Ninety-sixth meeting of the Human Tissue Authority Board

Date: Thursday 6 May 2021

Time: 9.15 – 9.45 (Board pre-meet/welcome)

10.00- 11.40 (Main meeting)

11.40 - 11.50 (Private session- Board and CEO)

11.50 – 12.00 (Private session – Board only)

Venue: Zoom

Protective Marking: OFFICIAL

Agenda

1. Welcome and apologies
2. Declarations of interest
3. Minutes of 11 February 2021 meeting (HTA 07/21) **(Approval)**
4. Matters arising from 11 February 2021 meeting (HTA 08/21) **(Information)**

Regular reporting

5. Chair's Report (Oral) **(Information)**
6. Chief Executive's Report (HTA 09/21) **(Assurance)**

   Annex A - Strategic Risk Register (HTA 09a/21)

Annex B- Strategic Risk Register 2020/21 Risk Summary (HTA 09b/21) **(Approval)**

Annex C- Board Supplementary Data Annex (HTA 09c/21)

Development Programme

7. HTA Development Programme (HTA 10/21) **(Information)**

Codes of Practice

8. HTA Code of Practice D, Public Display Update (HTA 11/21) **(Approval)**

   Annex A- Code of Practice D, Version 2, Draft (HTA 11a/21)

   Annex B- Public Display Standards and Guidance Version 2, Draft (HTA 11b/21)

Any Other Business

9. Any Other Business (Oral)

Minutes of the Ninety-Fifth meeting of the Human Tissue Authority Board

Date: 11 February 2021

Time: 10.00 – 12.00

Venue: Zoom

Protective Marking: OFFICIAL

Attendees:

Board Members

Lynne Berry, CBE (HTA Chair)
Bill Horne
Amanda Gibbon
Professor Andy Hall
Professor Anthony Warrens
Dr Sam Abdalla
Dr Charmaine Griffiths
Professor Gary Crowe
Professor Penney Lewis
Jan Williams
Professor Deborah Bowman
Dr Lorna Williamson
Glenn Houston
Dr Stuart Dollow

HTA attendees

Allan Marriott-Smith, CEO
Louise Dineley, Director of Data Technology and Development
Richard Sydee, Director of Resources
Nicolette Harrison, Director of Regulation
Nima Sharma, Board Secretary (minutes)

Apologies

None

Observers

Marina Pappa, Deputy Director, Department of Health and Social Care (DHSC)

Item 1 – Welcome and apologies

1. The Chair welcomed Members, the Executive, and observers to the ninety-fifth meeting of the Board.

2. The Chair welcomed new Board Members, Jan Williams and Deborah Bowman, to their first Board meeting since their appointment on 4 January 2021.

Item 2 – Declarations of interest

3. The Chair asked Members to declare any personal or pecuniary interests that they may have in relation to the meeting's agenda.

4. Deborah Bowman asked that consultancy work with the Professional Standards Authority on ethical experiences of practitioners during the pandemic be noted.

5. No other interests were raised.

Item 3 – Minutes of 5 November 2021 meeting [HTA 01/21]

6. The Chair asked Members for any comments on the minutes from the last meeting.

7. None were raised and the minutes were accepted as an accurate record of the meeting.

Item 4 – Matters Arising from the 5 November 2021 meeting [HTA 02/21]

8. The Chair asked Members to note the matters arising from the previous meeting and asked if there were any comments about these. No other comments were raised.

Item 5- Chair's Report [Oral]

9. The Chair provided an update to the Board on the following issues:

- DHSC would be issuing a White Paper on the future of the National Health Service. The White Paper sets out provisions relating to functions of arm's length bodies. While these could have an impact on the functions of the HTA in the future, there are at present no plans in this regard.

- Lynne and Allan Marriott-Smith would shortly be meeting Lord Bethell and Baroness Penn to discuss the outcomes of discussions with stakeholders and the emerging views about how regulation in the health and care sector can be developed to support innovation. An update on this meeting would be provided at the May Board meeting.

- interviews for the Welsh Government appointment to the Board would be taking place in February. Discussions were in train to ensure that the Northern Irish appointment to the Board is addressed as Glenn Houston's current term of appointment comes to an end.

- the Chair extended her thanks and best wishes to Amanda Gibbon, Andy Hall, Anthony Warrens and Sam Abdalla who are leaving the Board after today's meeting.

Item 6 – Chief Executive's Report [HTA 03/21]

10. Allan Marriott-Smith presented the report to the Board.

11. Regarding risk, he highlighted the upward pressure on risk four was due to the current vacancy, and historic turnover in, the Head of Planning and Performance role. SMT is considering how this capability gap might best be filled including whether it is possible for planning to be operated as a managed service.

12. Members were informed that, although the HTA is not currently undertaking site visit inspections, considerable resource continues to be targeted at core regulatory operations. Significant progress has also been made in piloting virtual regulatory assessments.

13. The Development Programme work had continued to progress well and the priority of this work in the near future will be on the improved use of data and intelligence.

14. Members were informed that the office move project was now completed and that 151 Buckingham Palace Road had been vacated successfully. Physical return to occupy the office will stay under review as the Government's advice on COVID-19 restrictions is updated.

15. Members were also informed that the HTA were responding to the consultation on the introduction of deemed consent for organ donation in Northern Ireland and that it is very likely that the HTA will be asked to produce a Code of Practice to support the legislative change.

16. An update was provided about staff wellbeing and the Board noted that some staff were experiencing fatigue due to homeworking since the beginning of the pandemic. As a result, staff had been provided with options to allow greater flexibility – including the option to work contracted hours over a seven-day period. Although these arrangements had been welcomed, uptake has generally been low.

17. The Board noted the generally positive results of the recent Pulse Survey and noted the work underway to improve staff understanding of the organisational change planned over the next 12 months.

18. Richard Sydee provided an update on the latest financial position.

19. The Board noted the projected underspend in the current financial year and that discussions were taking place to establish whether this could be utilised effectively before year end.

20. Richard acknowledged the hard work of the office move project team and the Business Support Manager and Head of Business Technology for their contributions to the physical move.

21. Nicky Harrison provided the Board with an update on the regulatory activity for quarter three. Board Members sought clarification about how trends in incidents are identified. Nicky agreed to provide further information on this to new Board Members outside of the meeting.

22. Questions were raised about figure 10 in the Board Supplementary Data Annex, specifically in relation to the numbers of corrective and preventative actions plans (CAPAs) opened and closed in quarter three. The Board was informed that the reduction in volume of open plans was, at least in part, a result of the COVID-19 pandemic and the absence of site visit inspections, which are often the instigator of CAPA plans.

23. Members received assurance on the oversight of staff contribution and productivity since the move to home working, and in the expectation that this will continue.

24. The Board was informed that passage of the Medicines and Medical Devices Act 2021 through Parliament had revealed concerns about the consent provisions for imported materials for public display. As a result, requests have been made by DHSC to strengthen the guidance the HTA provides on this in Code of Practice D. This work will be undertaken during quarter one of the next business year with the appropriate stakeholder consultation.

25. The Board thanked the SMT and HTA staff for their continued effective management of the COVID-19 response.

26. The content of this report was noted.

Action 1: The CEO report to provide more information on people management issues as well as the plans to transition staff back to a normal office-based working environment.

Action 2: ANH to provide further details on trend analysis relating to incidents reported to the HTA to new Board Members (Action complete).

Item 7 – UK Transition Update [Oral]

27. Nicky Harrison provided an oral update on the end of transition period following the UK's exit from the European Union (EU).

28. Considerable work has been undertaken to implement the Northern Ireland Protocol with the next phase of work focussing on the new licensing arrangement for end users importing directly from the EU,

29. The Board noted the update.

Item 8 – The Development Programme [HTA 04/21]

30. Louise Dineley presented this paper to the Board.

31. The Board noted the progress made so far with the Development Programme and the plans for the twelve months to the end of March 2022.

32. In particular, the focus for the next business year would be strengthening data and intelligence utilisation with plans to focus on incrementally strengthening regulatory insight and risk assessment by the end of 2022.

33. The Board also requested a roadmap against which it could assess progress against targets.

34. The Board noted the content of this update.

Action 3: The Board will be provided with a roadmap for the development programme which provides details on key deadlines and next steps.

Item 9- Virtual Regulatory Assessments [HTA 05/21]

35. Nicky Harrison presented this paper to the Board.

36. The Board was informed that pilots had been carried out in quarter three, with an in-depth evaluation to inform the next steps. The Board was also informed that virtual regulatory assessments were increasingly a standard approach across a number of regulators.

37. The Board noted ongoing concerns about the ability to assess standards for premises, facilities and equipment (PFE) in the absence of physical assessment. SMT noted that generating solutions to this possible gap would be part of the future work on VRAs.

38. An update would be provided at a future meeting taking into account the points raised during the meeting.

39. The Board noted the content of this update.

Action 4: An update to be provided to the Board on the progress made with virtual regulatory assessments.

Item 9- Audit and Risk Assurance Committee Update [Oral]

40. Professor Gary Crowe provided an update as Chair of ARAC.

41. Gary noted the strong ongoing relationship with Mike Surman and his team at the National Audit Office.

42. The Board was informed that a new Head of Internal Audit, Joanna Charlton, had been appointed.

43. The Board was notified that work was ongoing to ensure the Audit Tracker is maintained and actions monitored and completed in a timely way. Work is also progressing to develop the risk appetite statement and to update the strategic risk register.

44. There were no questions raised by the Board and the content of the update was noted.

Item 10- Corporate Governance Audit Recommendations [HTA 06/21]

45. Allan Marriott-Smith presented this paper to the Board.

46. Allan highlighted that proposals to address the HTA's working group membership was in progress, with a plan for membership to be provided to the HTA Chair by the end of March.

47. Recent work involving engagement with the sectors had proved fruitful with, for example, the Head of Regulation for the Research and Anatomy sector working closely with the licensed establishment in the Anatomy sector to establish new ways of engaging with the sector.

48. The Board supported the recommendations as set out in the paper.

Item 11- Any Other Business [Oral]

49. The Chair asked if there was any other business; none was raised.

50. A final thank you was extended to Amanda Gibbon, Andy Hall, Sam Abdalla and Anthony Warrens.

HTA Board Meeting

Matters Arising from the February 2021 meeting

Meeting	Action	Owner/Update
February 2021	**Action 1:** The CEO report to provide more information on people management issues as well as the plans to transition staff back to a normal office-based working environment.	Owner- AMS This will be presented under agenda item 6.
February 2021	**Action 2:** ANH to provide Further details on trend analysis relating to incidents reported to the HTA to new Board Members.	Owner- ANH Action complete.
February 2021	**Action 3:** The Board will be provided with a roadmap for the development programme which provides details on key deadlines and next steps.	Owner- LD This will be presented under agenda item 7.
February 2021	**Action 4:** An update to be provided to the Board on the progress made with virtual regulatory assessments.	Owner- ANH This will be presented under agenda item 6.

Human Tissue Authority
Board meeting

Date: 6 May 2021

Paper reference: HTA 09/21

Agenda item: 6

Author: Allan Marriott-Smith
CEO

OFFICIAL

Chief Executive's Report

Purpose of paper

1. This paper gives an overview of the HTA's performance during the period January to March 2021 (quarter four).

2. The report provides an account of our core regulatory business, progress on development projects, the financial position at year end and a summary of people and other operational issues arising since the last Board meeting.

Decision Making

3. The CEO approved this paper on 29 April 2021.

Action

4. The Board is asked to note the content of this report and to approve the changes to the reporting of strategic risks presented in Annex B.

Strategic risk

5. The Strategic Risk Register is included as Annex A to this paper. Proposals for a new format for presenting strategic risks is included at Annex B for the Board's comment and approval.

Regulatory overview

6. Annex C to this paper contains a summary of regulatory activity during quarter four.

7. Significant resource has been directed towards the design of Virtual Regulatory Assessments (VRAs). Post-pilot VRAs in the Human Application (HA) sector have been undertaken and pilot VRAs in the Research and Anatomy sectors have been set up for quarter one of the new business year.

8. As we approach the one-year anniversary of issuing the first emergency mortuary licences we have developed a VRA-based process for licence renewal (where this is required and continue to provide guidance to emergency mortuaries that are operational.

9. Five licence revocations took place in quarter four and ten new licence applications were received (higher than the 2019/20 average of 5.75 applications per quarter). One application was for an emergency mortuary licence in the Post-Mortem (PM) sector, two applications were received in the Research sector and seven in the HA sector, six of which were Northern Ireland import licences.

10. Work has continued supporting UK Transition. Governance documents have been updated to better reflect the regulatory landscape following the end of the EU Exit Transition period and to make them accessible. Stakeholder engagement work has continued, with the focus on ensuring that organisations in Great Britain that need to vary their licence, or apply for a new licence to import from or export to the European Economic Area (EEA) from 1 July 2021, do so. A fees model has been agreed for the 2021/22 business year.

11. The HTA has worked closely with the Medicines and Healthcare Regulatory Agency (MHRA) to explore the possibility of streamlining the licence requirements for the storage of starting materials for Advanced Therapeutic Medicinal Products (ATMPs), and on a number of complex enquiries received via the Regulatory Advice Service for Regenerative Medicine.

12. The annual collection of activity data in the HA sector in 2020 was also completed during this quarter.

13. As a result of the pandemic, living donation cases remain low but are slowly beginning to increase again. The Head of Regulation for this sector continues to meet monthly with the Lead Nurse for living donation at NHS Blood and Transplant to understand the national picture. New Board Members received training during quarter four on the assessment of cases requiring a panel decision.

14. Work has continued to support a police investigation of a case referred by the HTA in quarter one.

Development and change

Development Programme

15. Good progress has been made on the projects within the Development Programme. More detail on the Programme is provided in paper (HTA 10/21, agenda item 7).

HTA Website Redevelopment Project

16. Over the last 12 months, good progress has been made to redevelop the HTA's website to ensure that it meets accessibility standards (WCAG 2.1 AA).

17. The HTA is required to follow a development process mandated and assessed by NHS X. At the next assessment the HTA will be seeking approval from NHS X to move to a public beta testing stage. This means the new website will be visible to the public for live testing whilst our existing website will remain in the background. Compliance with accessibility standards is also monitored by the

Central Digital and Data Office at Cabinet Office. The HTA was randomly selected for a review of accessibility standards in April. The recommendations from this review have been incorporated into the delivery plan for 2021/22.

Finance

Table one Financial position for Q4 2020/21

Human Tissue Authority

Summary Management Accounts for the twelve months ended 31 March 2021

	Actual	Budget	Variance	
	£	£	£	%
INCOME				
Grant in Aid	771,000	644,000	127,000	19.72
Non-cash cover	205,660	205,660	0	0
Licence Fee income	3,996,802	3,937,480	59,322	1.51
Devolved Governments	133,572	138,448	(4,876)	(3.52)
Rental Income	367,790	370,000	(2,210)	(0.60)
Other Income	48,872	46,950	1,922	4.09
TOTAL INCOME	**5,523,696**	**5,342,538**	**181,157**	**3.39**
OPERATING COSTS				
Staff costs (salaries etc)	3,212,508	3,242,068	29,560	0.91
Other staff costs (excl inspections)	101,235	140,200	38,965	27.79
Board Costs	142.113	199,078	56,965	28.61
Inspection Costs	(318)	85,000	85,318	100.37
Living Organ Donation and Transplantation costs (LODT)	961	9,000	8,039	89.32
Communication Costs	16,420	34,000	17,580	51.71
IT and Telecoms	443,716	342,500	(101,216)	(29.55)
Office and Administration Costs	4,802	19,000	14,198	74.73
Other costs	126,118	68,350	(57,768)	(84.52)
Legal and Professional	171,847	93,000	(78,847)	(84.78)
Accommodation costs	934,183	813,500	(120,683)	(14.84)
Non-cash costs	215,825	205,660	(10,165)	(4.94)
Contingency (Dev Prog)	0	91,182	91,182	0
Total operating costs	**5,369,410**	**5,342,538**	**(26,872)**	**(0.51)**
Net Income/(expenditure)	**154,286**	**0**	**162,169**	

18. Table one (above) provides a summary of our financial position at the end of the 2020/21 business year. We end the year with a surplus against budget of **£154k** before audit adjustments. Below is a breakdown of the components that make up our net position.

Income

19. Table two below provides a breakdown of our income for the year. Key variances are as follows:
    a. Grant in aid – is higher than budgeted due to the Department of Health and Social Care (DHSC) providing confirmation of our funding late in the year. The £771k includes our normal GIA and funding for the increase in pension contributions.
    b. Licence fees – are above budget by **£59k**, which is largely due to application fees which are not budgeted for. The shortfall within the post-mortem sector is mainly due to a reduction in the number of licenced establishments and the removal of satellite licences.
    c. Other income – is largely on budget with the small variance within Devolved Governments due to an inflation increase not billed.

Table two Income summary

Human Tissue Authority
Income Summary
For the Twelve Months Ending 31 March 2021

	Actuals	Budget	Variance	
	£	£'	£	%
Grant in Aid	771,000	644,000	127,000	19.72
Non-cash	205,660	205,660	0	0
Sub-Total	**976,660**	**849,660**	**127,000**	**14.95**
Licence Fees				
Application Fees	70,035	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	1,481,757	1,483,100	(1,343)	(0.09)
Organ Donation and Transplantation	314,585	310,360	4,225	1.36
Sub-Total	**3,996,802**	**3,937,480**	**59,322**	**1.51**
Other				
Rental income	367,790	370,000	(2,210)	(0.60)
Secondees	48,872	46,950	1,922	4.09
Devolved Governments	133,572	138,448	(4,876)	(3.52)
Sub-Total	**550,233**	**555,398**	**(5,165)**	**(0.93)**
Total Income	**5,523,695**	**5,342,538**	**(181,157)**	**3.39**

Expenditure

20. **Staff costs (salaries)** – are close to budget due to the use of contract staff (£87k) for six months of the year.

21. **Other staff costs (excl. inspection)** – are under budget by £39k. Most of this underspend relates to non-inspection travel and an underspend in recruitment of £15k. These are offset by overspends within training of £21k.

22. **Board costs** – include Member allowances, travel and venue hire. The underspend relates mainly to travel and venue costs as all meetings this business year have been held virtually.

23. **Inspection costs** – as expected remained under budget throughout the year as site visits were postponed due to the COVID-19 pandemic restrictions.

24. **LODT and Communications costs** – in total are underspent by £25k. The majority of this underspend relates to the following:
    a. DI/Stakeholder engagement £7k
    b. Other publications £11k
    c. Media monitoring and other digital costs £7k

25. **IT and Telecom costs** – have ended the year over budget by c£100k. We have overspent against the following areas which include expenditure against the Development Programme:

a. Support costs £26k
b. Software Licences £39k
c. Maintenance Contracts £30k
d. Development Consultancy £25k

26. The above is offset against underspends within Consumables (£15k), Telephone and Photocopier charges £5k.

27. **Office and Administration costs** – this includes costs for office relocation, bad debts written off and other office administration costs. The most significant variance is for the office relocation (£27k). The balance are small underspends across several cost lines.

28. **Other costs** – are over budget by £60k as a result of overspend on the Website accessibility project. Further costs for this piece of work are expected in 2021/22 and have been budgeted.

29. **Legal and professional costs** – are significantly over budget (£79k). Legal fees are over budget by £46k. There has been more HR legal advice sought than in previous years (£55k). In addition, there are overspends against our Internal Audit fees (£13k) – where additional days were agreed for some of our audits. Set against this is an underspend on our External Audit fee (£1k). Consultancy costs are overspent by £21k, predominantly a result of the strategic risk development work with Accenture that started at the end of 2019/20.

30. **Accommodation costs** – are over budget by £121k. The overspend relates mainly to the covering rent and service charges for both 151 Buckingham Palace Road and 2 Redman Place for the period January to March 2021.

31. **Non-cash costs** – represent depreciation and amortisation of our tangible and intangible assets and include disposal cost of assets that are no further use to the HTA and were written off prior to the office move (£118k). All of these costs are covered by the ring-fenced RDEL provided by the DHSC.

Forecast outturn

Other key performance indicators

Debtors

32. At the end of March 2021 total debt was **£187k** from 48 accounts. This is a significant reduction on the same period in 2019/20 (56%).

