# Ninety-second Meeting of the Human Tissue Authority

**Date** 7 May 2020
**Time** 10.00 – 12.00
**Venue** Via Zoom

# Agenda

| 1. | Welcome and apologies | |
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| 2. | Declarations of interest | Oral |
| 3. | Minutes of 6 February 2020 meeting | HTA (07/20) |
| 4. | Matters arising from 6 February 2020 meeting | HTA (08/20) |
| | **Regular Reporting** | |
| 5. | Chair's Report | Oral |
| 6. | Chief Executive's Report | HTA (09/20) |
| | Operational data annex (part 1 and 2) | HTA (09a/20) |
| | **Business Continuity** | |
| 7. | Risks and Issues | HTA (10/20) |
| | Strategic Risk Register | HTA (10a/20) |
| 8. | Regulatory response | HTA (11/20) |
| 9. | Phase 5 Planning | HTA (12/20) |
| | Powerpoint presentation | HTA (12a/20) |
| | **Policy Updates** | |
| 10. | Deemed Consent Implementation | Oral |
| | **Any Other Business** | |
| 11. | Any Other Business | Oral |
| | **Close** | |

Meeting close 12.00pm

![HTA - Human Tissue Authority logo]

# Minutes of the ninety first meeting of the Human Tissue Authority

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| **Date** | 6 February 2020 |
| **Venue** | Viceroy Suite, The Amba Hotel Grosvenor Hotel, 101 Buckingham Palace Road SW1W 0SJ |
| **Protective Marking** | OFFICIAL |

| Present | |
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| **Members** | **In attendance** |
| Lynne Berry (Chair)<br>Dr. Stuart Dollow<br>Amanda Gibbon<br>Prof. Andrew (Andy) Hall<br>William (Bill) Horne<br>Glenn Houston<br>Prof. Penney Lewis<br>Bishop Graham Usher<br>Dr. Lorna Williamson, OBE<br>Prof. Anthony Warrens<br>Prof. Gary Crowe<br>Dr. Hossam (Sam) Abdalla | Allan Marriott-Smith (Chief Executive)<br>Nicolette (Nicky) Harrison (Director of Regulation)<br>Richard Sydee (Director of Resources)<br>Louise Dineley (Director of Data, Development and Technology)<br>Jess Porter (Head of Regulation, ODT) (items 12 and 13)<br>Matthew Silk, Head of Communications (item 12)<br>Ruth Joyce, Senior Policy Manager (item 13)<br>Nima Sharma (Board Secretary; minute taking) |
| **Apologies**<br><br>Dr. Charmaine Griffiths, Member<br>Jeremy Mean (Department of Health and Social Care) | **Observers**<br><br>Sarjana Tharin, Data Analyst |

| Item | Title | Action |
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| **Item 1** | **Welcome and apologies** | |
| | 1. The Chair welcomed Members, those in attendance and observers to the Board meeting. | |

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| | 2. Sam Abdalla was welcomed back following a period of absence.<br><br>3. The Chair informed Members that David Thomson, Head of Business Technology would be attending during the lunch break to resolve any IT issues being faced by Members.<br><br>4. The Chair also informed Members that a representative from the Health Research Authority (HRA) would be attending in the afternoon to deliver a seminar about the HRA's role and its collaboration with the HTA. | |
| **Item 2** | **Declarations of Interest** | |
| | 5. The Chair asked Members to declare any personal or pecuniary interests that they may have in relation to this meeting's agenda; none were declared. | |
| **Item 3** | **Minutes of 22 November 2019 meeting [HTA 35/19]** | |
| | 6. The Chair requested Members' comments on the factual accuracy of the minutes. There were no further comments made during the meeting.<br><br>7. Members agreed to approve the minutes. | |
| **Item 4** | **Matters arising from previous meetings [Oral]** | |
| | 8. The Chair noted that there were actions outstanding from the July meeting and actions from the November meeting have either been completed or would be addressed during the meeting. The Board agreed that, in future, the matters arising log should be circulated with the Board papers.<br><br>9. Board Members were asked to note that Action 10 from the July Authority meeting would now be managed within the Relocation Project as opposed to being part of Board business.<br><br>10. The Board noted the content of this update.<br><br>**Action 1:** The matters arising log for this meeting to be circulated to Members (action complete). | NS |

| Item 5 | **Chair's Report [Oral]** | |
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| | 11. The Chair provided an update to Members on her initial thoughts and reflections since joining the HTA in November 2019. | 3 |
| | 12. The Chair highlighted that whilst the HTA is guided by better regulation principles, there were further improvements that could be made in terms of proportionality and better targeting of regulatory risk. | |
| | 13. The Chair thanked Members for assisting with her induction and helping her to better understand the work of the HTA and the way in which the Board operates. | |
| | 14. The Chair informed Members that she, together with Allan Marriott-Smith, will be meeting a number of other stakeholders organisations as part of her induction, including other health sector Arm's-Length Bodies, with a view to strengthening our collaborative efforts. | |
| | 15. The Chair informed Members that she would be meeting the Welsh Minister for Health and Social Care with Bill Horne, and would use this as an opportunity to discuss the recruitment of a new Board Member to represent Wales. | |
| | 16. The Chair informed Members that Bill Horne and Andy Hall would be stepping down as ARAC members and would be replaced by Charmaine Griffiths and Gary Crowe. The Chair extended the Board's thanks to both Bill Horne and Andy Hall for their service to ARAC. | |
| | 17. The Board noted the content of this update. | |
| | **Action 2:** Member tenures for committee membership to be circulated to the Board (action complete). | NS |
| Item 6 | **Chief Executive's Report [HTA 01/20]** | |
| | 18. Allan Marriott-Smith presented this item and introduced this report. | |
| | 19. The Board was informed that the upward pressure on risk four, Failure to utilise people, data and business technology capabilities effectively, which was documented in the paper has subsequently reduced as a result of four appointments being made. These include an interim | |

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| | Project Manager (to lead on the office relocation project) and a permanent Project Manager. |
| | 20. The Board was informed that the Transplant Manager role is likely to be filled shortly after the current incumbent leaves the HTA. A good response had been received to the Communications Officer and HR Manager recruitment exercises. |
| | 21. The Board was informed that whilst some roles have been successfully filled, others (the Business Analyst and Governance and Quality Manager roles) are proving harder to attract the right candidates. |
| | 22. An update was provided about the outcomes from the strategy away day. Members were informed that work will focus on developing the HTA's risk management policy (including its approach to risk appetite and tolerance) and on enabling the Board to better understand the underlying drivers of risk. Members noted that this information would in future be presented in the CEO report. |
| | 23. The Board was informed that two complaints to the HTA were received over the last two quarters and that a lessons learnt exercise has taken place with an action plan adopted to update the complaints policy in line with the findings. |
| | 24. Allan Marriott-Smith provided a presentation to the Board on the staff survey results. The Board agreed that the results are largely positive and requested assurance on how the Executive proposes to track agreed actions stemming from the survey. The Board was assured that the actions would be tracked and reported as part of the Deployment report. |
| | 25. The Board noted the content of this report. |
| **Item 7** | **Delivery Report- Quarter Three 2020/21 [HTA 02/20]** | |
| | 26. Nicky Harrison presented this item and introduced the report. |

27. The Board was provided with updates on actions one, two and five that were still open following the July and November meetings.

28. In terms of action one, which relates to sharing information about Serious Adverse Events and Reactions in living donors with the Board, Members were informed that the Executive would in future report orally on such cases, as the low volume of cases runs the risk of individual cases being identified if documented in the delivery report. The Board agreed with this approach.

29. The Board noted that action two, which relates to the development of a policy for novel cases would be brought to the July meeting for discussion.

30. The Board noted that action five which relates to out-of-hours living donation cases would be brought back to the July Board meeting for discussion.

31. Nicky provided the Board with her assessment of the new style Delivery report and noted that from her perspective the report requires further development to ensure it provides the Board with adequate assurances about the HTA's key regulatory functions. The Board agreed that there should be careful consideration of the content of the report as it is a key tool in providing transparency to the public and other stakeholders.

32. The Board noted that in quarter three, the HTA refused a licence to an establishment for the removal of tissue on the basis that the premises did not meet the required standards and that they may re-apply once this has been rectified.

33. The Board noted that the increased number of closed serious adverse events and reactions (SAEARs) was due to the increased management focus on closing historic Human Application SAEARs in quarter three compared with the previous quarter.

