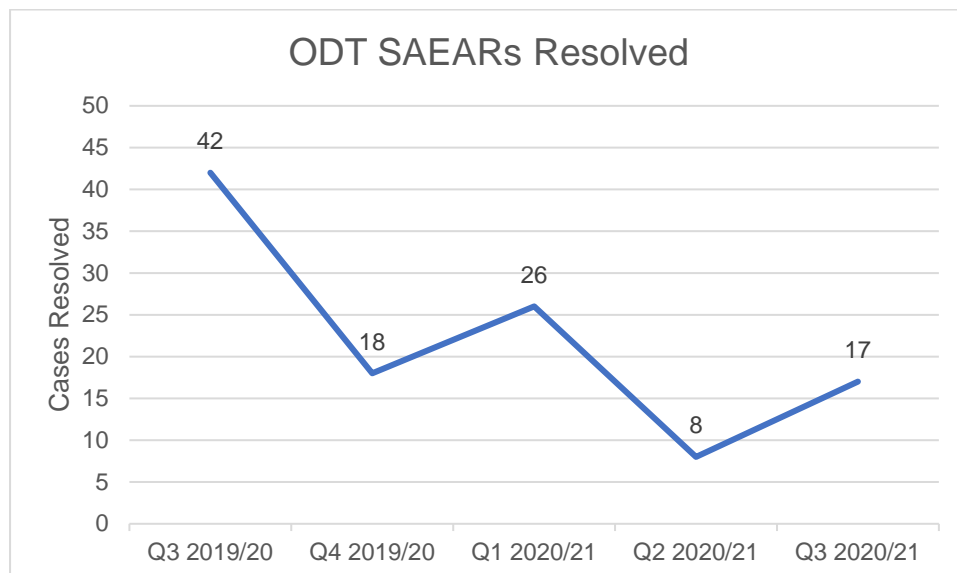
Incidents – Organ Donation and Transplantation Serious Adverse Events and Reactions (ODT SAEARs)

19. Figure 8 below displays the number of reported ODT SAEARs in quarter three compared to preceding quarters. In quarter three, 16 ODT SAEARs cases were opened, compared to 13 cases opened in quarter two.

Figure 8: SAEARs opened during quarter in the Organ Donation and Transplantation sector

20. Figure 9 below displays the number of ODT SAEARs resolved in quarter three compared to preceding quarters. 17 ODT SAEARs cases were resolved in quarter three, compared to eight cases resolved in quarter two.

Figure 9: SAEARs resolved during quarter in the Organ Donation and Transplantation sector

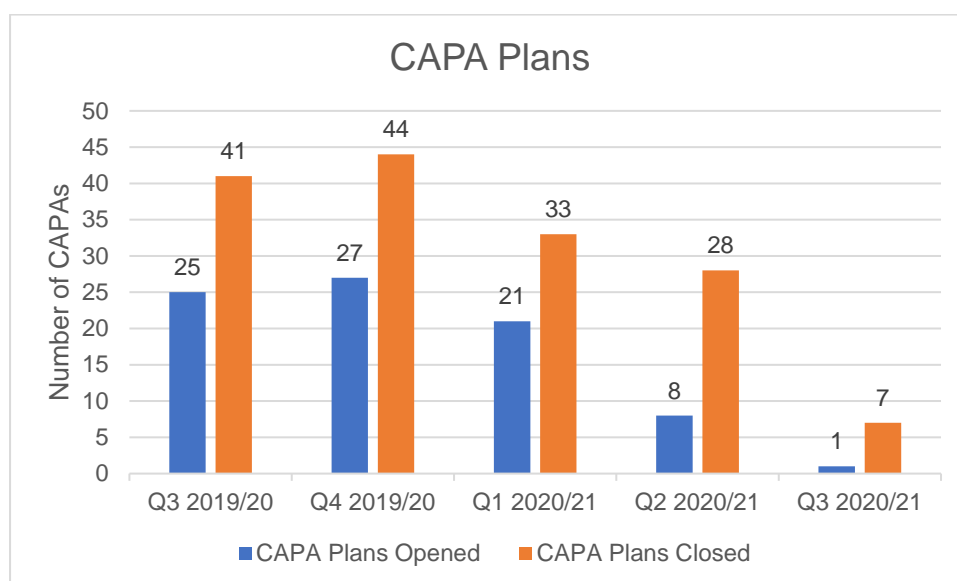


Corrective and Preventative Action Plans (CAPAs)

21. Figure 10 displays the number of CAPA plans opened and closed during quarter three, compared to previous quarters. The number of CAPA plans opened includes those opened as part of new licences offered and investigations.

22. A total of one new CAPA plan was opened in the Post Mortem sector during quarter three.

23. A total of seven CAPA plans were closed in quarter three. Four CAPA plans were closed in the Human Application sector, two were closed in the Post Mortem sector and one closed in the Research sector.

Figure 10: Number of CAPA Plans opened and closed during quarter

24. Table 5 shows all open CAPA plans at the end of quarter three and the length of time they have been open.

25. There was a total of 33 open CAPA plans at the end of quarter three. Three CAPA plans have been open for less than six months, thirteen have been open between six to 12 months and 17 CAPA plans have been open for longer than 12 months.

Table 5: All Open CAPA plans

Open CAPA Plans	Anatomy	Post Mortem	Human Application	Research	Public Display	ODT	Total
< 6 months	0	3	0	0	0	0	3
6-12 months	0	4	9	0	0	0	13
> 12 months	0	2	15	0	0	0	17
Total	0	9	24	0	0	0	33

Website Analytics

27. These analytics compare website activity during quarter three of 2020/21 with quarter three of 2019/20, as this represents the best direct comparison.

Table 6: Audience Size

	2020/21	2019/20
Visits	47,473	62,972
Sessions	66,260	87,778

28. Overall traffic is down roughly 20% compared to the same period last year. On 22 October 2019 the website saw a large spike in visits (over 4,000 in one day, eight times the average), so these numbers are inflated to some degree. This spike was due to a substantial item on BBC breakfast looking at body donation and anatomical research.

Table 7: Engagement

	2020/21	2019/20
Average time on page	2min 38s	2min 42s
Bounce rate	42.95%	39.59%

29. Time on page is consistent across both samples. Bounce rate has fallen by a moderate margin. There is no overall trend for engagement metrics, however this is the second quarter where these engagement statistics have fallen.

Popular Pages

30. As with last quarter, this fall-off in traffic can be partly attributed to the fall-off in people seeking information on body donation. This quarter 8% of website traffic was on the body donation page, last quarter it was 13%.

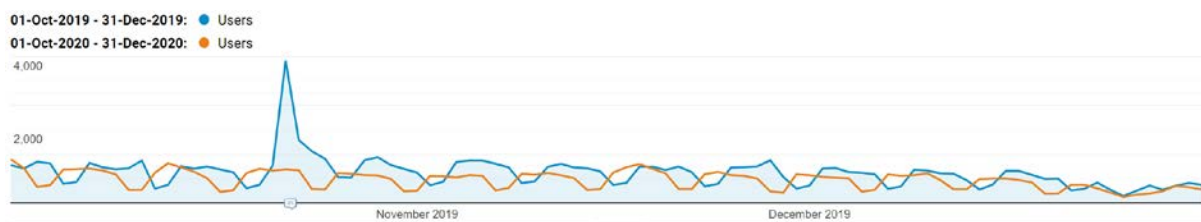
Additional notes

31. There were no noteworthy spikes or trends in this period, other than the expected drop in traffic over the Christmas period.

Conclusion

32. There is little to mark this period as especially significant, however the fall in traffic compared to last year now seems established. The three years previously saw traffic increase steadily, however 2020 has overall seen a significant fall in traffic.

Comparison graph (users over time)



Human Tissue Authority Board meeting

Date: 11 February 2021

Paper reference: HTA 04/21

Agenda item: 8

Author: Louise Dineley
Director of Data, Technology and Development

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HTA Development Programme

Purpose of paper

1. The purpose of this paper is to provide the Board with an update on progress against the Development Programme and its deliverables at the end of quarter three.
2. The paper also offers a forward look at the proposed areas of focus and incremental development to the end of March 2022.

Decision making to date

3. The Board is asked to note the update and provide comment on the proposed development pathway to March 2022.

Background

4. For the last three years the HTA Strategy has been committed to strengthening the use of data and intelligence and developing our technology to support the delivery

of effective regulation. The last nine months have provided an opportunity to focus time and resource on a Development Programme that has been designed around six priority projects which support these strategic goals.

5. The priorities identified seek to build capacity and capability in core areas of the HTA operations. Notable progress has been made in IT capability and resilience through targeted investment.

Quarter Three 2020/21 update on the Programme

6. During quarter three, issues affecting Programme delivery have emerged as part of business planning and staff engagement. In particular:
 - Gaps in a common understanding of the vision for the programme and benefits to be realised.
 - Striking the appropriate balance of resource allocation between operations and development.
7. This has impacted the pace of progress across the Programme previously anticipated for quarter three. Plans to recover the momentum developed in the first two quarters of 2020/21 have been developed alongside a delivery plan for the next 15 months (up to 31 March 2022). These plans will be supported by a relaunch of the Programme including strengthened engagement internally and with external stakeholders.
8. *Strengthening the use of data and intelligence:* Following the commissioning of Transforming Systems in August 2020, progress continued in quarter three on the proof of concept exercise to identifying opportunities for better use of data and intelligence in the delivery of effective regulation. This project has continued to explore the development of a Data and Intelligence Strategy and the identification of a core data set based on existing data collection. The proof of concept testing is currently being evaluated to inform the next stage of development in our digital data capacity and capability.
9. *Developing the HTA Operating Model:* The early scoping of the Operating Model has confirmed the HTA's core functions and provided a high-level view on proposed improvement and additions to existing regulatory methods.

10. *Implementing an Electronic Document Record Management System (EDRMS)*: In November 2020, the Senior Management Team (SMT) agreed to pursue phase one (of four) of the adoption of SharePoint online as the future strategic solution for HTA records management. Good progress has been made to prepare the organisation for the migration of records from the HTA's current system (IMPACT).
11. *Optimising Office 365 functionality*: The adoption of Office 365 at the end of quarter four 2019/20 provided the HTA with a potential wealth of functionality. The added functionality of Teams as a collaboration and communication tool has been a significant factor in the successful transition to remote working in the last six months. Throughout 2020/21 there has been a soft roll out of the wider functionality available through Office 365. This roll out has been supported by the identification of champions across the business to promote and support the adoption of the functionality on offer.
12. *Horizon Scanning and future regulation*: The insight from horizon scanning has acted as a key driver of the Development Programme design to date and to the early thinking for the HTA Strategy 2021-24.
13. One issue arising from the horizon scanning activity has been HTA involvement in the passage of the Medicines and Medical Devices Bill. A result of this work has been the request from the Department of Health and Social Care that the HTA review its Code of Practice on Public Display. An oral update on this issue will be provided at the February meeting.
14. *Organisational Preparedness*: During quarter three there been a programme of work led by the HTA's Change Manager to develop the internal awareness and understanding of change across the leadership team and organisation more widely. This programme has included a number of targeted sessions each sponsored by a member of the SMT covering Leading Change; Levers for Change and Managing resistance to change.

Deliverables by 31 March 2021

15. Figure 1 (below) sets out expected deliverables by the end of quarter four 2020/21.

Figure 1: Expected deliverables by 31 March 2021

Priority Project	Expected Deliverable 31 March 2021	Project RAG Status
Strengthening the Use of data & Intelligence	Commissioned an external supplier to support the incremental development of the use of data and intelligence in the HTA's approach to regulation.	Current: Amber Forecast 31 March 21: Green
Developing the HTA Operating Model	A defined Target Operating Model informed by stakeholder engagement with identified improvement and Development. Realisation of model to feed Into 2021/22 planning and refresh of the 2021-24 strategy.	Current: Amber Forecast 31 March 21: Green
Developing the HTA Operating Model	A defined Target Operating Model informed by stakeholder engagement with identified opportunities for improvement and Development. Realisation of model to feed Into 2021/22 planning and the refresh of the 2021-24 strategy.	Current: Amber Forecast 31 March 21: Green
Implementing an Electronic Document Records Management System (EDRMS)	Delivery of phase one of a comprehensive content management system with all files migrated from IMPACT to SharePoint online. Document management controls supported by refreshed behaviours through training and development.	Current: Green Forecast 31 March 21: Green

HTA meeting papers are not policy documents.
 Draft policies may be subject to revision following the HTA Board meeting

Optimising Office 365 functionality	Organic growth and adoption of Office 365. Focus for Q4 is the increased adoption of collaborative tools and functionality to support and strengthen flexible working arrangements.	Current: Amber Forecast 31 March 21: Green
Horizon scanning & future regulation	Delivery of a Horizon scanning framework and up to date log that will inform and drive Changes in our policy.	Current: Amber Forecast 31 March 21: Green
Organisation Preparedness	Continue to develop change readiness.	Current: Amber Forecast 31 March 21: Green

Looking ahead to 2021/22

16. It is anticipated that the progress achieved in quarter four 2020/21 will provide the foundation to build on throughout 2021/22.
17. Strengthening our use of data and intelligence in assessing compliance and providing assurance and confidence to the public will be a core driver of development activities over the next 12 months. This will include developing the analytical capability of HTA staff.
18. The vision over the next 12 months for each of the six priority projects is outline in Figure 2.