33. The table below gives a breakdown by sector.

Table three Debtors by sector

Sector	Number of establishments	Value of debt £	%ge
NHS	26	£137,615	74
Local Government Bodies	0	£NIL	0
Non-Government Bodies[1]	22	£49,101	26
Total	**48**	**£186,716**	**100**

34. Of the 26 NHS accounts, eight (£19k) have been outstanding since the 2019/20 billing round. We are in contact with each organisation and expect to clear these early in the new business year.

35. Of the 22 Non-Government Bodies, 14 (£12k) relate to the 2019/20 business year. As with the NHS organisations, we are actively pursuing these debts and expect resolution early in 2021/22.

Financial risks and mitigations

36. Financial risks are monitored on an ongoing basis. Below is a table of the current key risks identified and the mitigating actions and controls taken to minimise them. The financial risks in this summary are linked to one or more of

[1] Includes Universities and private organisations

the six high-level strategic risks that SMT has identified and is managing. The strategic risk five – insufficient, or ineffective management of financial resources –is rated yellow (medium) at year end as we have ended the year with a surplus.

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.

People

COVID-19 response

37. In late December 2020, the UK entered a further period of lockdown. As schools closed again the HTA re-launched additional flexible working support to staff and continued to invest in supporting staff wellbeing. All managers were encouraged to regularly review staff wellbeing within their teams and to report any concerns to HR, Heads and SMT.

38. Heads of Function continue to have a standing agenda item at each weekly HTA Management Group (HTAMG) meeting to review and raise any wellbeing or mental health concerns within their teams.

39. Most staff were able to informally apply a flexible approach to their working week around business and personal needs with line manager support. A small number of staff have had special arrangements agreed to further support caring responsibilities and/or mental health and wellbeing.

40. Staff were asked again to review their home office set up and to request any additional equipment to ensure a safe working environment.

New Ways of Working / Return to Office based Working

41. The Director of Resources produced a 'Return to office working' guidance document that mirrored the government's roadmap for an easing of lockdown restrictions. Currently there are no plans for staff to work from the office until the end of June at the earliest. Between June and late September, we plan to gradually introduce office-based activities e.g. training opportunities and all staff meetings.

42. A work team (Countdown to Redman Place) including Communications, Facilities and HR has been formed to develop a roadmap for a return to office-based working. This team will engage with staff directly, via the Engagement Team and Staff forum, to build momentum for our new ways of working and collocated working environment. There will be a 'Countdown to Redman Place' agenda item on weekly communications on Wave and in the All-Staff newsletter.

Wellbeing

43. Wellbeing continues to largely focus on our response to the impact of COVID-19. During the last quarter, our monthly themes have focused on Positivity, Wonder and Awe, Prosper and Belief.

44. In January we launched a meeting-free period between 12.00 and 1.00pm every day. Staff are encouraged to use this time as best suits them. This could be to take their lunch break, but could also be used as focus time, to catch up on emails or meet with a colleague for an informal chat. We also launched coffee and chat. This is where staff are paired to a different colleague each month for a 15-minute coffee break. Both have been well received.

45. In March we carried out a wellbeing survey of all staff. The response rate was 74% which is in line with the Pulse surveys. The survey results demonstrated that 84% believe Wellbeing is a priority for the HTA and 88% said they found the wellbeing pages on Wave helpful. 97% valued the Coffee and Chat and 66% valued the meeting free period. Some staff said they would have scored this initiative higher in the survey if they had appreciated that there is no requirement for them to take their lunch break at this time.

Recruitment and Retention

46. We had a turnover of 17% for 2020/21 compared with 28.9% in the previous year.

47. During quarter four, two members of staff resigned: one left with immediate effect due to personal circumstances and the other left at the end of April 2021.

48. Two members of staff on secondment into roles at a higher grade were formally appointed substantively following a formal recruitment process.

49. SMT has approved a phased programme of recruitment for eleven roles across the HTA over the next two quarters. The majority of those roles will be advertised during quarter one.

Sickness absence

50. There were 83 days of sickness related absence in 2020/21, this compares with 143 days in 2019/20. There is research available that suggests 'normal' sickness - for example colds, flu and respiratory transmitted bugs and viruses have been significantly reduced due to lockdowns, social distancing and the wearing of masks over the course of the pandemic.

Pulse Survey

51. A pulse survey was conducted in January with a response rate of 74%. The success scores were either the same or slightly improved when comparing the results with the October pulse survey. There were some comments relating to high workloads and some expressing a desire for more information regarding the HTA change objectives and goals.

Change

52. The Interim Change Manager has continued to build awareness of the Change process and the changes being implemented across the HTA. She supported the roll out of the Electronic Document Records Management System (EDRMS) and facilitated workshops for Heads and staff on 'New Ways of Working'. The Engagement Team has met regularly; sharing information with staff and gaining feedback as initiatives are progressed. The Change Manager initiated a small working group from across the five co-located Arms-Length Bodies in Redman Place, this work is continuing and building momentum as we approach a return to office-based working.

Personal Development Plan (PDP) toolkit

53. A new toolkit to support the PDP process was launched with workshops and Q&A sessions. The simplified PDP form that launched last year has been adapted to support staff in recognising the common objectives for all staff e.g. relating to the Development Programme and for Line Managers and Regulation Managers. The Toolkit includes discussion documents to upskill our line managers e.g. Holding Difficult Conversations.

Diversity and Inclusion

54. Research was conducted into Neurodiversity and how the HTA can adopt best in practice initiatives to improve our recruitment process and day to day activities. More will be available on this through quarter one.

Social Committee

55. The Social Committee has continued to deliver all staff events covering significant festival days and a music quiz. 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

Committee membership and role allocation

56. The recent changes in the HTA Board have prompted a review of membership of the Audit and Risk Assurance Committee and the Remuneration Committee and of the other roles that Members play. An oral update on this, and the latest plans for stakeholder groups, will be presented during the meeting.

Quarter three Accountability

57. 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.

58. The HTA's sponsor wrote in February 2021 to confirm there were no concerns with our performance in quarter three and gave positive feedback on our pandemic response. They thanked the HTA for its work in implementing the Northern Ireland Protocol as well as planning revisions to Code of Practice D, Public Display (HTA 11/21, agenda item 8).

Freedom of Information requests

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

Complaints

60. In quarter four, one informal complaint was received by the HTA.

HTA 09a-21 NEW - HTA Strategic risk register 2021-22 - April 2021

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT I	INHERENT L	PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL I	RESIDUAL L	ACTIONS TO IMPROVE MITIGATION	Risk Tolerance	LINE OF DEFENCE 1	LINE OF DEFENCE 2	LINE OF DEFENCE 3	TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION
1	***Failure to regulate in a manner that maintains public safety and confidence and is appropriate*** ***(Risk to Delivery objectives a-d & f Development objectives a-d)*** *Risk Owner:* ***Allan Marriott-Smith***	***Causes*** • *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.* ***Effects*** • *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**	**3**	*Ongoing*	**Regulatory model**	**5**	**2**		**10**	1	2	3			
						Fortnightly Transition Period oversight meetings from February 2020 with+H4:Q16+H4:Q15			In the current absence of site visit inspection, work will be undertaken to develop a risk assessment and a virtual regualtory assessment proposal..		X			Preventative	Board developed and approved the current HTA Strategy and is aware of the risk associated with current impossibility of site visit inspections.	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. .
						Regulatory decision making framework					X			Preventative	Reports of key decisions in Board Reporting.	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.
						Annual scheduled review of Strategy					X	X		Preventative	Outputs from annual strategy review translate into revised annual Strategy	Annual strategic planning away day completed in January 2020.
						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.					X	X		Preventative	Business plan for 2020/21 has been produced and approved for publication by the sponsor Department.	Quarterly reporting to Board and DHSC in November 2020 reflected progress against business plans.
						Well established processes support our core regulatory business.							X	Detective	Internal audit conducted on Key Regulatory Processes, receiving substantial assurance and noting good areas of best practice	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.
						Quality management systems										
						HTA quality management system contains decision making framework, policies and Standard Operating Procedures to achieve adherence to the regulatory model					X			Preventative/ Monitoring	Identified staff member temporarily responsible for QMS, automated review reminders, management oversight of progress on updates	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.
						People										
						Adherence to the HTA People Strategy which has been substantially amended and approved by the Board					X			Preventative	Management information and assessment presented to the Board quarterly.	Quarterly report made at November 2020 Board meeting. Mid-year PDP reviews were completed in October 2020.
						Training and development of professional competence					X			Preventative	Annual PDPs, Corporate Training Programme (led by Head of HR), RM Training programme, Career Investment Scheme proposals to SMT	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.
						Specialist expertise identified at recruitment to ensure we maintain a broad range of knowledge across all sectors and in developing areas			As vacancies arise, SMT take the opportunity to review business requirements and target building capability and filling skills gaps.		X	X		Preventative/ Monitoring	SMT assessment of skills requirements and gaps as vacancies occur, Recruitment policy	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.
						Transition period										
						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. HA Guide, ODT Framework and other external guidance being updated inline with new legislation to ensure we can regulate accordingly.			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.		X	X		Preventive / Detective / Monitoring	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.	Minutes of weekly SMT meetings.
									Regulatory model							
									Development work being undertaken to become a more data-driven risk based regulator as part of the HTA Development Programme.		X			Preventative		
									Other							
									Strengthening horizon scanning arrangements		X			Preventative		

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2	***Inability to manage an incident impacting on the delivery of HTA strategic objectives. This might be an incident:*** • ***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*** ***(Risk to all Delivery Development and Deployment objectives)*** *Risk owner:* ***Nicky Harrison***	***Cause*** • *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* ***Effect*** • *Loss of public confidence* • *Reputational damage* • *Legal action against the HTA* • *Intervention by sponsor*	***5***	***3***	Future, should event occur	Critical incident response plan, SOPs and guidance in place, regularly reviewed, including by annual training, and communicated to staff	***3***	***2***		***6***	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.
						All specific roles identified in the Critical Incident Response Plan are filled.					1 X	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.
						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.			Comms Team maintain close working relationships with colleagues across the business and proactively raise awareness of the need for Comms role in shaping lines and dealing with media.		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.
						Availability of legal advice					X			Preventative	Lawyers specified in Critical Incident Response Plan, SMT updates	In place
						Fit for purpose Police Referrals Policy					X			Preventative	Annual review of policy (minimum), usage recorded in SMT minutes	Police referral process used regularly by SMT and captured in SMT minutes.
						Onward delegation scheme and decision making framework agreed by the Board					X	X		Preventative	Standing Orders and Board minutes	Standing Orders published May 2017, due to be updated at November Board meeting.
						Regulatory decision making framework			Regulatory Decision Making process and SOP regularly reviewed and disseminated to staff.		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.
						IT security controls and information risk management					X	X		All	SIRO annual review and report Internal audit reports	Cyber security review - standing agenda item at ARAC - last discussed June 2020.
						Critical incident response plan regularly reviewed and tested			Actions associated with the internal audit reported in February 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.
						Evaluate test exercise of incident and feedback to all staff.			Question over whether a test of the Plan is required in light of the recent stress test presented by the coronavirus pandemic.		X			Preventative	SMT content that activation and use of CIRP during first wave and first lockdown superseded the need for a test.	Noted in ARAC Audit Tracker.
						Ensure DIs (or equivalent in ODT sector) are aware of and follow the incident reporting procedure for incidents reportable to the HTA.					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.
						Management of any risk of incidents likely to arise from the end of the Transition Period continues to be managed through the defined UK Transition project to 30 June 2021. Continuing engagement with DHSC to manage follow-up activity during the 6-month grace period for GB import / export licensing.			Specialist project manager recruited Autumn 2020 for the UK Transition Project.					Preventative / Detective / Monitoring	Continuing engagement with DHSC on ongoing aspects of the UK Transition Project, including the Northern Ireland Protocol (and engagement with NI Executive Department of Health). Director-level oversight as SRO (Director of Regulation), weekly Project meetings, 'stand-up' over the 6 weeks either side of 31/12/20, regular reporting to SMT through standing agenda item and specific papers for key decisions.	Regular reports to SMT - standing item on SMT agenda from February 2020. Smooth management of the end of the transition period at 31/12/20 through the regular stand-ups (based on the CIRP) and project oversight. SMT paper 14 January setting out scope of next phase to 30 June 2021.

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3	***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*** ***(Risk to Delivery objective e, and Development c)*** *Risk Owner:* ***Louise Dineley***	***Cause*** ***External factors*** • *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* ***Matters which certain stakeholder groups believe require review*** • *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* ***Matters which stakeholders/public may expect to be inside regulatory scope*** • *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* ***Effect*** • *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*	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	*4*	*3*		**9**	*1*	*X*	*3*	*Monitoring*	*Ongoing log*	*Log in place and stable.*
						Active management of professional stakeholders through a variety of channels including advice about relevant materials in and out of scope			*Comms & Engagement strategy under development to strengthen the HTA's approach and impact of stakeholder engagement. Updated C&E Strategy planned for Q4.*		*X*			*Preventative/ Detective*	*Stakeholder Group meeting minutes Authority minutes (including Public Authority Meeting) TAG and HWG meetings*	*Last stakeholder group meeting in October 2019 Public Authority Meeting in May 2019; Histopathology Working Group February 2020; Transplant Advisory Group October 2019*
						Active management of issues raised by the media – including the development of the HTA position on issues					*X*			*Preventative/ Detective*	*Quarterly reports to Board on communication (including media) activities*	*Last report July 2020*
						Regular reporting to DHSC sponsorship and policy team on matters which risk public and professional confidence						*X*		*Monitoring*	*Quarterly Accountability meetings with DH*	*Last assured position from DHSC on 31 July 2020*
						Action where we believe it will support public confidence					*X*			*Preventative*	*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.*	Update to the Board and DHSC at Board meeting May 2020.
						Clear view of use of s.15 duty to report issues directly to Ministers in England, Wales and Northern Ireland as new issues emerge					*X*			*Preventative*	*Duty and its uses understood by SMT and Chair*	*Advice and guidance continues to be provided, for example on the Private Members Bill - Organ Tourism and Cadavers on Display, 2020.*
						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).			Further work planned in 2021/22 to review and update codes of practice . Focus will be on factual update.		*X*			*Preventative*	*Updated guidance published. Updated Codes of Practice to support deemed consent published.*	*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.*
						Extensive Professional Evaluation Survey undertaken in Q4 2019/20, reported to Board in July 2020 and used to inform further developments.					*X*			*Preventative*	*Evidence from Professional Evaluation used as an evidence and information source to inform and drive improvements*	*Evidence from Professional Evaluation presented to the Board in July.*
						Proactive horizon scanning and development of policy in emerging/complex areas. Further strengthening building on existing system.					*X*			*Preventative*	*Horizon scanning improvement is one of the six strands of the development programme*	*Update on this work presented at July Board meeting*
						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.										
									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.		*x*			*Preventative*	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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4	***Failure to utilise people, data and business technology capabilities effectively*** ***(Risk to Delivery objectives a-e, Development a-d Deployment a, c and d)*** *Risk Owner:* ***Louise Dineley***	***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		***People capability***	4	3		9	1	2	3			
						People Strategy for the period 2019 to 2021 is in effect					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.*
						Full suite of people policies and procedures (including performance management)					X			*Preventative/ Monitoring*	*Full suite of policies in place and available on Wave*	*https://intranet.hta.gov.uk/pages/policies_forms*
						External assessment of utilisation of capabilities							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*
						Adherence to the HTA Workforce Capability Development Framework					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*
						Investment in the development of the HTA leadership team					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*
						Handover process is formalised via a checklist to ensure corporate knowledge is retained					X			*Preventative/ Monitoring*	*Handover checklist is in place and in operation.*	
									More formal assessment of future capability needs and how these should be met including through better knowledge of internal skills		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.*
									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.			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*
						Data capability										
						Data relating to establishments securely stored with the Customer Relationship Management System (CRM)					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
						Appropriate procedures to manage personal data including GDPR compliance.					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.
						Business technology capability										
						Staff training in key business systems					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.
						IT systems protected and assurances received from 3rd party suppliers that protection is up to date					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
									Business technology							

							Identify refresher training and targeted software specific training needs.		X			Preventative	Evidence of targeted training in last quarter. Further strengthening of core training requirements included in updated induction programme.		

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5	*Insufficient, or ineffective management of, financial resources* *(Risk to Deployment objective b* *Risk Owner:* *Richard Sydee*	***Cause*** • *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* ***Effect*** • *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* ***Leading to:*** • *Inability to deliver operations and carry out statutory remit* • *Reputational damage and non payment of fees*	5	4	Ongoing	Budget management framework to control and review spend and take early action	2	3		3	X	X		All	Budgetary control policy reviewed annually and agreed by SMT	Revised version reviewed by SMT in November 2020.
						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 outstsnding 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-finace 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 devleoped and presented to ARAC Oct-19. Annual training of staff completed n Q4	Cabinet Office - CDR submissions Counter-fraud activities now part of BAU.

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								3			1	2	3			
6	***Failure to achieve the benefits of the HTA Development Programme*** ***(Development objectives a-d)*** ***Risk owner*** ***Louise Dineley***	***Causes*** • *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* ***Effects*** • *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		SMT experience of organisational change, programme and project management.	3		*Change Manager appointed in August 2020 to support the development of capacity & capability across the organisation*	9	X			Preventative	Recruitment of an HTA Programme Director	The Director of Data, Technology and Development appointed in October 2019 will act as Programme Director.
						HTA approach to the management of change projects *(underpinned by project management methodologies)*					X			Preventative	Dedicated permanent project manager appointed	PM in place an operating effectively
						A number of trained project managers among HTA staff			*Project Management skills further strengthened by introduction of a toolkit and induction session by PM*		X			Preventative		
						Experience of procurement and contract management					X			Preventative		
						Existing mechanisms for engaging staff			*Plans developing for strengthening internal communciations function*		X			Preventative		
						Well established corporate governance arrangements and financial controls						X		Monitoring	*Internal audit of key controls*	Assurance provided by Internal Audit of adequacy of key financial controls
						Agreement to a phased delivery approach to avoid all or nothing investment and align with available funding			*Further alignment of projects on the business plan in Q3 & Q4 to strengthen phasing of actions, resource deployment and consolidation of actions to encourage smarter working.*		X			Preventative	*Progamme plan in place*	Update reported to July Board meeting
									Embed Benefits Realisation Management methodology within programme		X			Preventative		
									Introduce a Programme Management function		X			Preventative		*New PM appointed, procedures and PMO established. Ongoing focus to embed skills and build wider capability across the business*
									Board approval to proceed at key Gateway decision points			X		Monitoring		
									Training plan to encompass project and change management and HTA approach		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*
						Strengthened planning supports a single message and focus on an agreed set of priorities			Development of procurement plan to deliver the DDAT Strategy		X			Preventative		*Plan in place, work ongoing in 2020/21.*
									SROs identified for Programme and individual projects		X			Preventative		*Updating of the Business plan in Q4*
						Project management includes a monitoring of costs			Schedule a regular programme of staff engagement events		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.*
						Scope of projects aims to deliver benefits including on a phased and incemental design			Establish an external stakeholder communications and engagement plan		X			Preventative		*Work progressing Q4*
									Recruitment of new Board Member(s) with digital and organisational change experience			X		Monitoring		*This was not achieved as part of the recent recrutiment round, but will be a focus for the next round in 2021.*
						Agreed priorities in Business Plan and underpinning foundations for future strategy maintain required pace			Programme to become a focus for appropriate internal audit				X	Monitoring/ Detective		
									Appointment of external critical friend to counter potential optimism bias				X	Preventative		

(HTA 09b-21)

Latest review date – 29/04/2021

Strategic risk register 2020/21
Risk summary: high to low residual risks

Risk area	Strategy link*	Residual risk	Status	Trend**
R1: Failure to regulate appropriately	Delivery (a-d & f) and Development (a-d) objectives	**10 – Medium**	At tolerance	⇔⇔⇔
R2: Failure to manage an incident	Delivery, Development and Deployment objectives	**6 - Medium**	At tolerance	⇔⇔⇔
R3: Failure to manage expectations of regulation	Delivery e) and Development c)	**9 - Medium**	At tolerance	⇔⇔⇔
R4: Failure to utilise our capabilities effectively	Delivery, Development and Deployment (a, c and d)	**12 - High**	Above tolerance	⇔⇧⇔
R5: Insufficient or ineffective management of financial resources	Deployment (b) objective	**6 - Medium**	Above tolerance	⇔⇔⇔
R6: Failure to achieve the benefits of the organisational transformation program	Development (a-d) objectives	**9 - Medium**	At tolerance	⇔⇧⇔

* Strategic objectives 2019-2022:
** This column tracks the four most recent reviews by SMT (e.g.⇧⇔⇩⇔).