34. The Board questioned the Executive about its assessment of the increase in SAEARs relating to disease

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| | transmission. The Board was informed that these cases are predominantly the result of transmission of diseases which are not covered by mandatory testing requirements. | |
| | 35. The Board requested that the Executive review the purpose of the corrective and preventative action (CAPA) plans KPI and its scoring criteria. In particular, whether this is intended as a performance indicator for the HTA or a licensed establishment compliance indicator. The Executive confirmed that this will be reviewed as part of the development of the suite of KPIs for 2020/21. | |
| | 36. The Board noted the content of the report. | |
| **Item 8** | **Development Report- Quarter Three 2020/21 [HTA 03/20]** | |
| | 37. Louise Dinely presented this item and introduced the report. | |
| | 38. The Board was provided with an update on the technical issues experienced when circulating the Board papers. Members were informed that a number of diagnostic tests have been run to identify the root cause. The Board advised that if the tests indicate any significant issues the Executive should reflect on this before pressing ahead with further development work. | |
| | 39. The Board was informed that the Executive has put in place a revised support model which enables Members to have direct access to the BCC help desk during core hours for IT support. | |
| | 40. An update was provided about projects undertaken in quarter three in relation to cloud migration which is progressing well and the development of a HTA intranet, which will be a key tool in strengthening internal communication. | |
| | 41. An update was provided on the review of the HTA's system being undertaken by external advisors. An update on the outcomes of this work will be provided at the next Board meeting. | |

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| | 42. Bill Horne and Members congratulated the Executive team involved in the deemed consent project, particularly in the face of pressing timescales. It was stated during the meeting that the project evidenced the confidence that the DHSC has in the HTA and the level of goodwill that has been developed.<br><br>43. The Board noted the content of this report. | |
| **Item 9** | **Deployment Report- Quarter Three 2020/21 [HTA 04/20]** | |
| | 44. Richard Sydee presented this item and introduced the report.<br><br>45. The Board was asked to note, in particular, the committed spend position. Attention was also drawn to debtors figures which are lower compared with last year. The Board was asked to note that £17,000 of bad debt had been written off.<br><br>46. The Board was provided with information about the predicted rental costs once the relocation is complete and the reasons for the current uncertainty about the final figure pending decisions about allocation of costs for shared space.<br><br>47. The Board was informed that further staff communication has been carried out about phishing emails and how to avoid the risks they pose to the HTA systems and finances.<br><br>48. The Board noted the content of this report. | |
| **Item 10** | **Audit and Risk Assurance Committee (ARAC) Update [Oral]** | |
| | 49. Amanda Gibbon provided an update on the outcomes following the ARAC meeting held on 30 January 2020.<br><br>50. The Board was asked to note that ARAC had agreed with the Executive's advice, that completing the recommendations from the records management audit should be downgraded in priority for the time being. The Board also noted that two new internal audit reports on | |

critical incident and business continuity plans, had been given a moderate assurance.

51. The Board was asked to note that the new accounting standards for leases, IFRS 16, would have an impact on the HTA financial statements both in terms of costs and the creation of long term liability.

52. The Board was informed that;

- the Committee reviewed the Cyber Security Strategy, and noted that additional work would be required to develop this further.

- a Project Manager would assist in the migration to cloud.

- The home working policy would be launched next week.

- A deep dive was carried out focussing on office re-location and the risk to business critical roles at the HTA.

- ARAC would consider whether a deep dive about the Licensed Establishment Engagement Programme is carried out at its next meeting in June.

- the Risk Management policy was presented during the ARAC meeting but noted that it requires further work following the strategy away day. In particular, in how it addresses risk appetite and tolerance.

- the HTA was subject to an externally perpetrated payroll fraud which was reported via the correct channels. The funds were subsequently recovered.

53. Amanda Gibbon concluded her update by extending her thanks to both Bill Horne and Andy Hall for their service on ARAC.

54. The Board noted the content of this update.

| Item 11 | **Remuneration Committee (RemCo) [Oral]** | |
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| | 55. Bill Horne provide an oral update on this item. | 9 |
| | 56. The Board was informed that the last RemCo meeting on 16 July 2019 had considered the pay award to the senior team. The Committee had approved a pay increase in line with that made to HTA staff. In addition, the two eligible members of the team received a performance-related award. | |
| | 57. The Board noted the content of this update. | |
| Item 11a | **Histopathology Working Group (HWG) [Oral]** | |
| | 58. Lorna Williamson provided an oral update on the meeting of 5 February 2020. | |
| | 59. The Board was informed that there had been a reduction in the number of incidents for particular HTARI categories which is as a result of improved governance around traceability. | |
| | 60. The Board was made aware that the HTA is involved in the central planning for the response to any spread of coronavirus in the UK, including in relation to excess deaths. | |
| | 61. The Board was asked to note that the joint guidelines on non-invasive post mortem examination were awaiting sign off. | |
| | 62. The Board noted the content of the update. | |
| Item 12 | **Public Guide to Code F (HTA 05/20)** | |
| | 63. Matthew Silk introduced this paper. | |
| | 64. The Board was informed that the Public Guide to Code F had been updated to reflect the law change to deemed consent and will be used to supplement the professional Code which will be published in May 2020. | |

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| | 65. The Board provided comments that the Public Guide should provide greater clarity on:<br><br>- Living donation - making it clear that this applies to kidneys and livers;<br>- Distinguishing between paired/pooled and directed donation.<br>- Deceased donation, by creating a separate document covering this only<br><br>66. The Board agreed that a separate section should be included on children and to remove the reference to the consultation on novel transplants from the scope of the document.<br><br>67. The Board also asked that the Executive should provide a MS Word version of papers to Board Members where the Executive is seeking comments on a document.<br><br>68. The Board noted the content of this paper.<br><br>**Action 3:** Board Members to be provided with the MS Word version of this document (action complete). | <br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br>NS |
| **Item 13** | **Deemed Consent – Outline of the consultation response and next steps [HTA 06/20]** | |
| | 69. Ruth Joyce presented this paper.<br><br>70. The Board was informed that the aim of the paper was to give Members an outline of the plan to achieve the successful launch of Code F in May 2020 and to seek the Board's views on the proposed plan.<br><br>71. The Board questioned whether there is a documented rationale where comments made in the consultation had not been addressed in the revised Code. The Board was informed that there was a clear documented justification where this was the case which would be included in the response document.<br><br>72. The Board noted that NHS Blood and Transplant colleagues have thanked the HTA for its work in developing the updated Code F. | |

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| | 73. Ruth Joyce informed the Board that the response document would be circulated via email for comments from Members. | |
| | 74. The Board noted the content of this update.<br><br>**Action 4:** The response document to be circulated to the Board for review and comment. | RJ |
| **Item 14** | **HTA Office Relocation  [Oral]** | |
| | 75. Richard Sydee provided an oral update on this item. | |
| | 76. The Board was informed that the overall programme for relocation is being run by DHSC. | |
| | 77. The Board noted that the confidentiality issues which were identified at the July meeting would be dealt with as part of a programme sub-group which is chaired by Richard Sydee. | |
| | 78. He reassured the Board that the Executive would fully explore issues surrounding confidentiality but asked the Board to note that all bodies are bound by the Code of Conduct and privacy requirements. | |
| | 79. The Board was informed that the Executive had identified particular staff who would be most impacted by the office relocation. Individual interviews would be carried out to discuss any specific concerns staff members have as well as identifying any avoidable risks. | |
| | 80. The Board noted the content of the update. | |
| **Item 15** | **EU Exit  [Oral]** | |
| | 81. Nicky Harrison provide an oral update on this item. | |
| | 82. The HTA has received guidance on managing its operations during the transition period, and will continue to work closely with DHSC to provide advice and guidance on matters within our remit. | |

| Item 18 | AOB [Oral] | |
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| | 83. The Chair asked Members and those in attendance if they had any other business. There was no other business raised.<br><br>84. The Chair asked the Executive to ensure that papers provide the Board with information to help guide them on the next steps and decision making. The Executive noted this comment. | 12 |

**Next meeting:** Thursday 7 May 2020

# HTA Board Meeting - Matters Arising from previous meetings

## February 2020 meeting actions update

All actions complete.

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## November 2019 meeting actions update

**Action 2:** The Executive to review the relevant policy to ensure it is clear on the criteria to be met for Panel consideration of a novel transplant case **(ANH)**

**Update: Ongoing.** To provide an update at the July Board meeting. The Executive has reviewed current policies and currently none of the policies cover this so we will need to find a solution and come to an agreement so we can be clear on the criteria to be met moving forward.  The Executive will consider how to move forward with this and may seek legal advice.

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**Action 3: Ongoing.** The Executive to consider using statistical process control techniques in reviewing incident data, such as for HTARIs **(ANH)**

**Update: Ongoing.** To provide an update at the July Board meeting.

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**Action 5:** A proposal to be brought to a future Authority meeting on the possible remuneration for staff involved in the out of hours rota. **(ANH)**

**Update: Ongoing.** An update to be provided at the July Board meeting.

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## July 2019 meeting actions update

**Action 13:** The Executive to carry out further scoping to support an electronic way of working. **(NS)**

**Update: Ongoing.** To be kept under review under current working circumstances with an update to be provided at a future Board meeting.

