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

Ninety-third Meeting of the Human Tissue Authority

Date 16 July 2020
Time 10.00 – 12.10
Venue Via Zoom

Agenda

1. Welcome and apologies
2. Declarations of interest Oral
3. Minutes of 7 May 2020 meeting HTA (13/20)
4. Matters arising from 7 May 2020 meeting HTA (14/20)

Regular Reporting
5. Chair’s Report Oral
6. Chief Executive’s Report HTA (15/20)
   Strategic Risk Register HTA (15a/20)

Business Continuity
7. Business Continuity- Regulatory Update HTA (16/20)
   Supplementary Data Annex HTA (16a/20)
8. Business Continuity- Development Programme HTA (17/20)

Committees/Working Groups
9. Audit and Risk Assurance Committee Update HTA (18/20)

Policy Updates
10. Professional Stakeholder Evaluation HTA (19/20)
11. Living Donation Policy Issues HTA (20/20)

Any Other Business
12. Any Other Business Oral

Close
Minutes of the ninety-second meeting of the Human Tissue Authority

Date: 7 May 2020
Venue: Zoom meeting

Present

Members
- Lynne Berry (HTA Chair)
- Dr. Stuart Dollow
- Amanda Gibbon
- Prof. Andrew (Andy) Hall
- William (Bill) Horne
- Glenn Houston
- Prof. Penney Lewis
- Bishop Graham Usher
- Dr. Lorna Williamson, OBE
- Prof. Anthony Warrens
- Prof. Gary Crowe
- Dr. Hossam Abdalla
- Dr. Charmaine Griffiths

Apologies
- Nicolette (Nicky) Harrison, Director of Regulation

In attendance
- Allan Marriott-Smith (Chief Executive)
- Richard Sydee (Director of Resources)
- Louise Dineley, (Director of Data, Technology and Development)
- Amy Thomas (Head of Development)
- Nima Sharma (Board Secretary; minute taking)

Observers
- Jacky Cooper, Department of Health and Social Care (DHSC)

<table>
<thead>
<tr>
<th>Item</th>
<th>Title</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item 1</td>
<td>Welcome and apologies</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1.</td>
<td>The Chair welcomed Members, attendees and observers to the ninety-second meeting of the Board of the Human Tissue Authority (HTA).</td>
</tr>
<tr>
<td></td>
<td>2.</td>
<td>The Chair welcomed Jacky Cooper to the meeting and noted an apology from Nicky Harrison.</td>
</tr>
<tr>
<td>Item 2</td>
<td><strong>Declarations of Interest</strong></td>
<td></td>
</tr>
<tr>
<td>-------</td>
<td>----------------------------</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>The Chair asked Members to declare any personal or pecuniary interests that they may have in relation to this meeting’s agenda.</td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>There was one declaration of interest made by Dr Charmaine Griffiths in relation to the British Heart Foundation’s active support for deemed consent for organ donation. This was noted by the Board.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Item 3</th>
<th><strong>Minutes of 6 February 2020 meeting [HTA 07/20]</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>5.</td>
<td>The Chair requested Members’ comments on the minutes for factual accuracy. Dr Hossam Abdalla requested that the minutes from the previous meeting are amended to indicate that he was absent from the November meeting due to illness. There were no further comments made.</td>
</tr>
<tr>
<td>6.</td>
<td>The Board approved the minutes.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Item 4</th>
<th><strong>Matters Arising from 7 November and 18 July 2019 Meeting [08/20]</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>7.</td>
<td>The Chair noted that all actions from the last meeting on 6 February 2020 were complete.</td>
</tr>
<tr>
<td>8.</td>
<td>The Chair noted that actions from 18 July 2019 and 7 November 2019 were ongoing and referred Members to the matters arising log. The Board noted that some of these actions would be discussed at the July meeting.</td>
</tr>
<tr>
<td>9.</td>
<td>The Board asked for an update on recruitment to the Quality Governance Manager and Business Analyst roles. Allan Marriott-Smith informed the Board that the Executive had decided to delay the recruitment to these roles at present. The Board was informed that various functions of these roles were currently being undertaken by existing members of staff.</td>
</tr>
<tr>
<td>10.</td>
<td>The Board noted the content of this item.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Item 5</th>
<th><strong>Chair’s Report [Oral]</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>11.</td>
<td>The Chair provided an update on two key areas; Stakeholder meetings and Board appointments.</td>
</tr>
</tbody>
</table>
12. The Chair informed the Board that Ministers had decided not to extend the terms of those Members whose terms of appointment end in the autumn for a further year. The process for recruiting new Members would commence shortly, and brief extensions may be possible if appointments are not made by the time current Members’ terms end.

13. The Chair highlighted that the Board would be informed more fully about HTA committee membership in due course but in the mean time reiterated that Professor Gary Crowe would take on the role as Chair of Audit and Risk Assurance Committee (ARAC) from October 2020.

14. The Board discussed the importance of having sufficient Board Members in place to facilitate the assessment of living donation cases, which are expected to increase over time once the pandemic eases. The Board agreed that it is important to consider the risks to the approvals system if there are fewer Board Members available to consider cases.

15. The Board noted the content of this update.

**Item 6 Chief Executive’s Report [HTA 09/20]**

16. Allan Marriott-Smith presented this item and introduced the report.

17. Allan provided the Board with an overview of the report which includes details on the successful progress of development projects in the last quarter of the year, including the introduction of the HTA intranet which has been a great step forward for internal communications.

18. Richard Sydee provided a summary of the financial outturn position at year end and highlighted an anticipated underspend of £19,000 (subject to audit). The Board was informed that the auditors were in the process of completing their work and that there were no concerns highlighted over the HTA’s accounts for the financial year 2019/20.