R1: There is a risk that we fail to regulate in a manner that maintains public safety and confidence and is appropriate.

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
3	5	15 - High	**2**	**5**	**10 - Medium**
Tolerance threshold:					**10 - Medium**

Commentary
At tolerance. 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 2020. 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. Virtual regulatory assessments (VRAs) were piloted during quarter three in the Human Application (HA) sector and continued in quarter four. These are now being extended to Human Tissue Act sectors. There is a schedule of VRAs for Quarter one including HA, Research and Post-Mortem sectors during Quarter one with a view to scaling up the use of this tool across all sectors over the remainder of the 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 Department of Health and Social Care (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. **April 2021** - We continue to use all other regulatory tools and processes, such as managing and responding to incident reports (Serious Adverse Events and Reactions and HTA Reportable Incidents), whistleblowing / informant information and our ongoing engagement with our regulated sectors, with investigations and active regulatory action continuing throughout the pandemic restrictions. The Senior Management Team have agreed a tolerance of 10 as an interim position. This is higher than the indicative appetite agreed with the Board, but it is felt that the current operating environment limits the impact further internal mitigation. The exit from current restrictions

coupled with the roll out of developing activities should allow this to be reduced further in due course.

R2: There is a risk that we will be unable to manage an incident impacting on the delivery of HTA strategic objectives. This might be an incident: relating to an activity, we regulate; 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.

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
3	5	15 - High	**3**	**2**	**6 - Medium**
Tolerance threshold:					**6 - Medium**

Commentary
At tolerance. 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. April 2021 - SMT believe this risk is stable. Although there is a demonstrable link between risks one and two, in that a business continuity issue could destabilase the ability to regulate, this risk is focussed on our ability to respond. As such the Executive have set this risk at a lower tolerance level as our ability to respond appropriately is within the direct locus of control of the HTA.

R3: There is a risk that we will fail to manage public and professional expectations of human tissue regulation in particular stemming from limitations in current legislation or misperception of HTA regulatory reach.

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
3	4	12	**3**	**3**	**9 – Medium**
Tolerance threshold:					**9 - Medium**

Commentary
At tolerance. 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. In 2020/21 the Development programme included a specific workstream to strengthen horizon scanning on emerging changes to policy and activities where the HTA may be required to act or offer an authoritative voice. This proactive approach has gone live in quarter four and will continue to be embedded in 2021/22. The transition period for the UK's exit from the European Union (EU) ended 31 December 2020, although the HTA's EU exit Statutory Instruments (SIs) provide, in effect, for a six month period of grace for new import and export licensing obligations for material moving between the UK and the EU. The UK Transition Project has been proactively engaging with establishments and representative bodies to ensure those affected by these changes are aware of and adhere to these new obligations, providing advice and guidance through a variety of routes. The HTA has responded to ongoing concerns, including from Members of the House of Lords, concerning the consent provisions for material imported for the purposes of public display. As a result, the HTA has reviewed and updated Code D. Work has continued to support Public Health England in its pilot project to undertake post-mortem surveillance sampling for COVID-19 through the licensing of Funeral Directors, with several more applications now expected in the next phase of this project. All 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 April 2021.

R4: There is a risk that we will fail to utilise people, data and business technology capabilities effectively.

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
4	4	16 – High	**3**	**4**	**12 - High**
Tolerance threshold:					**9 - Medium**

Commentary
Above tolerance. 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 HTA's people capability. Planning is being undertaken to develop new flexible arrangements to maximise staff availability. The Audit and Risk Assurance Committee has supported the temporary de-prioritisation 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 Electronic Document Records Management System (EDRMS) has formed part of the development plans for 2020/21. The adoption of SharePoint as the HTA's EDRMS was completed in quarter four with all documents migrated from IMPACT to SharePoint and staff having received training on the new system. The EDRMS project has provided a foundation for further development and the adoption of an Enterprise Content Management system in 2021/22. 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 was upward pressure on this risk in January 2021 which has now stabilised - resource and business planning has been the primary focus of both HTA Management Group and SMT over the past two months and the clarity on deliverables over the next six months alongside post recruitment should see this risk reduce. April 20201 - SMT considered the current tolerance level as temporary, accepting a higher tolerance as an interim whilst we continue with the Development programme and the posts in the recently announced structure changes are recruited to, We believe the recruitment and the development programme will lower the current residual risk scoring over the next three months. .

R5: There is a risk that the HTA has insufficient or ineffective management of its financial resources

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
4	5	16 – High	**3**	**2**	**6- Medium**
Tolerance threshold:					**3 - Low**

Commentary
Above tolerance. 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. April 2021 - Planning for 2021/22 is now complete. DHSC have confirmed GIA funding for the new financial year and we expect additional funding for ongoing EU transition activities. 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 have allocated funds for the continuation of our development activities. Further discussions with DHSC on accessing reserves to fund our development priorities are in train and we are hopeful of some limited flexibility this financial year. Tolerance for the risk is low, in line with Board agreed appetite in this area. Although the medium term impact of the pandemic on our licensed centres remains difficult to predict, we will consider emerging trends as we start the 2022/23 fees work in May/June 2021 and would anticipate that this risk will reach tolerance once this work is finalised.

R6: There is a risk that we fail to achieve the benefits of the organisational transformation programme

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
4	5	20 – Very High	**3**	**3**	**9- Medium**
Tolerance threshold:					**9 - Medium**

Commentary
At tolerance. 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 complete and closed, 151BPR will be formally returned to GPA at the end of February 2021 and the new premises were ready for occupation on 18 January. Some activity relating to IT, records digitisation and resumption of office working will continue outside the project 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 March 2021. April 2021 – The executive proposes to close this risk in its current form. Large elements of this work is now complete, and it is felt that a risks in this area relate to the failure to derive the benefits from our Development programme and recruitment plans and that we fail to keep pace with wider developments in the Governments approach to the regulatory sphere we operate. We anticipate bringing this new risk for consideration by ARAC in June 2021 and then to the Board meeting currently scheduled for July 2021.

Reviews and revisions

(11/03/21) SMT review March 2021

SMT reviewed all risks - generally our risk levels are stable and there have been no significant changes from the last review conducted in February. A detailed review of our risk summary is being conducted.

(30/03/21) SMT review March 2021

SMT reviewed the risk and set tolerance levels for each risk. It was agreed that further review will be undertaken in early April prior to sharing this summary with both the Board and ARAC in May and June respectively. Particular to note, is the relationship between risks 1 and 2 and their respective tolerance levels as they are interdependent.

(29/04/21) SMT review April 2021

Updates to the narrative, reflect the new arrangements for this financial year. This new format will allow SMT to review the strategic risks and their respective tolerance levels and implement the necessary activities to either reduce residual risks to tolerance or maintain them at an accepted level.

Risk 6, SMT felt no longer reflects where we are now that key work pages within the Development Programme have been completed.

Strategic Aims

Delivery: 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.
(a) Deliver effective regulation of living donation.
(b) Provide high quality advice and guidance in a timely way to support professionals, Government and the public in matters within our remit.
(c) 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.
(d) 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: • 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.
(a) Make continuous improvements to systems and processes to minimise waste or duplicated effort, or address areas of risk.
(b) 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.
(c) Begin work on implementing a future operating model, which builds our agility, resilience and sustainability as an organisation.

Deployment: Manage and develop our people in line with the HTA's People Strategy
(a) 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

Criteria for inclusion of risks

Whether the risk results in a potentially serious impact on delivery of the HTA's strategy or purpose.

Whether it is possible for the HTA to do anything to control the risk (so external risks such as weather events are not included).

Rank

The risk summary is arranged in risk order.

Risk scoring system

We use the five-point rating system when assigning a rating to the likelihood and impact of individual risks:

Likelihood:	1=Rare	2=Unlikely	3=Possible	4=Likely	5=Almost certain
Impact:	1=Very low	2=Low	3=Medium	4=High	5=Very High

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

Risk appetite and tolerance

Risk appetite and tolerance are two different but related terms. We define risk appetite as the willingness of the HTA to take risk. As a regulator, our risk appetite will be naturally conservative and for most of our history this has been low. Risk appetite is a general statement of the organisation's overall attitude to risk and is unlikely to change, unless the organisation's role or environment changes dramatically.

Risk tolerances are the boundaries for risk taking. The risk appetite statement informs the development of risk tolerances for the HTA and provides guidance on how the risk appetite statement is to be applied in everyday business activities and decisions.

Assessing inherent risk

Inherent risk is usually defined as ‘the exposure arising from a specific risk before any action has been taken to manage it’. This can be taken to mean ‘if no controls at all are in place’. However, in reality the very existence of an organisational infrastructure and associated general functions, systems and processes introduces some element of control, even if no other mitigating action were ever taken, and even with no particular risks in mind. Therefore, for our estimation of inherent risk to be meaningful, we define inherent risk as:

‘the exposure arising from a specific risk before any additional action has been taken to manage it, over and above pre-existing ongoing organisational systems and processes.’

Contingency actions

When putting mitigations in place to ensure that the risk stays within the established tolerance threshold, the organisation must achieve balance between the costs and resources involved in limiting the risk, compared to the cost of the risk translating into an issue. In some circumstances it may be possible to have contingency plans in case mitigations fail, or, if a risk goes over tolerance it may be necessary to consider additional controls.

When a risk exceeds its tolerance threshold, or when the risk translates into a live issue, we will discuss and agree further mitigations to be taken in the form of an action plan. This should be done at the relevant managerial level and may be escalated if appropriate.

Human Tissue Authority
Board meeting

Date: 6 May 2021

Paper reference: HTA 09c/21 (Board Supplementary Data Annex)

Agenda item: 6

Author: Nicolette Harrison
Director of Regulation

OFFICIAL

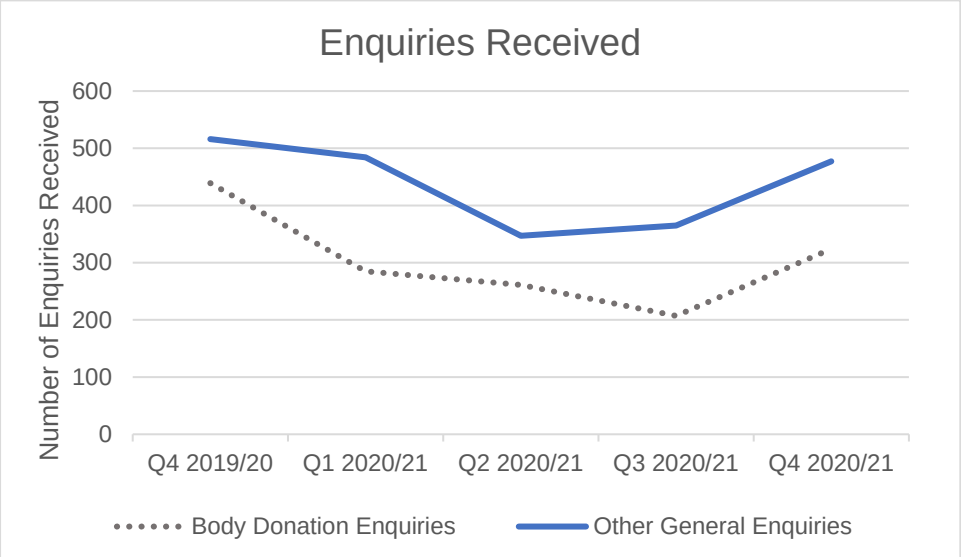
Purpose of Report

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

Enquiries

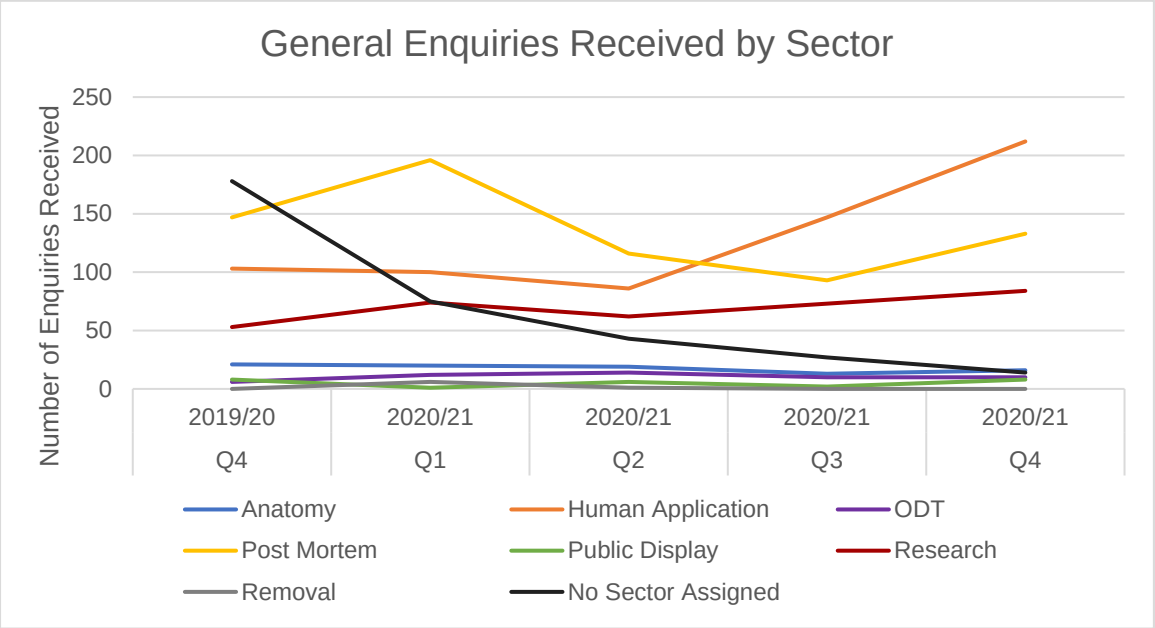
2. Figure 1 below displays the total number of body donation enquiries and other general enquiries received. In quarter four, 477 General Enquiries and 324 Body Donation Enquiries were received.

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



3. Figure 2 displays the number of general enquiries received for each sector (excluding body donation enquiries).

Figure 2: Number of body donation and other general enquiries received each quarter



Licensing

4. Table 1 displays the number of new licence applications, new licences offered, satellite additions and revocations in quarter four.

Table 1: New licence applications, new licences offered, satellite additions and revocations in quarter four

Sector	New Licence Application	No. of Licence Applications with Decision Made	Satellite Additions	Revocations	Satellite Revocations
Anatomy	0	0	0	0	0
Human Application	7	2	2	3	0
Organ Donation and Transplantation	0	0	0	0	0
Post Mortem	1	2	4	2	0

Public Display	0	0	0	0	0
Research	2	2	2	0	0
Total	10	6	8	5	0

5. 10 new licence applications were received in quarter four 2020/21. For comparison, in 2019/20 we received 5.75 applications per quarter on average.

6. Seven applications were received in the Human Application sector, of which six were Northern Ireland import licences. One emergency mortuary licence was received in the Post Mortem sector and two applications were received in the Research sector.

7. In quarter four 2020/21, decisions were made on six applications. Two licences were granted in the Human Application sector, two were granted in the Research sector and two applications were withdrawn in the Post Mortem sector.

8. There were eight satellite additions in quarter four (two in the Human Application sector, four in the Post-Mortem sector and two in the Research sector).

9. Five revocations took place in quarter four (three in the Human Application sector and two in the Post-Mortem sector).

10. No satellite revocations took place in quarter four.

Licensing Variations

11. Figure 3 displays the total number of licensing variations received each quarter. A total of 184 licensing variations were received in quarter four. Compared to the peak received in Q1 2020/21 (during the start of the COVID-19 pandemic), numbers have returned to the average before this period.

12. Licensing variations received by sector are displayed in Figure 4.

Figure 3: Total number of licencing variations received each quarter

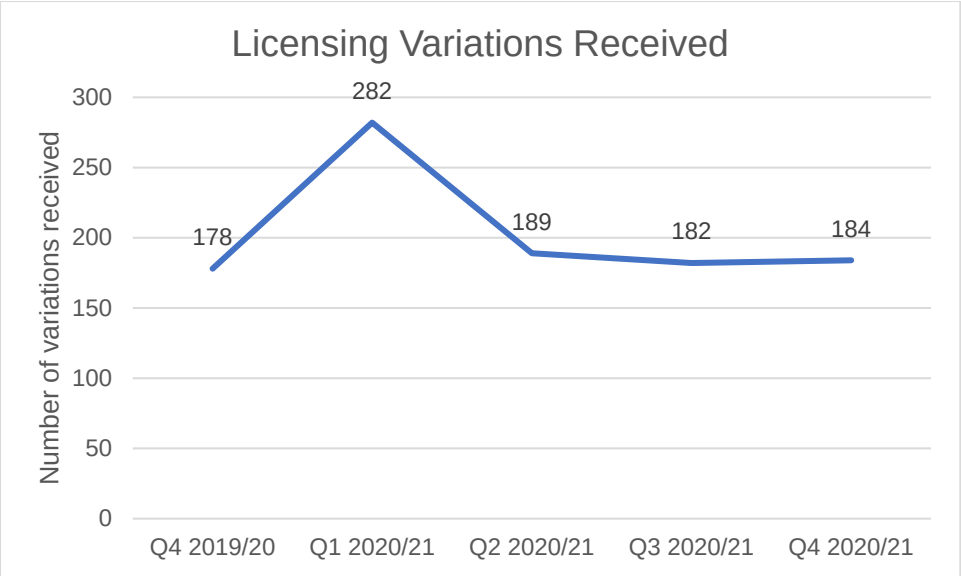
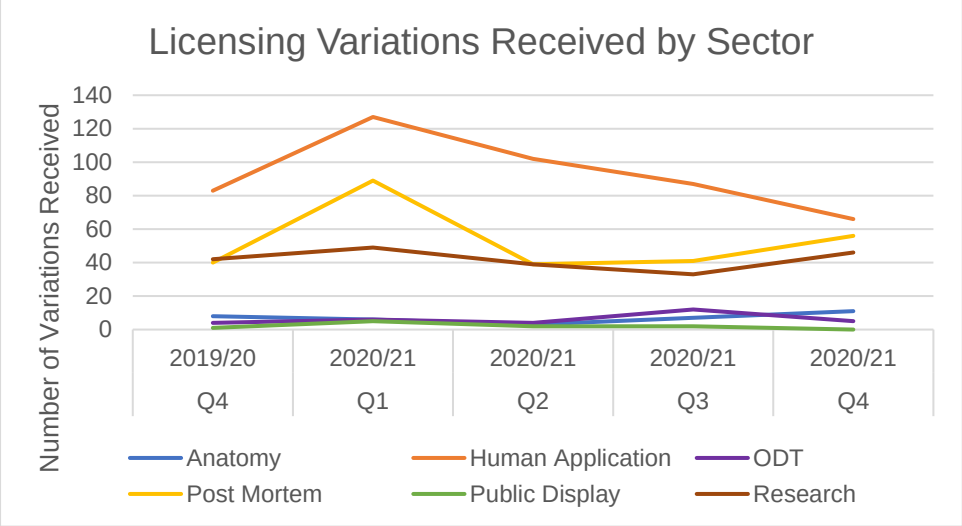


Figure 4: Total number of licencing variations by sector

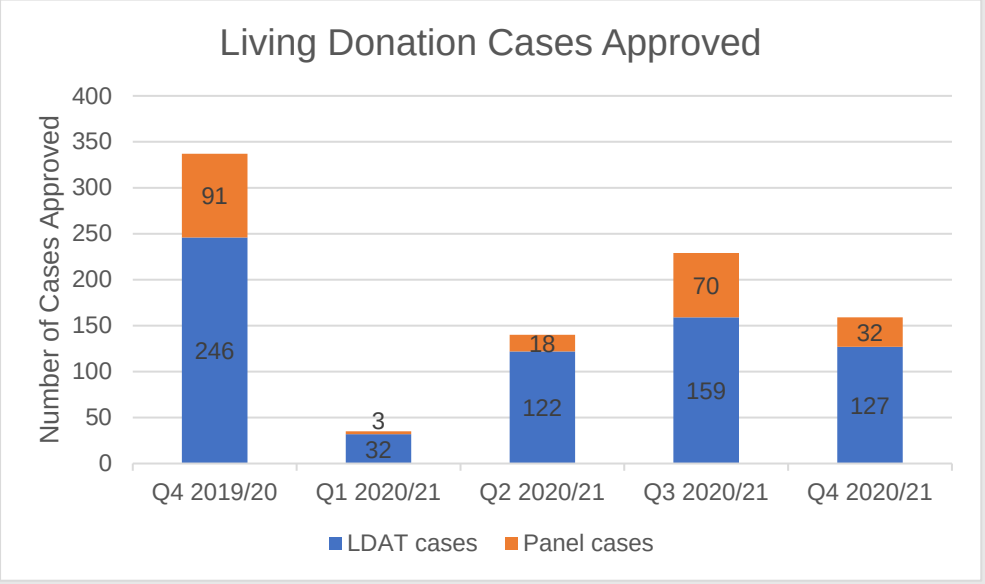


Living Donation

13. Figure 5 shows the total number of living donation cases approved by the Living Donation Assessment Team (LDAT) and HTA panels.