Figure 2: Development Programme – Intended achievements by 31 March 2022

Priority Project	Intended achievement by 31 March 2022
Strengthening the HTA's use of data and intelligence	Realisation of a clear data and intelligence strategy that supports the HTA to make better use of the information and insight that is available through more targeted data collection and collation. In 2021/22 the development will focus on the incremental development and operational adoption of the Regulatory Insight Model & Index
Establishing an HTA Operating Model	A refreshed HTA Operating Model will reflect our new ways of operating from our greater use of data, alternative approaches to assessment and a wider regulator offer that seeks to strengthen the regulatory relationship with establishments and other regulators as well as offering an authoritative voice that contributes to the improvement and development of the life sciences sector across the UK. The initial focus will be on the emerging model of assessment and alternatives to site visit inspection, alternative licensing models based on learning in the last 12 months and a strengthened authoritative voice through proactive stakeholder engagement.
Horizon Scanning	A live framework that offers the continual and proactive review of opportunities and challenges that may impact future regulation by the HTA or operations in the licensed establishments. The framework will act as a key source in informing strategic reviews, proposed updates to legislation and the ongoing credibility and effectiveness of the HTA as a regulator

Electronic Content Management System	<p>The achievement of a comprehensive Electronic Content Management (ECM) system will represent the culmination of a phased programme of development for records and information management, the fulfilment of an IT strategy that aims to build our technical capabilities through a more focused and compatible infrastructure and a critical dependency and commitment to make better use of data, intelligence and information. The achievement of an ECMS is a commitment that extends beyond 31 March 2022. Over the next 12 months we will be seeking to build on the benefits of improved records management delivered through phase one and the adoption of an Electronic Document and Records Management System (EDRMS). Phase two will seek to develop the background infrastructure, process mapping information flows and identify opportunities to rationalise systems and better target information collection for further onward use such as reporting.</p>
Optimising our technology & digital functionality	<p>Over the last 12 months the HTA invested in its IT infrastructure and functionality with the adoption of Office 365 and migration of activities to the cloud. Optimising the functionality of the tools and services available has developed organically with increasing familiarity fuelling confidence and appetite for further technology and digital developments. Over the next year we will continue to develop and exploit existing functionality.</p>
Organisational Preparedness	<p>Organisational preparedness is a theme and a capacity that we will be seeking to develop across our projects, people and processes in 2021/22. The design and delivery of the development programme is incremental with the phased delivery of projects drawing together interdependencies, continuous learning and skills</p>

HTA meeting papers are not policy documents.
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developments that collectively will strengthen the HTA's capacity and capability for sustainable regulation in a changing environment.

Human Tissue Authority Board meeting

Date: 11 February 2021

Paper reference: HTA 05/21

Agenda item: 9

Author: Nicolette Harrison
Director of Regulation

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Virtual Regulatory Assessment

Purpose of paper

1. To provide the Board with an overview of Virtual Regulatory Assessments (VRAs).
2. To set out the HTA's future plans for VRAs.

Decision making to date

3. VRAs have been proposed as a component of a future operating model. In advance of this development work, VRAs were implemented to provide a remote form of proactive regulatory assessment in the absence of site visit inspections (SVIs).

4. Following the completion of the first pilot VRAs, a post-piloting evaluation has been reported to Senior Management Team (SMT) and recommendations agreed. Implementation plans for quarter four of 2020/21 into quarter one of 2021/22 have been agreed for each sector.

Action required

5. Board Members are invited to review this paper and provide their comments.

Background

6. Prior to the COVID-19 pandemic, the HTA's approach to proactive assessment across regulated sectors was heavily reliant on site-visit inspections (SVIs).
7. As a consequence of COVID-19, the HTA took the strategic decision to halt routine SVIs, initially to comply with government guidance on travel and social distancing, to reduce burdens on front line services and to protect HTA staff safety.
8. There were no existing regulatory tools to directly compensate for the lack of SVIs, leading to a reduction in HTA's proactive regulation of licensed establishments. Though difficult to quantify, there is a concern that this has the potential to allow risks to develop unchecked within establishments.
9. The pausing of SVIs drove an increasing need to fill the perceived regulatory gap. This was particularly relevant to the Human Application (HA) sector, both in terms of the underlying risks to patient safety and the statutory requirement for HTA to carry out a site visit inspection every two years. On this basis, the decision was made to develop and initiate remotely undertaken assessments in the HA sector, before being rolled-out more widely, in line with our strategic aims and the emerging concept of a future 'Target Operating Model'. Inevitably, early VRAs had a strong continuity with established inspection practices; however, there has been a strong emphasis on feedback and critical evaluation through the initial pilot phase, and a 'test and learn' approach.
10. In addition to filling a regulatory gap and generating methodologies for future application, the VRA development work is an opportunity to encourage a cultural shift within the HTA that ensures that the risk is focused in the right

place and is not diluted by, or shared with, us. There is an opportunity to shift the emphasis from a culture of feeling a responsibility for identifying all regulatory shortfalls, to focussing on the main risks and making clear that the responsibility for compliance sits with those who are licensed. VRAs assist with this by having a greater reliance on the provision of evidenced assurances rather than directly-observed compliance, at least for some standards.

11. Although current VRA approaches can be seen as a transactional response to a temporary pausing of SVIs, the intention has also been to develop an adaptive methodology that can continue into the future, even after the time when we feel we can resume site-based activities. This will supplement the suite of regulatory approaches developed through, and in collaboration with, the HTA's Development Programme.
12. The periodic tightening of national restrictions, alongside the increased pressures on businesses and public sector organisations, has created challenging operating conditions. As the COVID-19 legislation currently stands, daily activities are severely restricted until at least 31 March 2021. While VRAs may allow the HTA to undertake regulatory assessments during the remainder of the pandemic, we are obliged to keep under consideration the extent to which our assessments may place additional pressures on people and establishments; it is important that we remain risk-based, proportionate and in compliance with both the requirements and spirit of pandemic restrictions.
13. It should be noted that the pausing of SVIs did not mean that other regulatory activity stopped. A substantial amount of process development and operational work has taken place on VRAs involving almost all Regulation Managers. Following a risk-profiling exercise, 10 pilot VRAs were undertaken in our Human Application (HA) sector, adopting a 'test and learn' approach. Performance data and feedback was collected during the piloting, for real-time consideration and post-piloting evaluation. In parallel, advanced development of VRA processes and supporting documentation has taken place for other sectors. The teams responsible for non-HA sectors have been able to learn from the HA pilots and consider modified approaches. An additional benefit of the VRA development work is that it has generated thinking about the full range of assessment interactions open to the HTA, including what site-based assessments could involve in the future.

14. It is also worth noting that licensing activities did not stop when SVIs were paused. In quarter three, 14 new licence applications were received, which is much higher than the 2019/20 average of 5.75 applications per quarter. We have a thorough licence application assessment process, which includes provision for a visit, and provides an early assurance to us that the establishments we license have sound regulatory foundations. No licence application assessment visits have taken place this business year, meaning that licences have been assessed and approved using a virtual approach.

Key messages from the evaluation of the 10 pilot HA VRAs

15. Subject to further refinement and standardisation, **VRAs are a useful and essential addition** to the HTA's regulatory 'toolbox'. However, there is a widely-held and reasonable view that the optimal regulatory model for licensed establishments at least involves the option for us to undertake site-based interactions so that we improve our chances of making accurate, contextual assessments of the suitability of practices and premises.
16. While **VRAs cannot replace site-based assessments**, they have numerous advantages over SVIs. Importantly, VRAs represent a cost-effective process for undertaking regulatory assessments in a targeted manner, with a faster turnaround time. If replicated across sectors, this could facilitate more regular assessments.
17. Nine of ten VRAs identified shortfalls against our licensing standards. Regulation Managers (RMs) felt that the **VRAs successfully delivered on the expected assessment outcomes**. The RMs acknowledged that it was not possible to review or assess all HTA licensing standards by direct observation, having to rely on evidenced assurances in several areas. This points to the limitations of a purely remote approach; however, with regard to the areas targeted during these pilot VRAs, the RMs felt that follow-up SVIs were not required.
18. In terms of further considerations, **RMs felt that the interactive element of the VRA process was more intense than an SVI**, requiring greater levels of concentration. This may be because it is a new development, being carried out in a test-and-learn fashion, or it may represent an unfamiliar shift away from preferred ways of working. RMs certainly felt that they missed the richness of

face-to-face non-verbal communication, possibly missing 'cues' they would have picked by being in the same physical space as either establishment staff or their colleagues.

19. Partly due to there being no costs associated with travel, accommodation or subsistence, **VRAs could result in cost savings compared with SVIs**. The pilot VRAs also appeared to result in less allocated time for the RMs involved (approximately 1 day) although more time was spent in communication with the establishment and in the pre-VRA document review.
20. **Feedback from establishments has been overwhelmingly positive.** Establishments appear supportive of the VRA process, with no negative comments received. Both the RMs and the establishment staff reported that the VRA process was engaging and allowed for an open dialogue between the HTA and licensed establishments. While helpful during the VRA itself, this relationship-building has enduring benefits.
21. **VRA processes are flexible and future-proofed**, being adaptive to risk, business need and able to support different communication and data platforms.

Piloting VRAs in practice

22. Due to the remote nature of VRAs, it has been necessary for the RMs to approach the preparation in a different manner to that undertaken for SVIs.
 - During an SVI, it is possible to review the majority of HTA standards by reviewing activities and identifying issues through real-time fieldwork. For example, reviewing traceability logs may identify inconsistencies and errors with the log as adjacent pages/entries are reviewed.
 - During an SVI, non-compliances may be identified by observing establishment staff undertaking their role.
 - It is not feasible to undertake a high-level review of documentation during a VRA, nor to observe staff undertaking their day-to-day activities. Therefore, it is necessary for RMs to undertake a more in-depth review of documentation and processes in advance of the VRA in order to target specific activities and records during the VRA. This approach includes identifying incidents and establishment audits for review, and specific samples for traceability audits, in advance of the VRA. The RM can then

focus on matters that require further exploration and have the potential to lead to the identification of non-compliances.

23. Shortfalls were identified in nine out of the ten pilot VRAs. All ten VRAs resulted in advice being issued. Three advice items were issued as a result of the VRA where no shortfall was identified.
24. RMs reported that for all VRAs, a subsequent site visit inspection would not be required to further assess the areas covered.
25. Feedback was received from five (50%) of the 10 establishments. All respondents were positive and supportive of the VRA process. All feedback to date has been either good or excellent (based on the scale provided).
26. RMs have required significant establishment involvement when reviewing completed documentation remotely; for example, patient or processing records. Greater co-working has possibly led to establishments feeling more involved in the process of identifying and owning non-compliances and shortfalls. As a consequence, establishments may understand the nature of findings, and how they were identified, more clearly. There has been less challenge to findings, perhaps because establishment staff were more actively involved in identifying the issues. Although also seen in SVIs, several establishments have addressed shortfalls rapidly, before the end of the VRA in some cases.
27. Overall, the RMs felt the intended scope of the VRA was covered and expected areas of non-compliance were identified. However, due to the purely remote nature of the assessment, it was not possible to directly confirm compliance against some standards, notable within Premises, Facilities and Equipment (PFE). Importantly, with regard to the areas targeted during these pilot VRAs, the RMs felt that follow-up SVIs were not required.
28. The RMs found that more preparation time was needed to review documents for a VRA compared to a SVI. In addition, more preparation time was needed in order to select topics and target the review process. There was a recognition that, while looking at fewer things than on a SVI, advanced selection is underpinned by strong and careful evidence base rather than on opportunistic findings.
29. The interactive component of the VRA process was found to be more intensive:

- RMs needed sustained concentration (which may reflect the challenges of a new process, carried out under new conditions but also highlights the need to consider how VRAs are timetabled)
- There was limited time for reflection in order to process information (which also highlights the need to consider how VRAs are timetabled).
- The remote nature of the VRA means there is a lack of physical cues between participants, which can be informative in face-to-face interactions.
- The RMs found they needed to constantly drive the discussion according to the timetable and there was less opportunity to pick up on subtle clues or serendipitous findings and explore these areas of potential risk.

30. IT and connectivity issues were resolvable and have led to further proposals to bring about improvements.

Next steps and future plans

31. Following evaluation of the pilot VRAs, recommendations have been agreed with SMT and implementation plans for quarter four of 2020/21 into quarter one of 2021/22 have been agreed for each sector.
32. Change management support is being employed to inform HTA staff engagement and training on VRAs.
33. Internal audit expertise is being used to independently review the quality and effectiveness of our VRA development and implementation work.

Human Tissue Authority Board meeting

Date: 11 February 2021

Paper reference: HTA 06/21

Agenda item: 11

Author: Allan Marriott-Smith
CEO

OFFICIAL

Corporate Governance Audit Recommendations

Purpose of paper

1. To seek the Board's agreement to the action plan stemming from the recent internal audit of the HTA's corporate governance arrangements.

Decision making to date

2. The proposals have been worked up in discussion with each member of Senior Management Team and with the Chair and were discussed by the Audit and Risk Assurance Committee (ARAC) at its meeting on 28 January 2021.

Action required

3. The Board is asked to review the proposals, provide comments, and agree the proposed actions.

Background

4. Discussion between the Chair and Members, since her appointment in November 2019, have identified common themes of ensuring that the HTA's Board fulfils its governance and strategic role effectively and dedicating its time and expertise at an appropriate level of direction and oversight.
5. For some time, for well-known reasons, a good deal of Member time has been directed to living donation case work, and there is a sense that scrutiny, at whole Board level, can focus on a degree of granularity that takes time away from a more strategic consideration of issues.
6. There are a considerable number of strategic questions on which the Board will be required to provide direction and advice over the coming twelve months, including but not limited to:
 - a. the future tone, style, and content of HTA regulation – in light of limited site visits, the opportunities presented by cheaper technology and more accessible data analytics tools, the desire to contribute to making post-Brexit UK a scientific superpower.
 - b. the role that that HTA can and should play in the future of the health regulation system as a whole and the health and care system more widely.
7. This audit was commissioned to contribute towards the thinking about what might need to change in order to allow the Board to most effectively direct its attention to these strategic issues and develop its governance role to best contribute to the HTA's success over the coming three years.
8. As these strategic challenges imply change, and change will affect stakeholders, the terms of reference for the audit had a specific emphasis on the Board's arrangements for stakeholder engagement. The terms of reference for the audit are included as Annex A, and the audit report can be found as Annex B and the 'Good Governance Standard for Public Services' publication can be found at Annex C to this paper.

Response to recommendations

Board Effectiveness, Strategic Focus and Development

Recommendation	Response	Detailed proposal
4 HTA to develop a Board evaluation programme	Agree - Evaluation and development to take place against and established framework for public sector governance	<ul style="list-style-type: none">• Propose the Good Governance Standard for Public Services• Board ownership but ARAC to oversee the evaluation on behalf of the Board. Preliminary assurance mapping has taken place against this standard.
1 Non-Executive training to be rolled out to all members with a clear programme on induction and refresher training.	Agree - Non-executive training at HTA to be centred around the agreed good governance standard to establish the Board and Member role with respect to good governance.	<ul style="list-style-type: none">• Induction should also include HTA specific strategic priorities and operational insight to allow effective scrutiny/challenge• Induction into case work Should be sufficient to ensure compliance with statutory responsibility while ensuring correct focus on strategic Board role. In train for new Members
11 HTA to include a shop floor programme to ensure all Members of the Board have the opportunity to attend inspections and other HTA activities	Agreed	<ul style="list-style-type: none">• Induction to build in attendance at site visit inspection when this becomes possible again• Continuing programme of knowledge development for effective scrutiny/challenge - to include other regulatory processes (e.g. VRAs).