19. The Board had a number of questions surrounding the report which were answered during the meeting.
- Queries were raised about whether licensed establishments are requesting deferral of licence fee payments as a result of COVID-19. The Board was informed that the HTA had not received any formal requests to revoke licences and all billing would be delayed until September 2020.

- Members commented that Board costs appear to be quite high relative to the overall cost. The Board was informed that these costs also include Member remuneration. Members requested that future reporting should include a separate breakdown of Board salary costs and travel and subsistence costs.

20. Allan highlighted the particular importance of staff well being in the current operating circumstances and noted the management focus on this. During the meeting Allan presented results from a short pulse survey. The results provided some evidence that staff are coping well and feel well informed about the forward plans. Amanda Gibbon commended the results and confirmed that this interpretation was corroborated by the Chair of the HTA Staff Forum.

21. Board Members were informed that a new move date for the planned move to Stratford would need to be confirmed by early 2021 and that the HTA would be able to occupy the current offices until March 2021.

22. Louise Dineley provided Members with a summary of the two data annexes included as part of the Chief Executive’s report. Members requested a more focussed analysis to be undertaken on HTA Reportable Incidents (HTARIs) and Serious Adverse Events and Reactions (SAEARs) to help the HTA to understand the potential indicators of risk and, in turn, maintain oversight of the relevant sectors.

23. The Board questioned whether there was any change in the nature of HTARIs, in particular, being reported to the HTA as a result of COVID-19 and the set up of emergency mortuaries. The Board was informed that there was no change in the nature of incidents reported to the HTA.

24. The Board highlighted their concerns about the increasing number of SAEARs identified over the last few years. Louise informed the Board that she would clarify these issues.
A fuller account would be provided to the July Board meeting.

25. The Board noted the content of this report.

**Action 1:** Nicky Harrison to provide a fuller account of trends in SAEARs at the July Board meeting and thereafter.

### Item 7 Business Continuity - Risks and Issues [HTA 10/20]

26. Allan Marriott-Smith presented this item to the Board.

27. Members were asked to note that only the first page of the strategic risk register was included. Allan highlighted that the pressure on risks, one, three and four were upward for quarter four.

28. The Board queried whether the Regulation Manager- Training role would continue. The Board was informed that it would not continue and should a need arise in the future the HTA would revisit the role.

29. The Board also questioned whether there had been a reduction in staff capacity due to the COVID-19 pandemic. Allan confirmed that there was currently no impact on staff directly, but, highlighted that there were a number of staff who had caring and childcare responsibilities and a number who had suffered bereavements.

30. The Board agreed that the eventual return to office working would need to be carefully considered by the Senior Management Team (SMT) taking into consideration preferences staff may have or other demands required of them, such as caring responsibilities. The Board also acknowledged that it would be critical to establish how social distancing could be maintained in the work environment.

31. The Board commended the SMT and HTA staff on their response to managing the COVID-19 crisis as well as all their efforts in ensuring a smooth transition to the current way of working.

32. The Board noted the content of this paper.
33. Allan Marriott-Smith presented this paper to the Board and Dr Robert Watson joined the meeting for this item to provide additional support in answering specific questions.

34. The Board was informed that the HTA had stood down inspections for quarters one and two across all sectors and that there remained a legal obligation to inspect every two years in the Human Application (HA) sector.

35. The HTA was currently reviewing the risk profile of each HA establishment. The HTA would need to consider other mechanisms with which to satisfy itself that standards continue to be met. At present the Executive is considering how desk based assessment could be developed to fulfil this role.

36. The Board asked whether any feedback from European colleagues on how they have dealt with this had been sought. The Board was informed that it is difficult to benchmark with equivalent organisations outside the UK but some regulatory bodies in both the UK and in Europe do not inspect as regularly as the HTA.

37. The Board noted that public confidence in mortuaries was a critical issue and that under the current circumstances the HTA would need to consider a full assessment of risks of non-compliance in this sector. The Executive informed the Board that all ideas were welcome on risk-based analysis and that the Board’s views would be sought to develop an approach to managing regulatory risk in the absence of inspection.

38. The Board emphasised the importance of the HTA considering the perceived risks and public expectation of any regulator during the pandemic and whether the HTA could coordinate its management of risk with similar regulators to understand their approach to this. Allan informed the Board that he was having regular meetings with the Human Fertilisation and Embryology Authority (HFEA) and Health Research Authority (HRA) to ensure that each regulator was taking a co-ordinated approach.

39. The Board noted the content of this paper.
<table>
<thead>
<tr>
<th>Item 9</th>
<th>Business Continuity Phase five planning [HTA 12/20]</th>
</tr>
</thead>
<tbody>
<tr>
<td>40.</td>
<td>Louise Dineley presented this paper to the Board.</td>
</tr>
<tr>
<td>41.</td>
<td>The Board was informed that the HTA was working in smarter ways in keeping with the changing landscape and that the emphasis was now on looking at the strategic and regulatory model and reviewing how this may look different once the HTA returns to a more normal way of working. The Board was also asked to note that the HTA would be strengthening partnerships with other regulators.</td>
</tr>
<tr>
<td>42.</td>
<td>The Board was referred to the associated power point presentation and it was emphasised that the HTA would be prioritising core functions as part of phase five planning.</td>
</tr>
<tr>
<td>43.</td>
<td>The Board noted the content of this paper.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Item 10</th>
<th>Deemed Consent Implementation [Oral]</th>
</tr>
</thead>
<tbody>
<tr>
<td>44.</td>
<td>Allan Marriott-Smith presented an oral update to the Board.</td>
</tr>
<tr>
<td>45.</td>
<td>The Board was informed that Codes A and F had been approved.</td>
</tr>
<tr>
<td>46.</td>
<td>The Board was asked to note that NHSBT had been unable to complete Specialist Nurses Organ Donation (SNOD) training on deemed consent due to staff redeployment. This would need to be completed before the new legal provisions will be used in practice. The Board was informed that the HTA would be communicating an identical position on the law change as NHSBT.</td>
</tr>
<tr>
<td>47.</td>
<td>The Board was updated on the work being carried out on the out of hours rota and that this would be presented at the next Board meeting.</td>
</tr>
<tr>
<td>48.</td>
<td>The Board noted this update.</td>
</tr>
</tbody>
</table>