14. In quarter four, 127 cases were approved by the LDAT and 32 cases were approved by the panel. The total number of cases approved also includes those using the emergency out-of-hours processes.

Figure 5: Number of living donation cases approved per quarter



15. Table 2 below shows the total number of bone marrow and peripheral blood stem cell (PBSC) cases approved in quarter four compared to preceding quarters.

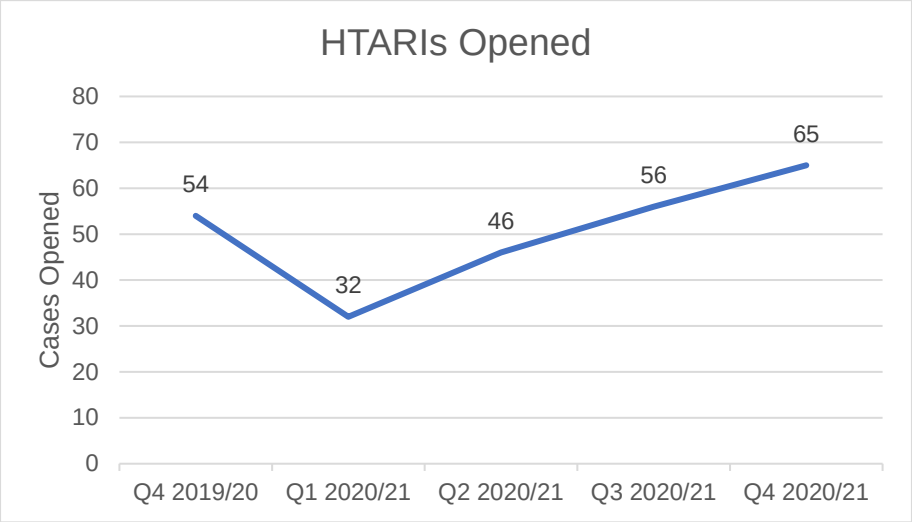
Table 2: Total number of bone marrow and PBSC cases approved

	Q4 2019/20	Q1 2020/21	Q2 2020/21	Q3 2020/21	Q4 2020/21	2018/19 Total	2019/20 Total
Bone Marrow/PBSC Cases Approved	17	16	15	17	14	71	66

Incidents – HTA Reportable Incidents (HTARIs)

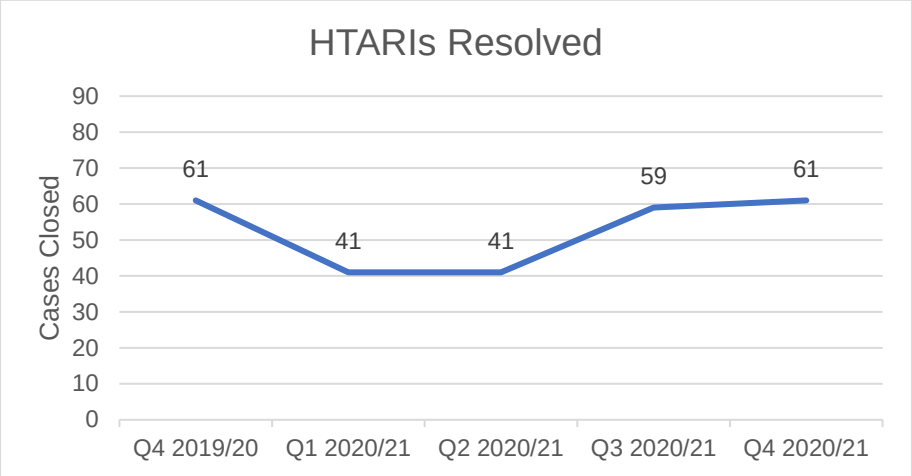
16. Figure 6 displays the number of reported HTARIs in quarter four compared to preceding quarters. This also includes any near misses and incidents that may, on investigation, be found not to be reportable incidents. In quarter four, 65 HTARI cases were opened, compared to 56 cases opened in quarter three.

Figure 6: HTARI cases opened during quarter in the Post-Mortem sector



17. Figure 7 displays the number of HTARIs resolved in quarter four compared to the preceding quarters. 61 HTARIs were resolved in quarter four, compared to 59 resolved in quarter three.

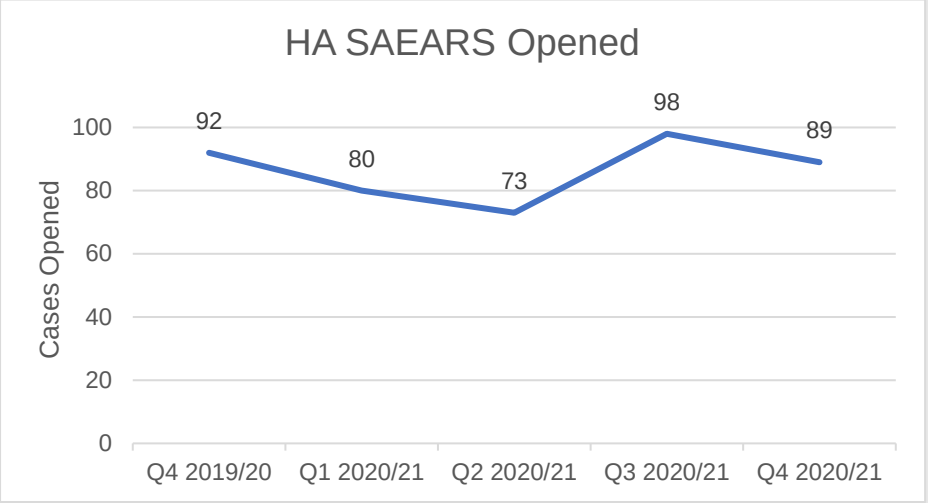
Figure 7: HTARI cases resolved during quarter in the Post-Mortem sector



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

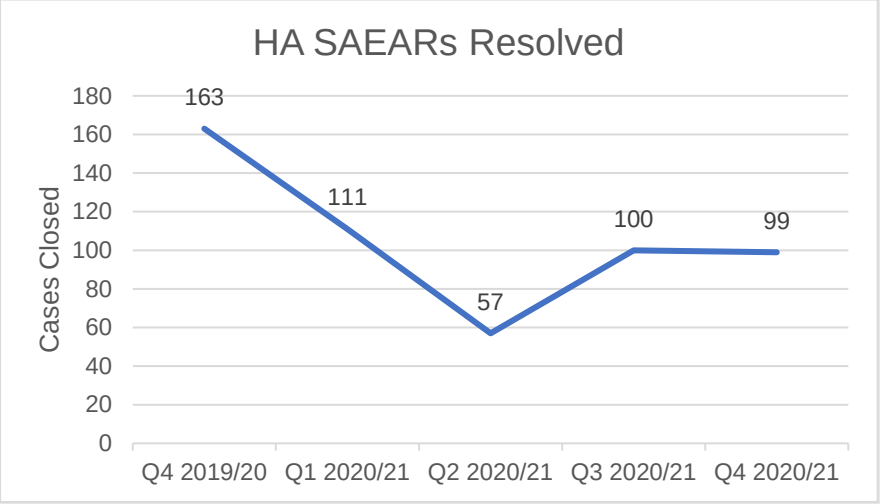
18. Figure 8 below displays the number of reported HA SAEARs in quarter four compared to preceding quarters. This also includes any near misses and incidents that may, on investigation, be found not to fit the criteria of a SAEAR. In quarter four, 89 HA SAEARs cases were opened, compared to 98 cases opened in quarter three.

Figure 8: SAEARs opened during quarter four in the Human Application sector



19. Figure 9 displays the number of HA SAEARs resolved in quarter four compared to preceding quarters. 99 HA SAEARs cases were resolved in quarter four, compared to 100 cases resolved in quarter three.

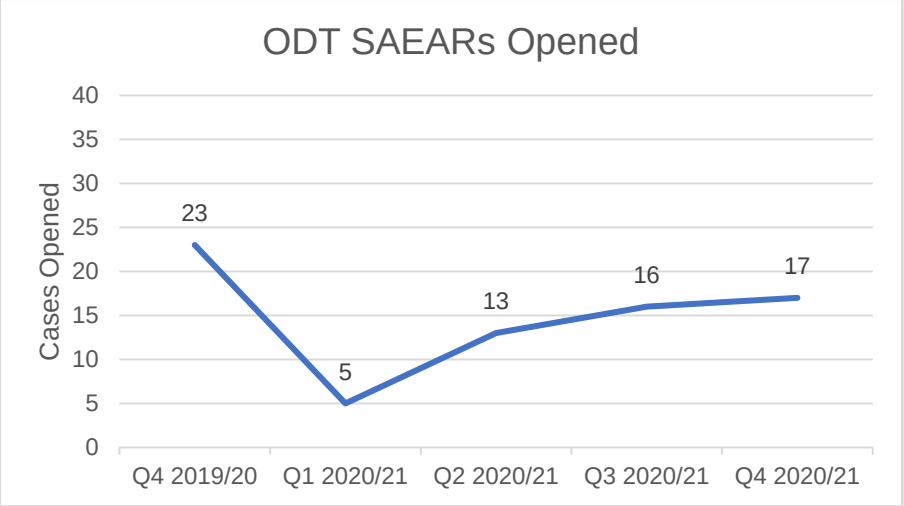
Figure 9: SAEARs resolved during quarter four in the Human Application sector



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

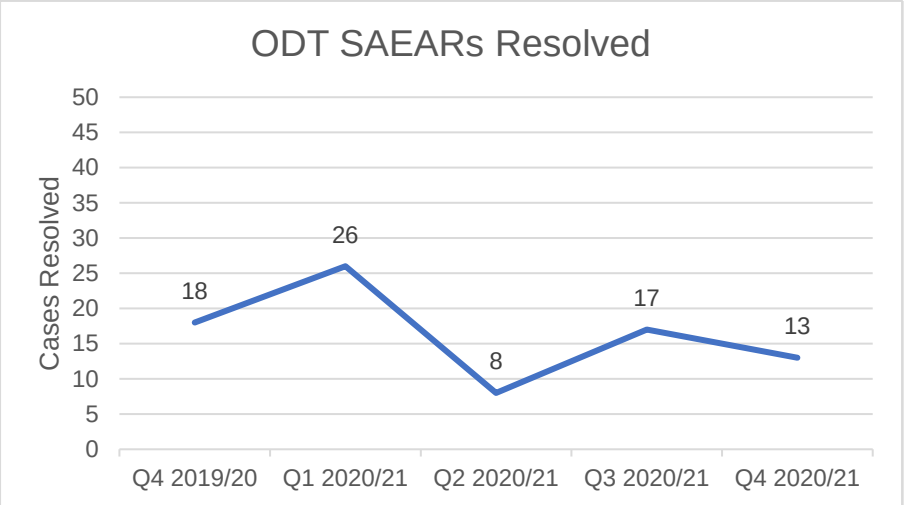
20. Figure 10 below displays the number of reported ODT SAEARs in quarter four compared to preceding quarters. In quarter four, 17 ODT SAEARs cases were opened, compared to 16 cases opened in quarter three.

Figure 10: SAEARs opened during quarter four in the Organ Donation and Transplantation sector



21. Figure 11 below displays the number of ODT SAEARs resolved in quarter four compared to preceding quarters. 13 ODT SAEARs cases were resolved in quarter four, compared to 17 cases resolved in quarter three.

Figure 11: SAEARs resolved during quarter four in the Organ Donation and Transplantation sector



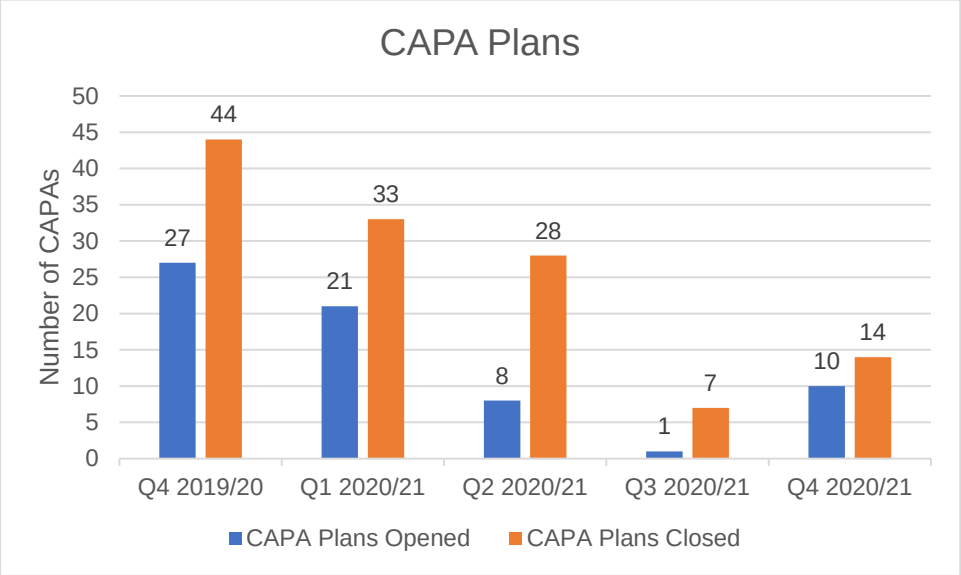
Corrective and Preventative Action Plans (CAPAs)

22. Figure 12 displays the number of CAPA plans opened and closed during quarter four, compared to previous quarters. The number of CAPA plans opened includes those opened as part of new licences offered and investigations.

23. A total of ten new CAPA plans were opened in quarter four. This includes nine opened in the Human Application sector and one opened in the Post-Mortem sector.

24. A total of fourteen CAPA plans were closed in quarter four. This includes ten in the Human Application sector and four in the Post-Mortem sector.

Figure 12: Number of CAPA Plans opened and closed during quarter



25. Table 3 shows all open CAPA plans at the end of quarter four and the length of time they have been open.

26. There were a total of 23 open CAPA plans at the end of quarter four. Six CAPA plans have been open for less than six months, five have been open between six to 12 months and twelve CAPA plans have been open for longer than 12 months.

Table 3: All Open CAPA plans

Open CAPA Plans	Anatomy	Post Mortem	Human Application	Research	Public Display	ODT	Total
< 6 months	0	1	5	0	0	0	6
6-12 months	0	3	2	0	0	0	5
> 12 months	0	2	10	0	0	0	12
Total	0	6	17	0	0	0	23

Website Analytics

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

Table 4: Audience Size

	2020/21	2019/20
Visits	52,569	59,779
Sessions	74,931	82,846

28. Traffic has recovered to a degree since the previous two quarters where traffic was down 20%.

Table 5: Engagement

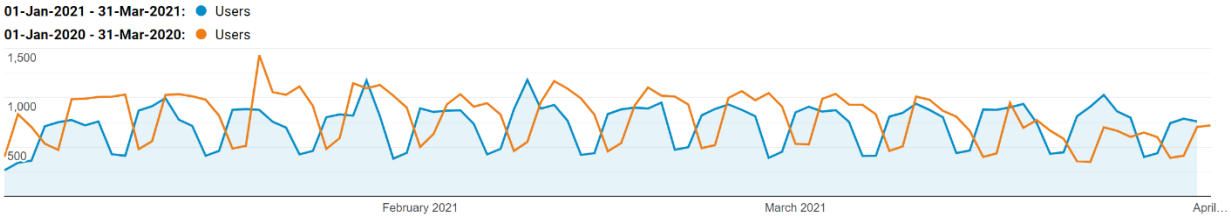
	2020/21	2019/20
Average time on page	3min 5s	2min 41s
Bounce rate	41.91%	40.63%

29. Engagement has increased this quarter, with average time on page increasing by a large degree, and bounce rate falling by a small degree. This is generally expected behaviour. A smaller audience is generally more engaged.

Popular Pages

30. The body donation page continues to experience far fewer visits than prior to the COVID-19 pandemic. For this quarter page views were down 31% compared to last year, with similar falls in supporting pages (find a medical school and the body donation FAQs). Other pages targeted at professional stakeholders have seen small some increase in visits e.g. the Codes of Practice (up 12%), and list of relevant material (up 6%). The largest increase in visits is the homepage, which is up 69% compared to last quarter.

Comparison graph (users over time)



Human Tissue Authority
Board meeting

Date: 6 May 2021

Paper reference: HTA 10/21

Agenda item: 7

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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 the Development Programme. This update will include the status of planned deliverables in quarter four 2020/21 and a high-level roadmap for the next 12 months.

Decision making to date

2. This paper was reviewed and approved by the CEO on 30 April 2021.

Action required

3. The Board is asked to note the update and support the planned developments up to 31 March 2022.

Background

4. Over the last 12 months, the outputs of the Development Programme have focussed on establishing the foundations for the year ahead and the move from the conceptual to the delivery of change and the realisation of the benefits. This work, delivered through a number of projects, has been centred around:

    - The development of our IT capabilities
    - Better understanding the HTA's data and intelligence requirements
    - Preparing the organisation for change and for individual projects establishing a state of readiness
    - Exploring opportunities and adopting new ways of working that have the potential to shape a future regulator model.

5. The collective output and learning from setting these foundations have informed the projects for the next 12 months, the incremental approach to development and delivery and the integration and alignment of change.

Quarter four 2020/21 Deliverables – update on progress

6. Quarter four represented an ambitious and important period of delivery. It provided the transition from "thinking" to "doing" with changes establishing the foundations for further developments in 2021/22. This is important as the changes are not only feeling more real, they are also more visible to the organisation. Most notable in this has been the technology developments and the move from IMPACT to SharePoint.

7. Table 1 provides a summary of the projects, the expected deliverables by year end and the status of each project. In all cases the required progress has been achieved and where the status is ongoing this is reflective of the further embedding and adoption that will be a part of how we work.

Table 1: Summary of Quarter four projects

Priority Project	Expected Deliverable 31 March 2021	Project Status
Strengthening The use of data And intelligence	Commission an external supplier to support the incremental development of the use of data and intelligence in the HTA's approach to regulation.	Status: Complete Draft report received in mid-April and used to inform Q1 and 2 planning. Further Progress subject to agreement of Business case by Senior Management Team (SMT).
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 refresh of the 2021-24 strategy.	Status: Complete Target Operating Model drafted by end of March. Presentation at SMT on 7 May for discussion and to agree to further opportunities for development in 2021/22.
Implementing an Electronic Document Record 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.	Status: Complete Implementation of the EDRMS completed with final migration from IMPACT completed in early April. Training delivered to staff to Support go live.