# HTA Board paper

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| **Date** | 7 May 2020 | **Paper reference** | HTA (09/20) |
| **Agenda item** | 6 | **Author** | Allan Marriott-Smith |
| | | | Chief Executive |

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| **Protective Marking** | OFFICIAL |

## Chief Executive's Report

### Background

1.  In the absence of the full suite of reporting, this paper provides an overview of the position at the end of quarter four.  It provides the Board with an update on the progress of Development projects, a summary of the financial position at year end, and an overview of HTA people issues arising since the Board last met in February.

2.  While the last two weeks of the quarter were defined by our need to respond to the COVID-19 pandemic, excellent work had been undertaken up until that point to achieve our business plan objectives. This paper focuses on the work across quarter four.

3.  An overview of operational activity is included in the Annex.

### Decision-making to date

4.  This report was approved by SMT on 30 April 2020.

### Action required

5.  The Board is asked to note the content of this report.

### Overview

6.  The HTA made some excellent progress towards its objectives in the final quarter of 2019/20. Inevitably, SMT's decision to send staff home on 13 March, followed by

government advice that made remote working mandatory (where this was possible) as a result of the COVID-19 pandemic, has meant that there has been no office presence for eight weeks. This, alongside the decision to suspend routine site visit inspections inevitably shaped the end of the business year and will have long-term impact on operations.

7.   This period has been a very real test of both our business continuity and critical incident response arrangements, and also of whether the HTA's three-year Strategy (which is due to end in March 2021) with its underpinning vision of a more agile, sustainable and resilient organisation has been effective.

8.   While it is undoubtedly true that not all of the outputs envisaged in the Strategy have yet been delivered, there is growing evidence of excellent progress towards the achievement of the vision. The coming year will provide additional opportunities to realise our ambitions.

9.   Overall, the HTA achieved a rapid move to full remote working without any loss of business continuity, while undertaking core regulatory business (in particular a rapid growth in activity in the post-mortem sector) and also making significant progress in development activities.

**Regulatory overview**

9.   The Annex to the paper provides a detailed account of both the core regulatory activity undertaken over the quarter, and data to highlight the additional regulatory activity which has resulted from responding to the pandemic.

**Quarter four development projects overview**

10. A number of projects supporting the HTA Strategy 2019/20 and setting the foundations for the future Strategy were identified for delivery and successfully completed in quarter four.

*Development of the HTA Intranet*

11. On 8 April, the HTA launched its first local intranet.  The proposed development of an HTA Intranet gained quick support from across the organisation from the initial proposal stage.  The intended benefits of this development included strengthened internal communications, streamlined and consistent messaging and a user-friendly interface to access corporate policies and guidance.  The early feedback on the Intranet has been positive and will be used to target future and further developments throughout 2020/21.

*Adoption of Office 365 and Cloud Migration*

12. The successful adoption of Office 365 and cloud migration have been key deliverables of the HTA's Digital, Data and Technology Strategy. Work in quarter three focused on the scoping and planning of the projects with work in quarter four focusing on the delivery and implementation of Office 365 and its adoption as the HTA's operating system.  The final implementation stages of staff awareness and training were delivered at pace to ensure the functionality of Office 365 was available as the organisation transitioned to full remote working in mid-March.  Embedding the development and the completion of migration has continued into April.  Looking forward we will continue to embed the adoption of both the system and the additional functionality that it offers to support the HTA's remote working capacity and capability.

13. The HTA's investment in and adoption of Office 365 and cloud services provides a platform for us to build and strengthen our arrangements for cyber security and information security.  A number of priorities have been identified in quarter one including the review of the Cyber Security policy; making use of the additional functionality in Office 365 to review the organisation's security configuration and continued delivery of the cloud security action plan.

*IT equipment*

14. A further investment in new equipment was made at the end of quarter four to enhance the experience of remote working across the organisation.  The additional equipment includes, headsets and e-pens and planned upgrades to mobile phones to provide additional functionality in line with our migration to the cloud.  This investment in equipment is designed to support flexible and remote working for all staff.

*Internet Development*

15. In quarter three the HTA commenced a 12-month programme to develop and improve the HTA's internet.  This planned development seeks to improve accessibility to the site and its content through the use of a range of different formats in line with statutory accessibility standards.  Phase 1 of this work which included developing proposals and initial stakeholder engagement was completed in quarter four.  Phase 2 which includes the delivery of the changes and further stakeholder engagement will be delivered between April and September 2020.

*Commissions*

16. An additional focus of quarter four projects has been an investment in establishing the foundations for future developments through better understanding our business

requirements.  In the last quarter we commissioned two pieces of work to provide an independent review to support the organisation develop its understanding of its data and intelligence systems and electronic document and record management system.  These reviews have helped to enhance our local understanding of the strengths and opportunities to improve our systems as well as set a clear set of business requirements for future development.

17. In addition to the development commissions, the HTA also commissioned the evaluation of its stakeholders.  This work will be reported to the Board in July.

**Financial overview**

18. The table below provides the pre-audit outturn position at the end of the 2019/20 financial year and shows a net surplus against budget of **£19k.**

HUMAN TISSUE AUTHORITY
Summary Management accounts
For the Twelve Months Ending 31 March 2020

| | Year-to-date | | |
|---|---|---|---|
| | Actual | Budget | Var |
| | £'000s | £'000s | % |
| **INCOME** | | | |
| Government Grant in Aid | 693,000 | 795,000 | (12.83%) |
| RF RDEL | 197,700 | 197,700 | 0.00% |
| Licence Fee income | 3,727,964 | 3,716,405 | 0.31% |
| Devolved Governments | 133,572 | 136,011 | (1.79%) |
| Rental income | 406,773 | 369,936 | 9.96% |
| Other income | 46,753 | 45,001 | 3.89% |
| **TOTAL INCOME** | **5,205,761** | **5,260,052** | **(1.07%)** |
| | | | |
| **OPERATING COSTS** | | | |
| Staff costs (salaries etc) | 3,077,804 | 3,238,068 | (4.95%) |
| Other staff (exc inspection) | 186,654 | 133,200 | 40.13% |
| Authority costs | 182,096 | 193,606 | (5.95%) |
| Inspection costs | 52,171 | 110,000 | (52.57%) |
| LODT costs | 7,790 | 9,000 | (13.45%) |
| Communication costs | 36,605 | 41,800 | (12.43%) |
| IT and Telecom costs | 441,247 | 341,100 | 29.36% |
| Office and Administration | 84,176 | 72,600 | 15.94% |
| Other costs | 65,281 | 61,500 | 6.15% |
| Legal and Professional costs | 31,952 | 40,000 | (20.12%) |
| Accommodation | 578,182 | 813,500 | (28.93%) |
| Non-cash | 442,480 | 199,000 | 122.35% |
| Contingency | | 15,500 | (100.00%) |
| **Total operating costs** | **5,186,437** | **5,268,874** | **(1.56%)** |
| | | | |
| **Net Income/(expenditure)** | **19,324** | **(8,822)** | |

19. Income was below our initial budget; this is due to a reduction in Grant in Aid from the Department to meet the increase in NHS pension scheme contribution rates which was settled centrally.  The additional rental income during 2019/20 is due to increased rent charges for NHS Resolution which now includes VAT.

20. Staff costs were five per cent below budget due to the level of staff turnover and some delays to filling posts, the increase in Other staff costs represents increased investment in staff training and development.

21. The significant underspend in Accommodation costs results from the release of the historic rent provision relating to a disputed rent increase from April 2016.  This provided funds for a number of investments activities described earlier in this report.

22. Increased Non-cash costs relate to a material increase in our accrual for staff leave and a provision to meet the additional travel costs for staff upon our relocation to Stratford in 2020/21.

23. Overall, we have been able to deliver a balanced position for this financial year whilst also delivering some of the transformation activity we outlined at the start of the strategic period.

**People overview**

*Recruitment and onboarding*

24. The HTA has temporarily halted recruitment until the short to medium-term demands on resources become more apparent. We have, however, welcomed two new members of staff to the organisation, both of whom have been inducted remotely.

*Increased communications*

25. The move to remote working has necessitated an increase in the frequency of communications with and between staff. This is taking place at all levels within the organisation, from an increase in the number and style of briefings coming from the senior leadership team, more regular contact within the wider management group, more frequent team meetings and 1-2-1s. This has been eased considerably by the introduction of Teams and will increasingly be supported by the HTA Intranet as a key communications channel.

*Focus on wellbeing*

26. The shift to remote working, the general anxiety caused by the pandemic and the possibility of blurring between work and home life, all increase the risk of stress and

anxiety for HTA staff. We have significantly ramped up our wellbeing programme and the provision of support services to staff.

*Pulse Survey*

27. In order to assess the overall mood of the organisation a five question "pulse" survey was launched on 27 April. Results will be provided as an oral update at the Board meeting.