**Action 2:** An update to be provided to the Board on the progress made with changes to the operation of the HTA’s out of hours rota
<table>
<thead>
<tr>
<th>Item 11</th>
<th>Any Other Business</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>49. Members noted that the next full Board meetings would take place using Zoom. An interim update will be organised to take place in June, also by Zoom.</td>
</tr>
<tr>
<td></td>
<td>50. There was no other business raised.</td>
</tr>
</tbody>
</table>

Date of next meeting- 16 July 2020
# HTA July Board Meeting - Matters Arising from previous meetings

<table>
<thead>
<tr>
<th>Meeting</th>
<th>Action</th>
<th>Update</th>
</tr>
</thead>
<tbody>
<tr>
<td>May 2020</td>
<td><strong>Action 1:</strong> Nicky Harrison to provide a fuller account of trends in SAEARs at the July Board meeting and thereafter (ANH)</td>
<td>To provide an update at the July meeting</td>
</tr>
<tr>
<td>Nov 2019</td>
<td><strong>Action 2:</strong> 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)</td>
<td>Agenda item 11 (July)</td>
</tr>
<tr>
<td>Nov 2019</td>
<td><strong>Action 3:</strong> Ongoing. The Executive to consider using statistical process control techniques in reviewing incident data, such as for HTARIs (ANH)</td>
<td>To provide an update at the July Board meeting.</td>
</tr>
<tr>
<td>Nov 2019</td>
<td><strong>Action 5:</strong> A proposal to be brought to a future Authority meeting on the possible remuneration for staff involved in the out of hours rota. (ANH)</td>
<td>Agenda item 11 (July)</td>
</tr>
<tr>
<td>July 2019</td>
<td><strong>Action 13:</strong> The Executive to carry out further scoping to support an electronic way of working. (NS)</td>
<td>Board to be updated as part of Board IT requirement project work</td>
</tr>
</tbody>
</table>
Chief Executive’s Report

Background

1. This paper provides an overview of performance at the end of quarter one.

2. It provides the Board with an overview of core regulatory business, the progress of development projects, a summary of the financial position at the end of the first quarter, and a summary of people, resource and other key operational issues arising since the Board last met in May.

3. Whilst pressures associated with the response to COVID-19 have slightly eased by the end of the quarter, work continues to ensure that we balance our regulatory responsibilities, our development goals and respond to a fast-changing environment in an agile way.

Decision-making to date

4. This report was approved by the CEO on 9 July 2020.

Action required

5. The Board is asked to note the content of this report.
General overview and strategic risks

6. Over the quarter, the HTA has made excellent progress in moving to remote working arrangements for all staff.

7. The HTA deployed its Critical Incident Response Plan in mid-March to manage its response to the COVID-19 pandemic. The Plan has proved effective in responding to the situation and business continuity has been maintained.

8. Site visit inspections were suspended for quarter one and quarter two. This has resulted in the failure to fulfil our statutory duty to inspect establishments in the Human Application sector every two years. The Board and Department of Health and Social Care (DHSC) sponsors are aware of this issue and the risks it poses. Work has commenced on developing alternative procedures to mitigate these risks.

9. As reported in HTA (16/20) we have, over the quarter, responded to stakeholder demand and actively managed Corrective and Preventative Action plans (CAPAs), SAEARs and HTARIs. The pandemic has affected our regulated sectors in different ways, and there has been pressure to manage the demands in the post-mortem sector associated with the licensing of emergency mortuaries.

10. In its assessment of risk in June, the senior management team concluded that all six risks remained stable since its assessment in May. Specifically, risk one (failure to regulate appropriately) has stabilised due to work underway to develop a desk-based assessment model. The strategic risk register for June is at Annex A.

Quarter Four Accountability

11. In view of the current circumstances, we are meeting our accountability requirements to the Department of Health and Social Care (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.

12. The HTA’s sponsor wrote to confirm there were no concerns with our performance in quarter four and praised the HTA staff for their response in these exceptional circumstances. We expect to follow a similar model until we return to more normal ways of working.
Quarter One development projects overview

13. Four key development projects have been prioritised in 2020/21.

Implementation of Deemed Consent

14. The Deemed Consent law change was implemented on 20 May 2020. There has been no increase to enquiries as a result of the law change at present and we have worked collaboratively with NHSBT to ensure our communication remains aligned.

HTA Website redevelopment project

15. The project, its deliverables and key milestones have been reviewed in quarter one to ensure we have a clear plan and set of deliverables that will support the development of the HTA website and ensure that we meet the required accessibility standards.

16. Oversight of the development process is provided by NHS X. Each stage of the process from discovery through the Alpha and Beta development stages is assessed by NHS X with approval given to move to the next stage.

17. The development of the website will be informed by a number of different sources. In quarter one we completed user testing sessions with members of the public. Further sessions with professional stakeholders are due to be completed by mid-July. This testing is critical in informing the development.