Priority Project	Expected Deliverable 31 March 2021	Project Status
Optimising Office 365 Functionality	Organic growth and adoption of Office 365. Focus for Q4 was the increased adoption of Collaborative tools and Functionality to support and Strengthen flexible working arrangements.	Current: Ongoing The status of this project is ongoing to reflect the embedding of the tools as well as making use of the Functionality offered by MS365. In Q4 there was a notable increase in the use of Teams channels for projects and in the sharing of documents for information and collaboration.
Horizon Scanning & future regulation	Delivery of a Horizon scanning framework and up to date log that will inform and drive the change in our policy development.	Status: Complete Horizon scanning framework revised and implemented. First Iteration of the new, updated list completed.
Organisational Preparedness	Continue to develop change readiness.	Status: Ongoing Over the next 12 Months organisational Preparedness will need to be a future of individual projects and overall. This preparedness may take different forms from communication & engagement; organisational design; developing skills and managing transition to new ways of working.

Looking ahead – 2021/22 Roadmap

8. Over the next 12 months, the Development Programme will build on progress to date in developing the capacity and capability of our systems, our people, and our processes. SMT has identified three priority projects that are highly interdependent.

Strengthening the use of data and intelligence

9. The aim of this project is to establish a data and intelligence model for the HTA. The scope of this project includes, what data should be collected; how it is collected; how it is stored and presented and developing reporting and presentational capabilities.

10. The scope of the model extends beyond data management to include functionality. The future functionality requirements have been informed by the preparatory work completed in quarters three and four 2020/21.

The implementation of an Enterprise Content Management system

11. The implementation of an Enterprise Content Management System builds on the work to introduce an Electronic Document Record Management system and strengthen the interoperability and rationalisation of the IT systems used in in the HTA.

12. The aim of this project is to build a platform upon which the HTA conducts a significant portion of its business. It will involve the mapping of current and future systems, identifying opportunities for change and development. This blueprint will be critical to informing the redesign and development of what we do and how we do it and in building the capability of our systems.

Establishing a target operating model for the HTA, and with it, the opportunity to further develop our regulatory offer

13. The aim of this project is to develop a Target Operating Model for the HTA that describes a systematic way of working, identifies the relationship between regulatory functions and sets out a consistent way of working across the HTA.

14. Assessment of the current model has identified a number of opportunities for improvement and development based on what we currently do. These opportunities are linked to the rationalisation of the number of systems used, establishing connections across the systems and between functions that minimise manual intervention and support more timely information and data exchange through auto-population, and seeks to build additional options for the provision of regulatory oversight.

Programme approach

15. The approach to planning the delivery of individual projects and the overall change from these developments has used a common set of principles:

- Incremental development across the projects that recognises and actively manages any interdependencies. This approach supports learning between stages and the opportunity to flex plans as necessary.
- Phased delivery plans with clear milestones, deliverables, and outputs for the individual projects and to reflect interdependencies.
- Identified benefits and success measures for each stage with steps being taken to move towards reporting an overall return on investment against the programme at year end.
- Resource plans that aim to make use of and blend existing internal skills, the development of HTA capacity and capability in the longer term and buying in skills and expertise to support delivery at pace.

16. A high-level timeline to support delivery has been developed. It is characterised by incremental development and contributions from individual projects and supporting activity such as stakeholder engagement and testing and piloting new approaches that will help to validate and inform the programme of development.

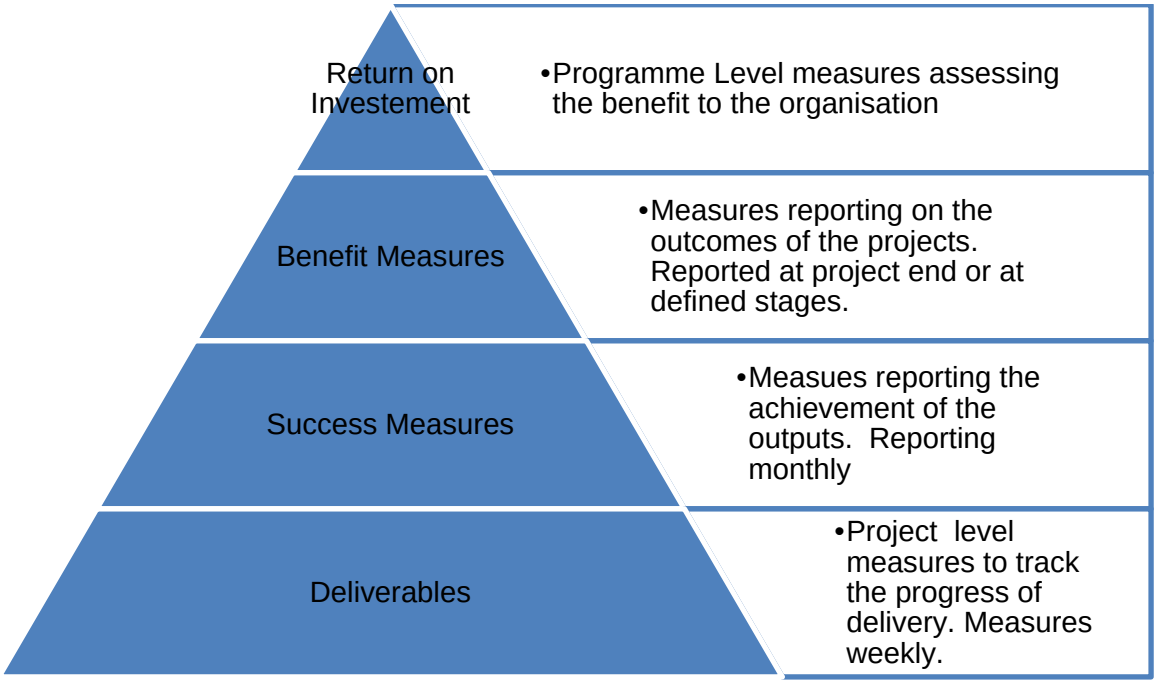
Measuring Success and Benefits Realisation

17. The Development Programme delivery in 2021/22 will be supported by a newly developed framework to support the identification of success measures and benefits to be realised as part of projects and programmes. The framework also

aims to complete an initial assessment of return on investment (ROI) for the programme overall.

18. The framework sets out the approach to be adopted to monitor, review, track and support the progress of the Programme. The levels have been designed to define impact at a programme level, show the success of the projects linking together and provide the evidence that individual projects are delivering. The framework is shown in the diagram below.

HTA Framework for Measuring Success, Benefits and Return on Investment



19. Each level will have a process for defining the measures. The process will ensure the measures are meaningful, relevant for the work being carried out and understandable for the audience reviewing the measure.

Next Steps

20. The delivery of these projects is subject to agreement of detailed business cases by SMT in early May.

Human Tissue Authority
Board meeting

Date: 6 May 2021

Paper reference: HTA 11/21

Agenda item: 8

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HTA Code of Practice D, Public Display Update

Purpose of paper

1. To present to the Board proposed changes to Code of Practice D (Code D). These changes aim to bring consent expectations for the public display of imported bodies and body parts in line with consent requirements for bodies and body parts sourced domestically.

2. In addition, to present to the Board the proposed changes to the accompanying Standards and Guidance document for Code D, specifically the guidance information provided for Consent standard C1.

3. To seek agreement from the Board on the proposed changes to Code D prior to it being submitted to Department of Health and Social Care to arrange for it to be laid in Parliament as soon as possible.

Decision making to date

4. This paper was reviewed and approved by the CEO on 30 April 2021.

Background

5. At the Board meeting on 11 February, Members agreed to a review of Code D. This was to address concerns previously raised by the HTA (and its former chair, Nicola Blackwood, in 2018) about the difference in consent provisions described in paragraph one (above) and more recently in Parliament and by Ministers.

6. The proposed changes to the Code are targeted changes to specifically address these concerns. We have sought legal advice to assure ourselves that the proposed changes do not contradict the Human Tissue Act (2004) (The HT Act) and are in accordance with our powers under the HT Act.

7. The proposed revisions have been worded so that consent expectations will be applicable from the date the revised Code comes into force. From this date all bodies and body parts imported for storage and use for public display in England, Wales and Northern Ireland will be required to meet the revised expectations. It will therefore apply to both existing and new licence holders wishing to import bodies and body parts for storage or use for public display.

8. The Code must be laid in Parliament for 40 days, to allow Ministers the opportunity to respond to the proposed changes. If no objections to the proposed changes are received during this 40-day period, the HTA will issue Directions to the sector to bring the revised Code into force.

9. The Regulatory team will lead the internal changes required to implement the revised Code and our Communications team will undertake appropriate activity to alert stakeholders to the changes. Preparations for the implementation are underway. Alongside the revisions to the Code, we will update our standards and guidance document and provide guidance on the terms “body” and “body parts” for the purpose of the Code.

10. The HTA will take proportionate regulatory action if a licensed establishment fails to meet the new consent expectations in relation to material imported after the specified date.

11. In the longer term, a change to the primary legislation will be needed to make the consent requirements for imported and domestically sourced material the same. There are no current plans to amend the HT Act, but we will continue to work with DHSC to identify possible legislative vehicles for change.

Legislative Background

12. There have been concerns for some time about the impact of differing consent requirements for imported human bodies and body parts used in public display compared to those originating in England, Wales and Northern Ireland.

13. Schedule 1, Part 1, paragraph 5 makes public display a scheduled purpose under the HT Act.

14. Section 1(1) (s1(1)) sets out the requirement for there to be appropriate consent for relevant material to be used for a scheduled purpose.

15. Sections 2, 3 and 4 set out the definitions of ‘appropriate consent’, including the requirement for ‘consent in writing’ and being signed ‘by the person concerned or at the direction of the person concerned’ for public display (s3(3), (4) and (5)).

16. Section 1(4)(5) and (6) disapply the consent provisions in s1(1) for imported bodies or relevant material. Therefore the legal requirement for appropriate consent does not apply to imported material for public display (or other scheduled purposes).

17. The HT Act makes the provision for the HTA to prepare and issue Codes of Practice. Each of the HTA’s Codes reflect the HTA’s interpretation of the HT Act in relation to the carrying out of licensable activities. They also provide practitioners at licensed establishments with practical guidance they are expected to follow.

18. Paragraph 64 of Code D currently states it is good practice for HTA licensed establishments involved in public display to have effective and reliable processes to ensure that imported human tissue is obtained with valid consent, in line with legal requirements of the country of origin, and that its use is in accordance with the consent given.

Actions taken to date

19. We have sought legal advice on the changes we are proposing. We believe that the proposed changes are a reasonable position for the HTA to take and we are confident in our legal position in implementing this revised policy position.

20. We have held engagement and consultation events, inviting all establishments currently licensed in the public display sector. These were well-attended. At each event we presented an overview of, and rationale for, the proposed changes. Feedback from stakeholders was overwhelmingly supportive of the proposed changes. A copy of the presentation provided at the events has also been shared with all establishments licensed for public display.

21. An overview of the proposed changes has been sent by email to known plastination and exhibition companies whom we believe have been involved in arranging public displays of such material. Information about the proposed changes has also been added to the HTA website to broaden engagement on our proposals with other stakeholders.

22. A dedicated email mailbox has been set up to receive comments and questions. Initial engagement with stakeholders began on 26 February 2021, and the opportunity to respond to the proposed changes has been open for nine weeks at the time of finalising this Board paper.

23. The Devolved Administrations of Wales and Northern Ireland have been consulted on the proposed changes throughout the course of the project and have confirmed they are content. We will continue to engage with colleagues in Wales and Northern Ireland during the implementation phase of the project

Proposed changes

24. Please see paragraphs 64, 65 and Annex C in the attached document (Code of Practice D Version 2 DRAFT at Annex A) for proposed amendments.

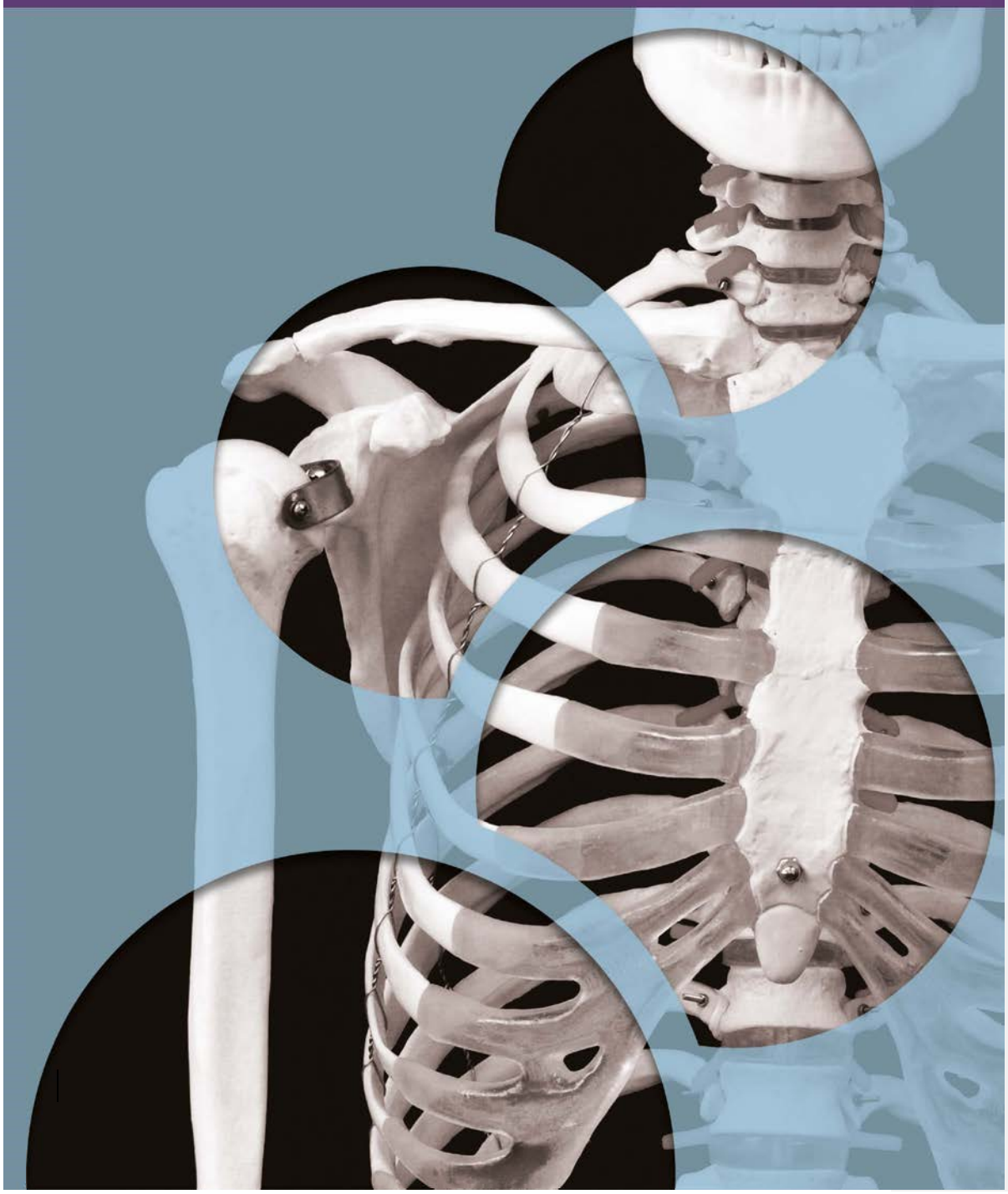
25. Please see section Guidance on the Standards, Consent standard C1 in the attached document (Public Display Standards and Guidance Version 2 DRAFT at Annex B) for proposed revisions.

Action required

26. Board Members are invited to review this paper and the proposed amendments to Code D and are asked to approve these changes.

D Public Display

Code of Practice and Standards



Code D: Public display

Contents

Introduction to the Human Tissue Authority Codes of Practice

1. The Human Tissue Authority's (HTA) regulatory remit is defined in the Human Tissue Act 2004 (HT Act). The HTA regulates the following activities through licensing:

   a) post-mortem examination;
   b) anatomical examination;
   c) public display of tissue from the deceased; and
   d) the removal and storage of human tissue for a range of purposes, including research, medical treatment, education and training.

2. The HTA also assesses applications for organ, bone marrow and peripheral blood stem cell (PBSC) donations from living people.

3. Further information about the legislative background and context of the HTA and its Codes of Practice (including geographic coverage) is set out at Annex A.

4. This document is part of a suite of seven Codes of Practice produced by the HTA. The Codes give practical guidance to professionals carrying out activities which lie within the HTA's remit under the HT Act and the Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 (the Regulations). They will also be of interest to members of the public.

5. The HTA Codes of Practice provide guidance on activities within the scope of the HTA's remit. Whilst the HTA may offer advice on matters outside its remit, it has no power to act in relation to these and will endeavour to provide signposts to other agencies where issues arise that are beyond its regulatory reach.

6. HTA Code A: Guiding principles and the fundamental principle of consent contains information that is applicable to all establishments and professionals operating under the HT Act and the Regulations. It sets out the following four guiding principles, which should inform the actions of anyone undertaking activities falling within the remit of the HTA:

   a) consent;
   b) dignity;
   c) quality; and
   d) honesty and openness.

7. For the public display sector, this means that bodies of the deceased, body parts or other human specimens should be treated with respect in an environment that is safe and secure; that the dignity of the deceased should be maintained at all times whilst they are being stored or are on display; and that their display is in line with the consent given. For specimens that are imported, it means that the country of origin should have a legal and ethical framework which includes consent and protects the interests of the deceased and their families.

8. In combination, Code A and this Code aim to provide anyone undertaking activities relevant to this sector with a reference source which gives practical advice on the minimum steps necessary to comply with the relevant legislation and HTA policy.

Introduction to the Public Display Code

9. The display of human bodies and tissue of human origin is not new to the United Kingdom (UK), but it has primarily been carried out by establishments involved in medical education and training and public museums. The HT Act makes consent a legal requirement for the storage and display of human material where it is less than 100 years since the person's death. It also makes these activities subject to licensing by the HTA, where the material is from the body of a deceased person. This Code explains the consent and licensing requirements of the HT Act as they apply to public display, and includes practical advice to those involved in the public display of human material, whether on a permanent or temporary basis.

10. Although advice and guidance on the care and display of human remains has been available from the Department for Culture, Media and Sport (DCMS) since 2005, the activity of public display was not covered by statute before the HT Act. Prior to this, there was no restriction on the display of human bodies or material of human origin (referred to in the HT Act as relevant material).

11. A key principle of the HT Act is that all human bodies and materials of human origin within its scope should be treated with respect and dignity. In relation to the public display of human material, this principle applies both to those showing the material, and to those viewing it.

12. Ethical issues raised by the display of human materials are explored in DCMS Guidance for the care of human remains in museums, which should be read by anyone involved in the display of human material. This acknowledges their unique status within museum collections and the special responsibilities placed on those who acquire and display them. The DCMS guidance has a longer historical reach, dealing with material collected before the period covered by the HT Act. However, the DCMS guidance covers some areas of museum activity which are also affected by the HT Act, and the HTA advises anyone involved in the display of human material to refer to this guidance.

13. HTA-licensed establishments in the public display sector form a diverse group. This includes:

    a) national museums that maintain largely static, permanent collections;
    b) a charitable foundation dedicated to achieving improvements in human and animal health; and
    c) small specialist museums and organisations that stage temporary exhibitions.

14. The public display of human material and public engagement with human specimens in the areas of medicine and the humanities are becoming increasingly popular. As the interest of the public grows, museums are finding new roles for their collections and exploring novel ways of engaging with the public. This Code seeks to ensure that all those involved in activities that involve the public display of human material are aware of the statutory and regulatory requirements, as well as the guiding principles of consent, dignity, quality and honesty and openness, which should underpin the conduct of these activities.

15. The HTA recognises that many museums holding permanent collections are accredited under the Arts Council England's Museum Accreditation Scheme. These establishments must make sure that they meet all relevant legal, ethical and safety requirements, and have well established collections management procedures. The Accreditation Scheme includes standards on care and conservation, which satisfy many of the HTA's requirements relating to the public display of human material. These establishments are also subject to the Museum Association's code of ethics and associated guidance.