*HTA Values*

28. The Board will be aware of the recent refresh of the organisational Values. In quarter four we developed branding for these values to make them more memorable and appealing for use publicly, for example as part of recruitment. The roll out will be supported by a small selection of values branded merchandise.

*Office move*

29.  The office move is likely to be delayed as a result of delays to the fit out of the premises in Stratford. It is still anticipated that the building will be available for occupation before the contract for occupancy of 151 BPR is completed. Contingency plans are being developed if this is not the case. In quarter four, we employed an external contractor to project manage the move for the HTA, which provides a great deal of assurance of our preparedness for the move when the time comes.

**Other issues**

*Business Planning 2020/21*

30. A lot of resource was dedicated to business planning in quarter four. Much of this was predicated on undertaking site visit inspections; this will no longer be the case. An interim business plan has been developed for quarter one which prioritises supporting the core functions identified as part of the business continuity plans. The four key development projects will also be prioritised:

- Deemed Consent – which the Government has pledged to proceed with on 20 May as set out in this answer to a [Parliamentary question](#). Further detail on Deemed Consent will be provided at agenda item 10.
- Office move – see paragraph 29.
- EU Exit – which is continuing to the same timescale but with fewer requests of the HTA from DHSC as a result of COVID-19.
- Website redevelopment - continuing as a priority with the accessibility deadline unchanged. See paragraph 15.

*31.* The rest of the plan comprises activities that had previously been deprioritised due to resource constraints. Finally, detailed planning for Phase 5 of the business continuity will begin in quarter one.

*Quarterly Accountability to DHSC*

32. As DHSC is under considerable resource pressure, we have agreed arrangements with the sponsorship team for a light touch accountability arrangement for the foreseeable future. This will consist of DHSC being provided with the materials supplied to the HTA Board with the option of a follow up discussion with the CEO to clarify any specific points.

*Freedom of Information requests*

33. The HTA responded to seven requests for information under the Freedom of Information Act (FOIA). We publish FOIA responses on our [website](website).

34. In addition, we have put in place temporary triage arrangements for non-urgent requests, such as those relating to our contractual arrangements, to try to reduce organisational pressures.

*Complaints*

35. In quarter four, no complaints were received by the HTA.

# Board Supplementary Data Annex document (part 1)
## Delivery – Quarter 4 2019/20

| Date | 7 May 2020 | **Paper Reference** | HTA (09a/20) part 1 |
|---|---|---|---|
| **Agenda Item** | 6 | **Author** | Louise Dineley |
| **Protective Marking** | OFFICIAL | **Author Contact** Louise.dineley@hta.gov.uk | |

## Purpose of Report

This report sets out a high level overview of activity from quarter four 2019/20.  The report is supplemented by a second annex (part 2) which details COVID-19 related activity from 16 March to 26 April 2020.

## Site visits and Inspection Outcomes

Table 1 shows the number of site visits, including licence application assessment visits that took place in quarter four compared to preceding quarters.

**Table 1: Site visits (including licence application assessment visits (LAAVs))**

| Type of site visit | Q4 2019/20 | Q3 2019/20 | Q2 2019/20 | Q1 2019/20 | 2018/19 Total Year | 2017/18 Total Year | 2016/17 Total Year |
|---|---|---|---|---|---|---|---|
| Routine inspection | 21 | 22 | 22 | 40 | 157 | 150 | 136 |
| LAAV – new application | 7 | 2 | 6 | 4 | 9 | 11 | 18 |
| LAAV – variation | 1 | 0 | 0 | 0 | 2 | 0 | 1 |
| Satellite site inspection | 8 | 9 | 9 | 20 | 49 | 66 | 46 |
| CAPA follow up | 0 | 0 | 0 | 4 | 6 | 5 | 1 |
| Non-routine inspection | 1 | 0 | 0 | 0 | 0 | 4 | 1 |
| **Total sites visited** | **38** | **33** | **37** | **68** | **223** | **236** | **203** |

To note all site visits (all types) have been suspended since 16 March 2020.

Due to the time taken to finalise inspection reports, inspection findings are reported in quarterly arrears and cumulatively as year to date*. Tables 2a) below shows the numbers of shortfalls identified during routine inspections carried out during quarter three (previous quarter). Table 2b) shows the total number of shortfalls identified from all routine inspections carried out during quarter one, two and three and partial figures for quarter four (current quarter).

**Table 2a): Quarter 3: October – December 2019**

| Sector | Inspections | Minor | Major | Major cumulative | Critical | Critical cumulative |
|---|---|---|---|---|---|---|
| **Anatomy** | 0 | 0 | 0 | 0 | 0 | 0 |
| **Post Mortem** | 6 | 35 | 25 | 2 | 0 | 0 |
| **Public Display** | 1 | 4 | 0 | 0 | 0 | 0 |
| **Research** | 3 | 3 | 0 | 0 | 0 | 0 |
| **Human Application** | 12 | 80 | 5 | 4 | 0 | 0 |
| **Organ Donation and Transplantation** | 0 | 0 | 0 | 0 | 0 | 0 |

**Table 2b): *Year to Date: 2019/20**

| Sector | Inspections | Minor | Major | Major cumulative | Critical | Critical cumulative |
|---|---|---|---|---|---|---|
| **Anatomy** | 2 | 3 | 0 | 0 | 0 | 0 |
| **Post Mortem** | 28 | 192 | 123 | 8 | 0 | 0 |
| **Public Display** | 5 | 10 | 0 | 0 | 0 | 0 |
| **Research** | 12 | 68 | 18 | 0 | 0 | 0 |
| **Human Application** | 56 | 235 | 11 | 6 | 0 | 0 |
| **Organ Donation and Transplantation** | 2 | 0 | 0 | 0 | 0 | 0 |

*Year to date includes total figures from previous quarters and shortfalls identified for inspections in quarter four where the final report was issued before 30 April 2020.

## Regulatory Activity

Table 3 below shows the regulatory activity that took place during quarter four.

**Table 3: Regulatory activity**

| Sector | Investigations | Police Referrals considered by SMT | Legal notices | RDMs | Revocations | Other* |
|---|---|---|---|---|---|---|
| **Anatomy** | - | - | - | - | - | - |
| **Post Mortem** | 2 | - | - | 2 | - | - |
| **Public Display** | - | - | - | - | - | - |
| **Research** | 1 | - | - | - | 3 (1 main, 2 satellite) | - |
| **Human Application** | 1 | - | - | 4 | 1 (main) | - |
| **Organ Donation and Transplantation** | - | - | - | - | - | - |

## Living Donation

Table 4 below shows the total number of kidney, liver and small bowel cases approved by the LDAT and panel during quarter four. The total from preceding quarters is also shown below. The total number of cases approved includes those considered using the emergency out of hour's process.

**Table 4: Total number of living donation cases approved**

| Quarter | TOTALS | | |
|---|---|---|---|
| | Number of cases considered | Approvals by the Living Donation Assessment Team | Approvals by Authority panels |
| **Q4 19/20** | 337 | 246 | 91 |
| **Q3 19/20** | 363* | 240 | 123 |
| **Q2 19/20** | 300 | 214 | 86 |
| **Q1 19/20** | 289* | 208 | 81 |
| **19/20 Total Year To Date** | **1289** | **908** | **381** |
| **18/19 Total Year** | **1228**** | **906**** | **322** |

* includes one case considered using the emergency out-of-hours process.
**includes one small bowel case.

Table 5a) below shows the number of kidney cases approved by LDAT and panel and Table 5b) below shows the number of liver cases approved by LDAT and panel.

**5a): Kidney**

| Q4 | LDAT | Panel |
|---|---|---|
| Directed | 235 | 0 |
| Directed Altruistic | 4 | 0 |
| Non Directed Altruistic | 0 | 23 |
| Paired/Pooled | 0 | 68 |

**5b): Liver**

| Q4 | LDAT | Panel |
|---|---|---|
| Directed | 7 | 0 |
| Directed Altruistic | 0 | 0 |
| Non Directed Altruistic | 0 | 0 |

Table 6 below shows the total number of bone marrow and PBSC cases approved (donors are children lacking competence to consent) in quarter four compared to preceding quarters.

**Table 6: Total number of bone marrow and PBSC cases approved**

| | Q4 2019/20 | Q3 2019/20 | Q2 2019/20 | Q1 2019/20 | 2019/20 Total Year To Date | 2018/19 Total Year |
|---|---|---|---|---|---|---|
| Approvals | 17 | 15 | 19 | 15 | 66 | 71 |

## Incidents

A further analysis of incident data will be carried out in quarter one to understand the impact that the coronavirus emergency and the HTA's response has had on reporting patterns and the quarter four figures.

## HTA Reportable Incidents (HTARIs)

In 2018/19, mortuaries licensed by the HTA admitted around 317,500 bodies, and performed over 90,000 post-mortem examinations. In this context, the number of reported HTARIs is very low.