18. During the Alpha phase we will work with the developer to construct a prototype of the new site, based on intelligence coming from user research, our web analytics, and other internal data. Following further testing we will be seeking further assessment from NHS X (estimated early September) to move into the Beta phase.

19. The Beta phase will include further testing through the commission of an accessibility audit, to ensure the new site meets new accessibility requirements when launched.

20. A final assessment is required by NHS X to gain approval to move into a live site. This final stage is scheduled for November 2020.

EU Exit / Transition preparedness

21. The work we carried out in 2019/20 in preparation for the UK’s departure from the EU has set us in good stead for the transition period. As previously, we continue to plan to the legal default. We have used 2019 Annual Activity data collected from Human Application sector establishments to update our planning assumptions and carried out
focused work in quarter one to understand the impact of the Northern Ireland Protocol. We are in the process of revising our project plans to account for possible implications of COVID-19 on resourcing and interdependencies with other projects.

22. During quarter one there was an increase in enquiries from stakeholders relating to regulation of the Human Application sector following the UK’s departure from the EU. These were mainly from stakeholders seeking clarity on licensing changes following the end of the transition period.

Office Re-location

23. The HTA’s relocation plans remain on track. The construction work is continuing, and the Department expect to have the formal handover of the completed floor in early September 2020. This allows for furniture and IT equipment to be installed – with the provisional first date available for occupancy being 12 October 2020. Although some organisations are expected to begin relocation to 2 Redman Place at that time, the HTA plan is for our move to take place in January 2021.

24. Our internal project team is working through a number of logistical issues, with plans for packing and moving stored documents being created for different scenarios relating to building access at Buckingham Palace Road.

25. It is now clear that all five organisations relocating to 2 Redman Place will be looking to revisit their accommodation requirements in the near future. Given that these requirements will take some time to work through, all five organisations, have committed to honouring their initial space commitment through to March 2022, at which point we hope to collectively consider future needs and potentially renegotiate occupancy levels.

Horizon scanning

26. Through horizon scanning we continue to monitor trends and emerging areas of focus relating to our remit.

27. Two areas receiving increased attention in quarter one related to: consent provisions for imported material; and, licensing requirements for the removal of relevant material from the deceased.
Finance

Financial position for Q1 2020/21

Table one: Income summary

Human Tissue Authority
Income Summary
For the Three Months Ending 30 June 2020

<table>
<thead>
<tr>
<th>Year to Date</th>
<th>Actuals</th>
<th>Budget</th>
<th>Variance</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>£</td>
<td>£</td>
<td>£</td>
<td>%</td>
</tr>
<tr>
<td>Grant In Aid</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GIA</td>
<td>176,000</td>
<td>161,000</td>
<td>15,000</td>
<td>9.32%</td>
</tr>
<tr>
<td>Non Cash cover</td>
<td>51,405</td>
<td>51,405</td>
<td>0</td>
<td>0.00%</td>
</tr>
<tr>
<td>Sub-Total</td>
<td>227,405</td>
<td>212,405</td>
<td>15,000</td>
<td>7.06%</td>
</tr>
<tr>
<td>Licence Fees</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Application Fees</td>
<td>4,050</td>
<td>0</td>
<td>4,060</td>
<td>0.00%</td>
</tr>
<tr>
<td>Sub-Total</td>
<td>4,050</td>
<td>0</td>
<td>4,050</td>
<td>0.00%</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other income (Rent)</td>
<td>91,947</td>
<td>92,500</td>
<td>(553)</td>
<td>-0.60%</td>
</tr>
<tr>
<td>Other income (Secondees)</td>
<td>11,696</td>
<td>11,738</td>
<td>(41)</td>
<td>-0.35%</td>
</tr>
<tr>
<td>Devolved Assemblies</td>
<td>133,572</td>
<td>138,448</td>
<td>(4,876)</td>
<td>-3.52%</td>
</tr>
<tr>
<td>Sub-Total</td>
<td>237,215</td>
<td>242,685</td>
<td>(5,470)</td>
<td>-2.25%</td>
</tr>
<tr>
<td>Total Income</td>
<td>468,670</td>
<td>455,090</td>
<td>13,580</td>
<td>2.98%</td>
</tr>
</tbody>
</table>

28. Table one shows the breakdown of income to date. The variance to budget within our Grant in aid (£15K) is the result of drawing down a higher sum this quarter with the balance being spread over quarters two to four.

29. We are yet to receive official confirmation of our funding from the Department, but it has been assumed we will receive the same as last year which includes funding for paying the increased NHSPS employers’ pension contributions and cover for our depreciation and amortisation costs.
30. Licence fee income shows no activity as we have deferred billing of Human Application establishments until September.

31. Within other income there is a small variance of £5k against income from devolved governments. This is because the budget assumed a small increase which was subsequently not billed as part of our COVID-19 response.

32. Table two provides a summary position at the end of quarter one of the 2020/21 financial year, a year to date net surplus against budget of £19k. A more detailed breakdown is given below.