Scope of this Code

16. Under the HT Act, public display of the body of a deceased person and relevant material from a living or a deceased person is a scheduled purpose for which consent is required. In some cases, it is also a licensable activity. Detailed information about scheduled purposes and licensable activities is explained in Annexes B and C.

17. The HT Act does not contain a definition of public display. The HTA considers public display to be 'an exhibition or display in which the body of a person, or relevant material which has come from the body of a person, is used for the purpose of being exposed to view by the public'.

18. Public display may mean many things and the Code includes examples which illustrate situations that are, or are not, considered to be display to the public. In broad terms, it should be taken to mean events that are open to the public, whether by ticket sale or free access, regardless of the location and purpose of the venue and whether temporary or permanent. It includes static installations or exhibitions, as well as performance art or theatrical productions.

19. The HT Act includes hair and nails from the body of a deceased person within the scope of its definition of relevant material. Human material that has been modified in some way, or that is bound up with non-human materials, is also within scope, as are human body fluids or soft tissue used, for example, in the creation of an art work. This includes human cells used in the making of 'bioart'.

20. Throughout this guidance, examples are given to help establishments determine whether or not their activities fall within the remit of the HTA.

21. The legal requirements of the HT Act and the guidance given in this Code do not apply in the case of bodies or relevant material where:

    a) the person died before the HT Act came into force on 1 September 2006; and
    b) at least 100 years have elapsed since the date of the person's death.

22. Nor do they apply to display for the purposes of:

    a) enabling people to pay their final respects to the deceased;
    b) display which is incidental to the deceased's funeral; or
    c) the display of bodies or relevant material displayed in a place of public religious worship and used for the purposes of religious worship or contemplation.

23. The display of photographic or electronic images falls outside the scope of the HT Act. Therefore, this Code does not apply to broadcast or printed images. The HTA endorses the guidance on images provided by the General Medical Council (GMC). Further guidance on images is provided in paragraphs 58-60.

24. The HT Act provides for a number of specific museums to transfer from their collections any human remains that they reasonably believe to be the remains of a person who died less than one thousand years before section 47 the HT Act commenced on 3 October 2005. Section 47 is in Part 3 of the HT Act and is headed 'Power to de-accession human remains'. However, the HTA has no regulatory remit in relation to this power.

Offences under the HT Act

25. The HT Act sets out a number of offences, for which the maximum penalty is three years imprisonment and/or a fine. In relation to the Public display sector, the offences are as set out below.

26. Section 5 of the HT Act makes it an offence to remove relevant material from the deceased and to store and use bodies and relevant material for a purpose set out in Schedule 1 of the HT Act (a scheduled purpose), including determining the cause of death, without appropriate consent. Where there is consent to use material for one purpose, it may not be used for another purpose without appropriate consent for that purpose. Section 5 of the HT Act also makes it an offence to falsely represent that there is appropriate consent

to undertake an activity, or that Section 1 of the HT Act does not apply. A person does not commit an offence if they reasonably believed that appropriate consent was in place, or that the activity carried out was not one that required consent.

27. Section 16(1) and (2) of the HT Act prohibit (amongst others) the following activities, except under the authority of a licence:

    a) the storage of the body of a deceased person, or relevant material which has come from a human body, for use for scheduled purposes; and
    b) the use of the body of a deceased person or relevant material which has come from the body of a deceased person for the purpose of public display.

28. To undertake an activity listed in section 16(2) without the authority of a licence from the HTA is an offence under section 25(1). A person does not commit an offence if they reasonably believe the activity they are carrying out is not licensable, or that they are acting under the authority of a licence.

29. It is not an offence to display relevant material from a living person on unlicensed premises, even if the person has since died.

30. In addition, it is not an offence to sell material of human origin, unless, in doing so, relevant material from the body of a deceased person is on view to the public on unlicensed premises.

31. Finally, it is not an offence to exhibit or broadcast images of the body of a deceased person or relevant material from the deceased.

Structure and navigation

32. The main body of the Code is divided into two main sections: consent and licensing. In each section, the requirements of the HT Act and any exemptions are explained. There follow separate sections on particular issues relating to the public display of human material, such as the import and disposal of material.

33. Annex B explains the difference between licensable activities and scheduled purposes. This distinction has sometimes caused confusion.

34. Annex C provides flowcharts which summarise the licensing and consent requirements for public display of human tissue from the living and the deceased.

35. A glossary with terms specific to this Code is available at the end of the document. You can view, download and print copies of all the Codes from the HTA's website.

Consent

36. The HT Act and common law make consent a legal requirement for the removal, storage and use of relevant material which has come from a human body for scheduled purposes. Scheduled purposes are listed in Schedule 1 of the Human Tissue Act and include public display. Therefore, anyone removing, storing or using material for the purpose of public display, whether from a deceased person or from a living person, must be satisfied that consent is in place.

37. The consent requirements of the HT Act are not retrospective. This means that establishments do not need to obtain consent for the storage or public display of bodies or relevant material that were already in their possession at the time the HT Act came into force on 1 September 2006. Material held before this date is referred to as existing holdings.

Example

A surgeon has a private collection of preserved human body parts and tissue thought to have come from the body of a deceased person, which she acquired early in her career and uses for teaching medical students. On retirement, she offers the specimens to a museum for public display. The museum has concerns that consent may not have been obtained appropriately for all specimens. As the consent requirements of the HT Act are not retrospective, the specimens can be treated as existing holdings and consent is not required for their display. However, an HTA public display licence is required if the material came from people who died less than 100 years ago.

38. Where the person has died, consent must have been given by them in life for storage for public display or actual public display of their body, body parts or tissue after death (whether an adult or a child). Their consent must be written and (i) signed by the person concerned in the presence of at least one witness who attests the signature, or (ii) signed at their direction in their presence and the presence of at least one witness who attests the signature. Alternatively, it can be stated in an adult's legally made will. Neither the relatives nor any other person can consent to the use of an individual's body after their death for public display. This applies whether the person is an adult or a child.

39. Anyone organising a public display of bodies or relevant material that are not existing holdings must have the necessary assurance that valid consent has been given. They do not need to have taken or recorded the consent personally.

40. Although the displaying of photographic or electronic images falls outside the scope of the HT Act, the HTA believes that it is good practice for consent to be obtained for the making and subsequent display of such images.

Licensing

41. Licensing is one of the regulatory functions of the HTA. The HT Act lists among its licensable activities the storage and use, for the purpose of public display, of the body of a deceased person or relevant material which has come from the body of a deceased person. Therefore, a licence is required for the public display of bodies or relevant material from the deceased, but not from the living.

42. In considering whether to issue a licence for the public display of human material, the HTA will seek assurance that licensing Standards are met by the establishment (see paragraphs 75-79). This will include ensuring that it has a clear policy on the behaviours, actions and attitudes demonstrated by staff and visitors, whether or not directed at the exhibits, that might be considered to disregard the dignity of the deceased.

Example

An art gallery is staging an exhibition, which includes plastinated bodies in a variety of poses demonstrating the anatomy of the human body. The gallery usually offers its exhibition space as a venue for private functions such as birthday parties and wedding receptions. Reflecting its policy on the display of human material, it decides not to offer this service for the duration of the exhibition, out of respect for the deceased.

43. A licence is required regardless of the number of items that are on display and the HTA may take into account the number of items on display when setting licence fees, which are reviewed annually and set out on the HTA's website. A collection of items of the same type and known to have come from a single person can be counted as one item for the purpose of licensing.

Example

A music school displays the preserved hands of the school's founder, a famous pianist. The founder specifically asked for them to go on display in the school before he died in 1948. The music school has no plans to display any other human exhibits but wants to continue to display the hands, in line with the founder's wishes. For the purpose of HTA licensing, the school has one exhibit of human material on public display.

44. The existing holdings exemption to the consent requirements of the HT Act referred to in paragraph 37 does not apply to the licensing requirement. This means that material less than 100 years old that was already in the possession of museums at the time the HT Act came into force on 1 September 2006 is subject to licensing by the HTA.

Example

A museum is displaying a number of human skulls in an exhibition about the history of dentistry. The exhibition has been staged since the early 1970s and no additions have been made to the collection since 1987. Although consent was given for many of the exhibits, there is no legal requirement under the HT Act for it to be in place. However, in accordance with the HT Act, a licence for storage for public display is required.

45. The HTA does not consider the display of bodies or relevant material to small groups of relevant professionals as part of a pre-determined programme of education and training to be public display.

Example

A hospital allows police officers that are dealing with scenes of crime to witness a post-mortem examination as part of their introduction to forensic medicine. The hospital is unsure whether it is required to have an HTA licence for public display. It is advised that a public display licence is not required as training involving the examination of bodies, which is delivered to the police or paramedics as part of their professional development, is not considered public display.

46. The HTA also does not consider the display of bodies or relevant material to students who are embarking on a career in healthcare to be public display. This includes where the students are invited to visit from a different establishment.

Example

Medical students beginning their first year of study are taken on a tour of the anatomy and pathology museum of a teaching hospital licensed by the HTA for anatomical examination. As access to this museum is restricted to practitioners and medical students, the hospital's licences are sufficient and no additional licence is required for public display.

47. Display of bodies, or relevant material from bodies of the deceased, to members of the general public, for whatever reason, is considered to be public display.

Example

At a university open day for the general public, visitors are shown the lungs of a smoker and a non-smoker to demonstrate the effects of smoking. As members of the public are viewing the exhibits, an HTA public display licence is required. The lungs were obtained after death from people who died after 1 September 2006, so written and attested consent for public display is required from the individuals in life in order for the public display to lawfully take place.

48. Any individual or organisation displaying material of human origin should make sure that visitors are aware they will come across human remains, whose display may provoke an emotional or ethical response, particularly in the very young. Giving consideration to the format of the display to ensure that it is appropriate to the material being shown, and does not disregard the dignity of the deceased, may help promote a positive visitor experience.

Example

A city museum and art gallery is mounting an exhibition on death and the human experience. The exhibition is intended to provide an educational experience for visitors; stimulating a discussion on death and increasing their awareness of how individuals and different cultures respond to death. It has a range of artefacts, all less than 100 years old, from different areas of the world, including a human jaw bone incorporated into a necklace from the Andaman Islands which was worn as a sign of mourning, human trophy skulls from Papua New Guinea and a human skull with attached cattle horns from India, believed to prevent the deceased from hearing the voices of their relatives. To ensure that visitors get the most out of their visit to the exhibition and are not alarmed by any of the exhibits, the museum has placed warning signs to alert

visitors about the sensitive items on display and provided contextual information about each exhibit. There is also a notice which suggests that the exhibition is suitable for children over 14 years. There is a dedicated seating area which visitors can use for reflection, if the exhibition provokes an emotional response.

49. As noted earlier, storage for the purpose of public display or the actual public display of body parts or tissue from the living do not require licensing. Neither is a licence needed for the continued storage or public display of that material should the person subsequently die.

Example

A human heart is on permanent display in a museum. The heart came from a patient who underwent a successful heart transplant and consented for her diseased heart to be displayed. A licence is not required, and will not be required for the continued display of the heart following the donor's death.

50. Bodies or relevant material from the deceased imported into the UK for public display are subject to licensing by the HTA.

51. The duration of the public display does not affect the requirement for licensing. Establishments that wish to exhibit human material must ensure that they have the necessary licences in place before they begin to store or exhibit the material.

Example

A temporary exhibit of several preserved human bodies sourced from an establishment in another EU country is displayed in a public museum in order to illustrate the physiology of athletes. The exhibition is for six months and the museum does not display any other human bodies or relevant material. A licence is required from the HTA and the establishment is advised to refer to the advice given in this Code on the import of human material.

52. Some museums hold material with no intention of ever putting it on public display. Instead, they keep it as part of a museum archive of items of historical interest or for ethnographic or anthropological research. In these cases, a licence is not required. If the establishment informs the HTA in writing of its intention never to display the material, the HTA will be satisfied that the retention of this material falls outside its remit.

Material over 100 years old

53. The legislative requirements of the HT Act do not apply to bodies or relevant material if more than 100 years have elapsed since the date of the person's death. Consent is not, therefore, required for the public display of bodies or human material over 100 years old. Nor is a licence required.

54. Some museums hold collections where the age of the material is unknown. This may be because no documentary evidence, such as archival records, receipts or scientific evidence (such as carbon dating) is available. Where investigations are inconclusive and it is uncertain whether the material is over 100 years old or not, the earliest known acquisition date may be taken as an indicator of the age of the material.

55. There may be circumstances where the acquisition date is within the last 100years, but there is good reason to believe that the material is more than 100 years old. In such cases, the HTA will accept a written statement of this from an independent and objective expert in the field. Where no acquisition date is available, an HTA licence should normally be applied for.

Example

A national museum has obtained a large number of preserved human organs from a hospital museum that has closed down. It has records which show that the hospital museum obtained the exhibits in the 1930s and 1940s. However, it believes that the donors died more than 100 years ago. As there are no records to confirm when the people died, the museum has sought advice from the Professor of Biological Anthropology at a well-respected academic institution. The professor has stated in writing that, in their professional opinion, the specimens are more than 100 years old. The HTA has accepted this as evidence of the age of the specimens and advised that no licence for public display is required.

Loans to other museums

56. The HT Act does not allow the loan of items or collections containing human material within the scope of the HT Act from a licensed establishment to a non-licensed establishment, except in the case of anatomical specimens (see the Code of Practice on Anatomical examination). Where relevant material from a deceased person is to be stored or used in a public display, a licence is required by the establishment on whose premises the material is to be stored or displayed.

57. Where material is moved between licensed establishments, there should be a documented loan agreement, which sets out:

a) the steps taken to ensure safe handling of the material;
b) any environmental controls required; and
c) procedures to deal with adverse events, such as damage to the material or a breach of security.

Photographic/electronic images

58. The display of photographic or electronic images falls outside the scope of the HT Act; therefore, a licence is not required for the public display of photographs containing images of bodies, body parts or other human tissue samples or for electronic images, for example on television.

Example

A small independent gallery is exhibiting the work of a photographic journalist who has spent several years taking photographs of the homeless and dispossessed in major cities around the UK. These include a small number of images of the bodies of homeless people who have died whilst living on the streets. The exhibition is not subject to licensing by the HTA and the consent provisions do not apply to the display of these images.

Example

A television production company plans to film a group of schoolchildren observing the dissection of a human body for a documentary on human anatomy. The filming of the programme and its subsequent broadcast on television are outside the remit of the HTA. However, the real time viewing of the dissection by the schoolchildren is considered by the HTA to be a public display and a licence is required. In addition, the television production company is advised that as the body will be that of a person who died after the commencement of the HT Act, consent for their body to be used for public display will have to have been given by the person before they died.

59. If filming takes place on premises licensed by the HTA, the anonymity of subjects should be preserved. The number of people present at the filming should be kept to a minimum to ensure, as far as possible, the dignity of the deceased. The Coroner should be informed and their agreement sought if any bodies being filmed are under coronial jurisdiction.

60. The Designated Individual (DI) of the licensed establishment has a statutory duty to ensure that suitable practices take place on the premises. This includes ensuring that the bodies in their care are treated with dignity and respect. This responsibility must be understood and given due regard by anyone entering the premises, for whatever purpose, and should be reiterated to the film crew.

Import and export

61. The import and export of bodies or material of human origin, whether fresh, frozen, plastinated, dried or embalmed, is not a licensable activity under the HT Act. However, the storage of the material once it is imported may be licensable if this is for use for a scheduled purpose.

62. In the HT Act, 'import' means import into England, Wales or Northern Ireland from a place outside England, Wales and Northern Ireland. 'Export' means export from England, Wales or Northern Ireland to a place outside England, Wales and Northern Ireland.

63. The guidance in this section does not apply to whole bodies or parts of bodies that are historical human remains, or human remains incorporated into artefacts, which are more than 100 years old.

Imported material

~~64. The consent provisions of the HT Act do not apply to material that has been imported. However, it is good practice for establishments involved in public display to have effective and reliable processes to ensure that imported human tissue is obtained with valid consent, in line with legal requirements of the country of origin, and that its use is in accordance with the consent given. Furthermore, when considering the import of material, establishments should give due regard to the guiding principles referred to earlier in this Code.~~

64. The HTA has had concerns over the impact of differing consent requirements for imported human bodies and body parts used in public display compared to those originating in England, Wales and Northern Ireland. The HTA considers **that the same consent expectations should apply for imported bodies and body parts as set out in paragraphs 37 to 40 in this Code as for such material sourced domestically (England, Wales and Northern Ireland),** unless the HTA is satisfied that there are exceptional circumstances for not doing so.

65. Anyone removing, storing or using bodies or body parts imported for the purpose of public display from the date this Code of Practice (Version 2) comes into force should ensure that they have been sourced legally in the country of origin and the person whose body or body parts are intended for public display has given consent for this purpose. Establishments should be confident in the validity and authenticity of the documentation they intend to rely on for assurance. Furthermore, when considering the import of material, establishments should give due regard to the guiding principles referred to earlier in this Code.

~~64.~~66. Good practice requires that effective and reliable processes should be in place for acquiring evidence of informed consent. This means that the importer should have implemented policies and/or Standard Operating Procedures (SOPs), which clearly set out how to obtain this evidence. This includes safeguarding the confidentiality of all information relating to consent. If a third party is importing the material, a Service Level Agreement (SLA) should be in place demonstrating that there is a record of consent in a suitable format.

~~65.~~67. Any individual or organisation wishing to import human bodies and material of human origin should be able to demonstrate that the purposes for which they wish to import such material cannot adequately be met by comparable material available from sources within England, Wales or Northern Ireland, or that it is for a particular purpose which justifies import. Importers should assure themselves of the integrity of the material and that, as a minimum, it has been sourced with appropriate consent.

~~66.~~68. ~~As good practice, i~~Importers should therefore satisfy themselves that, in the countries from which they seek to import tissue, the gaining of consent for the purpose to which the tissue is subsequently put is part of the process by which the material is obtained. This involves ensuring that procedures are in place giving the necessary assurances.

~~67.~~69. The HT Act makes it clear that bodies and relevant material are not to be exported and then re-imported simply to avoid the Act's consent requirements.

Exported material

~~68.~~70. When seeking consent, donors should be advised that their samples may be exported and used abroad. SLAs should be in place to ensure that human bodies and material of human origin to be exported from England, Wales and Northern Ireland are used in accordance with the consent which has been obtained. Material should be handled, stored and transported in a manner

consistent with safety considerations, and with due regard to the dignity and respect that should be accorded to human bodies.

Disposal

~~69.~~71. Disposal of relevant material is one of the activities within the statutory remit of the HTA. Most establishments engaged in the public display of human material, particularly those that are accredited by Arts Council England under the Museums Accreditation Scheme, will have acquisition and disposal/deaccession policies that consider cultural issues, such as repatriation. Where this is not the case, the guidance on disposal in this code should be followed if material is to be disposed of.

~~70.~~72. The HT Act does not mandate any particular method of disposal, for example according to the type or size of the relevant material, and does not stipulate methods of disposal for specific body parts. Instead, the HTA encourages staff at HTA-licensed establishments to make decisions about the most suitable method of disposal in each case.

~~71.~~73. In cases where cremation is not possible, it is permissible to dispose of material or body parts which have been displayed by incineration, provided they are disposed of separately from other clinical waste. HTA-licensed establishments should have SOPs supporting the process for preparing, documenting and transporting specimens and body parts for incineration.

~~72.~~74. When seeking consent for use of their body or tissue for public display, individuals should be informed how it is planned that tissue will be disposed of after use and any options available.

~~73.~~75. Staff should be familiar with the establishment's arrangements for disposal. This includes what is available locally, basic legal requirements and the options available to those wanting to make their own arrangements to dispose of tissue.

HTA licensing Standards

~~74.~~76. In order to obtain a HTA licence, the applicant must demonstrate that they and the relevant premises are suitable. The HTA will assess whether they can meet a number of core Standards, which were developed in consultation with representatives from the regulated sectors. These relate to the consent provisions of the HT Act and the regulatory requirements for governance and quality systems, traceability and premises. They reinforce the HT Act's intention that:

a) consent is paramount in relation to activities involving the removal, storage and use of human tissue;
b) bodies of the deceased and organs and tissue removed from bodies are treated with respect; and
c) the dignity of the person, whether living or deceased, is maintained.