2 HTA to seek counsel on how much the Board can delegate to the Executive on case review process. Agreed

3 Development of a clear assurance process for Members on work of the Executive on case reviews Agreed

Effective Stakeholder Relationships

Recommendation Response

10 HTA to develop a Stakeholder Engagement Strategy and Map. Agreed

5 HTA Executive to submit a proposal to the Chair for the future arrangements for Advisory Groups. Agreed

Timing tbc

• Completed and reported at October Board Meeting

Changes have already been implemented.

• In progress

Formal review of new process scheduled for Nov 2021

Detailed proposal

• Stakeholder mapping currently in train

Due in Quarter four.

• Communications and Engagement Strategy is in development with a particular focus on relationship management, (we have employed a Communications specialist on contract to increase pace on this).

Due in Quarter four.

• Analysis of SWOT for the existing sub-groups - history, pros and cons
Develop short term (incl recommendation six below) and medium-term solutions (including Board numbers on committees).

• Assess apparent gaps and how these might be filled.

To be developed in conjunction with the Communications and Engagement Strategy (Recommendation 10).

6 Advisory Groups to be chaired by the Executive with Board member attendance	Agreed	From next round of meetings to be reinstated in early 2021
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7 Written summary for all Advisory meeting where possible presented at next Board meeting or issued at subsequent meeting	Agreed	• Agreed with meetings timed to best support this reporting requirement From next round of meetings to be reinstated in early 2021
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Risk management

Recommendation	Response	Detailed proposal
8 Reports to the Board on strategic risk to be condensed so only key changes are included	Agreed in principle	Risk management is a work in progress under separate work, and further development is planned during Quarter four

Board Support

Recommendation	Response	Detailed proposal
9 HTA to identify opportunities to strengthen the functions provided by the Secretariat and develop contingency arrangements for the role.	Agreed	Will be undertaken in Quarter four.



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Human Tissue Authority Corporate Governance including Committee Effectiveness

Final Terms of Reference

Introduction

The Board of the Human Tissue Authority (HTA) is made up of both lay and professional Members, whose primary role is to ensure that the HTA's statutory responsibilities are met and discharged effectively.

More specifically, the Chair and Board Members have the following governance responsibilities:

- setting the strategic direction of the HTA, encouraging and enabling the HTA to be a first-class regulator of human tissue;
- developing the HTA in-line with the organisation's strategic aims while maintaining a positive, constructive and appropriate relationship with its stakeholders to ensure confidence in the work of the HTA;
- provide an independent view, a substantive contribution, and constructive challenge at Board meetings and sub committees;
- monitor the performance of the HTA's Executive, holding it to account for the delivery of the HTA's business plan, HM Treasury and Department of Health and Social Care requirements

Effective stakeholder engagement is a key element of HTA's regulatory delivery to support the goals above. Formal groups, which report to the Board include:

- Stakeholder and Fees Group;
- Histopathology Working Group; and
- Transplantation Advisory Group

HTA also work with a number of other organisations and has bilateral agreements with the following:

- The Care Quality Commission;
- The Health Research Authority;
- The Human Fertilisation and Embryology Authority;
- The Medicines and Healthcare products Regulatory Agency; and
- The United Kingdom Accreditation Service.

Objective

The objective of this audit is to provide advice and guidance on the current structures and processes adopted by the Board of the HTA to fulfil its governance responsibilities.

The audit will have a specific focus on the adequacy of the HTA's arrangements for maintaining positive, constructive and appropriate relationships with institutional stakeholders and the public, including direct engagement between stakeholders and the Board, and the assurances it receives that stakeholder views are appropriately reflected in HTA decision making. The audit will identify where improvements can be made.

As this is an advisory review, we will not provide an audit opinion on the adequacy and effectiveness of key controls but highlight areas of best practice and suggest areas for improvement.

The HTA has a well-established governance structure for ensuring that the CEO fulfils his responsibilities as Accounting officer. This includes oversight by the Audit and Risk Assurance Committee. These governance arrangements which are subject to internal and external audit are not within scope.

Risks

The following key risks to HTA will form the structure of our approach within this advisory review in assessing key controls

and making any suggestions for improvement:

- Inadequate governance frameworks results in unclear accountabilities, ineffective decision making, lack of effective challenge to the Executive Team and inadequate response to risks and issues; and
- Ineffective engagement and communications with key stakeholders results in a failure to develop and embed effective stakeholder engagement and communication across HTA.

Scope and limitations

This audit will review:

- The roles and responsibilities of the Board, in particular their effectiveness in providing challenge and support to the Executive Team. We will also review the mechanisms for gaining assurance, information and insight on key issues, as well as wider stakeholder engagement arrangements (for example with the other stakeholder engagement groups);
- The Governance and communication arrangements of the stakeholder engagement groups, focusing on the Stakeholder and Fees Group and the Histopathology Working Group. In particular we will be reviewing how these groups interact with each other, the Board and the Executive Team, identifying any significant gaps;
- How HTA's governance and stakeholder engagement arrangements have been impacted by Covid-19, and how any changes are being managed; and
- How the Board and stakeholder groups are supported (from a logistics and administration point of view).

Exclusion from the scope:

We will not examine any areas that are not specifically outlined above.

Approach and deliverables

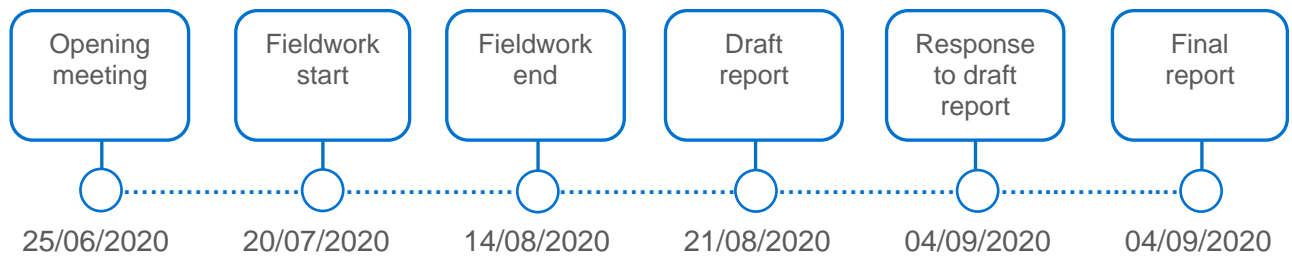
Approach

The audit fieldwork will be limited to document review and remote interviews with staff, Board Members, Committee Chairs and other key stakeholders.

Key deliverables

An audit report will be issued at the end of the fieldwork. Any significant issues uncovered as part of fieldwork will be raised immediately with the client.

Timings



Commitments and contacts

GIAA customer agreement

We commit to:

Complete all audits to published professional standards, which requires us to consider as appropriate the adequacy and effectiveness of governance, risk management and control, including propriety, regularity, and value for money.

Consult with management throughout the review.

Obtain feedback on our performance by issuing a Customer Service Questionnaire.

Follow-up of agreed audit actions and reporting on progress to the Audit and Risk Assurance Committee.

Handle data in accordance with relevant policies on data security and retention.

Our customer commits to:

Provide information and make staff available to enable the audit to be accomplished within the stated timescale.

Provide feedback on our performance by completing the Customer Service Questionnaire and returning it to the Head of Internal Audit.

Provide a management response to the draft audit report within 10 working days of its issue.

Provide periodic updates on the implementation of agreed actions after the audit completes.

Audit sponsor

Allan Marriott-Smith – Chief Executive

Lynne Berry – Chair

Audit team

Tony Stanley, Head of Internal Audit

Auditor

To be allocated

Distribution

Allan Marriott-Smith, Chief Executive Officer

Lynne Berry, Chair of the Human Tissue Authority

This document has been prepared for HTA and is only for its management and staff. It must consult with GIAA (pursuant to part 3 of the Secretary of State Code of Practice issued under section 45 of the FOI Act) before disclosing information within the reports to third parties. Any unauthorised disclosure, copying, distribution or other action taken in reliance of the information contained in this document is strictly prohibited. The report is not intended for any other audience or purpose and we do not accept or assume any direct or indirect liability or duty of care to any other person to whom this report is provided or shown, save where expressly agreed by our prior consent in writing.

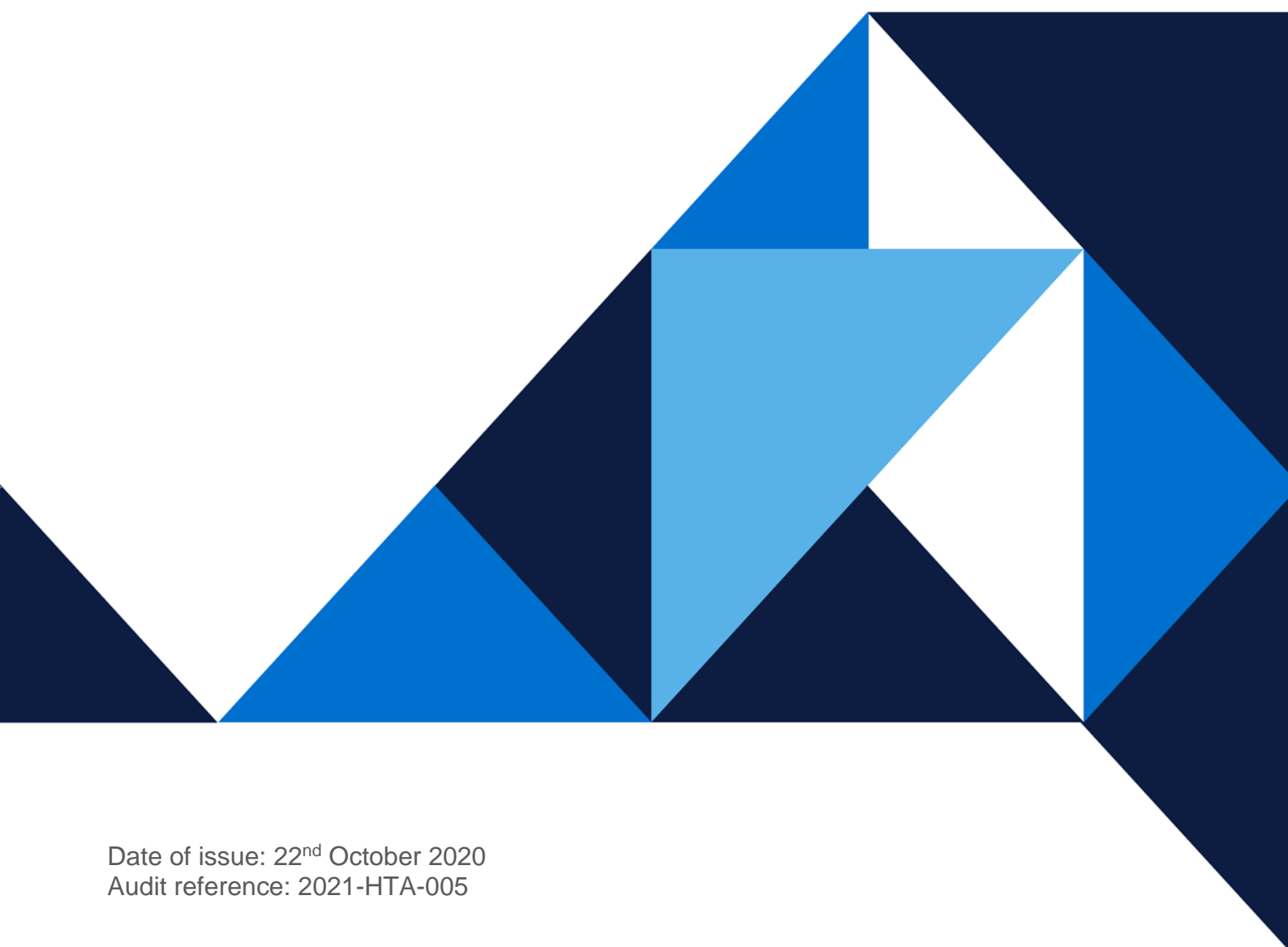


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HTA 06b/21

Human Tissue Authority Corporate Governance

Final Report



Date of issue: 22nd October 2020
Audit reference: 2021-HTA-005



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Executive summary

The Board of the Human Tissue Authority (HTA) is made up of both lay and professional Members, whose primary role is to ensure that HTA's statutory responsibilities are met and discharged effectively.

More specifically, the Chair and Board Members have the following governance responsibilities:

- Setting the strategic direction of the HTA, encouraging and enabling the HTA to be a first-class regulator of human tissue;
- Developing the HTA in-line with the organisation's strategic aims while maintaining a positive, constructive and appropriate relationship with its stakeholders to ensure confidence in the work of the HTA;
- Provide an independent view, a substantive contribution, and constructive challenge at Board meetings and sub committees;
- Monitor the performance of the HTA's Executive, holding it to account for the delivery of the HTA's business plan, HM Treasury and Department of Health and Social Care requirements.

Effective stakeholder engagement is a key element of HTA's regulatory delivery to support the goals above. Formal groups, which report to the Board include:

- Stakeholder and Fees Group;
- Histopathology Working Group; and
- Transplantation Advisory Group

This advisory review was undertaken at the request of management to provide advice and guidance on the current structures and processes adopted by the Board of the HTA to fulfil its governance responsibilities. As this is an advisory review, we have not provided a formal assurance rating and have not made formal recommendations for management comment and future follow up action.

As part of the fieldwork for this review, we interviewed a sample of members from the Board, ARAC, Advisory Groups, External Stakeholders and the Executive and Management. We reviewed documentation ranging from Board and Advisory Group papers, meeting notes, and the Terms of Reference for the groups.

Key findings

Positives:

Documentation: Roles and responsibilities of the Chair and Board members are documented within the framework agreement between DHSC and HTA. The roles and responsibilities of the Advisory Groups: Stakeholder & Fees (SFG) and the Histopathology Working Group (HWG) are clearly articulated within the Terms of Reference (ToR) for each group.

Board Turnover & Working Relationship with the Executive: HTA has a regular turnover of members, which ensure a refresh and introduction of new ways of thinking, experience and expertise but also maintains an effective transparent working relationship with the Executive Team.