Table two: Summary management accounts

HUMAN TISSUE AUTHORITY
Summary Management accounts for the period
For the Three Months Ending 30 June 2020

<table>
<thead>
<tr>
<th>Year-to-date</th>
<th>Actual</th>
<th>Budget</th>
<th>Var</th>
<th>Var</th>
<th>Forecast</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>£</td>
<td>£</td>
<td>£</td>
<td>%</td>
<td>£'000s</td>
</tr>
<tr>
<td><strong>INCOME</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Government Grant in Aid</td>
<td>176,000</td>
<td>161,000</td>
<td>15,000</td>
<td>9.32%</td>
<td>644,000</td>
</tr>
<tr>
<td>RF RDEL</td>
<td>51,414</td>
<td>51,414</td>
<td>0</td>
<td>0.00%</td>
<td>205,660</td>
</tr>
<tr>
<td>Licence Fee income</td>
<td>4,050</td>
<td>0</td>
<td>4,050</td>
<td>0.00%</td>
<td>3,914,530</td>
</tr>
<tr>
<td>Devolved Governments</td>
<td>133,572</td>
<td>138,448</td>
<td>(4,876)</td>
<td>(3.52%)</td>
<td>133,572</td>
</tr>
<tr>
<td>Rental income</td>
<td>91,947</td>
<td>92,500</td>
<td>(553)</td>
<td>(0.60%)</td>
<td>369,447</td>
</tr>
<tr>
<td>Other income</td>
<td>11,696</td>
<td>11,738</td>
<td>(41)</td>
<td>(0.35%)</td>
<td>46,909</td>
</tr>
<tr>
<td><strong>TOTAL INCOME</strong></td>
<td>468,679</td>
<td>455,099</td>
<td>13,580</td>
<td>2.98%</td>
<td>5,341,118</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Operating costs</th>
<th>Actual</th>
<th>Budget</th>
<th>Var</th>
<th>Var</th>
<th>Forecast</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staff costs (salaries etc)</td>
<td>763,906</td>
<td>810,013</td>
<td>(46,107)</td>
<td>(5.69%)</td>
<td>3,118,034</td>
</tr>
<tr>
<td>Other staff (exc inspection)</td>
<td>6,624</td>
<td>14,830</td>
<td>(8,206)</td>
<td>(55.33%)</td>
<td>114,990</td>
</tr>
<tr>
<td>Authority costs</td>
<td>40,107</td>
<td>42,770</td>
<td>(2,663)</td>
<td>(6.23%)</td>
<td>171,637</td>
</tr>
<tr>
<td>Inspection costs</td>
<td>(318)</td>
<td>0</td>
<td>(318)</td>
<td>0.00%</td>
<td>41,682</td>
</tr>
<tr>
<td>LODT costs</td>
<td>307</td>
<td>0</td>
<td>307</td>
<td>0.00%</td>
<td>9,000</td>
</tr>
<tr>
<td>Communication costs</td>
<td>9,312</td>
<td>2,619</td>
<td>6,693</td>
<td>255.57%</td>
<td>32,817</td>
</tr>
<tr>
<td>IT and Telecom costs</td>
<td>98,269</td>
<td>80,615</td>
<td>17,654</td>
<td>21.90%</td>
<td>372,454</td>
</tr>
<tr>
<td>Office and Administration</td>
<td>4,665</td>
<td>4,695</td>
<td>(30)</td>
<td>(0.65%)</td>
<td>18,094</td>
</tr>
<tr>
<td>Other costs</td>
<td>17,791</td>
<td>15,960</td>
<td>1,831</td>
<td>11.47%</td>
<td>112,941</td>
</tr>
<tr>
<td>Legal and Professional costs</td>
<td>39,281</td>
<td>23,250</td>
<td>16,031</td>
<td>68.95%</td>
<td>109,031</td>
</tr>
<tr>
<td>Accommodation</td>
<td>207,869</td>
<td>203,375</td>
<td>4,494</td>
<td>2.21%</td>
<td>817,994</td>
</tr>
<tr>
<td>Non-cash costs</td>
<td>56,095</td>
<td>51,415</td>
<td>4,680</td>
<td>9.10%</td>
<td>224,376</td>
</tr>
<tr>
<td>Development Programme</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0.00%</td>
<td>198,068</td>
</tr>
<tr>
<td><strong>Total operating costs</strong></td>
<td>1,243,906</td>
<td>1,249,542</td>
<td>(5,635)</td>
<td>(0.45%)</td>
<td>5,341,118</td>
</tr>
</tbody>
</table>

Net Income/(expenditure) | (775,227) | (794,442) | 19,215 | (2.42%) | (0) |
Expenditure (by exception)

33. **Staff costs (salaries)** - year to date we are under budget by **£46k** (5.69%) and this is due to vacancies being carried, mainly at Manager level, since the start of the year.

34. **Other staff costs** – are underspent against budget (**£8k**) which is largely due to underspends within conference travel and training.

35. **Site visit costs** – there is no expenditure in the first quarter due to deferment of site visits until the latter part of the year.

36. **Communication costs** - are over budget by **£7k**. Costs relating to Code of Practice publication costs (**£2k**) and online survey costs (**£5k**).

37. **IT and Telecom costs** – are over budget due to the inclusion of costs relating to the annual cost of the new Office 365 licences which overlap the end of the current contract and additional support costs included in the initial budget.

38. **Legal and professional costs** – are overspent by **£16k** that is the result of the consultancy work that began at the end of 2019/20 and was completed in May, the cost of which is apportioned to this year.

Forecast outturn

39. We have undertaken a first review of our plans for the remainder of the year and this has been reflected in our forecast.

40. Currently we are forecasting a balanced position. This takes into account all current plans and includes a reduction in our site visits budget. Work pertaining to the Development Programme will be funded from the current forecast surplus. The utilisation of these funds will be overseen by SMT and discussed and approved over the remainder of the year.

Other key performance indicators

**Debtors**

41. Our outstanding debtors as at 30 June 2020 is **£0.4m** compared to **£0.6m** in the same period last year. The outstanding amount is represented by **45** accounts of which:
• 19 (£45k) relate to the 2018/19 business year. We have pursued these accounts through chaser letters and telephone calls and will continue to do so particularly as we will be issuing invoices for the new fee year in September.