The table below describes the number of HTARIs that were reported in each period. This also includes any near misses and incidents that may, on investigation, be found not to be reportable incidents.

Table 7 below shows the number of reported HTARIs in quarter four compared to preceding quarters.

**Table 7: HTARIs Reported during quarter in the Post Mortem sector**

|  | Q4 2019/20 | Q3 2019/20 | Q2 2019/20 | Q1 2019/20 | 2018/19 Total Year | 2017/18 Total Year | 2016/17 Total Year |
|---|---|---|---|---|---|---|---|
| **Number of reported HTARIs** | 54 | 60 | 59 | 44 | 205 | 230 | 160 |

## Human Application SAEARs

Given the nature of regulated activities carried out in the human application sector, it is difficult to calculate a total number of activities to establish a denominator to compare with numbers of events and reactions.

The table below describes the number of SAEARs that were reported in each period. This also includes any near misses and incidents that may, on investigation, be found not to fit the criteria of a SAEAR.

Table 8 below shows the number of reported SAEARs in quarter four compared to preceding quarters.

**Table 8: Reported SAEARs in the human application sector**

|  | Q4 2019/20 | Q3 2019/20 | Q2 2019/20 | Q1 2019/20 | 2018/19 Total Year | 2017/18 Total Year | 2016/17 Total Year |
|---|---|---|---|---|---|---|---|
| **Number of reported SAEs** | 86 | 61 | 74 | 73 | 279 | 157 | 83 |
| **Number of reported SARs** | 6 | 4 | 9 | 7 | 44 | 27 | 24 |
| **Total** | **92** | **65** | **83** | **80** | **323** | **184** | **107** |

## Organ Donation and Transplantation SAEARs

During 2018/19, a total of 5090 organ transplants, from 1574 deceased and 1051 living donors, were carried out in the UK.

The table below describes the number of ODT SAEARs that were reported in each period. This also includes any incidents that were, on investigation, found not to fit the criteria of an ODT SAEAR.

Table 9 below shows the number of reported SAEARs in quarter four compared to preceding quarters.

**Table 9: Reported SAEARs in the Organ Donation and Transplantation sector**

| | Q4 2019/20 | Q3 2019/20 | Q2 2019/20 | Q1 2019/20 | 2018/19 Total Year | 2017/18 Total Year | 2016/17 Total Year |
|---|---|---|---|---|---|---|---|
| **Number of reported ODT SAEs** | 17 | 24 | 12 | 19 | 33 | 22 | 38 |
| **Number of reported ODT SARs** | 6 | 8 | 7 | 12 | 29 | 15 | 26 |
| **Total** | **23** | **32** | **19** | **31** | **62** | **37** | **64** |

![HTA logo - Human Tissue Authority]

# Board Supplementary Data Annex document
# PART 2
## COVID-19 Period (16 March 2020 – 26 April 2020)

## Purpose of Report

1. This report sets out the data collated during the COVID-19 pandemic, specifically from the 16 March 2020 to 26 April 2020.

## Enquiries

2. Figure 1 displays the number of COVID-19, Non COVID-19 and Body donation enquiries received.

**Figure 1: Total Enquiries Received**
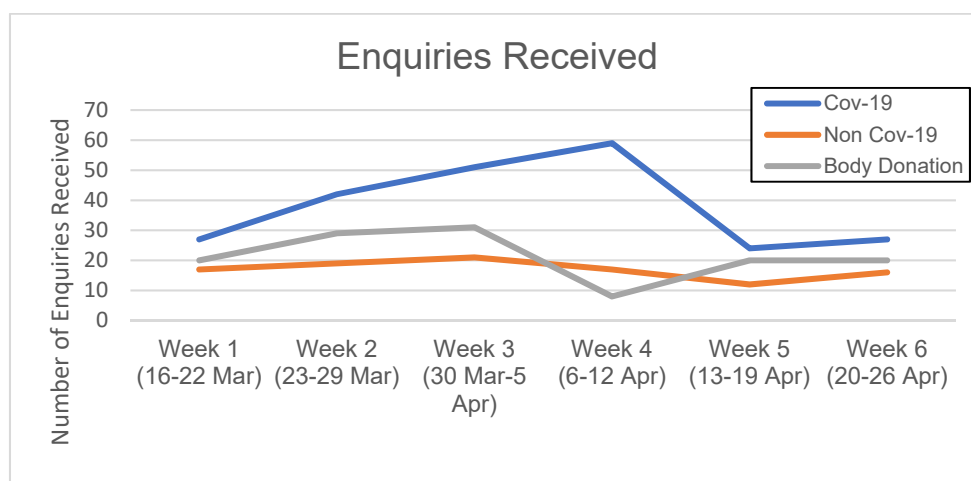
3.  Table 1 displays the number of COVID-19 and Non COVID-19 enquiries received for each sector.  Table 2 displays the number of body donation enquires received each week.

**Table 1: General Enquires Received (C19 = COVID-19, NC19 = Non COVID-19)**

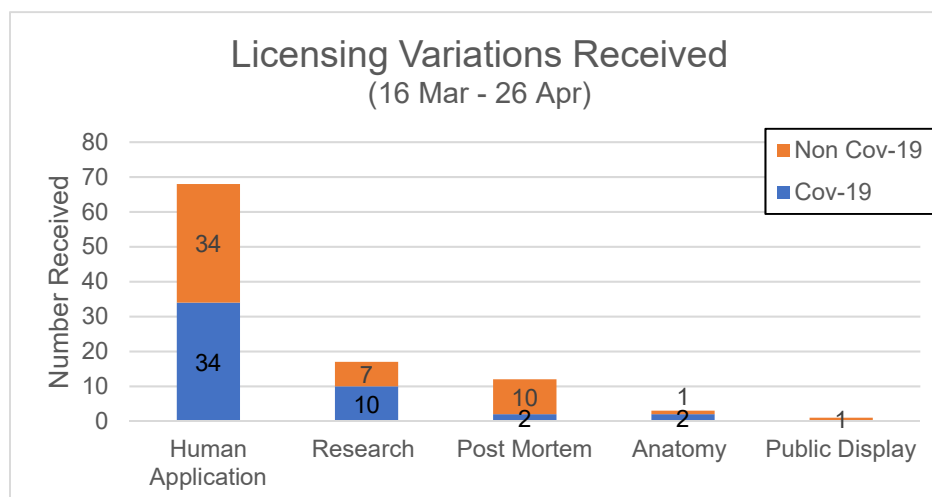| Sector | Week 1 (16-22 Mar) | | Week 2 (23-29 Mar) | | Week 3 (30-5 Apr) | | Week 4 (6-12 Apr) | | Week 5 (13-19 Apr) | | Week 6 (20-26 Apr) | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | C19 | NC19 | C19 | NC19 | C19 | NC19 | C19 | NC19 | C19 | NC19 | C19 | NC19 |
| Post Mortem | 21 | 6 | 20 | 3 | 35 | 1 | 29 | 2 | 14 | 1 | 13 | 3 |
| Human Application | 3 | 5 | 5 | 5 | 4 | 3 | 11 | 5 | 2 | 3 | 0 | 3 |
| Research | 0 | 1 | 4 | 2 | 4 | 3 | 2 | 2 | 2 | 2 | 3 | 0 |
| Anatomy | 0 | 0 | 1 | 1 | 0 | 1 | 1 | 1 | 0 | 0 | 0 | 1 |
| ODT | 0 | 0 | 0 | 0 | 1 | 2 | 0 | 0 | 0 | 0 | 0 | 0 |
| Public Display | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Removal | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 0 | 0 |
| No Sector Field | 3 | 5 | 12 | 6 | 7 | 11 | 15 | 7 | 6 | 5 | 11 | 9 |
| Total | 44 | | 61 | | 72 | | 76 | | 36 | | 43 | |

**Table 2: Body Donation Enquiries**

| | Week 1 (16-22 Mar) | Week 2 (23-29 Mar) | Week 3 (Mar-5 Apr) | Week 4 (6-12 Apr) | Week 5 (13-19 Apr) | Week 6 (20-26 Apr) |
|---|---|---|---|---|---|---|
| Body Donation Enquiries | 20 | 29 | 31 | 8 | 20 | 20 |

## Licensing Variations

4.  Figure 2 displays the number of licensing variations received for each sector and whether the variation was a result of the COVID-19 pandemic or whether it was unrelated.