Information to Board: We found the Board are in receipt of timely comprehensive information allowing members to review the information, inform discussion and decision making. There is an open and transparent relationship with members having access to the information they need and the Executive willing to provide any further information if required.

Response to COVID-19: The impact of Covid-19 did not result in a change in governance arrangements or decision-making process, but an increase in the formal and informal contact between the Executive and the

Board, to ensure members were fully informed on management plans and actions. This also allowed for quicker decision making due to the frequency of Board meeting.

Stakeholder Feedback: HTA has several methods of collecting feedback from its key stakeholders. The Annual Conference allows Board members seek feedback direct from stakeholders from across its regulatory spectrum. Post Conference feedback is collated by HTA and each inspection has a feedback element. HTA also commissions a feedback survey carried out by an external provider. In 2017 this focused on public engagement and this year it has focused on professional working at establishments licensed by HTA. This allows HTA to collect a vast wealth of intelligence on how its performing and where improvement can be made.

Areas for improvements

- **Role of the Board:** Through our review of Board papers, meeting minutes and interviews with both the Board and Executive we found a misbalance between time spent on the stewardship role of the Board in ensuring HTA meets its statutory obligations and that its operations meet the expected standards and the time spent setting the overall strategic direction of the organisation and overseeing the Executive delivery of the strategic objectives.
- **Review of Advisory Groups Effectiveness:** The Advisory Groups are predominantly to advise the Executive and may deepen Member knowledge to scrutinise, but Members chairing the Groups is potentially blurring the line between advisory to the Executive and scrutiny and setting of Executive direction. Furthermore, there is an opportunity to assess if the core principle of the Advisory Groups can be fulfilled via other means of engagement.
- **Information to Board Members:** Given the work of the ARAC in this area there is an opportunity to refine and distil the information presented to the Board in relation to the strategic risks. The Advisory Group Terms of Reference have provision on production of a written summary but this activity is not carried out. Through predominately oral updates to the Board there is a risk the work of the groups is not recognised to the extent it should and there is a lack of documentation audit trail to justify the impact of groups.
- **Development of Secretariat role:** Through our interviews, members are happy with the administrative support provided by the Secretariat. However, there is an opportunity to further enhance the performance of the role beyond the administrative support to the Board. There is scope to further strengthen the functions provided by the Secretariat and build the resilience of the role.
- **Stakeholder Engagement:** Currently HTA does not have a Stakeholder Engagement Strategy or Map. The communication team have the experience to identify and engage key stakeholders when needed for specific issue and projects, ensuring engagement is targeted to key stakeholders for the issue or project in question. There is an opportunity to change this activity from a reactive to a proactive process through developing a comprehensive Stakeholder Strategy that ensures a proportionate, consistent and proactive approach to its stakeholder engagement.

Findings

Assessed risk

Inadequate governance frameworks results in unclear accountabilities, ineffective decision making, lack of effective challenge to the Executive Team and inadequate response to risks and issues

Opinion on management of risk

N/A Advisory Review

Findings and implications

Roles & Responsibilities:

Documentation: There is clear documentation of the roles and responsibilities of the Chair and Board members within the framework agreement between DHSC and HTA. This sets out the expectation for the Board to act in accordance with the corporate governance code for central government departments. The roles and responsibilities of the Advisory Groups: Stakeholder & Fees (SFG) and the Histopathology Working Group (HWG) are clearly articulated within the Terms of Reference (ToR) for the group. ToR are subject to regular review.

The Board:

Role of the Board: Through our document review and interviews with colleagues from across the Board, Executive Team and external members of the advisory groups there was a clear understanding of the current ways of working. The Board and Executive have a good working relationship built on transparency and trust. Members have a vast array of expertise and experience in their professional fields allowing them to bring this to HTA. However legacy arrangements going back to the inception of HTA means members are part of the out of hours rota for HTA, due to an interpretation of the Human Tissue Act 2014. A panel made up of three Board members have been involved in assessing cases considered complex, i.e. where the donor and recipient are not related. In 19/20 the panel reviewed 381 cases out 1289 (29.5%). This has meant a weekly activity for Board members reviewing cases as part of their role.

Through our review of Board papers, meeting minutes and interviews with both the Board and Executive we found a misbalance between time spent on the stewardship role of the Board in ensuring HTA meets its statutory obligations and that its operations meet the expected standards and the time spent setting the overall strategic direction of the organisation and overseeing the Executive delivery of the strategic objectives. Board papers and discussion can be very detailed and due to members expertise and professional background and interest in the related fields. This has the advantage of allowing an informed discussion and scrutiny but does present the risk of the Board blurring the line between performance oversight and operational management. The current convergence of changes to its corporate governance arrangements such as the introduction of a new Chair to the Board, new Chair to the ARAC, new members to the Board, new ways of working and the upcoming transformational changes from the development Programme, present HTA with the idea opportunity to rebalance and focus the role of the Board. Allowing the Board to focus on its role at the strategic level, working with the Executive to set the direction of travel, support and act as a critical friend to the Executive on the delivery of the agreed strategy. This ensures effective use of the limited members time. **(Suggestion1-3)**

In line with good practice, Boards continually need to monitor and improve their performance. An objective and rigorous evaluation process, that uses input from both the Board, Executive and other stakeholders against the Board's overall responsibilities of performance and strategic oversight, can provide a valuable feedback mechanism for improving effectiveness, maximising strengths and highlighting areas for further development. **(Suggestion 4)**

Advisory Groups:

The Stakeholder & Fees Groups (SFG) was established as part of the recommendations from the McCracken Review, which recommended the establishment of a permanent fees review group to improve accountability

and facilitate dialogue with licence fee payers. The current SFG has a broader remit of considering regulatory issues across all sectors to inform the continued development of HTA regulation and fee-setting.

The purpose of the Histopathology Working Group (HWG) is to consider issues facing post-mortem sector establishments to inform the continued development of HTA policy affecting the sector and its overlap with the research sector.

The Advisory Groups provide HTA with a pathway to gain insight and communicate its thinking with stakeholders ensuring a flow of sector insight and feedback into HTA decision making processes. Through our interviews it was clear the Advisory Groups and annual conference were two key connection points that stakeholders appreciated. However, it is our opinion that HTA should carry out a review of the role of the advisory groups to assess if the groups are still meeting their intended aims. There is an opportunity to assess if the core objective of the SFG can be fulfilled by other means of consultation, that open up the representation and still give HTA the input it requires. However, a thorough review is required to ensure all benefits of having the advisory groups can be obtained via other means of engagement. **(Suggestion 5)**

The Advisory Groups are predominantly to advise the Executive and may deepen Member knowledge to scrutinise, but Members chairing the Groups is potentially blurring the line between advisory to the Executive and scrutiny and setting of Executive direction. Furthermore, chairing the group also adds an administrative burden to the members. The running of these groups could be managed by the Executive, with a formal brief presented to the Board. Member participation in the groups is valuable as it allows the Board to have access to insight from a wider range of stakeholders, hearing the issues discussed at the ground level helps inform members understanding and ultimately allows for the Board to make better informed decisions. **(Suggestion 6)**

Information to the Board

Board Papers: Through our document review and interviews we found comprehensive papers are prepared for the Board. The Chair is involved in the shaping of the content and format to ensure members have the information they need to make informed decisions. We found a clear production timeline which aims to issue papers 7 days before the meeting. Our interviewees felt this gave them sufficient time to review the papers. Furthermore, through the working relationships between the Board and the Executive members felt comfortable they could request further information if needed and the Executive would make this available. However due to the comprehensive nature of the papers, members felt well informed and able to fulfil their role.

Advisory Groups Reporting: The Chair of the Advisory Group gives an oral update to the Board on the Group's discussion. Where time allows a paper is presented to the Board. However, scheduling to reduce logistical costs mean advisory groups are planned around the Board meeting giving the Chair little time to prepare the written paper for the Board. The Advisory Group Terms of Reference have provision on production of a written summary but this activity is not carried out. Through predominately oral updates to the Board there is a risk the work of the groups is not recognised to the extent it should and there is a lack of documentation audit trail to justify the impact of groups. **(Suggestion 7)**

Risk reporting: Currently the Executive present a risk report to every ARAC meeting with a Chair providing an oral update the Board. The Executive will also present the strategic risk register covering the 6 strategic risks, cause and effects, mitigate action and types of controls and lines of defence. Given the work of the ARAC in this area there is an opportunity to refine and distil the information presented to the Board in relation to the strategic risks. Allowing the Board to have a clear view on the key risks where there has been change and the key underlying contributors to that change, and where their consideration is required. This also ensures the work of the ARAC is not duplicated in the Board meeting. **(Suggestion 8)**

Secretariat role: HTA has experienced some disruptive transition to the Secretariat role. The organisation went through a period with a vacancy at the Secretariat role. To ensure a continuation of the Secretariat activities several individuals covered elements of the job profile, which meant when the current holder was recruited there was a lack of a full and comprehensive handover. However, through our interviews it was clear members are content with the administrative support to the Board, the current holder has brought stability and consistency to this. However, there is an opportunity to further strengthen the functions provided by the Secretariat and build resilience of the role. **(Suggestion 9).**

Covid-19 Impact on decision making Process: The impact of Covid-19 wasn't a change in governance arrangements but instead in increase in formal and informal contact between the Executive and the Board. From our interviews and document review we found an appreciation from the Board on the Executive reaction to the pandemic. Initially regular meeting allowed the Board to be kept fully informed on the impacts of the virus on HTA business, the proposed arrangements the Executive was putting in place and where necessary quicker

decision making by the Board due to the frequency of meetings. Board meetings have now returned to the quarterly arrangements.

Suggestions

Rebalancing Board Focus:

To reset the role of the Board and ensure there is a clear demarcation between the roles of the Board and Executive, it would be beneficial to provide all members with Non-Executive refresher training. Furthermore, to ensure the Board can step away from operational tasks such as the case reviews, whilst being assured it is still fulfilling its legislative duty it would be prudent to get counsel advice on the level of delegation permissible. Lastly, a mechanism to provide members with assurance over the quality of work being carried out by the Executive in case reviews would help support the Board's delegation of the activity to the Executive.

Suggestions

1. Non-Executive refresher training to be rolled out to all members timed to coincide with the recruitment of new Board members
2. HTA to review and agree how much the Board can delegate to the Executive on case review process
3. Development of a clear assurance process for members on work of the Executive on case reviews.

Effectiveness of the Board and Advisory Groups:

In line with good practice, Boards continually need to monitor and improve their performance. An objective and rigorous evaluation process, that uses input from both the Board, Executive and other stakeholders against the Board's overall responsibilities of performance and strategic oversight, can provide a valuable feedback mechanism for improving effectiveness, maximising strengths and highlighting areas for further development.

There is an opportunity to assess if the core objectives of advisory groups could be fulfilled in other means of consultation that open up the representation and still give HTA the input it requires. However, a thorough review is required to ensure all benefits of having the advisory groups can be obtained via other means of engagement. If the outcome of the review is to keep the Advisory groups, then consideration should be given to changing the group governance and reporting. In line with rebalancing members focus and ensuring the most effective use of members time, consideration should be given to moving the role of the Chair to the Executive. Lastly, the submission of a written summary to the Board would help ensure the organisation maintains a clear view on the impact and effectiveness of the groups.

Suggestions:

4. HTA to develop a Board evaluation programme.
5. HTA Executive to submit a proposal to the Chair for the future arrangements for Advisory Groups
6. Advisory Groups to be chaired by the Executive with Board member attendance.
7. Written summary for all Advisory meeting where possible presented at next Board meeting or issued at subsequent meeting

Information to the Board:

As part of work to ensure the most effective use of members, there is an opportunity to refine and distil the information presented to the Board in relation to the strategic risks. Allowing the Board to have a clear view on the key risks where there has been change and the key underlying contributors to that change, and where their consideration is required. Whilst ensuring the work of the ARAC is not duplicated in the Board meeting:

Suggestion:

8. Reports to the Board on strategic risk to be condensed so only key changes are included.

Development of Secretariat Role:

The Secretariat role plays a key part in helping the board balance its role of performance oversight and strategic planning. There is an opportunity to develop the Secretariat role within HTA beyond administrative support to the Board through targeted training and networking with other regulators. Lastly, given that Advisory Groups have Secretariats, it would be useful to set up reciprocal arrangements to provide cover and learn from each other's role. Allowing HTA to build a contingency arrangement for the Secretariat role.

Suggestions:

9. HTA to identify opportunities to strengthen the functions provided by the Secretariat and develop contingency arrangements for the role.

Assessed risk

Ineffective engagement and communications with key stakeholders' results in a failure to develop and embed effective stakeholder engagement and communication across HTA.

Opinion on management of risk

N/A Advisory Review

Findings and implications

Stakeholder Feedback: HTA has several methods of collecting feedback from its key stakeholders. The Annual Conference allows Board members seek feedback direct from stakeholders from across its regulatory spectrum. Post Conference feedback is collated by HTA and each inspection has a feedback element. HTA also commissions a feedback survey carried out by an external provider. In 2017 this focused on public engagement and this year it has focused on professional working at establishments licenced by HTA. Allowing HTA to collect a vast wealth of intelligence on how its performing and where improvement can be made.

Stakeholder Engagement: Through the Board membership and Advisory Groups membership, HTA is able to exploit the secondary connections of its Board and advisory group members from their professional engagements, giving HTA a long reach to gather intelligence and insight from key stakeholders across the sectors it regulates. The Communication Team have the experience to identify and engage key stakeholders when needed for specific issue and projects, ensuring engagement is targeted to key stakeholders for the issue or project in question. There is an opportunity to change this activity from a reactive to a proactive process that ensure a consistent approach to stakeholder engagement for both its project work but also its business as usual activities. A comprehensive Stakeholder Strategy which includes a Stakeholder map covering the areas of HTA business and its strategic ambitions, would allow HTA to have a clear understanding where power and interest sits with its stakeholders, which stakeholders are key to HTA strategic ambitions etc. Ensuring HTA has a proportionate, consistent and proactive approach to its stakeholder engagement. We must note the Head of Communications is aware of the need for a Stakeholder Strategy and Map. **(Suggestion 10)**

Shop Floor Programme: Through our interviews it was clear members believe in the benefits a 'back to the shop floor' programme. Some members have been involved in inspections, which has provided members with the opportunity to see first hand the inspection process and engage with establishments under inspections. Currently, members have to request through the Executive the opportunity to join in on the visits. It would be prudent to develop a formal programme embedded in the induction process to afford all members the opportunity to be involved inspections. The inspections, participations in the Advisory Groups and Annual Conference should provide members with insight, awareness and assurance to ensure members can effectively fulfil their role of supporting the Executive setting strategic direction and performance oversight. **(Suggestion 11)**

Suggestions

Stakeholder Engagement:

Currently stakeholder engagement is a reactive activity. A comprehensive Stakeholder Strategy which includes a Stakeholder map covering the areas of HTA business and its strategic ambitions, would allow HTA to have a clear understanding where power and interest sits with its stakeholders, which stakeholders are key to HTA strategic ambitions etc. Ensuring HTA has a proportionate, consistent and proactive approach to its stakeholder engagement

Suggestions:

10. HTA to evaluate the benefits of a Stakeholder Engagement Strategy and Map as part of its overall Communications Strategy.
11. HTA to include a shop floor programme to ensure all members of the Board have the opportunity to attend inspections when this is possible again and other HTA activities.