• 25 (£333k) relate to the 2019/20 business year and will be pursued in advance of the September billing run.

• 1 account is not due as the invoice was raised in June for the Welsh Government (£62k).

42. Below is a breakdown by sector of the outstanding debts as at 30 June 2020.

Table Three: Debtors by sector

<table>
<thead>
<tr>
<th>SECTOR</th>
<th>Number of accounts</th>
<th>Value of debt</th>
<th>%ge</th>
</tr>
</thead>
<tbody>
<tr>
<td>NHS</td>
<td>23</td>
<td>92,000.00</td>
<td>21%</td>
</tr>
<tr>
<td>Gov't bodies/ALBs</td>
<td>2</td>
<td>305,000.00</td>
<td>69%</td>
</tr>
<tr>
<td>Non Gov't bodies/NHS</td>
<td>20</td>
<td>44,000.00</td>
<td>10%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>45</strong></td>
<td><strong>441,000.00</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

**Financial risks**

43. 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 the five high-level strategic risks that SMT has identified and is managing. The strategic risk five – insufficient, or ineffective management of financial resources – is currently rag status yellow, which remains unchanged from the previous quarter.

44. The impact of COVID-19 is noted in this assessment and a new, albeit medium to low proximity, risk relating to cashflow has been added to the key risks table.
Table Four: Risks and mitigations

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

People overview

COVID-19 response

45. HTA staff have not attended the office since 16 March. From a people perspective, quarter one has been characterised by supporting staff in the move to remote working, helping them to manage their work/life balance and wellbeing, and latterly, ensuring that regular human resources functions and processes are maintained.

46. New supplementary guidance on flexible working was developed and launched to support staff in balancing home and work commitments. The guidance encourages staff to consider how they might best deliver their objectives in challenging circumstances including managing home schooling, caring responsibilities and their own mental and physical health. A range of options are open including dividing the working day into active and non-active periods and working in the evening and or at weekends (subject to taking adequate rest periods).

47. A home risk assessment was undertaken at the start of the quarter by all staff and repeated six weeks later. This included the need for IT equipment, ergonomic office set up and home security, including personal safety. The Head of HR contacted every
member of staff individually regarding their submission and the required equipment or furniture was approved for purchase.

48. Daily 'virtual coffee breaks' were introduced in the early stages of the pandemic. These were hosted by a member of the SMT or Head of HR. Staff were encouraged to talk about non work-related issues and to air concerns. The need for this initiative has reduced significantly and is now combined with twice weekly SMT drop in sessions.

49. Daily, and latterly weekly, HTAMG situation report (sitrep) meetings were initiated to ensure transparent and timely communication between SMT and Heads of function as the pandemic situation and the HTA’s response evolved. These meetings continue but discussing day to day business, as the situation has stabilised.

Wellness

50. The Wellbeing Programme has been further developed through the period of the pandemic taking full advantage of Wave (the HTA’s intranet).

51. Wellbeing material posted has included Stress Awareness in Lockdown, Toolkits for Line Managers with Remote Teams, Working from Home and Healthy Working along with a Top Tips guide.

52. We have also built a monthly topic programme that has been further supported by weekly connected themes. These have included Managing Mental and Physical Fitness, Staying Connected, Care for Carers and Heathy Eating.

53. We developed and launched Diversity and Inclusion page on Wave raising awareness of national and international events and celebrations.

Pulse survey

54. We conducted a Pulse survey in early May to judge how well staff believed the HTA had responded to COVID-19 and lockdown. The survey had an 85% response rate and the results ranged between 79%- 83% positive for each of the 5 questions.

Training

55. The following training-related activities have been undertaken over the quarter:

- a training page with links to many free online training programmes was launched on Wave;
- three Line Managers attended a three-month modular online Leadership course;
- HTA Act training was delivered by Field Fisher segmented into four separate online sessions that have been recorded for future viewing;
• the Career Investment scheme was opened for staff to apply and four members of staff have requested support though this scheme; and
• the Lunch and Learn programme covered topics including trans equality and unconscious bias, introduction to projects and creating and using dashboards in CRM.

**Personal Development Plans (PDPs)***

56. All staff have held and recorded end of year PDP reviews with their line managers. A new simplified PDP form has been launched for 2020/2021, with a new automated toolkit planned for 2021/2022.

57. A Competency Framework has been developed to guide the behaviours that form part of measures within the PDP objectives and is in pilot stage.

**Recruitment and Retention***

58. Recruitment has been on hold during the pandemic. We have developed and are currently piloting a new induction programme. This has been used to successfully induct three new members of staff over the quarter, whose job offers were in place before the lockdown. Feedback to date has been very positive from the new starters and their line managers.

59. We currently have five vacancies, three Regulation Managers, one Administrator and the Governance and Quality Manager.

**Other***

60. The positive and inclusive culture of the HTA has been externally recognised with an accreditation by Business in the Community Race at Work Charter and Disability Confident Charter. We have received the ‘badge’ from the Race at Work Charter which has been added to the Internet, Wave and all internal external documentation. We expect the Disability Confident badge in the coming days.

**Freedom of Information requests***

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

**Complaints***

62. In quarter one, no complaints were received by the HTA.
HTA Strategic Risk Register
June 2020

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

Overview: Risks without the strategy for 2019 - 2020. Our highest scored risks are failure to regulate appropriately. The score for which has increased as a result of the removal of routine site visits and inspections as a regulatory tool and the current position on introducing an alternative. Failure to manage development priorities, which reflects the fast pace of change within the sectors we regulate, the low likelihood of regulation change in the forthcoming budget and the removal of statutory site visits for inspection on a regulated list. Failure to utilise our capabilities effectively, which reflects the fast pace that business plans are developed over a longer time horizon. There are not, however, any capability gaps that are impeding the achievement of current developments in 2020/21.