~~75.~~77. The HTA works with establishments through its inspection process to help them comply with these Standards.

~~76.~~78. Each licensed establishment is required to appoint a Designated Individual (DI) for their licence, who has a statutory responsibility under the HT Act to supervise activities taking place under a licence. The DI has a duty to ensure that suitable practices are carried out by those working under the licence, that the premises are suitable and that the conditions of the licence are complied with. By ensuring that the establishment is meeting the HTA's licensing Standards, the DI will be meeting their statutory responsibility.

~~77.~~79. When HTA staff undertake inspections of HTA-licensed establishments, they make judgements about the suitability of the Licence Holder (LH), the DI, the practices taking place and the premises on which they take place. They do this by assessing the establishment's compliance with the HTA's licensing Standards, which reflect the guiding principles set out in Code A and provide the operational detail of how establishments should meet the requirements of the HT Act and the Codes of Practice.

~~78.~~80. The HTA's licensing Standards are grouped under four headings: Consent (C); Governance and quality systems (GQ); Traceability (T); and Premises, facilities and equipment (PFE). Under each of these headings, there are overarching statements, from which the Standards flow.

Consent (C)

~~79.~~81. Establishment's meeting the consent Standards will be able to demonstrate that their processes for seeking and gaining consent comply with the HT Act and the HTA's Codes of Practice. The Standards also cover the documentation and information used to support the establishment's consent procedures, and ensure that staff involved in seeking consent are suitably trained and equipped for the task.

Governance and quality systems (GQ)

~~80.~~82. Establishments meeting these Standards will be able to demonstrate that they have a suitable governance framework, underpinned by clear and controlled documentation, effective audit, staff training and organised record-keeping. In addition, they will have an effective system of risk management and suitable systems to deal with adverse events.

Traceability (T)

~~81.~~83. Establishments meeting these Standards will be able to demonstrate full traceability for the human material for which they are responsible, from receipt to final disposal/disposition. HTA inspectors will test this through traceability audits carried out on site and the HTA expects establishments to take a proactive approach to assuring themselves of effective traceability throughout the lifetime of their licence. In addition, as the final traceability step, they will have established disposal arrangements which are in accordance with the HTA's Codes of Practice.

Premises, facilities and equipment (PFE)

~~82.~~84. Establishments meeting these Standards will be able to demonstrate that their premises and facilities are appropriate for the licensed activities taking place and that they are safe, secure and clean. In addition, establishments will have systems for on-going monitoring to ensure all key quality specifications are maintained. These Standards also cover equipment, ensuring that it is appropriate, and suitably maintained, and that it does not present an impediment to the staff using it.

~~83.~~85. The HTA licensing Standards which are applicable to the Public Display sector are included at Annex D and on the HTA website. The Standards are supported by comprehensive guidance notes.

Annex A

Legislative background and context

1. The Human Tissue Authority (HTA) is the regulator for human organs, tissues and cells. The HTA was established by the Human Tissue Act 2004 (HT Act) in 2005, following the discovery of establishments removing and retaining human organs and tissue without consent. The HT Act addressed this issue and brought together other existing laws that related to human tissue and organs.

2. The HT Act applies to the removal, storage and use of human organs and tissue for scheduled purposes[1] in England, Wales and Northern Ireland, with the exception of the provisions relating to the use of DNA, which also apply to Scotland.

3. Under section 14(3) of the HT Act, the HT Act and the guidance given in the Codes of Practice do not apply to bodies or relevant material where:

   a) the person died before the HT Act came into force on 1 September 2006; and
   b) at least 100 years have elapsed since the date of the person's death.

4. The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 (the Regulations) lay down the responsibilities of the HTA in relation to the donation of transplantable material from living donors, including those who lack capacity to consent.

5. The HTA is the Competent Authority in the UK for the implementation of the European Union Tissue and Cells Directive 2004/23/EC (EUTCD). The EUTCD sets standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.

6. The requirements of the EUTCD are transposed into UK law via the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations). With the exception of Code A: Guiding principles and the fundamental principle of consent, the Codes of Practice do not provide guidance on complying with the requirements of the EUTCD. Establishments licensed under the Q&S Regulations should refer to the HTA's Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment.

7. The HTA is the Competent Authority in the UK for the implementation of the European Union Organ Donation Directive 2010/53/EU (EUODD), which sets quality and safety standards for organ donation and transplantation. The

[1] Defined by the HT Act and explained in further detail in the glossary.

requirements set out by the EUODD have been transposed into UK law through The Quality and Safety of Organs Intended for Transplantation Regulations 201[2] (the Q&S (Organs) Regulations) and The Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2014. With the exception of Code A: Guiding principles and the fundamental principle of consent, the Codes of Practice do not provide guidance on complying with the requirements of the EUODD. Establishments licensed under the Q&S (Organs) Regulations should refer to the HTA's The Quality and Safety of Organs Intended for Transplantation: a documentary framework.

8. On 1 December 2015 a deemed consent system for organ donation after death became operational in Wales, as a result of the implementation of the Human Transplantation (Wales) Act 2013. This legislation relates to donation of organs and tissue from the deceased, and as such does not have an impact on the HTA's regulation of living organ donation. These Codes of Practice do not apply to organ and tissue donation from the deceased in Wales; the HTA has published a Code of Practice on the Human Transplantation (Wales) Act 2013 for establishments in Wales who work under the deemed consent for deceased organ donation system.

Scotland

9. The HTA's remit does not extend to Scotland, and therefore the HTA's Codes of Practice do not apply to establishments in Scotland.

10. A separate piece of legislation, the Human Tissue (Scotland) Act 2006 (HT (Scotland) Act), applies to Scotland. The HTA's remit in Scotland is described in a letter titled Human Tissue (Scotland) Act 2006: A guide to its implications for NHS Scotland, which the Scottish Health Department letter issued on 20 July 2006[2].

11. The HTA assesses applications for living organ donation and donation of bone marrow and PBSCs on behalf of Scottish Ministers who delegated this responsibility to the HTA. The law in Scotland is significantly different from that in the rest of the UK, so this code does not apply in Scotland. Guidance for practitioners in Scotland is available here.

[2] Ref: NHS HDL (2006) 46. (updated 2017)

Status and use of the Codes of Practice

12. Throughout the Codes, the word '**must**' applies to all legal requirements derived from primary and secondary legislation (for example, the legal requirement to hold a licence to store human tissue for use for a scheduled purpose, the conditions of any licence and the requirements set out in any directions issued by the HTA). It also applies to the duty to abide by the HTA's licensing Standards. We use the word '**should**' when providing advice on how to meet these requirements.

13. Establishments are expected to follow the guidance contained in the Codes. Observance of the guidance is one of the ways in which the HTA assesses that establishments are complying with legal requirements. Failure to follow a Code of Practice is not in itself a criminal offence under the HT Act, but the HTA will consider carefully any breach of a Code of Practice when considering whether there are grounds to take regulatory action.

Other advice and guidance

14. The Codes of Practice complement each other and should be read alongside other relevant advice and guidance, which is either referenced in the text or provided on the HTA's website. The Codes of Practice may also refer to guidance which has been produced by a number of other organisations. The HTA is not responsible for the content of others' guidance, but does recommend that practitioners follow this guidance when they fall within its remit. Guidance that has been produced in collaboration with the HTA will appear on our website.

15. The HTA's Codes of Practice and other HTA guidance should, however, be used as the definitive source of information for issues within our remit. If you are in any doubt, please contact the HTA or seek your own legal advice. Regulated sectors should also keep up to date with other relevant legislation.

Annex B

Scheduled purposes and licensing in the Public Display sector

1. To understand fully the requirements of the HT Act, knowledge of scheduled purposes and licensable activities is required.

2. The HT Act differentiates between scheduled purposes, for which consent is required, and activities for scheduled purposes, which are licensable. This is an important distinction, and one which sometimes causes confusion because in not all cases are both consent and a licence required.

Scheduled purposes

3. There are three scheduled purposes which relate to the public display sector; consent is required to store or use bodies or relevant material for all of them:

   a) public display, which applies to material from the living and deceased;
   b) research in connection with disorders or the functioning of the human body, which applies to material from the living and the deceased;
   c) education or training relating to human health, which applies to material from the deceased only.

4. Note that only (a) requires consent from the person themselves; where the person has since died, their consent must be in writing and have been witnessed and attested. Where the person has died, consent for the scheduled purposes in (b) and (c) can be provided by the deceased person's nominated representative or relatives (those in a qualifying relationship to the deceased before they died; see Code A for more information).

Licensable activities

5. There are two licensable activities which are relevant to the public display sector:

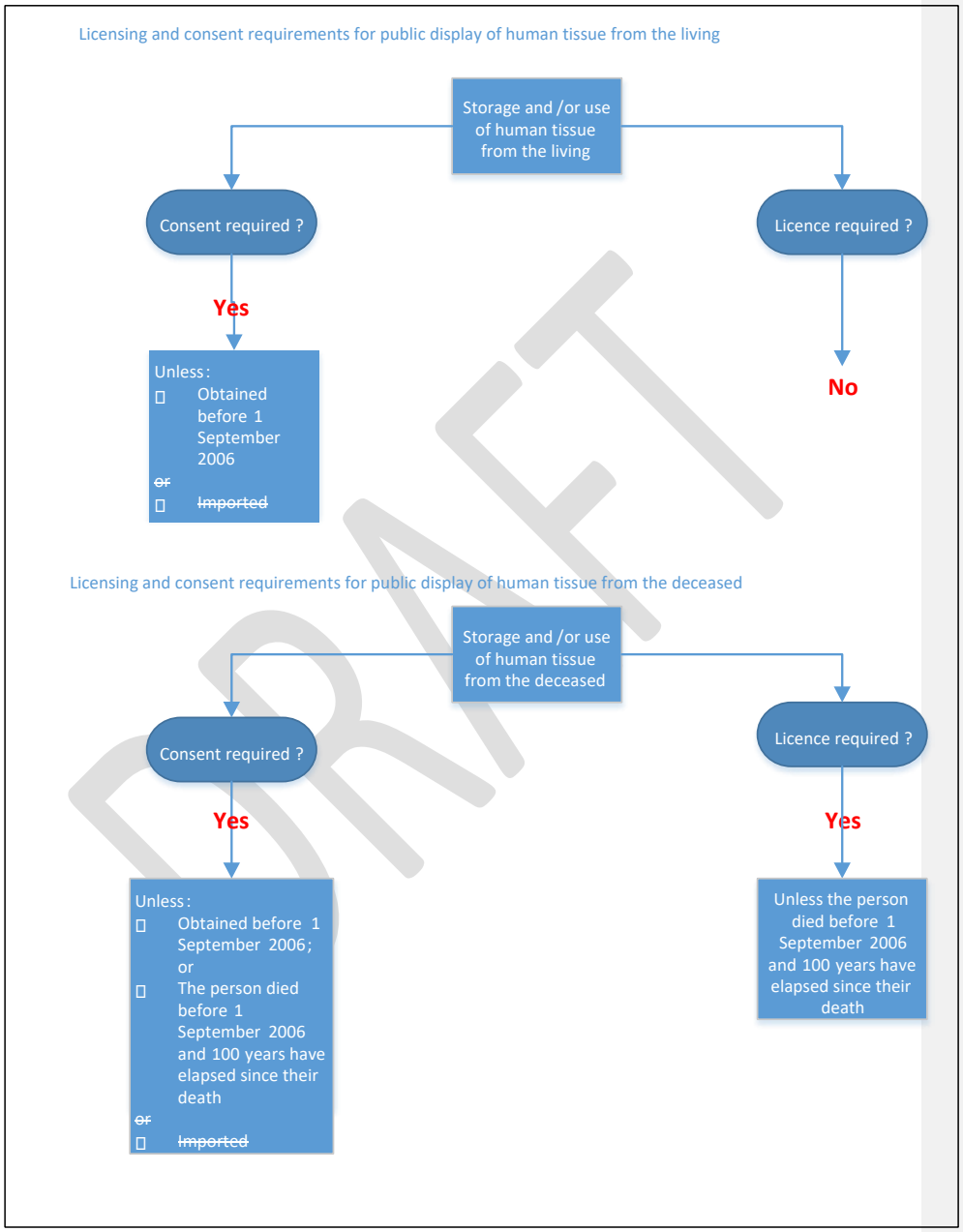
   a) the storage of the body of a deceased person, or relevant material which has come from a human body, for use for scheduled purposes; and
   b) the use of the body of a deceased person or relevant material which has come from the body of a deceased person for the purpose of public display.

6. The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006, exempt from licensing the storage of relevant material from a human body for use for public display, where the material is from a living person. That means that a licence is

not required for the storage or public display of body parts or tissue from the living.

Annex C Licensing and consent flowcharts

Commented [RKM1]: Consent requirements updated



Annex D

HTA licensing Standards: Public Display sector

Consent
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in its codes of practice
a) If the establishment is required to seek consent, a process is in place which is in accordance with the requirements of the HT Act and the HTA's Codes of Practice, and records of consent are maintained. b) If relevant, there is training for staff on how to seek consent for the public display of human material, which addresses the requirements of the HT Act and the HTA's Codes of Practice and records demonstrate attendance. c) Where applicable, there are agreements with other parties to ensure that consent is sought in accordance with the requirements of the HT Act and the HTA's Codes of Practice.
C2 Information about the consent process and the activity for which consent is sought is provided
a) There is written information about the consent process for those giving consent, which reflects the requirements of the HT Act and its codes of practice b) Standard operating procedures (SOPs) specify how information on consent is provided.

Governance and quality systems
GQ1 All aspects of the establishment's work are governed by documented policies and procedures
a) There are collections management policies and procedures, or equivalent, governing the storage and public display of bodies and human tissue which give due regard to the dignity of the deceased. These should include, as relevant to the establishment's activities: i. an overarching policy on the care and treatment of exhibits containing human tissue;

ii. seeking consent for donation of bodies and human tissue for public display;
iii. specimen acquisition e.g. by bequest, exchange, loan or purchase from another individual or organisation nationally or internationally; iv. specimen preservation, monitoring and conservation;
v. control of environmental conditions;
vi. the management of sensitive material, such as fetal remains;
vii. transportation of specimens e.g. on loan to or return to other collections;
viii. the disposal/deaccession of specimens;
ix. storage contingency arrangements;
x. the creation, amendment, retention and destruction of records;
xi. the management of incidents and complaints.

b) There are procedures that govern the work of temporary staff and contractors, which ensure that they are sensitive to the special status of human remains and exhibits consisting of human material.

c) Regular governance meetings are held; for example, health and safety and risk management committees, that have agendas and minutes.

d) Policies and procedures are reviewed regularly and are version controlled.

GQ2 There is a documented system of audit

a) There is a documented system of audit, which includes records of traceability and specimens.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks

a) There are clear reporting lines and accountability, and documented roles and responsibilities.

b) There is documented induction and training for staff, which includes the handling of human remains; attendance at training is recorded.

GQ4 There is a systematic and planned approach to the management of records
a) There are suitable systems for the creation, review, amendment, retention and destruction of records.
b) Systems ensure data protection, confidentiality and public disclosure (whistle-blowing).
GQ5 There are systems to ensure that untoward incidents are investigated promptly
a) There is a system for reporting and investigating serious untoward incidents.
b) Corrective and preventive actions are taken where necessary and improvements in practice are made.
GQ6 Risks associated with the establishment's practices and processes in relation to the storage and display of human material are assessed and monitored
a) Risk assessments are documented.
b) Risk assessments set out steps taken to mitigate risks
c) Risk assessments are reviewed regularly
d) Staff can access risk assessments and are made aware of them in training

Traceability
T1 A coding and records system facilitates traceability of bodies and human tissue
a) Bodies and human tissue are traceable through a unique identification number or code.
b) The system of record-keeping should include the location of material at the establishment and may include a description or photographic record and details of any specialist storage conditions, shelf-life or contamination risk.
T2 Records of traceability are maintained
a) Records of receipt, storage, transportation and delivery of bodies and human tissue are maintained.
b) Disposal or de-accession records include the date, reason and method of disposal/deaccession.

c) Where applicable, disposal arrangements reflect specified wishes of the donor.

Premises, facilities and equipment
PFE1 The premises and facilities are secure and safeguard the dignity of the deceased and the integrity of human tissue
a) Areas used for storage or public display provide an environment that is safe for staff and visitors and preserves the integrity of the material and the dignity of the deceased. b) The establishment is clean, well maintained and subject to a programme of planned preventative maintenance. c) Staff have access to the protective clothing, materials and equipment they need. d) A documented risk assessment has been carried out of the premises to ensure that they are appropriate for the licensed activities. e) There are policies in place to review and maintain the safety of staff and visitors. f) The premises are secure with controlled access to bodies, human tissue and records. g) Security measures include the use of lockable display areas and alarm systems.
PFE2 There are appropriate facilities for the storage of bodies and human tissue
a) Where chemicals are used for preservation, the area is adequately ventilated to control exposure. b) Critical storage conditions are monitored and recorded c) There are systems to deal with emergencies. d) There is a documented contingency plan for storage of bodies and human tissue.

Glossary

Term	HTA definition
Anatomical examination	Macroscopic examination by dissection for the purposes of teaching or studying, or researching into, the gross structure of the human body.
Anatomical specimen	The body of a deceased person, including separated parts of such a body, to be used for the purpose of anatomical examination.
Appropriate consent	Defined in the HT Act by reference to the person who may give consent. This is broadly either the consent of the person concerned, their nominated representative or (in the absence of either of these) that of a person in a qualifying relationship to them immediately before they died.
Bone marrow	A spongy tissue found in the hollow centres of some bones. It contains specialist stem cells, which produce the body's blood cells.
Cells	Individual human cells or a collection of human cells that are not bound by any form of connective tissue.
Clinical waste	The Controlled Waste Regulations 1992 define clinical waste as any waste which consists wholly or partly of: human or animal tissue; blood or other body fluids; excretions; drugs or other pharmaceutical products; swabs or dressings; or syringes, needles or other sharp instruments which, unless rendered safe, may prove hazardous to any person coming into contact with it. Clinical waste also refers to any other waste arising from medical, nursing, dental, veterinary, pharmaceutical or similar practice, investigation, treatment, teaching or research, being waste which may cause infection to any person coming into contact with it.
Coroner	Coroners are independent judicial office holders, appointed by a local council. They investigate deaths that have been reported to them if it appears that the death was violent or unnatural, the cause of death is unknown or the person died in prison, police custody, or another type of state detention. In these cases coroners must investigate to find out, for the benefit of bereaved people and for official records, who has died and how, when, and where they died. As part of their duties, coroners authorise post-mortem examinations and conduct inquests.

Term	HTA definition
Designated Individual (DI)	The person named on a licence issued by the HTA, under whose supervision licensed activities are carried out. The DI has a statutory responsibility to ensure that those carrying out licensed activities, and their practices, are suitable, and that the conditions of the licence are met.
DNA	DNA stands for deoxyribonucleic acid. DNA is found in the nucleus of all cells, and contains the genetic information for the development and working of living organisms including human beings. The study of DNA is used in forensics, gene therapy, relationship (including paternity) testing and bioinformatics. Find out more information about the HTA's role with regards to DNA on the HTA's website.
Donation	The act of giving human tissue, cells, organs or part organs for a scheduled purpose, either during life or after death.
Donor	Every human source, whether living or deceased, of tissue, cells, organs or part organs.
Embalming	The use of chemicals to preserve human tissue.
Existing holding	Material from the living or deceased that was already held for use for scheduled purposes when the Human Tissue Act came into force on 1 September 2006.
Export	The movement of human tissue from England, Wales or Northern Ireland to a place outside England, Wales and Northern Ireland.
Human application	In relation to tissue or cells, human application means use on or in a human recipient, including use in applications situated or occurring outside the body, but not including use when tissue and cells are removed from and applied in the same person within the same surgical procedure.
Import	The movement of human tissue into England, Wales or Northern Ireland from a place outside England, Wales and Northern Ireland.
Incineration	A process used to destroy human body parts. Incineration of human tissue as clinical waste is normal practice and is subject to separate regulation. Incineration does not usually have any associated ceremony. Technically, cremation and incineration are similar processes, both using burning to reduce part or whole deceased human bodies to basic chemical compounds in the form of ashes.