**Figure 2: Licensing variations received by sector**

5. The number of licensing variations received for each sector is displayed in Table 3.

**Table 3: Variations by sector (C19 = COVID-19, NC19 = Non COVID-19)**

| Sector | Week 1 (16-22 Mar) | | Week 2 (23-29 Mar) | | Week 3 (30-5 Apr) | | Week 4 (6-12 Apr) | | Week 5 (13-19 Apr) | | Week 6 (20-26 Apr) | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | C19 | NC19 | C19 | NC19 | C19 | NC19 | C19 | NC19 | C19 | NC19 | C19 | NC19 |
| Post Mortem | 0 | 2 | 1 | 0 | 2 | 0 | 1 | 2 | 1 | 1 | 0 | 2 |
| Human Application | 0 | 3 | 0 | 3 | 2 | 6 | 6 | 5 | 17 | 8 | 9 | 9 |
| Research | 0 | 2 | 0 | 1 | 0 | 2 | 5 | 0 | 4 | 0 | 1 | 2 |
| Anatomy | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 1 | 0 | 0 | 0 |
| ODT | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Public Display | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 |
| Total | 7 | | 5 | | 13 | | 21 | | 32 | | 23 | |

6. A total of 101 licensing variations have been received since 16 March 2020. 51 variations were COVID-19 related and 50 were unrelated.

7. The large number of COVID-19 variations in the Human Application sector and Research sector are mainly Minor Change variations. The Minor Change variation is a newly added category used to collect information that organisations have been asked to send us regarding their current activities. The majority of these Minor Change variations involve suspension of activities due to COVID-19.

8. In the Post Mortem sector, variations were focused on:
   - Change of Persons Designate (PDs)
   - Change of Corporate Licence Holder contact (CLHc)

9. In the Human Application sector, variations were focused on:
   - Minor Changes (majority were suspension of activities at establishments, changes to consent processes for stem cell patients/donors at NHSBT and changes to JPAC donor selection guidelines).
   - Change of PDs
   - Change of Tissue/Organ types

10. In the Research sector, variations were focused on:
   - Minor Changes (majority were suspension of activities at establishments)
   - Change of Designated Individuals (DIs)

11. The number of variations in the Anatomy and Public Display sector are low. The variations in these sectors involved:
   - Minor Changes (suspension of activities at establishments)
   - Change of PDs

**Licensing – New Applications and Licences Offered**

12. Eleven licence applications have been made since 16 March (nine emergency mortuary licenses in the PM sector and two research licence applications).

13. Four emergency mortuary licences have been offered in the PM sector to date

14. One HA and one Research licence were offered (these applications were made pre COVID-19)

**Table 4: Number of new applications received per week (C19 = COVID-19, NC19 = Non COVID-19)**

| Sector | Week 1 (16-22 Mar) | | Week 2 (23-29 Mar) | | Week 3 (30-5 Apr) | | Week 4 (6-12 Apr) | | Week 5 (13-19 Apr) | | Week 6 (20-26 Apr) | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | C19 | NC19 | C19 | NC19 | C19 | NC19 | C19 | NC19 | C19 | NC19 | C19 | NC19 |
| Post Mortem | 0 | 0 | 1 | 0 | 1 | 0 | 3 | 0 | 2 | 0 | 2 | 0 |
| Research | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Total | 0 | | 3 | | 1 | | 3 | | 2 | | 2 | |

**Table 5: Number of licences offered per week (C19 = COVID-19, NC19 = Non COVID-19)**

| Sector | Week 1 (16-22 Mar) | | Week 2 (23-29 Mar) | | Week 3 (30-5 Apr) | | Week 4 (6-12 Apr) | | Week 5 (13-19 Apr) | | Week 6 (20-26 Apr) | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | C19 | NC19 | C19 | NC19 | C19 | NC19 | C19 | NC19 | C19 | NC19 | C19 | NC19 |
| Post Mortem | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 2 | 0 |
| Human Application | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Research | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Total | 0 | | 2 | | 0 | | 0 | | 2 | | 2 | |

**Licensing – Revocations and Satellite Revocations**

15. Two revocations (HA and Research sector) and one satellite revocation (Research sector) have taken place since 16 March 2020. These were unrelated to COVID-19.

**IT Support**

16. Table 6 shows the number of IT tickets raised per week. Themes of tickets raised include migration to office 365, one drive follow ups and CRM and IMPACT support.

17. There have been no reported issues with the ongoing resilience of the IT system.
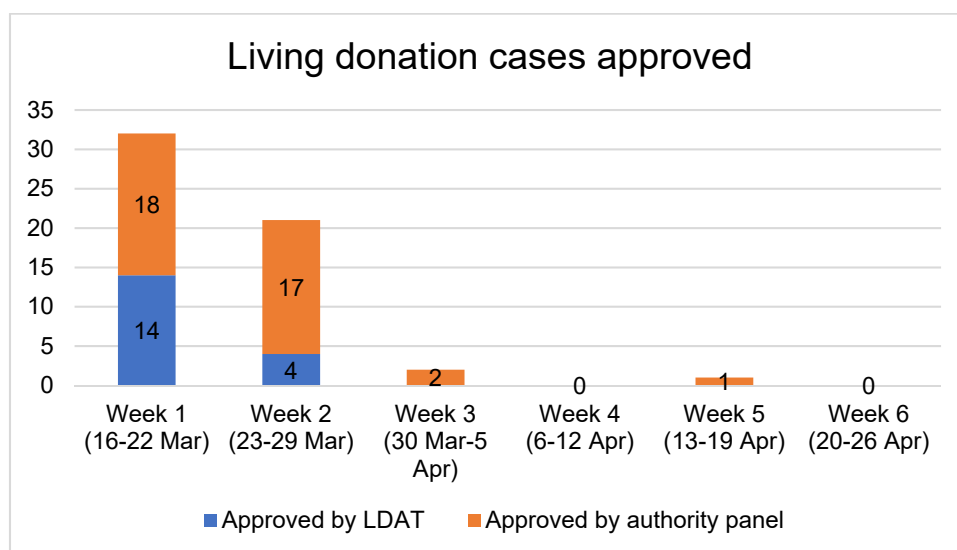
**Table 6: Number of IT tickets raised per week**

| | Week 3 (30 Mar-5 Apr) | Week 4 (6-12 Apr) | Week 5 (13-19 Apr) | Week 6 (20-26 Apr) |
|---|---|---|---|---|
| Number of tickets raised | 59 | 39 | 26 | 42 |
| Number closed | 48 | 28 | 22 | 32 |
| Number open | 11 | 11 | 4 | 10 |

## ODT Assessments

18. Activity for living donation cases has decreased in past weeks, as shown by Figure 3.

**Figure 3: Number of living donation cases approved per week**



**Incidents**

**HTA Reportable Incidents (HTARIs)**

19. The table below describes the number of HTARIs that were reported each week.

**Table 7: HTARIs reported in the Post Mortem sector**

| | Week 1 (16-22 Mar) | Week 2 (23-29 Mar) | Week 3 (30-5 Apr) | Week 4 (6-12 Apr) | Week 5 (13-19 Apr) | Week 6 (20-26 Apr) |
|---|---|---|---|---|---|---|
| Number of reported HTARIs | 2 | 2 | 2 | 3 | 2 | 3 |

**Human Application SAEARs**

20. The table below describes the number of SAEARs that were reported each week.

**Table 8: HA SAEARS**

| | Week 1 (16-22 Mar) | Week 2 (23-29 Mar) | Week 3 (30-5 Apr) | Week 4 (6-12 Apr) | Week 5 (13-19 Apr) | Week 6 (20-26 Apr) |
|---|---|---|---|---|---|---|
| Number of reported HA SAEARs | 7 | 9 | 6 | 4 | 4 | 5 |

## Organ Donation and Transplantation SAEARs

21. The table below describes the number of SAEARs that were reported each week.

**Table 9: ODT SAEARS**

|  | Week 1 (16-22 Mar) | Week 2 (23-29 Mar) | Week 3 (30-5 Apr) | Week 4 (6-12 Apr) | Week 5 (13-19 Apr) | Week 6 (20-26 Apr) |
|---|---|---|---|---|---|---|
| Number of reported ODT SAEARs | 1 | 2 | 1 | 0 | 0 | 1 |

# HTA Board paper

| **Date** | 7 May 2020 | **Paper reference** | HTA (10/20) |
|---|---|---|---|
| **Agenda item** | 7 | **Author** | Allan Marriott-Smith |
| | | | Chief Executive |

| **Protective Marking** | OFFICIAL |
|---|---|

## Business Continuity – Risks and Issues

### Background

1.  This agenda item provides an assessment of the strategic risks facing the HTA as of April 2020, and an assessment of the specific risks posed, and issues being managed, as a result of the pandemic. The paper consists of:

    *   Annex A – the HTA Strategic Risk Register

2.  An oral update will be provided at the meeting on the risks and issues being managed as a result of the pandemic.

### Decision-making to date

3.  This report was approved by SMT on 30 April 2020.

### Action required

4.  The Board is asked to note the content of this report.

# HTA Strategic Risk Register
# April 2020

The escalating impact of the coronavirus pandemic has enforced changes in ways of working and our ability to oversee the sectors we regulate using existing processes and practices. Authority Members have been updated on issues as they emerge - the SRR currently presents the assessment of the remaining areas of strategic risk.