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 Department of Health and Social Care.

We continue to communicate our remit and advise where appropriate. There is ongoing dialogue with DHSC and stakeholders about increasing our visibility and influencing this agenda. There is also improving this area. The introduction of the new Inspection Report templates reduces the risk of inconsistencies in reporting and ensures we have less executive impact on the data.

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 visits and inspections as a regulatory tool and the current position on introducing an alternative; reflects the fast pace of change within the sectors we regulate, the low likelihood of regulation change in the forthcoming budget and the removal of statutory site visits for inspection on a regulated list. Authority Members have been updated on issues as they emerge - the SCR currently presents the assessment of the remaining areas of strategic risk.

Risks are assessed by using the grid below

<table>
<thead>
<tr>
<th>Likelihood</th>
<th>Very Low</th>
<th>Low</th>
<th>Medium</th>
<th>High</th>
<th>Very High</th>
</tr>
</thead>
<tbody>
<tr>
<td>Impact</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Risk Score</td>
<td>Impact x Likelihood</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Lines of defence are:
1. Management control and internal controls (frontline)
2. Risk Management functions (senior management)
3. Internal Audit (board/audit committee)
4. Strategic Leadership and oversight (senior management and board)
5. Contingency planning for managing capacity and capability needs has been deployed throughout the organisation, which reflects the fast pace of change within the sectors we regulate, the low likelihood of regulation change in the forthcoming budget and the removal of statutory site visits for inspection on a regulated list. Authority Members have been updated on issues as they emerge - the SCR currently presents the assessment of the remaining areas of strategic risk.
<table>
<thead>
<tr>
<th>REP</th>
<th>RISK/RISK OWNER</th>
<th>CAUSE AND EFFECTS</th>
<th>SIENHENT</th>
<th>PROXIMITY</th>
<th>EXISTING CONTROLS/MITIGATIONS</th>
<th>RESIDUAL</th>
<th>ACTIONS TO IMPROVE MITIGATION</th>
<th>LINE OF DEFENCE</th>
<th>TYPE OF CONTROL</th>
<th>ASSURANCE OVER CONTROL</th>
<th>ASSURED POSITION</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td>Failure to regulate in a manner that sustains patient safety and confidence and is appropriate</td>
<td>Ongoing</td>
<td></td>
<td>Regulatory/audit</td>
<td></td>
<td>N/A</td>
<td></td>
<td>Preventative</td>
<td>Authority developed and approved the current HTA Strategy and is aware of the risk associated with current impossibility of site visit inspections.</td>
<td>HTA Strategy published in May 2019 and report on the proposals for site-based inspection was made in May 2020.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Detective</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>N/A</td>
<td></td>
<td>Preventative</td>
<td>Reports to Authority of key decisions in Delivery Report</td>
<td>Satisfactory Delivery Report made in February 2020.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Assurance</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>N/A</td>
<td></td>
<td>Preventative</td>
<td>Outputs from annual strategy review translate into revised annual Strategy</td>
<td>Annual strategic planning day completed in January 2020.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Assurance</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>N/A</td>
<td></td>
<td>Preventative</td>
<td>Business plan for 2019/20 signed-off by the Interim Chair on behalf of the Authority and by sponsor Department at the start of the year.</td>
<td>Quarterly reporting to Authority and DHSC in May 2020 reflected progress against quarterly business plans.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Assurance</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>N/A</td>
<td></td>
<td>Preventative</td>
<td></td>
<td>Final report received April 2019 and showed substantial assurance. Two key 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.</td>
</tr>
</tbody>
</table>

**Quality management systems**

**HTA quality management system contains decision making framework, policies and Standard Operating Procedures to achieve adherence to the regulatory model**

**People**

**Inference to the HTA People Strategy which has been substantially extended and approved by the Authority**

**Training and development of professional competence**

**Specialist expertise identified at recruitment to ensure we maintain a broad range of knowledge across all sectors and in developing areas**