Annex 1: Management action plan

Suggestion

-
- 1 Non-Executive training to be rolled out to all members with a clear programme on induction and refresher training.

 - 2 HTA to seek counsel on how much the Board can delegate to the Executive on case review process

 - 3 Development of a clear assurance process for members on work of the Executive on case reviews.

 - 4 HTA to develop a Board evaluation programme.

 - 5 HTA Executive to submit a proposal to the Chair for the future arrangements for Advisory Groups

 - 6 Advisory Groups to be chaired by the Executive with Board member attendance.

 - 7 Written summary for all Advisory meeting where possible presented at next Board meeting or issued at subsequent meeting

 - 8 Reports to the Board on strategic risk to be condensed so only key changes are included.

 - 9 HTA to identify opportunities to strengthen the functions provided by the Secretariat and develop contingency arrangements for the role.
-

Suggestion

- 10 HTA to develop a Stakeholder Engagement Strategy and Map

- 11 HTA to include a shop floor programme to ensure all members of the board have the opportunity to attend inspections and other HTA activities

Annex 2: Objective, scope and limitations

Objectives

The objective of this audit is to provide advice and guidance on the current structures and processes adopted by the Board of the HTA to fulfil its governance responsibilities.

The audit will have a specific focus on the adequacy of the HTA's arrangements for maintaining positive, constructive and appropriate relationships with institutional stakeholders and the public, including direct engagement between stakeholders and the Board, and the assurances it receives that stakeholder views are appropriately reflected in HTA decision making. The audit will identify where improvements can be made.

As this is an advisory review, we will not provide an audit opinion on the adequacy and effectiveness of key controls but highlight areas of best practice and suggest areas for improvement.

The HTA has a well-established governance structure for ensuring that the CEO fulfils his responsibilities as Accounting officer. This includes oversight by the Audit and Risk Assurance Committee. These governance arrangements which are subject to internal and external audit are not within scope.

Scope and limitations

This audit will review:

- The roles and responsibilities of the Board, in particular their effectiveness in providing challenge and support to the Executive Team. We will also review the mechanisms for gaining assurance, information and insight on key issues, as well as wider stakeholder engagement arrangements (for example with the other stakeholder engagement groups);
- The Governance and communication arrangements of the stakeholder engagement groups, focusing on the Stakeholder and Fees Group and the Histopathology Working Group. In particular we will be reviewing how these groups interact with each other, the Board and the Executive Team, identifying any significant gaps;
- How HTA's governance and stakeholder engagement arrangements have been impacted by Covid-19, and how any changes are being managed; and
- How the Board and stakeholder groups are supported (from a logistics and administration point of view).

Exclusion from the scope:

We will not examine any areas that are not specifically outlined above.

Distribution:

Allan Marriott-Smith

Chief Executive Officer

Lynne Berry

Chair of the Human Tissue Authority



The Good Governance Standard for Public Services

**The Independent Commission
on Good Governance
in Public Services**

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Membership of the Commission

Chair of the Commission

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Lord Richard Best, Director, Joseph Rowntree Foundation

Sir Ian Blair, Deputy Commissioner, Metropolitan Police Service

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Ms Lucy de Groot, Executive Director, Improvement and Development Agency

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Mr Bob Kerslake, Chief Executive, Sheffield County Council

Mr Ed Mayo, Chief Executive, National Consumer Council

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Foreword

By 2005/6, public expenditure in the UK will exceed £500 billion¹. How this money is spent and the quality of services it provides is critically important to us all as users of services and as taxpayers. Because of this we all need governance of our public services to be of a high standard. Good governance leads to good management, good performance, good stewardship of public money, good public engagement and, ultimately, good outcomes².

The governors of our public service organisations face a difficult task. They are the people responsible for governance – the leadership, direction and control of the organisations they serve. Their responsibility is to ensure that they address the purpose and objectives of these organisations and that they work in the public interest. They have to bring about positive outcomes for the people who use the services, as well as providing good value for the taxpayers who fund these services. They have to balance the public interest with their accountability to government and an increasingly complex regulatory environment, and motivate front-line staff by making sure that good executive leadership is in place. Governors shoulder a heavy responsibility in relation to health, education, housing, criminal justice and many other aspects of public service.

More than 450,000 people³ contribute as governors to a wide range of public service organisations and partnerships. There is clear evidence that many have difficulties in fulfilling these responsibilities⁴. To help them with their tasks, there is an urgent and ongoing need to be clear about the purpose of governance and the role of the governor, expand the supply of governors, improve induction programmes and encourage good relationships between governors and the executive teams who are accountable to them.

It is perhaps surprising that there is no common code for public service governance to provide guidance across the complex and diverse world of public services, which are provided by the public sector and a range of other agencies. The *Good Governance Standard for Public Services* addresses this issue head on. It builds on the Nolan principles⁵ for the conduct of individuals in public life, by setting out six core principles of good governance for public service organisations. It shows how these should be applied if organisations are to live up to the Standard and provides a basis for the public to challenge sub-standard governance. I hope that the publication of the Standard will encourage public bodies to review their own effectiveness, and that it will provide commissioners and regulators of public services with a common framework for assessing good governance practice.

It has been a privilege to take part in this work and my personal thanks go to the members of the Commission, the Commission secretaries and the head of research, who simply want to help governors do a difficult job better. I also gratefully acknowledge the support provided by the Joseph Rowntree Foundation and the commitment of CIPFA (Chartered Institute of Public Finance and Accountancy) and OPM[®] (Office for Public Management).

Sir Alan Langlands
Chair of the Commission
January 2005

About the Commission

The Independent Commission on Good Governance in Public Services was established by the Office for Public Management (OPM[®]) and the Chartered Institute of Public Finance and Accountancy (CIPFA), in partnership with the Joseph Rowntree Foundation. The role of the Commission was to develop a common code and set of principles for good governance across public services.

The Commission began work early in 2004. The first stage was to consult a wide range of stakeholders, through face-to-face discussions and meetings around the UK and a process of inviting written contributions from all types of public service organisations. This consultation focused on the potential value of a common code or set of principles for governing all public services, and sought views on what the code should include.

Following this consultation, the Commission produced a draft of the *Good Governance Standard for Public Services*. The draft was the subject of a second round of consultation in the autumn of 2004. This included meetings with service users and citizens, to explore the potential value of the Standard from their point of view. The Standard was then amended to reflect the views expressed in the consultation.

Further information about the work of the Commission and the responses to both rounds of consultation are available at www.opm.co.uk/ICGGPS.

-
- 1 *Spending Review 2004*, HM Treasury
 - 2 For example, standards of corporate governance have a central place in the Audit Commission's comprehensive performance assessment of the quality of services provided by local authorities
 - 3 Estimated number of members of governing bodies of public services in the UK
 - 4 For example *Rubber Stamped?*, OPM, 2003
 - 5 Committee on Standards in Public Life, 1995

Using the Standard

The purpose of the Standard

We intend the *Good Governance Standard for Public Services* as a guide to help everyone concerned with the governance of public services not only to understand and apply common principles of good governance, but also to assess the strengths and weaknesses of current governance practice and improve it. We hope that the Standard will be useful to governors who are striving to do a difficult job better, and to individuals and groups who have an interest in scrutinising the effectiveness of governance.

The Standard focuses on the ways different functions of governance can support each other. Governance is dynamic: good governance encourages the public trust and participation that enables services to improve; bad governance fosters the low morale and adversarial relationships that lead to poor performance or even, ultimately, to dysfunctional organisations.

Scope of the Standard

The *Good Governance Standard for Public Services* is intended for use by all organisations and partnerships that work for the public, using public money. Most of these are public sector organisations whose services are used directly by members of the public or who are responsible for less visible activities, such as regulation and policy development.

However, the use of public money to provide public services is not limited to the public sector. The public also has an interest in the governance of non-public sector organisations that spend public money, and the Standard is designed to help them too.

Relationship with other codes and guidance

While the Standard has a wide scope, it does not seek to duplicate the codes and guidance that already exist for some specific types of organisation. We hope that those who develop and set these codes will refer to the Standard in updating and reviewing their own codes, and use it to enhance the debate about governance within and between different sectors. Where codes and guidance do not already exist, as in many formal and informal partnerships, we hope that the Standard will provide a shared understanding of what constitutes good governance.

Applying the Standard to different governance structures and sizes of organisation

The principles form a universal Standard of good governance and we encourage all organisations to show that they are putting it into practice in a way that reflects their structure and is proportionate to their size. We recognise that not all parts of the Standard will appear to be directly applicable to all types and size of organisation.

The many types of organisations to which the Standard applies – central government and local service providers, and public sector and independent organisations – have a wide range of governance structures; for example, some governing bodies will be elected and some appointed. Organisations also vary enormously in size and complexity, from, for example, a small school to a large hospital trust.

We call on governing bodies to report publicly on the extent to which they live up to the Standard, and explain why and how they have adapted any of the principles and their applications to suit their type and size of organisation. In doing so, we ask organisations to demonstrate the spirit and ethos of good governance, which the Standard aims to capture and which cannot be achieved by rules and procedures alone.

Putting the Standard into practice

The Standard comprises six core principles of good governance, each with its supporting principles. The 'Application' box next to each supporting principle explains what should be done to put it into practice. At the end of each section, good practice examples illustrate ways of putting the principles into practice.

Appendix A comprises questions that governing bodies should ask themselves to test how far they live up to the Standard, and to develop action plans for making any necessary improvements.

Appendix B comprises questions for members of the public or their representatives to ask if they want to understand or challenge the governance of public service organisations. We also suggest that organisations ask themselves these questions to test their own openness and accountability to the public. The questions could be used as a basis for 'frequently asked questions' (FAQs) on public websites.

Terminology

In order to be applicable to different kinds of organisation, the Standard uses some general terms, with the following definitions:

- ◆ **Governing body:** the body with overall responsibility for directing and controlling an organisation. For example, the police authority; the governors of a school; the board of a housing association, an NHS trust or a non-departmental public body; the council in local government
- ◆ **Governor:** member of the governing body, whether elected or appointed. For example, member of a police authority, school governor, board member of a housing association or non-departmental public body, executive or non-executive director of an NHS trust, elected member or councillor of a local authority
- ◆ **Non-executive:** governors without executive responsibilities (non-executive directors are sometimes referred to as independent directors)
- ◆ **Executive:** the senior staff of the organisation. Some types of boards include executive directors as governors.

The term 'executive' has a different meaning in local government in England and Wales, where the executive comprises elected representatives. There are three possible structures for the 'executive': a council leader, elected by the full council, who appoints councillors to a cabinet; a directly elected mayor who appoints councillors to a cabinet; a directly elected mayor and a council manager, who is an officer. In NHS foundation trusts, the 'governing body' is the board of directors while the group known as governors form a separate body.

We hope that the Standard will help all those with an interest in public governance to assess good governance practice.

Sir Alan Langlands

Mr Bob Kerslake

Lord Richard Best

Mr Ed Mayo

Sir Ian Blair

Dr Greg Parston

Mr Jim Coulter

Ms Bharti Patel

Ms Lucy de Groot

The Honourable Barbara Thomas

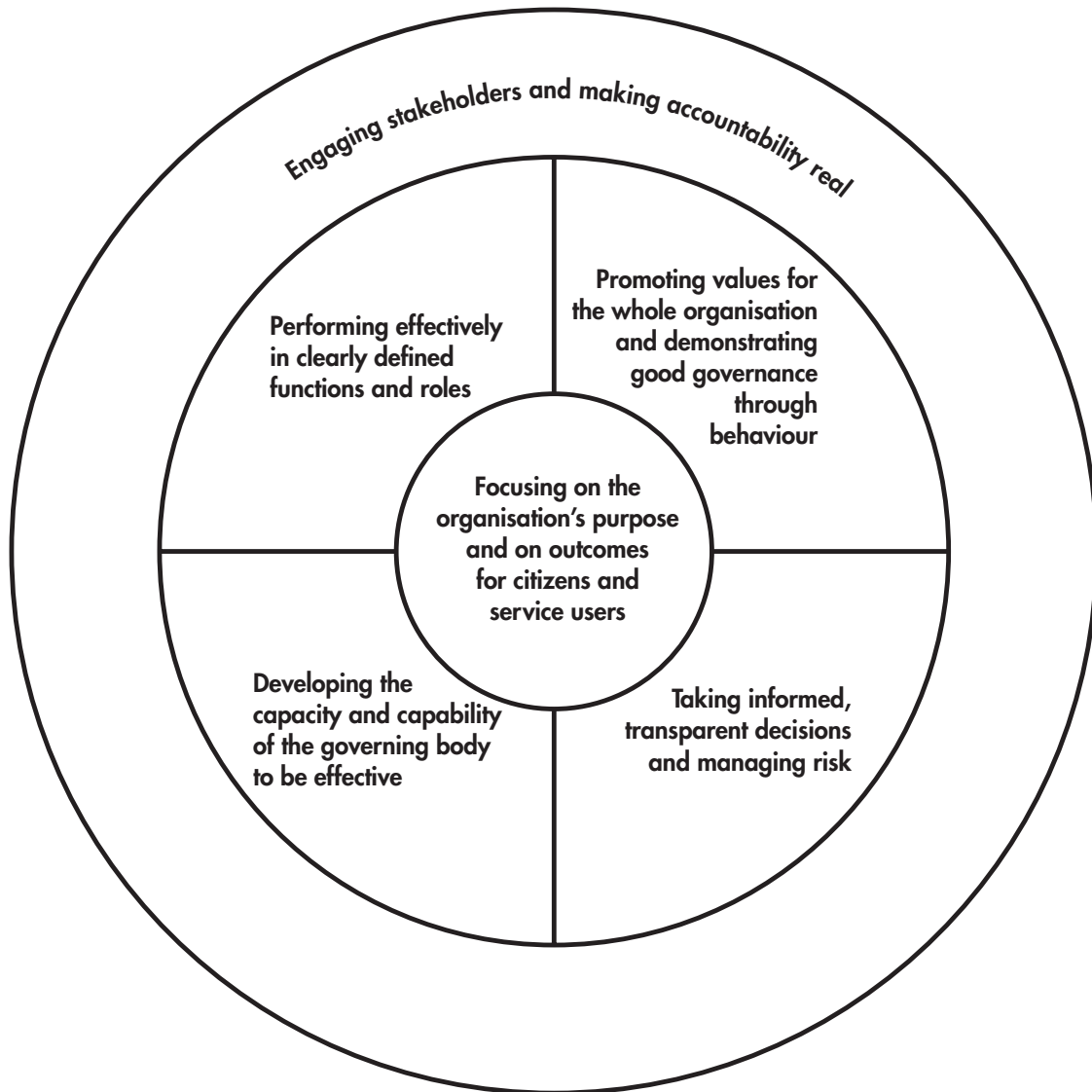
Ms Liz Kerry

Ms Jo Williams CBE

Members of the Independent Commission on Good Governance in Public Services
January 2005

Principles of good governance

The standard comprises six core principles of good governance, each with its supporting principles.