**Overview:** Risks reflect the strategy for 2019 - 2022. Our highest scored risks are: ***failure to regulate appropriately*** - the score for which has increased as a result of the removal of routine site visit inspection as a regulatory tool and the current position on introducing an alternative; ***failure to manage expectations of regulation***, which reflects the fast-pace of change within the sectors we regulate, the low likelihood of legislative change in the foreseeable future and the removal of routine site visit inspection as a regulatory tool; ***failure to utilise our capabilities effectively***, which reflects the fact that business plans are being redeveloped at pace to adjust to the current limitations on activities as a result of government restrictions.

**Other notable risks:** Post EU departure, understanding the impact and resource required to deal with the impact of the departure is proving challenging. Horizon scanning for emerging issues and liaison with DHSC remain a key focus.
Progress on other development activity regathered pace during January and February with additional funds available to year end being invested for optimum benefit in the next business year. In particular, work to support our office move, or which builds a foundation for future development. Work is commencing to scope the development priorities for the coming twelve months.

DHSC spending controls will place continuing pressures on ALBs to make savings. We have received confirmation of GIA funding for the 2020/21 financial year, but anticipate that we will continue to be unable to access reserves to fund our wider development project ambitions - we will need to consider the options to provide some contingency funding next financial year to enable the completion of the development work we undertake from now until March 2020.

| Risk | Jan 2020 | Feb 2020 | Mar 2020 | Apr 2020 | Comments |
|---|---|---|---|---|---|
| **1 - Failure to regulate appropriately** (Risk to Delivery a-d & f and Development a-d) | → | → | ↑ | ↑ | A good regulatory framework and processes are in place, with a strong assured position on our key regulatory processes confirmed in the recent internal audit of these processes. Further continuous improvement is planned through mechanisms such as the recently introduced quality forum and the investment in the new one-year role of Regulation Manager - Training. Regular training sessions coupled with work to improve and standardise reporting processes along with an increasing focus on using data and data quality is also improving this area. The introduction of the new Inspection Report templates reduces the risk of inconsistencies in reporting which we feel has a positive impact on this risk.<br><br>The restrictions imposed by government to manage the pandemic mean that the statutory obligation to inspect in the HA sector cannot be met; this being managed as an issue (and the Board and DHSC sponsors are aware of this). The removal of routine site visit inspection as a regulatory tool (in the absence of an alternative) results in increased risks in some sectors, but is moderate to low in others. Action to assess the viability of desk-based model is underway and may provide greater assurance while site visit inspections remain suspended. On balance the risk is trending upward. |
| **2 - Failure to manage an incident** (Delivery, Development and Deployment) | → | → | ↑ | → | Plans are in place to manage an incident. We have received the final reports from the internal audit review of our Business Continuity and Critical Incident Management arrangements providing moderate levels of assurance in both areas. Actions will be discussed with ARAC in due course.<br><br>The reponse to managing the impact of the pandemic using the existing plans has been a significant stress test of their adequacy. They have not at this point proved wanting. At present the greatest concern is the emergence of another significant incident in parallel that results in compound management stretch. |
| **3 - Failure to manage expectations of regulation** (Risk to Delivery e and Development c) | → | → | → | ↑ | 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. The number of perimeter issue shows no sign of decreasing. These issues and the planning for EU exit continue to occupy regulatory resource. We are conscious that we have staff operating in the front-line roles who may be challenged about our response to issues outside our remit.<br><br>The upward pressure in this area, is a result of the increased risk of failing to meet public/stakeholders' expectations as a result of the loss of routine site visits as a regulatory tool and any public expectations surrounding the introduction of deemed consent for organ and tissue donation in England. |
| **4 - Failure to utilise our capabilities effectively** (Delivery a-e) (Development a-d) (Deployment a, c and d) | ↑ | → | ↑ | ↑ | We are now using the skills of our more recent recruits more fully. Some specialist posts have been harder to fill successfully. Limited success in recruiting into key roles in combination with new vacancies has increased the pressures on our resources, as a result we identified upward pressure on this risk in January, but which we believe stabilised in February. Workload and pressure continue to be monitored closely by the management team and an action plan is in place to deal with the recommendations of the stress survey and audit.<br><br>ARAC has supported the temporary deprioritisation of the response to the records management internal audit. As a result, the HTA will be tolerating a degree of risk in the medium term. Additional funding released as a result of the resolution of the rent dispute means that some funding can be used during this financial year which allowed us to buy in specialist resource to mitigate this risk.<br><br>The current upward pressure is a result of the current status of our response to the pandemic. There may be reduced staff capacity and also reduced utilisation as some BAU activity cannot be undertaken and there will be a lag until decisions are take how best to utilise excess capacity. We have increased the residual risk scoring to 4/4 to recognise this and would expect to review this as our replacement business plans emerge and when we enter business continuity phase 5. |
| **5 - Insufficient, or ineffective management of, financial resources** (Deployment b) | → | → | ↑ | ↑ | We await final confirmation of the GIA settlement for the 2020/21 financial year from DHSC finance colleagues, we hope this will be received in time to inform budget and fees setting for the next financial year, in particular the ongoing funding of the NHS Pension contributions increase is a key concern.<br><br>The ability to maintain the organisation and ensure continuity of payments and salaries processing could be impacted by the pandemic. Although the decision to defer invoicing for the HA sector until September does not represent an explicit risk, the wider implications for organisations in all sectors unable to undertake activity could reduce income for 2020/21. At present we believe this to be a increased likelihood which has increased the pressure on risk 4. |
| **6 - Failure to achieve the benefits of the HTA Development Programme** (Development objectives a-d) | → | → | → | ↓ | DHSC did not agreed funding for this Programme in the last business year which delayed planning and project initiation. Some funding became availbe in quarter four which allowed significant progress to be made, and the foundations laid for future development.<br><br>The office move project is underway and we have recruited a PM to support detailed planning. The impact of the move on other activities in the next business year are being accounted for and this remains one of our priority activities for the next year.<br>Although there has been more uncertainty about the timing of the office move the successful delivery of a number of projects to the end of the 2019/20 business year (HTA Intranet, Office 365 upgrade, adoption of remote working, future EDRMS requirements and data and intelligence review) has lead 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. |

**Risks are assessed by using the grid below**

| Impact | | 1. Rare (≤10%) | 2. Unlikely (11%-33%) | 3. Possible (34%-67%) | 4. Likely (68%-89%) | 5. Almost Certain (≥90%) |
|---|---|---|---|---|---|---|
| | **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 |
| **Risk Score = Impact x Likelihood** | | 1. Rare (≤10%) | 2. Unlikely (11%-33%) | 3. Possible (34%-67%) | 4. Likely (68%-89%) | 5. Almost Certain (≥90%) |
| | | | | Likelihood | | |

**Strategic Objectives**

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

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

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

| Lines of defence are: |
|---|
| 1 - Embedded in the business operation |
| 2 - Corporate oversight functions |
| 3 - Independent of the HTA |

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

# HTA Board paper

| | | | |
|---|---|---|---|
| **Date** | 7 May 2020 | **Paper reference** | HTA (11/20) |
| **Agenda item** | 8 | **Author** | Allan Marriott-Smith |
| | | | HTA Management Group |

| | |
|---|---|
| **Protective Marking** | OFFICIAL |

## Business Continuity – Regulatory Response

### Background

1.  This agenda item provides an overview of the issues facing each of the HTA's regulated sectors and the proposed plans for regulating each sector in the face of the likely continued social distancing and travel restrictions for the foreseeable future.

### Decision-making to date

2.  This content for this agenda item was approved by SMT on 30 April 2020.

### Action required

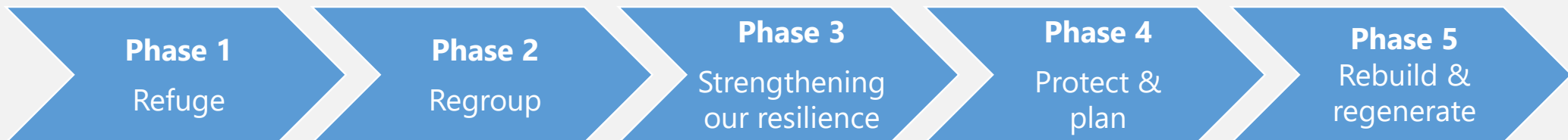3.  The Board is asked to note the content of this report.

# HTA Board paper

| | | | |
|---|---|---|---|
| **Date** | 7 May 2020 | **Paper reference** | HTA (12/20) |
| **Agenda item** | 9 | **Author** | Allan Marriott-Smith |
| | | | HTA Management Group |
| **Protective Marking** | OFFICIAL | | |

## Business Continuity – Phase 5 Planning

### Background

1. This agenda item provides an overview of the plans currently underway for phase 5 of the current business continuity planning relating to the return to full operations. This item is supported by an annex of Powerpoint slides which will provide the basis for the oral presentation which will be made at the Board meeting.