Term	HTA definition
Licensed premises	Where the licensed activity takes place.
Licensing	A number of activities can only be carried out when an establishment is licensed under the Human Tissue Act by the HTA. Organisations whose activities involve the removal, storage or use of relevant material may need to work under a HTA licence. All establishments working under a HTA licence must work to specified standards set by the HTA.
Nominated representative	A person appointed by a person to represent them after their death for the purposes of activities under the Human Tissue Act for which consent is required. A nominated representative may be entitled to consent to the removal, storage and use of the body or tissue for any of the scheduled purposes, other than anatomical examination or public display.
Organ	Defined by the Human Tissue Act (Persons who Lack Capacity to Consent and Transplants) Regulations 2006, as amended, as a differentiated part of the human body, formed by different tissues, that maintains its structure, vascularisation and capacity to develop physiological functions with a significant level of autonomy. Part of an organ is also considered to be an organ if its function is to be used for the same purpose as the entire organ in the human body, maintaining the requirement of structure and vascularisation.
Pathology	The science of the causes and effects of diseases.
Peripheral blood stem cells (PBSCs)	Peripheral blood stem cells are the source of all blood cells. They are found in the bloodstream and are formed in bone marrow. They receive signals that direct them to differentiate into all the cell types found in blood (red cells, white cells or platelets). They can be mobilised from the bone marrow into the blood stream by giving a drug, and collected with an apheresis machine.
Plastination	A method of preserving human tissue using plastics.
Post-mortem examination	Dissection and examination of a body after death, principally in order to determine the cause of death or the presence of disease processes.
Practitioner	A person working with relevant material in an establishment licensed by the HTA.

Term	HTA definition
Procurement	The processes by which tissues and cells are made available, including the physical act of removing tissue and the donor selection and evaluation.
Relatives	Throughout the Codes, the term 'relatives' should be taken to include a spouse or partner and, in cases where there are no relatives, close friends of the deceased person. Decisions regarding consent should be made according to the hierarchy of qualifying relationships as set out in the Human Tissue Act.
Relevant material	Defined by the HT Act as material other than gametes, which consists of, or includes, human cells. In the HT Act, references to relevant material from a human body do not include: (a) embryos outside the human body, or (b) hair and nail from the body of a living person. See policy guidance on how to apply this definition on the HTA's website.
Research	A study which addresses clearly defined questions, aims and objectives in order to discover and interpret new information or reach new understanding of the structure, function and disorders of the human body. Research attempts to derive new knowledge and includes studies that aim to generate hypotheses, as well as studies that aim to test them or develop practical applications or new knowledge.

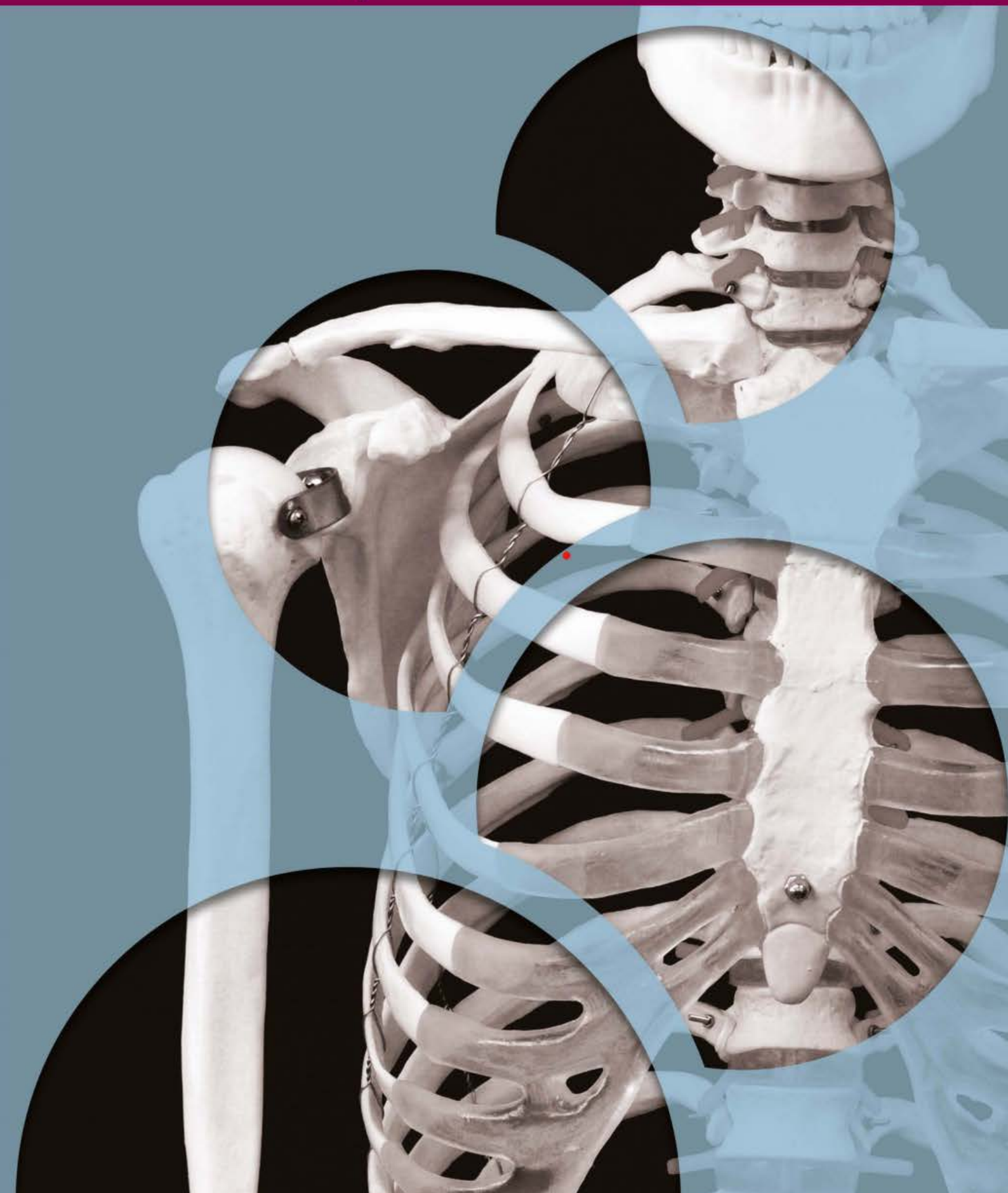
Term	HTA definition
Scheduled purpose	Under the Human Tissue Act, consent must be obtained to remove, store or use bodies or relevant material for scheduled purposes. The licensing requirements of the Human Tissue Act also refer to the scheduled purposes. Scheduled purposes are divided into those which apply general, and those which apply to the deceased only. • Part 1: Purposes requiring consent: General – anatomical examination; determining the cause of death; establishing after a person's death the efficacy of any drug or other treatment administered to him; obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person); public display; research in connection with disorders; or the functioning; of the human body, transplantation. • Part 2: Purposes requiring consent: Deceased persons – clinical audit, education or training relating to human health, performance assessment, public health monitoring, quality assurance.
Service Level Agreement (SLA)	A formal agreement that sets out the roles and responsibilities of two parties. An SLA cannot be used to provide a third party that is not licensed by the HTA with the authority to undertake licensable activities on behalf of a licensed establishment, only a Third Party Agreement (TPA) may be used for that purpose. Neither is it sufficient for governing the supply of goods or services which may affect the quality or safety of tissues and cells. If two establishments are licensed by the HTA and one undertakes licensable activities on behalf of the other, an SLA setting out roles and responsibilities is sufficient to document the working relationship between the two licensed establishments.
Standard Operating Procedure (SOP)	A document that sets out the established process to be followed to complete a task.
Tissue	Any and all constituent part/s of the human body formed by cells.
Transplantation	An implant of an organ or part organ, tissue or cells either from and into the same body or from one person to another.

Term	HTA definition
Valid consent	Consent which has been given voluntarily, by an appropriately informed person who has the capacity to agree to the activity in question. Valid consent is explained in detail in Code A: Guiding principles and the fundamental principle of consent.

D Public Display

HTA
Human Tissue Authority

Standards and guidance



Public Display Licensing Standards and Guidance

Revision history

Version	Date	Changes
1.0	23/01/2016	First version published
2.0	DD/MM/YYYY	Second version published

About the guidance documents

1. The purpose of these guidance documents is to assist licensed establishments to meet the HTA's licensing standards. The documents contain additional information and examples of how to meet certain Standards.
2. These documents will be reviewed regularly to include additional guidance. In reviewing these documents we will take into consideration enquiries, inspection findings and additional examples of good practice.
3. For further guidance on meeting the HTA's standards, please contact the HTA either by:
    a) Email: enquiries@hta.gov.uk
    b) Telephone: 020 7269 1900

About the Standards

4. In order to obtain an HTA licence, the applicant must demonstrate that:
    a) the premises where the activity will take place are suitable; and
    b) the proposed Designated Individual is a suitable person to supervise the activity.
5. As part of the application process, the HTA will assess whether the establishment can meet a number of licensing Standards. These were developed in consultation with representatives from the Public Display sector. These relate to the consent provisions of the Human Tissue Act 2004 (HT Act), governance and quality systems, traceability and premises.
6. The Standards reinforce the HT Act's intention that:
    a) consent is paramount in relation to activities involving the removal, storage and use of human tissue;
    b) bodies of the deceased and organs and tissue removed from bodies are treated with respect;
    c) the dignity of the person, whether living or deceased, is maintained.
7. The HTA works with establishments through its inspection process to help them comply with these Standards.
8. The Standards are grouped under four headings: Consent (C); Governance and quality systems (GQ); Traceability (T); and Premises, facilities and equipment (PFE). Under each of these headings, there are overarching statements, from which the standards flow.

Consent (C)

9. Establishment's meeting the consent Standards will be able to demonstrate that their processes for seeking and gaining consent comply with the HT Act and the HTA's Codes of Practice. The Standards also cover the documentation and information used to support the establishment's consent procedures, and ensure that staff involved in seeking consent are suitably trained and equipped for the task.

Governance and quality systems (GQ)

10. Establishments meeting these Standards will be able to demonstrate that they have a suitable governance framework, underpinned by clear and controlled documentation, effective audit, staff training and organised record-keeping. In addition, they will have an effective system of risk management and suitable systems to deal with adverse events.

Traceability (T)

11. Establishments meeting these Standards will be able to demonstrate full traceability for the human material for which they are responsible, from receipt to final disposal/disposition. HTA inspectors will test this through traceability audits carried out on site and the HTA expects establishments to take a pro-active approach to assuring themselves of effective traceability throughout the lifetime of their licence. In addition, as the final traceability step, they will have established disposal arrangements which are in accordance with the HTA's Codes of Practice.

Premises, facilities and equipment (PFE)

12. Establishments meeting these Standards will be able to demonstrate that their premises and facilities are appropriate for the licensed activities taking place and that they are safe, secure and clean. In addition, establishments will have systems for on-going monitoring to ensure all key quality specifications are maintained. These Standards also cover equipment, ensuring that it is appropriate, and suitably maintained, and that it does not present an impediment to the staff using it.

13. The HTA licensing Standards which are applicable to the Public Display sector are included at Annex D and on the HTA website. The Standards are supported by comprehensive guidance notes.

Guidance on the Standards

Consent

C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in its codes of practice

a) If the establishment is required to seek consent, a process is in place which is in accordance with the requirements of the HT Act and the HTA's Codes of Practice, and records of consent are maintained.

b) If relevant, there is training for staff on how to seek consent for the public display of human material, which addresses the requirements of the HT Act and the HTA's Codes of Practice and records demonstrate attendance.

c) Where applicable, there are agreements with other parties to ensure that consent is sought in accordance with the requirements of the HT Act and the HTA's Codes of Practice.

Guidance

~~*Establishments should seek to receive written assurance that, for imported specimens, the donor's consent was sought in line with that country's requirements*~~

The HTA considers that ***the same consent expectations should apply for imported bodies and body parts as set out in paragraphs 37 to 40 in the Code of Practice D (Version 2) as for such material sourced domestically (England, Wales and Northern Ireland),*** *unless the HTA is satisfied that there are exceptional reasons for not doing so.*

Establishments removing, storing or using bodies or body parts imported for the purpose of public display from the date Code of Practice D (Version 2) comes into force, should ensure that they have been sourced legally in the country of origin and the person whose body or body parts are intended for public display have given consent for this purpose in accordance with the HTA's Code of Practice. Establishments should be confident in the validity and authenticity of the documentation they intend to rely on for assurance. The HTA will review this documentation as part of its regulatory oversight of licensed establishments and when assessing applications for HTA licences.

C2 Information about the consent process and the activity for which consent is sought is provided

a) There is written information about the consent process for those giving consent, which reflects the requirements of the HT Act and its codes of practice

b) Standard operating procedures (SOPs) specify how information on consent is provided.

Governance and quality systems

GQ1 All aspects of the establishment's work are governed by documented policies and procedures

a) There are collections management policies and procedures, or equivalent, governing the storage and public display of bodies and human tissue which give due regard to the dignity of the deceased. These should include, as relevant to the establishment's activities:

   i. an overarching policy on the care and treatment of exhibits containing human tissue;

   ii. seeking consent for donation of bodies and human tissue for public display;

   iii. specimen acquisition e.g. by bequest, exchange, loan or purchase from another individual or organisation nationally or internationally;

   iv. specimen preservation, monitoring and conservation;

   v. control of environmental conditions;

   vi. the management of sensitive material, such as fetal remains;

   vii. transportation of specimens e.g. on loan to or return to other collections;

   viii. the disposal/deaccession of specimens;

   ix. storage contingency arrangements;

   x. the creation, amendment, retention and destruction of records;

   xi. the management of incidents and complaints.

   Guidance

   Individual SOPs for each activity are not required; some SOPs will cover more than one activity. Where appropriate, procedures should be developed in

consideration of potential risks. For example, where staff undertake cleaning of material on public display, the procedure should be based on the assessment of risk to staff from contamination and the cleaning materials they will be exposed to, as well as the potential risk of damage to the item being cleaned.

b) There are procedures that govern the work of temporary staff and contractors, which ensure that they are sensitive to the special status of human remains and exhibits consisting of human material.

c) Regular governance meetings are held; for example, health and safety and risk management committees, that have agendas and minutes.

Guidance

Team meetings provide an ideal opportunity to pass on relevant information to staff working under the licence, as well as allowing them to raise any issues or concerns.

d) Policies and procedures are reviewed regularly and are version controlled.

Guidance

Governance documentation should be up to date, subject to regular review and reflective of good practice, including guidance from organisations such as Arts Council England and the Department for Culture, Media and Sport (DCMS).

GQ2 There is a documented system of audit

a) There is a documented system of audit, which includes records of traceability and specimens.

Guidance

Audits should include compliance with documented procedures; the completion of records; and traceability

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks

a) There are clear reporting lines and accountability, and documented roles and responsibilities.

b) There is documented induction and training for staff, which includes the handling of human remains; attendance at training is recorded.

GQ4 There is a systematic and planned approach to the management of records

a) There are suitable systems for the creation, review, amendment, retention and destruction of records.

b) Systems ensure data protection, confidentiality and public disclosure (whistle-blowing).

GQ5 There are systems to ensure that untoward incidents are investigated promptly

a) There is a system for reporting and investigating serious untoward incidents.

Guidance

This should include incidents relating to the safety and integrity of human material and those that may impact on the establishment's ability to meet the requirements of the HTA codes of practice and licensing Standards. Staff should understand what is meant by an incident and be familiar with the procedure to follow when such an incident occurs.

Serious incidents should be reported to the HTA.

b) Corrective and preventive actions are taken where necessary and improvements in practice are made.

GQ6 Risks associated with the establishment's practices and processes in relation to the storage and display of human material are assessed and monitored

a) Risk assessments are documented.

Guidance

Risk assessments should consider risks to, for example: tissue traceability; storage of specimens; and dignity of the deceased. Where actions are identified to mitigate risks, these should have deadlines for completion and a person responsible for completing them.

For risk assessments to be meaningful, they should be undertaken by a suitably trained person, who has an objective view or who is following an established risk-assessment process. It may not be appropriate for staff working under the authority of the licence to undertake their own risk

assessments. In any event, the results of risk assessments should be shared with staff so that they have an understanding of the issues identified.

b) Risk assessments set out steps taken to mitigate risks

c) Risk assessments are reviewed regularly

Guidance

Risk assessments should be reviewed every 1-3 years

d) Staff can access risk assessments and are made aware of them in training

Traceability

T1 A coding and records system facilitates traceability of bodies and human tissue

a) Bodies and human tissue are traceable through a unique identification number or code.

Guidance

Procedures relating to indexing and record-keeping should reference the establishment's system of labelling bodies and body parts.

b) The system of record-keeping should include the location of material at the establishment and may include a description or photographic record and details of any specialist storage conditions, shelf-life or contamination risk.

T2 Records of traceability are maintained

a) Records of receipt, storage, transportation and delivery of bodies and human tissue are maintained.

b) Disposal or de-accession records include the date, reason and method of disposal/de-accession.

Guidance

If relevant material is loaned to or borrowed from another licensed establishment, consideration should be given to minimising the likelihood of theft or damage during transport. Loan agreements should define how the material is preserved and any potential contamination risks associated with it. There should be clear instructions on how to deal with an untoward incident

and contact details for the person responsible at the establishment loaning relevant material.

c) Where applicable, disposal arrangements reflect specified wishes of the donor.

Premises, facilities and equipment

PFE1 The premises and facilities are secure and safeguard the dignity of the deceased and the integrity of human tissue

a) Areas used for storage or public display provide an environment that is safe for staff and visitors and preserves the integrity of the material and the dignity of the deceased.

Guidance

As advised in the DCMS Guidance for the care of human remains in museums*, visitors should not come across human remains unaware. The establishment should give consideration to suitable signage, explaining the presence of bodies, body parts or other relevant material and the requirement to treat them with dignity and respect.*

b) The establishment is clean, well maintained and subject to a programme of planned preventative maintenance.

c) Staff have access to the protective clothing, materials and equipment they need.

d) A documented risk assessment has been carried out of the premises to ensure that they are appropriate for the licensed activities.

Guidance

An assessment can cover such risks as fire, theft and vandalism.

e) There are policies in place to review and maintain the safety of staff and visitors.

f) The premises are secure with controlled access to bodies, human tissue and records.

g) Security measures include the use of lockable display areas and alarm systems.

PFE2 There are appropriate facilities for the storage of bodies and human tissue

a) Where chemicals are used for preservation, the area is adequately ventilated to control exposure.

Guidance

Control of Substances Hazardous to Health (COSHH) regulations require the exposure of formaldehyde to be controlled as low as possible and below the maximum exposure limit (2 ppm). This may include regular monitoring of formaldehyde levels and continuous operation of extract ventilation.

b) Critical storage conditions are monitored and recorded

Guidance

This could include, for example, temperature; humidity, dust or light levels, in storage and display areas.

c) There are systems to deal with emergencies.

Guidance

This could include, for example, fire, flood, power failure or public disturbance.

d) There is a documented contingency plan for storage of bodies and human tissue.

Guidance

For example, the establishment could have arrangements for material to be transferred to alternative licensed premises.

Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as ‘Critical’, ‘Major’ or ‘Minor’. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

Critical shortfalls

A critical shortfall is:

- a shortfall which poses a significant risk to human safety and/or dignity or is a breach of the Human Tissue Act 2004 (HT Act) or associated Directions; or
- a combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

A critical shortfall may result in one or more of the following:

- a notice of proposal being issued to revoke the licence
- some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented
- a notice of suspension of licensable activities
- additional conditions being proposed
- directions being issued requiring specific action to be taken straightaway

Major shortfalls

A major shortfall is a non-critical shortfall that:

- poses a risk to human safety and/or dignit;
- indicates a failure to carry out satisfactory procedures;
- indicates a breach of the relevant CoPs, the HT Act and other relevant professional and statutory guidelines;
- has the potential to become a critical shortfall unless addressed; or

- is a combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

Minor shortfalls

A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based or site visit.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.