1. Good governance means focusing on the organisation's purpose and on outcomes for citizens and service users

- 1.1 Being clear about the organisation's purpose and its intended outcomes for citizens and service users
- 1.2 Making sure that users receive a high quality service
- 1.3 Making sure that taxpayers receive value for money

2. Good governance means performing effectively in clearly defined functions and roles

- 2.1 Being clear about the functions of the governing body
- 2.2 Being clear about the responsibilities of non-executives and the executive, and making sure that those responsibilities are carried out
- 2.3 Being clear about relationships between governors and the public

3. Good governance means promoting values for the whole organisation and demonstrating the values of good governance through behaviour

- 3.1 Putting organisational values into practice
- 3.2 Individual governors behaving in ways that uphold and exemplify effective governance

4. Good governance means taking informed, transparent decisions and managing risk

- 4.1 Being rigorous and transparent about how decisions are taken
- 4.2 Having and using good quality information, advice and support
- 4.3 Making sure that an effective risk management system is in operation

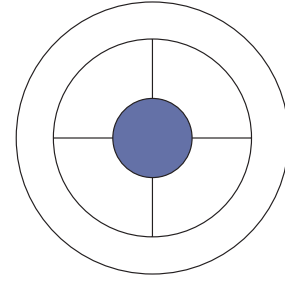
5. Good governance means developing the capacity and capability of the governing body to be effective

- 5.1 Making sure that appointed and elected governors have the skills, knowledge and experience they need to perform well
- 5.2 Developing the capability of people with governance responsibilities and evaluating their performance, as individuals and as a group
- 5.3 Striking a balance, in the membership of the governing body, between continuity and renewal

6. Good governance means engaging stakeholders and making accountability real

- 6.1 Understanding formal and informal accountability relationships
- 6.2 Taking an active and planned approach to dialogue with and accountability to the public
- 6.3 Taking an active and planned approach to responsibility to staff
- 6.4 Engaging effectively with institutional stakeholders

1. Good governance means focusing on the organisation's purpose and on outcomes for citizens and service users



The function of governance is to ensure that an organisation or partnership⁶ fulfils its overall purpose, achieves its intended outcomes for citizens and service users, and operates in an effective, efficient and ethical manner⁷. This principle should guide all governance activity.

Each organisation has its own purpose. There are also some general purposes that are fundamental to all public governance, including providing good quality services and achieving value for money.

The concept of 'public value' can be helpful when thinking about the unique purpose of public services and therefore of their governance. Public value refers to the things that public services produce, either directly or indirectly, using public money. Public value includes: outcomes (such as improved health and improved safety); services (such as primary care services and policing); and trust in public governance.

1.1 Being clear about the organisation's purpose and its intended outcomes for citizens and service users

Having a clear organisational purpose and set of objectives is a hallmark of good governance. If this purpose is communicated effectively, it can guide people's actions and decisions at all levels in an organisation.

For many organisations, others (in particular, central government⁸) play a major role in determining policy and resources and in setting or agreeing objectives. In these circumstances, it is critically important that there is a common view of the organisation's purposes and its intended outcomes.

Application

The governing body should make sure that there is a clear statement of the organisation's purpose and that it uses this as a basis for its planning. It should constantly review the decisions it takes, making sure that they further the organisation's purpose and contribute to the intended outcomes for citizens and users of services.

6 Throughout the document, 'organisation' should be read to include 'partnership'.

7 For example, a school's purpose might be to educate children; its intended outcomes might include improved literacy and numeracy of children by the age of 11.

8 Often described as a 'dominant stakeholder' role.

1.2 Making sure that users receive a high quality service

All public service organisations provide a service to other people and/or organisations, although not all provide services directly to members of the public. The quality of service is an important measure of how effective an organisation is, and so it is particularly important in governance.

Users of public services, unlike consumers in the private sector, usually have little or no option to go elsewhere for services or to withdraw payment⁹. Providers of public services have fewer direct financial incentives than private companies to improve consumer satisfaction. Organisations that provide public services therefore need to take additional steps to ensure that services are of a high quality.

Application

The governing body should decide how the quality of service for users is to be measured and make sure that it has the information it needs to review service quality effectively and regularly.

As part of this, it should ensure that it has processes in place to hear the views of users and non-users from all backgrounds and communities about their needs, and the views of service users from all backgrounds about the suitability and quality of services. The governing body should use this information when making decisions about service planning and improvement.

1.3 Making sure that taxpayers receive value for money

All organisations that spend public money, either in commissioning services or providing them directly, have a duty to strive for economy, efficiency and effectiveness in their work. Citizens and taxpayers have an important and legitimate interest in the value for money provided by organisations that use public money.

Application

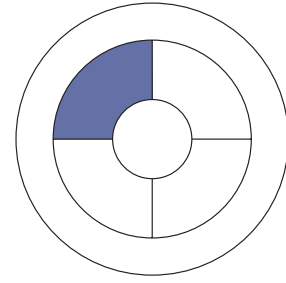
The governing body should decide how value for money is measured and make sure that it has the information it needs to review value for money effectively, including information about similar organisations, for comparison. It should use this information when planning and reviewing the work of the organisation.

Good practice examples: focusing on the organisation's purpose and on outcomes for citizens and service users

- Compare information about the efficiency, effectiveness and quality of service provided by similar organisations; analyse why levels of efficiency, effectiveness and quality are different elsewhere.
- Give non-executive directors a specific responsibility to ensure that information about users' experiences is collected, brought to the attention of the governing body and used in its decision making.

⁹ Government policy is to increase choice in public services; nevertheless, consumer choice is either not available or limited in most areas of public services.

2. Good governance means performing effectively in clearly defined functions and roles



Good governance requires all concerned to be clear about the functions of governance and their own roles and responsibilities and those of others, and to behave in ways that are consistent with those roles. Being clear about one's own role, and how it relates to that of others, increases the chance of performing the role well. Clarity about roles also helps all stakeholders to understand how the governance system works and who is accountable for what.

2.1 Being clear about the functions of the governing body

Members of governing bodies are elected or appointed to *direct and control public service organisations in the public interest*¹⁰.

The primary functions of the governing body are to:

- ◆ establish the organisation's strategic direction and aims, in conjunction with the executive
- ◆ ensure accountability to the public for the organisation's performance
- ◆ assure that the organisation is managed with probity and integrity.

In order to direct strategy and ensure that this is implemented and that the organisation achieves its goals, the governing body has to:

- ◆ allocate resources and monitor organisational and executive performance¹¹
- ◆ delegate to management
- ◆ oversee the appointment and contractual arrangements for senior executives, and make sure that effective management arrangements are in place
- ◆ understand and manage risk.

Ways of achieving these primary functions include:

- ◆ constructively challenging and scrutinising the executive
- ◆ ensuring that the voice of the public is heard in decision making
- ◆ forging strategic partnerships with other organisations.

10 Governors of charities (trustees) have an overriding duty to act in the interests of their charity and its beneficiaries, who are defined as part of its registration as a charity. Industrial and provident societies (mutuals) may be either for the mutual benefit of their members or of the community, depending on their form of registration.

11 Throughout, the term 'executive' is used to refer to the senior members of the organisation's paid staff.

Some of these functions are the particular responsibility of non-executive directors, where the governing body comprises both non-executive and executive members (see 2.2).

Application

The governing body should set out clearly, in a public document, its approach to performing each of the functions of governance. This should include a process, agreed with the executive, for holding the executive to account for achieving agreed objectives and implementing strategy. The governors should explain how and why their approach to each function is appropriate for the size and complexity of the organisation.

2.2 Being clear about the responsibilities of non-executives and the executive, and making sure that those responsibilities are carried out

Different public services have different types of governing body. In some cases, executive directors are members of the governing body; in other cases the governing body is made up entirely of non-executives. For example, NHS trusts have 'unified boards' that usually comprise five executive directors, five non-executive directors and the non-executive chair. In contrast, police authorities and some national public bodies have a 'supervisory body' made up entirely of non-executives. Government departments and non-departmental public bodies have accounting officers (usually the permanent secretary of a government department and the chief executive of an NDPB) who have personal responsibility to Parliament for the use of public funds.

In all cases, the governors take collective responsibility for the governing body's decisions. In both unified and supervisory arrangements, non-executives have specific responsibilities in relation to the executive.

Non-executive

The non-executive role is to:

- ◆ contribute to strategy: non-executives bring a range of perspectives to strategy development and decision making
- ◆ make sure that effective management arrangements and an effective team are in place at the top level of the organisation
- ◆ delegate: non-executives help to clarify which decisions are reserved for the governing body, and then clearly delegate the rest
- ◆ hold the executive to account: the governing body delegates responsibilities to the executive. Non-executives have a vital role in holding the executive to account for its performance in fulfilling those responsibilities, including through purposeful challenge and scrutiny
- ◆ be extremely discriminating about getting involved in matters of operational detail for which responsibility is delegated to the executive.

Chair and chief executive (or lead executive)

The chair and chief executive share in the leadership role. The chair's role is to lead the governing body, ensuring it makes an effective contribution to the governance of

the organisation; and the chief executive's is to lead the organisation in implementing strategy and managing the delivery of services. A good working relationship between the two can make a significant contribution to effective governance.

The deputy chair's role includes supporting the chair in his or her role, and, on occasion, informing the chair of any concerns that governors have about the conduct of the governing body.

Application

The governing body should clarify that all its members have collective responsibility for its decisions and have equal status in discussions. The chair and other governors should challenge individual governors if they do not respect constructive challenge by others or if they do not support this collective responsibility for fulfilling the organisation's purpose and for working towards intended outcomes for citizens and users of services.

The governing body should set out a clear statement of the respective roles and responsibilities of the non-executives and the executive and its approach to putting this into practice.

The roles of chair and chief executive should be separate and provide a check and balance for each other's authority. The chair and the chief executive should negotiate their respective roles early in the relationship (within a framework in which the chair leads the governing body and the chief executive leads and manages the organisation) and should explain these clearly to the governing body and the organisation as a whole.

2.3 Being clear about relationships between governors and the public

Governors and governing bodies need to be clear about the nature of their relationship with the public. The governing body's role is to direct and control the organisation in the public interest (see 2.1) and to ensure accountability to the public (see 6.2). Being clear about this increases the chances that governors and others will understand governors' responsibilities to the public and be aware of the limitations of what they can be expected to do.

Public service governors are either elected directly by the public or appointed by governing bodies and/or government¹². All governors share collective responsibility and accountability for the governing body's decisions¹³. This includes the governing body of a partnership, whose members may come from a range of organisations. As governors of the partnership, they are responsible for taking decisions that support the partnership's purpose, not simply the interests of their 'parent' organisation.

Their different routes to becoming a governor mean that elected and appointed governors have different types of relationship with the public. However, both are

12 Some charity trustees or governors of other independent not-for-profit organisations, such as housing associations, are appointed by a wider voting membership or by other external bodies.

13 Organisations in which political parties are prominent, e.g. local authorities, may by convention operate a system of collective responsibility within the controlling party or alliance, rather than within the governing body as a whole.

accountable to the public and should develop a dialogue that connects the organisation properly with the public they serve (see 6.2). The electoral process provides an additional accountability mechanism for elected governors and they can be said to represent the public, in the democratic sense of 'represent'.

Appointed governors' backgrounds and experience are often factors in their appointment. This means that they bring particular perspectives or expertise, but their views cannot be expected to be 'representative' or typical of others with similar backgrounds.

It is very important that a wide range of experiences and perspectives inform governance decisions. This is enhanced by the participation of a cross-section of the public in governance decision making (see 5.1).

Application

Governors should recognise their collective responsibility for the governing body's decisions and strive to make decisions that further the organisation's purpose, rather than the interests of any specific group or organisation with which they are associated.

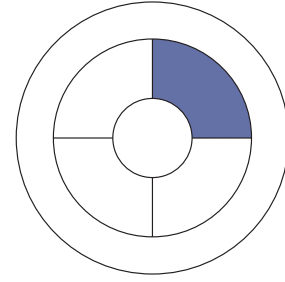
The governing body should value the perspectives which governors appointed from different backgrounds bring, but should make clear that these appointed governors are not expected to provide the only source of information about the specific groups whose background or experiences they share. Where appointed governors are asked to provide authoritative information about the views and experiences of such groups, they should have access to systems for collecting this information.

The governing body, whether elected or appointed (or made up of both elected and appointed governors) should ensure that the organisation engages effectively with the public and service users to understand their views, and that the governing body has access to reliable information about the range of public opinions and the satisfaction of all groups of users of services.

Good practice examples: performing effectively in clearly defined functions and roles

- The governing body can meet its responsibility for strategy by scrutinising and challenging proposals developed by the executive, or by involving itself actively in strategy formulation from the earliest stages.
- In developing and pursuing the organisation's strategic direction, the governing body is advised to make judgements about, and help to regulate, the scale and pace of change that the organisation can handle successfully.
- In appointing and remunerating the top team, it is good practice to establish a remuneration and appointments committee, made up of governors who are free of vested interests, to make recommendations to the governing body.
- Publishing job descriptions for the chair, deputy chair and chief executive can help others to know what to expect.
- Even for small organisations or partnerships with limited resources, separation of the chair and the executive role is advisable, with the executive being responsible for putting decisions into practice.