### Decision-making to date

2. This content for this agenda item was approved by SMT on 30 April 2020.

### Action required

3. The Board is asked to note the content of this report.

# Phase 5
# Rebuild & Regenerate

HTA Authority - 7 May 2020

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**Phase 1**
Refuge

**Phase 2**
Regroup

**Phase 3**
Strengthening our resilience

**Phase 4**
Protect & plan

**Phase 5**
Rebuild & regenerate

Progress through the stages informed by the national guidance in response to COVID-19

| | Phase 1 Refuge | Phase 2 Regroup | Phase 3 Strengthening our resilience | Phase 4 Protect & Plan | Phase 5 Rebuild & Regenerate |
|---|---|---|---|---|---|
| Vision / Purpose | Identification of BAU functions to be deferred as we seek safety for our staff and operations | Reassess priorities and regroup using technology and new ways of working | Focus of resource on priorities to help build foundations and prepare the HTA for next steps | Reframe core regulatory activity protecting key activities and providing oversight to key risks | Identifying opportunities to rebuild & regenerate the HTA's Operating Model and realise the strategic vision for 2021 |
| Risks & Issues | | • Understanding the impact of school closures and the need for flexible working<br>• Ongoing stakeholder engagement and engagement<br>• Emerging themes and needs from sectors eg HA | • Flexible working and resourcing of priority functions<br>• Clarity of policy positions to support response to Coronavirus<br>• Pace of delivery | • Protection of core activity and the resource required (nos & skills) over emergency period<br>• Support and protection to staff noting potential to redeploy skills internally<br>• Need to flex policy in response to greater need | Operating environment and regulatory approach. Organisational and cultural preparedness for changes to how we operate and ways of working Maintenance of key activities to support a rescoped Q1 BAU |
| Critical Success Factors / Triggers for change | | • Resourcing of priority functions<br>• Sustainable operating position | • Oversight of regulatory risk<br>- Identified risk in sectors<br>- Safe suspension of activities by LEs (permanently / temporarily) | • Robust contingency arrangements support the delivery of priority functions.<br>• Support provided to national response and pressures faced by stakeholder<br>• Resilience to move to "rebuild" phase | Responsive to the value offered by regulation and the needs of the sectors during the rebuild phase. Clear strategic direction with opportunities realised. |
| Priority Functions | • New applications and variations to licenses to support covid response<br>• Living organ donation assessments<br>• OOH living organ donation assessments<br>• Unscheduled inspections | • New applications and variations to licenses to support covid response<br>• Living organ donation assessments<br>• OOH living organ donation assessments | • New applications and variations to licenses to support covid response<br>• Living organ donation assessments<br>• OOH living organ donation assessments | • New applications and variations to licenses to support covid response<br>• Living organ donation assessments<br>• OOH living organ donation assessments<br>• Projects to support rebuild<br>• Regulatory risk oversight<br>• Locally led BAU | Scoping of workstreams and potential opportunities for redesign and in the return to a new business as usual. |
| Key messages / decisions | | | Regulatory risk oversight HTA policy positions – flexed or changed | Heads leading the maintenance of BAU with resources available. Priorities to be identified for Q1 | |
| RAG status | Completed | Completed | Completed | In progress | |

**HTA Contingency arrangements & Rebuild Strategy - summary**

# Looking ahead

As we enter phase 4 of our contingency planning we have embedded the arrangements to support and protect core activities, released and redeployed resources to other activities and identified BAU priorities for quarter 1.  We now have an opportunity to look at the future and develop our planning to support the HTA to "rebuild & regenerate".

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The spread of the COVID-19 and the emergency situation created in the response to coronavirus meant that adjustments to our ways of working needed to be made at pace in response to safeguard the safety and welfare of our staff and to maintain delivery of regulatory activity.  Our experience over the last 6 weeks has identified that in addition to our internal changes, the sectors and activities that we regulate are also having to adjust.  As a result we anticipate that when restrictions allow for a return to normal working, there will be a "new" normal both for ourselves and the sectors that we regulate and that  business as usual will be different to how we worked in March 2020.

A "new normal" will inevitably emerge, for the sectors and the activities we regulate based on inevitable changes to the operating landscape.   Changes we need to be prepared for include: the loss of licensed establishments from the market; variations in the pace of recovery across sectors and activities; reset priorities (centrally or internally as part of statutory obligations).

The current situation also provides the opportunity to pursue strategic developments that may have been paused or limited due to resource availability.

The following set of slides sets out a high level proposal including a broad scope of work, high level timeline and suggested priority areas for how the HTA might return and the opportunities that may exist to rebuild and regenerate during this period.

The timeline for this change is detailed in a later slide and proposes:

Q1 – planning

Q2 & 3 – developments and early delivery

Q4 – delivery & embedding

2021/22 – adoption in full of HTA v 2.0.

Throughout this period there will be a number of constants to maintain:

- BAU and priorities for Q1 and 20/21

- Stakeholder engagement (eg DHSC, Licensed establishments)

- Internal communications

- Ongoing organisational and cultural development

## Strategic Direction & Opportunities

The current period provides an opportunity to consider the strategic direction of the HTA and the realisation of development plans previously constrained by resources (financial, people & time). The initial scoping and planning for the rebuild is based on the following principles.

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- HTA Strategy refresh (February 2020) and the direction of travel for 2021 and beyond remain valid

- Regulatory model is unchanged and will continue to be grounded in the principles of better regulation

- Strengthened partnership working and opportunities to collaborate across ALBs and Life Sciences as a whole

- Use the insight from previous strategic development commissions to inform and drive improvements
    - Taking opportunities to improve the efficiency, effectiveness and economics of what we do and how we do it
    - Strengthening the use of data and actionable insight

- Adopt learning gained over the last 4-6 weeks

**High Level Strategic & Operational Plan 2020/21**
Delivery of phase 5 will be against a backdrop the HTA maintaining its response to the COVID-19 emergency, statutory obligations and the delivery of a revised plan of regulatory activity. Although each programme will have a set of specific objectives and deliverables, the phase 5 programme will aim to identify opportunities and interdependencies across the workstreams as part of future improvements initiatives.

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| | Q1 20/21 | Q2 20/21 | Q3 20/21 | Q4 20/21 |
|---|---|---|---|---|
| **Phase 5** | Scope & high level planning on opportunities for development | Detailed planning on key workstreams | Delivery | Delivery & preparation for 21/22 strategic and operational delivery |
| **COVID-19 Contingencies** | Focus on priority activities in response to COVID-19 | Contingency arrangements maintained in response to ongoing COVID-19 needs. | Contingency arrangements subject to review | Contingency arrangements subject to review |
| **HTA Business Plan 2020/21 (Business as usual)** | Q1 priorities identified. Planned inspections suspended. Oversight of risk maintained. | Q2 priorities to be confirmed. Planned inspections subject to review. Oversight of risk maintained. | Q3 priorities to be confirmed. Planned inspections subject to review. Oversight of risk maintained. | Q4 priorities to be confirmed. Planned inspections subject to review. Oversight of risk maintained. |

**Phase 5 – Rebuild & Regenerate**
It is important that the scope of phase 5 and the organisational redesign achieves a balance between maintaining what works well as part of current practice and the opportunities for development and transformation. There are three key areas, each with opportunities to explore, that we will be structuring the design phase around.

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**People**
Opportunities to explore:
- Future needs of our workforce model
- Learning & development
- Improving expertise to support delivery
- Working environment & culture

**Technology**
Opportunities to explore:
- Strengthened remote working by design
- Better use of information
- Improved digital interface and content for stakeholders
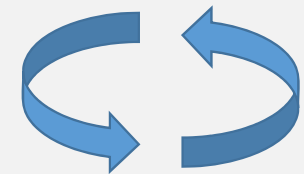- HTA IT capability

**Process**
Opportunities to explore:
- Use of data and intelligence
- Regulatory risk & oversight
- Process flow (streamline & standardise) between core functions
- Focus on individual systems eg Records management , Governance.

People

Technology

Process

Commitment to continual improvement

**Next steps**
The scale of the change ahead requires detailed planning from the initial proof of concept of high level proposals, organisational preparedness and delivery plans.  Quarter 1 will be focused on preparing the organisation and planning .  This work in the immediate term will be planned through the Senior Management Team.

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Key actions to be delivered by the end of Quarter 1:

- Collate business requirements as key driver for change and developments

- Identify and understand business requirements to inform design phase including options

- Develop detail to support high level proposals and delivery plan

- Proposals to be costed for an initial test of (1) affordability (2) feasibility (3) delivery

- Draft resource model for development & delivery with consideration to internal and external options

- Scope impact of different phases and engagement requirements

- Identify potential risks and challenges and mitigation measures

- Identify interdependencies across programmes, deliverables in quarter and in 20/21

- Develop programme structure and governance arrangements for Q2 and beyond