3. Good governance means promoting values for the whole organisation and demonstrating the values of good governance through behaviour



Good governance flows from a shared ethos or culture, as well as from systems and structures. It cannot be reduced to a set of rules, or achieved fully by compliance with a set of requirements. This spirit or ethos of good governance can be expressed as values and demonstrated in behaviour.

Good governance builds on the seven principles for the conduct of people in public life that were established by the Committee on Standards in Public Life. Known as the Nolan principles, these are: selflessness, integrity, objectivity, accountability, openness, honesty and leadership.

3.1 Putting organisational values into practice

A hallmark of good governance is the development of shared values, which become part of the organisation's culture, underpinning policy and behaviour throughout the organisation, from the governing body to all staff. These are in addition to compliance with legal requirements on, for example, equal opportunities and anti-discrimination.

Application

The governing body should take the lead in establishing and promoting values for the organisation and its staff. These values should be over and above legal requirements (for example, anti-discrimination, equal opportunities and freedom of information legislation) and should build on the Nolan principles. They should reflect public expectations about the conduct and behaviour of individuals and groups who control public services¹⁴. The governing body should keep these values at the forefront of its own thinking and use them to guide its decision making.

14 For example, *National Centre for Social Research and Centre for Research into Elections and Social Trends Guiding Principles: Public Attitudes Towards Conduct in Public Life*, The Committee on Standards in Public Life, January 2003

3.2 Individual governors behaving in ways that uphold and exemplify effective governance

Individual behaviour is a major factor in the effectiveness of the governing body, and also has an influence on the reputation of the organisation, the confidence and trust members of the public have in it and the working relationships and morale within it. Conflicts, real or perceived, can arise between the organisation's interests and those of individual governors (see 4.1). Public trust can then be damaged unless the organisation implements clear procedures to deal with these conflicts.

Application

Governors should live up to the Nolan principles and to any approved codes or guides to ethical conduct for their organisation or sector. They should also demonstrate through their behaviour that they are focusing on their responsibilities to the organisation and its stakeholders.

Good practice examples: promoting values for the whole organisation and demonstrating the values of good governance through behaviour

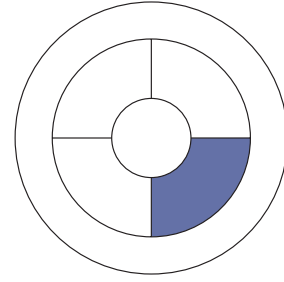
The governing body promotes and upholds values for the organisation. These may include:

- responding to a diverse public and striving to reduce inequality among service users
- committing to openness and transparency in decisions and use of resources
- striving for public good and ignoring personal interests
- promoting good relationships within the organisation, with the public and service users and with other organisations.

The governing body makes clear the standards of behaviour that it expects from governors and staff. Good practice in the behaviour of individual governors may include:

- attending regularly and being actively involved in decision making
- informing oneself and preparing for decision making
- making contact with other organisations and forging and maintaining links with the world outside the organisation
- engaging willingly and actively with the public, service users and staff, within an agreed communication framework.

4. Good governance means taking informed, transparent decisions and managing risk



Decision making in governance is complex and challenging. It must further the organisation's purpose and strategic direction and be robust in the medium and longer terms. To make such decisions, governors must be well informed.

Governors making decisions need the support of appropriate systems, to help to ensure that decisions are implemented and that resources are used legally and efficiently. A governing body may, for example, adopt the discipline of formally reviewing implementation of a new policy after a defined initial period, to see whether it is working as intended.

Risk management is important to the successful delivery of public services. An effective risk management system identifies and assesses risks, decides on appropriate responses and then provides assurance that the chosen responses are effective.

4.1 Being rigorous and transparent about how decisions are taken

Different types of organisation have different statutory requirements for the publication of their decisions¹⁵. Over and above these requirements, transparent decisions that are clearly explained are more likely to be understood by staff, the public and other stakeholders and to be implemented effectively. It is also easier to evaluate the impact of decisions that are transparent, and therefore to have evidence on which to draw in making future decisions.

A hallmark of good governance is a clearly defined level of delegation by the governing body to the executive for decision making. The governing body sets policies as parameters within which the executive works on the behalf of the governing body. For this to work well, it is important that governors do not concern themselves with levels of detail that are inappropriate for their role, while ensuring that they are not too far removed to provide effective oversight and scrutiny.

Application

The governing body should draw up a formal statement that specifies the types of decisions that are delegated to the executive and those that are reserved for the governing body.

Governing bodies should state clear objectives for their decisions. In their public record of decisions and in explaining them to stakeholders, they should be explicit about the criteria, rationale and considerations on which decisions are based, and, in due course, about the impact and consequences of decisions.

¹⁵ There are also statutory requirements for the types of decisions and information that can or must be excluded from the public domain, e.g. information about individuals.

Conflicts can arise between the personal interests of individuals involved in making decisions and decisions that the governing body needs to make in the public interest. To ensure probity and to avoid public concern or loss of confidence, governing bodies have to take steps to avoid any such conflicts of interest, whether real or perceived.

4.2 Having and using good quality information, advice and support

Good quality information and clear, objective advice can significantly reduce the risk of taking decisions that fail to achieve their objectives or have serious unintended consequences. Governors need to receive rigorous analyses of comprehensive background information and evidence, and of the options for action. As governance decisions are complex and can have significant consequences, governors also need professional advice. This includes advice on, for example, legal and financial matters and governance procedures. Such professional advice is also needed at other levels in the organisation where decisions are taken.

Application

The governing body should ensure that it is provided with information that is fit for purpose. It should be tailored to the functions of the governing body (see 2.2) and not to detailed operational or management issues, with which the governing body should not, in general, be concerned. Information should provide a robust analysis and not obscure the key information by including too much detail.

The governing body should ensure that information is directly relevant to the decisions it has to take; is timely; is objective; and gives clear explanations of technical issues and their implications. The governing body should also ensure that professional advice on legal and financial matters is available and used appropriately in its own decision making and elsewhere throughout the organisation when decisions that have significant legal or financial implications are taken.

The governing body should not be reluctant to use the organisation's resources to provide the information and advice that is needed for good governance. However, it should not make disproportionate demands on the executive by asking for information that is not necessary or appropriate for the governing body's role. The governing body should arrive at a judgement about its information needs in discussion with the executive.

4.3 Making sure that an effective risk management system is in operation

Public service organisations face a wide range of strategic, operational and financial risks, from both internal and external factors, which may prevent them from achieving their objectives. Risk management is a planned and systematic approach to identifying, evaluating and responding to risks and providing assurance that responses are effective.

A risk management system should consider the full range of the organisation's activities and responsibilities, and continuously check that various good management disciplines are in place, including:

- ◆ strategies and policies are put into practice in all relevant parts of the organisation
- ◆ strategies and policies are well designed and regularly reviewed
- ◆ high quality services are delivered efficiently and effectively
- ◆ performance is regularly and rigorously monitored and effective measures are put in place to tackle poor performance
- ◆ laws and regulations are complied with
- ◆ information used by the organisation is relevant, accurate, up-to-date, timely and reliable
- ◆ financial statements and other information published by the organisation are accurate and reliable
- ◆ financial resources are managed efficiently and effectively and are safeguarded
- ◆ human and other resources are appropriately managed and safeguarded.

A risk management system also supports the annual statement on internal control that many public service organisations now have to produce. Appropriate responses to risk will include implementing internal controls, insuring against the risk, terminating the activity that is causing the risk, modifying the risk or, in some circumstances, accepting the risk.

Application

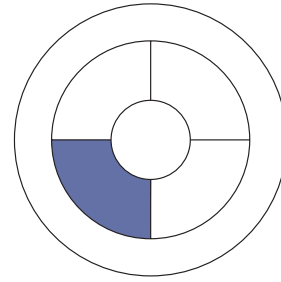
The governing body should ensure that the organisation operates an effective system of risk management. This should include:

- identifying key strategic, operational and financial risks
- assessing the possible effects that the identified risks could have on the organisation
- agreeing on and implementing appropriate responses to the identified risks (internal control, insure, terminate, modify, accept)
- putting in place a framework of assurance from different sources, to show that risk management processes, including responses, are working effectively
- reporting publicly on the effectiveness of the risk management system through, for example, an annual statement on internal control, including, where necessary, an action plan to tackle any significant issues
- making it clear that the governing body carries ultimate responsibility for the risk management system.

Good practice examples: taking informed, transparent decisions and managing risk

- It is helpful to draw on the support of an officer or independent adviser who can advise on legal issues and procedure, and who has the authority and status to challenge governance practice if necessary. This works best where there are safeguards and reporting relationships in place to make sure that advice is not easily ignored.
- A register of governors' and executives' interests will make governing bodies and others aware of any real or perceived conflicts of interest and facilitate the exclusion of people with personal interests in a decision from influencing or taking part in that decision.
- Documenting all risks in a risk register, together with the risk 'score' and the job title of the person responsible for ensuring that the risk is managed, will help with risk management.
- The highest risks in the register can be given priority in review procedures to provide assurance on the effectiveness of risk responses.
- Gaining assurance that risk management arrangements are working effectively can be delegated to an audit committee or equivalent body, where the size of the organisation makes this practical.
- Relevant work of internal audit, external audit, review agencies and inspectorates can be drawn on to provide assurance on the effectiveness of risk management.
- From time to time, governing bodies may decide to commission information from independent sources, outside the executive, in order to supplement or validate information from the executive.

5. Good governance means developing the capacity and capability of the governing body to be effective



Public service organisations need people with the right skills to direct and control them effectively. Governing bodies should consider the skills that they need for their particular situation. To increase their chances of finding these people – and to enrich governance deliberations by bringing together a group of people with different backgrounds – governing bodies need to recruit governors from different parts of society. Public trust and confidence in governance will increase if governance is not only done well, but is done by a diverse group of people who reflect the community.

Governance is also likely to be more effective and dynamic if new people with new ideas are appointed regularly, but this needs to be balanced with the need for stability to provide continuity of knowledge and relationships.

5.1 Making sure that appointed and elected governors have the skills, knowledge and experience they need to perform well

Governance roles and responsibilities are challenging and demanding, and governors need the right skills for their roles. In addition, governance is strengthened by the participation of people with many different types of knowledge and experience¹⁶.

Good governance means drawing on the largest possible pool of potential governors to recruit people with the necessary skills. Encouraging a wide range of people to apply for appointed positions or to stand for election will develop a membership that has a greater range of experience and knowledge. It will also help to increase the diversity of governors in terms of age, ethnic background, social class and life experiences, gender and disability¹⁷.

Paying governors for their time may make participation in governance a practical option for more people and encourage a wider range of people to take part; it can also be a way of publicly recognising the seriousness of governance responsibilities¹⁸.

16 For example www.london.edu/tysonreport/Tyson_Report_June_2003.pdf – *Tyson Report on the Recruitment and Development of Non-Executive Directors*, London Business School, June 2003 (A report commissioned by the Department of Trade and Industry following the publication of the Higgs Review of the Role and Effectiveness of Non-Executive Directors in January 2003).

17 See, for example, *A Simple Step Guide to Recruitment*, Office of the Commissioner for Public Appointments.

18 Approaches to paying governors are generally determined by statute and vary between types of organisation. For example, charities are generally prohibited from paying their governors (trustees).

Application

The governing body should assess the skills that appointed governors need to fulfil their functions. It should appoint governors who have these skills, using an open and skills-based recruitment process.

A governing body with elected members should commit itself to developing the skills that it has decided its members need, so that they can carry out their roles more effectively.

Where governing bodies are responsible for their own recruitment processes, they should establish an appointments committee and ensure that their recruitment processes can identify and attract the types of people they want. Where an outside body makes appointments, it should consult the governing body about the skills and experience it considers to be necessary or desirable in the new appointee. In these cases, the process should include an independent assessor – a person from outside the organisation who can advise on the suitability of candidates.

Where other organisations nominate people to become governors, the governing body should set out clearly to the nominating body the set of skills and perspectives that would be most helpful.

The governing body should decide how to encourage more people, from a wider cross-section of society, to come forward as potential governors. This includes reviewing the governor's role to make sure that: it is fulfilling and coherent; it is feasible to do within the time and with the support available; and it is sufficiently well understood by potential governors. The search for a more diverse membership of the governing body should not be at the expense of a membership that has the necessary skills.

5.2 Developing the capability of people with governance responsibilities and evaluating their performance, as individuals and as a group

Governors need both skills and knowledge to do their jobs well. Skills need to be developed continually to improve performance in the functions of the governing body (see 2.1). The necessary skills include the ability to scrutinise and challenge information received from the executive, including skills in financial management and the ability to recognise when outside expert advice is needed. Knowledge also needs to be updated regularly to equip governors for changing circumstances.

An appraisal and performance review of individual governors demonstrates that their role and contribution is important and valued and provides an opportunity for them to take stock of their own development needs. The governing body can improve its collective performance by taking the time to step back and consider its own effectiveness.

Application

New governors should receive a thorough induction that is tailored to their role in the organisation. All governors should have opportunities to develop further skills and to update their knowledge throughout their period of membership of the governing body, and should take seriously their responsibilities to identify and address their development needs.

Individual governors should be held to account for their contribution through regular performance reviews. These should include an assessment of any training or development needs.

The governing body should regularly review its performance as a whole. The review should involve assessing its ways of working and achievements and agreeing an action plan to put in place any necessary improvements.

5.3 Striking a balance, in the membership of the governing body, between continuity and renewal

All governing bodies need continuity in their membership, so that they can make the most of the pool of knowledge and understanding and the relationships that have been formed both inside and outside the organisation. It is also important that governing bodies are stimulated by fresh thinking and challenge and that they avoid lapsing into familiar patterns of thinking and behaviour that may not best serve the organisation's purpose. However, turnover in membership that is too extensive or too frequent can mean that the organisation loses the benefit of longer-serving members' learning and experience.

Application

The governing body should decide how to strike the necessary balance, in its appointed membership, between continuity in knowledge and relationships on the one hand, and renewal of thinking on the other. It should explain the reasons for its policy.

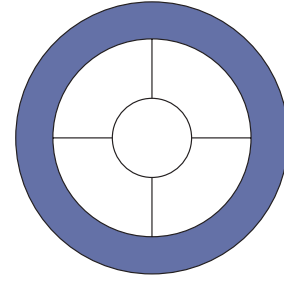
Where an outside body appoints governors, the governing body should explain its preferred approach to continuity and renewal.

Options include fixed terms of membership or limits on the number of terms a governor can serve. Another option is to assess individual governors for their continuing objectivity every time they are being considered for reappointment; independence of mind and the ability to take new approaches are enduring characteristics of some individuals.

Good practice examples: developing the capacity and capability of the governing body to be effective

- Bodies that nominate governors for other organisations are advised to present more than one nominee for interview.
- People appointing governors to public service organisations could consider what they might do to develop further the pool of people interested in public service governance, and to develop the capability of potential governors who do not yet have the skills needed for the role.
- It is good practice to review continually the range of expertise needed on the governing body, so that any gaps can be filled when posts become vacant and when training and development plans are made.
- A skills audit of the members of a governing body is a useful way of identifying their strengths and any skills gaps.
- The governing body can avoid over-dependence on a few individuals by making sure that enough governors have the critical skills.
- Induction for governors could include an introduction to the local environment and the sector, the organisation's relationships with other bodies and the context for the organisation's strategy.
- It can be useful to review a governor's needs for further information or explanation six months or a year after his or her induction.
- Paying governors for their time (as well as meeting expenses) is controversial in some sectors. Considering the advantages and disadvantages can help organisations decide whether payment will strengthen the membership and performance of the governing body or undermine its values.
- By sharing specific responsibilities among its members on a rota basis, the governing body can ensure that important knowledge is not vested in one or a few individuals.

6. Good governance means engaging stakeholders and making accountability real



Governing bodies of public services have multiple accountabilities: to the public (citizens) and to those who have the authority, and responsibility, to hold them to account on the public's behalf. These include: commissioners of services, Parliament, ministers, government departments and regulators¹⁹.

Real accountability requires a relationship and a dialogue. The Public Services Productivity Panel²⁰ said that accountability involves an agreed process for both giving an account of your actions and being held to account; a systematic approach to put that process into operation; and a focus on explicit results or outcomes. Real accountability is concerned not only with reporting on or discussing actions already completed, but also with engaging with stakeholders to understand and respond to their views as the organisation plans and carries out its activities.

6.1 Understanding formal and informal accountability relationships

The range and strength of different accountability relationships varies for different types of governing bodies. For any governing body, some relationships will be, or will feel, more formal and possibly more important than others. For example, the board of a non-departmental public body is likely to have a closer and more direct relationship with a minister than a school would have. However, the large majority of governing bodies need to be particularly active in developing and maintaining a dialogue with the public.

Governing bodies that are elected by the public (such as local councils) have accountability relationships with central government that are less direct and less powerful than, for example, the relationships that non-departmental public bodies have with central government. But even elected bodies are held to account by central government and regulators for some responsibilities. This is why it is important for central government and regulators to facilitate good governance in the organisations they direct or hold to account.

Application

The governing body should make clear, to itself and to staff, to whom it is accountable and for what. It should assess the extent to which each relationship serves its purpose, including whether any relationships need to be strengthened and whether any dominate to the detriment of serving the purpose of the organisation and being accountable to other stakeholders. If so, the governing body should discuss those tensions and work to fill any gaps in its accountability. It should also raise any concerns with those organisations to which it is formally accountable and, where possible, try to negotiate a more balanced position.

¹⁹ Outside the public sector, accountability is not to citizens but to their own stakeholders and to regulators acting in the public interest.

²⁰ *Accountability for Results*, Public Services Productivity Panel, HM Treasury, 2002

6.2 Taking an active and planned approach to dialogue with and accountability to the public

For elected governors, the manifesto and the ballot box are the foundation of the accountability relationship; but good governance also requires an ongoing dialogue between them and their electorate. Appointed governing bodies also have to develop an accountability relationship through dialogue.

The fuel of this dialogue is interest and confidence. If dialogue is to develop and continue, organisations need to encourage and maintain the interest and confidence of the public and service users. Although these two groups overlap to a large extent in their relationship with public service organisations, the relationship with the public is one of accountability, whereas the relationship with service users is one of consultation and responsiveness. Both groups are diverse, consisting of people with different characteristics and experiences and from many different backgrounds. Approaches to developing a dialogue have to recognise these differences, so that the views of a full range of people are heard.

Confidence and interest can both be damaged easily, especially when things go wrong. The organisation's ability to respond to such circumstances is also an important demonstration of its accountability.

Application

The governing body should make it clear that the organisation as a whole seeks and welcomes feedback, and ensure that it responds quickly and responsibly to comment. Complaints are a vital and necessary part of feedback, and there should be clear leadership within the governing body on handling and resolving them, and ensuring the lessons learnt are used to improve the service.

The governing body should ensure that the organisation has a clear policy on the types of issues on which it will consult or engage the public and service users, respectively. This policy should clearly explain how the organisation will use this input in decision making and how it will feed these decisions back to the public and to service users. The policy should make sure that the organisation hears the views and experiences of people of all backgrounds.

Each year, the governing body should publish the organisation's purpose, strategy, plans and financial statements, as well as information about the organisation's outcomes, achievements and the satisfaction of service users in the previous period.

6.3 Taking an active and planned approach to responsibility to staff

Staff are accountable to the governing body, but the governing body also has serious responsibilities, as an employer, to the staff. Recruiting, motivating and keeping staff are vital issues if public services are to be effective. The governing body needs to provide an environment in which staff can perform well and deliver effective services, by creating a culture that welcomes ideas and suggestions, responds to staff views

and explains decisions. The governing body is itself the last point of appeal for staff with complaints or concerns that they have not been able to deal with through the organisation's management structures.

Application

The governing body should have a clear policy on when and how it consults and involves staff and their representatives in decision making.

The governing body should make sure that effective systems are in place to protect the rights of staff. It should make sure that policies for whistle blowing, and support for whistle blowers, are in place.

6.4 Engaging effectively with institutional stakeholders

Institutional stakeholders are other organisations with which the organisation needs to work for formal accountability or to improve services and outcomes. Public services have a complex network of governance relationships involving lateral relationships between partners and hierarchical relationships between Parliament, central government and local organisations. Some of these are accountability relationships, while others are to do with working together to achieve better outcomes.

Few public service organisations can achieve their intended outcomes through their own efforts alone. Relationships with other organisations are important, especially if they provide similar or related services or serve the same users or communities. Developing formal and informal partnerships may mean that organisations can use their resources more effectively or offer their services in a different and, for service users, more beneficial way.

Application

The governing body should take the lead in forming and maintaining relationships with the leaders of other organisations, as a foundation for effective working relationships at operational levels.

Good practice examples: engaging stakeholders and making accountability real

- It is good practice to assess the effectiveness of policy and arrangements for dialogue with service users and accountability to the public, to evaluate their impact on decisions and to decide what improvements may be needed.
- Organisations can use a range of models, from citizens' juries to community time banks (mutual volunteering by members of the public, working alongside service providers to support their neighbours), to promote public and user involvement in public service design, delivery and evaluation.
- It is good practice to publish information on research into the public's views of the organisation and information on service users' views of the suitability and quality of the services they receive. It is important to include the diversity of the public and of service users in this information, to give a complete and accurate picture.
- The Independent Commission on Good Governance recommends that governing bodies assess the extent to which they are applying these principles of good governance, and report publicly on this assessment, including an action plan for improvement where necessary.
- By organising systematic '360-degree' feedback from a representative sample of stakeholders, governing bodies can gain valuable insights about the organisation's relationships.

Appendix A: Assessment questions for governors and governing bodies to ask themselves

1. Good governance means focusing on the organisation's purpose and on outcomes for citizens and users

- ◆ How clear are we about what we are trying to achieve as an organisation? Do we always have this at the front of our minds when we are planning or taking decisions? How well are we doing in achieving our intended outcomes?
- ◆ To what extent does the information that we have about the quality of service for users help us to make rigorous decisions about improving quality? Do we receive regular and comprehensive information on users' views of quality? How could this information be improved? How effectively do we use this information when we are planning and taking decisions?
- ◆ To what extent does the information that we have on costs and performance help us to make rigorous decisions about improving value for money? How effectively do we use this information when we are planning and taking decisions? How well do we understand how the value we provide compares with that of similar organisations?

2. Good governance means performing effectively in clearly defined functions and roles

- ◆ Do we all know what we are supposed to be doing?
- ◆ Is our approach to each of the governing body's main functions clearly set out and understood by all in the governing body and the senior executive? What does the size and complexity of our organisation mean for the ways in which we approach each of the main functions of governance?
- ◆ How clearly have we defined the respective roles and responsibilities of the non-executives and the executive, and of the chair and the chief executive? Do all members of the governing body take collective responsibility for the governing body's decisions?
- ◆ How well does the organisation understand the views of the public and service users? Do we receive comprehensive and reliable information about these views and do we use it in decision making?

3. Good governance means promoting values for the whole organisation and demonstrating the values of good governance through behaviour

- ◆ What are the values that we expect the staff to demonstrate in their behaviour and actions? How well are these values reflected in our approach to decision making? What more should we do to ensure these values guide our actions and those of staff?
- ◆ In what ways does our behaviour, collectively as a governing body and individually as governors, show that we take our responsibilities to the organisation and its stakeholders very seriously? Are there any ways in which our behaviour might weaken the organisation's aims and values?

4. Good governance means taking informed, transparent decisions and managing risk

- ◆ How well do our meetings work? What could we do to make them more productive and do our business more effectively?
- ◆ Have we formally agreed on the types of decisions that are delegated to the executive and those that are reserved for the governing body? Is this set out in a clear and up-to-date statement? How effective is this as a guide to action for the governing body and the executive? How well do we explain the reasons for our decisions to all those who might be affected by them?
- ◆ Is the information we receive robust and objective? How could the information we receive be improved to help improve our decision making? Do we take professional advice to inform and support our decision making when it is sensible and appropriate to do so?
- ◆ How effective is the organisation's risk management system? How do we review whether this system is working effectively? Do we develop an action plan to correct any deficiencies in the systems? If so, do we publish this each year?

5. Good governance means developing the capacity and capability of the governing body to be effective

- ◆ What skills have we decided that governors must have to do their jobs effectively? How well does our recruitment process identify people with the necessary skills and reach people from a wide cross-section of society? What more could we do to make sure that becoming a governor is practical for as many people as possible?
- ◆ How effective are we at developing our skills and updating our knowledge? How effective are our arrangements for reviewing the performance of individual governors? Do we put into practice action plans for improving our performance as a governing body?

- ◆ What is our approach to finding a balance between continuity of knowledge and renewal of thinking in the governing body? What are our reasons for this approach? Do we need to review it?

6. Good governance means engaging stakeholders and making accountability real

- ◆ Who are we accountable to and for what? How well does each of these accountability relationships work? Do we need to take steps to clarify or strengthen any relationships? Do we need to negotiate a shift in the balance between different accountability relationships?
- ◆ What is our policy on how the organisation should consult the public and service users? Does it explain clearly the sorts of issues on which it will consult which groups and how it will use the information it receives? Do we need to review this policy and its implementation?
- ◆ What is our policy on consulting and involving staff and their representatives in decision making? Is this communicated clearly to staff? How well do we follow this in practice? How effective are systems within the organisation for protecting the rights of staff?
- ◆ Who are the institutional stakeholders that we need to have good relationships with? How do we organise ourselves to take the lead in developing relationships with other organisations at the most senior level?

Applying the good governance Standard

- ◆ To what extent does the *Good Governance Standard for Public Services* apply to our organisation, bearing in mind its type and size?
- ◆ Are we upholding and demonstrating the spirit and ethos of good governance that the Standard sets out to capture?
- ◆ Do we have a process for regularly reviewing our governance arrangements and practice against the Standard? What further improvements do we need to make?
- ◆ Are we making public the results of our reviews and our plans for future improvements and are we inviting feedback from stakeholders and service users?

Appendix B: Questions for members of the public and their representatives to ask if they want to assess and challenge standards of governance

Organisations can also ask themselves these questions if they want to test their openness and responsiveness to the public and their service users.

1. Good governance means focusing on the organisation's purpose and on outcomes for citizens and service users

- ◆ What is this organisation for?
- ◆ Can I easily find a clear explanation of what this organisation is doing?
- ◆ Can I easily find out about the quality of service provided to the public?
- ◆ What is being done to improve services?
- ◆ Can I easily find out about the organisation's funding and how it spends its money?

2. Good governance means performing effectively in clearly defined functions and roles

- ◆ Who is in charge of the organisation?
- ◆ How are they elected or appointed?
- ◆ At the top of the organisation, who is responsible for what?

3. Good governance means promoting values for the whole organisation and demonstrating the values of good governance through behaviour

- ◆ According to the organisation, what values guide its work?
- ◆ Does it follow these values in practice?
- ◆ What standards of behaviour should I expect?
- ◆ Do the senior people in the organisation put these standards of behaviour into practice?
- ◆ Do they put into practice the 'Nolan' principles for people in public life (selflessness, integrity, objectivity, accountability, openness, honesty and leadership)?

4. Good governance means taking informed, transparent decisions and managing risk

- ◆ Who is responsible for what kinds of decisions in the organisation?
- ◆ Can I easily find out what decisions have been taken and the reasons for them?
- ◆ Are the decisions based on up-to-date and complete information and good advice?
- ◆ Does the organisation publish a clear annual statement on the effectiveness of its risk management system?
- ◆ Does the organisation publish a clear annual account of how it makes sure that its policies are put into practice? Is the statement reassuring? How does it compare with my own experience?

5. Good governance means developing the capacity and capability of the governing body to be effective

- ◆ How does the organisation encourage people to get involved in running it?
- ◆ What support does it provide for people who do get involved?
- ◆ How does the organisation make sure that all those running the organisation are doing a good job?

6. Good governance means engaging stakeholders and making accountability real

- ◆ Can I easily get information to answer all these questions?
- ◆ Are there opportunities for me and other people to make our views known?
- ◆ Does the organisation publish an annual report containing its accounts for the year? Are copies freely available? Is the content informative?
- ◆ How do I find out what decisions were taken as a result of my and others' opinions being asked for?
- ◆ Are there opportunities to question the people in charge about their plans and decisions?
- ◆ Can I easily find out how to complain and who to contact with suggestions for changes?