**Cross 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.**

**Regulatory model**

**Strengthening historic risk based system to become a more data driven risk based regulatory as part of the HTA Development Programme.**
<table>
<thead>
<tr>
<th>REF</th>
<th>RISK/RISK OWNER</th>
<th>CAUSE AND EFFECTS</th>
<th>INHERENT</th>
<th>PROXIMITY</th>
<th>EXISTING CONTROLS/MITIGATIONS</th>
<th>RESIDUAL</th>
<th>ACTIONS TO IMPROVE MITIGATION</th>
<th>LINE OF DEFENCE</th>
<th>TYPE OF CONTROL</th>
<th>ASSURANCE OVER CONTROL</th>
<th>ASSURED POSITION</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Nicky Harrison</td>
<td>Inability to manage an impact on the delivery of HTA strategic objectives. This might be an incident:</td>
<td>5 3 Future, should event occur</td>
<td>Critical incident response plan, SOP’s and guidance in place, regularly reviewed, including by annual training, and communicated to staff</td>
<td>2 2</td>
<td>Preventative</td>
<td>Policies etc. reviewed annually, training specification and notes after incident reviews</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 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)</td>
<td></td>
<td>All specific risks identified in the Critical Incident Response Plan are filled.</td>
<td>1 2 3 Preventative</td>
<td>Evidence of regular review and updating of the CIRP and no specific CIRP roles vacant.</td>
<td></td>
<td></td>
<td>Community</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• caused by deficiency in the HTA’s regulation or operation</td>
<td></td>
<td></td>
<td></td>
<td>CIRP reviewed and updated to version 19 in July 2019. Further minor changes proposed in February 2020.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• where we need to regulate, such as with emergency mortuaries</td>
<td></td>
<td></td>
<td></td>
<td>Media issues are included in the Delivery Report as they arise and as relevant.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• that causes business continuity issues (Risk to all Delivery Development and Deployment objectives)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Risk owner: Nicky Harrison</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cause</td>
<td>5 3 Future, should event occur</td>
<td>Critical incident response plan, SOP’s and guidance in place, regularly reviewed, including by annual training, and communicated to staff</td>
<td>2 2</td>
<td>Preventative</td>
<td>Policies etc. reviewed annually, training specification and notes after incident reviews</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Insufficient capacity and/or capability (for instance, staff availability, multiple incidents or ineffective knowledge management)</td>
<td></td>
<td>All specific risks identified in the Critical Incident Response Plan are filled.</td>
<td>1 2 3 Preventative</td>
<td>Evidence of regular review and updating of the CIRP and no specific CIRP roles vacant.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Failure to recognise the potential risk caused by an incident (for instance poor decision making, lack of understanding of sector, poor horizon scanning)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>REF</td>
<td>Risk/Risk Owner</td>
<td>Cause</td>
<td>Effect</td>
<td>Impact</td>
<td>Proximity</td>
<td>Existing Controls/Mitigations</td>
<td>Resident Risk</td>
<td>Actions to Improve Mitigation</td>
<td>Line of Defence</td>
<td>Type of Control</td>
<td>Assurance User</td>
</tr>
<tr>
<td>-----</td>
<td>----------------</td>
<td>-------</td>
<td>--------</td>
<td>--------</td>
<td>-----------</td>
<td>-----------------------------</td>
<td>--------------</td>
<td>-----------------------------</td>
<td>--------------</td>
<td>----------------</td>
<td>--------------</td>
</tr>
<tr>
<td>3</td>
<td>Failure to manage public and professional expectations of human tissue regulation in particular relating to current legislation or non-regulation of HTA regulatory reach</td>
<td>Preventative/Regulation relating to child bone marrow</td>
<td>Imported material</td>
<td>Scope of relevant material e.g. waste</td>
<td>Rapidly advancing life sciences</td>
<td>Reduced public confidence in regulation of matters relating to human tissue</td>
<td></td>
<td>Active management of stakeholders through a variety of channels including advice about relevant materials in and out of scope</td>
<td></td>
<td>Preventative/Active</td>
<td>Stakeholder Group meeting minutes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Action where we believe it will support public confidence</td>
<td></td>
<td>Preventative/Active</td>
<td>Quarterly reports to Authority on communication (including media) activities</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Clear view of use of s.15 duty to report issues directly to Ministers in England, Wales and Northern Ireland as new issues emerge</td>
<td></td>
<td>Preventative/Active</td>
<td>Duty and to uses understood by SMT and Chair</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Legal advice now gives a clearer view of our Schedule 2, s. 20 powers</td>
<td></td>
<td>Preventative/Active</td>
<td>Legal advice to be followed</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>No further changes to HTA’s Standards since significant changes launched April 2017 but significant activity to update Codes of Practice for Organ Donation and Transplantation (and consent) to support the introduction of deemed consent for organ donation, with the new duty to go live in May 2020.</td>
<td></td>
<td>Preventative/Active</td>
<td>Updated guidance published, updated Codes of Practice to support deemed consent published.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Partial implementation of internal review recommendations March 2017</td>
<td></td>
<td>Preventative/Active</td>
<td>Recommendations form part of business plan</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Programme underway</td>
<td></td>
<td>Preventative/Active</td>
<td>Programme monitored by SMT and HTAMG</td>
</tr>
</tbody>
</table>

**Risk Owner:** Louise Dinley

**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 in the 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
- Cryptics
- Body stores / Anatomical stores
- Imported material
- 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
Regular meetings with DHSC policy team and attendance at other departmental meetings (ALB delivery partners) to inform planning for the Transition Period and the period after 31 December 2020.

Preventative Development programme workstream 20/21. Programme reporting via a fortnightly steering group and weekly updates to SMT.
<table>
<thead>
<tr>
<th>REF</th>
<th>RISK/RISK OWNER</th>
<th>CAUSE AND EFFECTS</th>
<th>INHERENT</th>
<th>PROXIMITY</th>
<th>EXISTING CONTROLS/MITIGATIONS</th>
<th>RESIDUAL</th>
<th>ACTIONS TO IMPROVE MITIGATION</th>
<th>LINE OF DEFENCE</th>
<th>TYPE OF CONTROL</th>
<th>ASSURANCE OVER CONTROL</th>
<th>ASSURED POSITION</th>
</tr>
</thead>
</table>
| 4   | Failure to utilise people, data and business technology capabilities effectively | - 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 Heads  
- Data holdings poorly managed and under-exploited  
- Inadequate business technology or training in the technology available  
- Lack of ingoing personal resource for ‘no-deal’ EU Exit | 4 4 | | | | | Preventative/ Monitoring | QMS reminders as policies due for review. SMT review of all revised polices | Regular review cycle recommenced in late summer |
|     | Risk Owner: Louise Dineley | 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 | | | | | | Preventative | Recruiting to the currently agreed organisational structure and approved job descriptions | Role and job descriptions reviewed as posts become vacant. Decision to recruit driven by business needs rather than assumes like for like replacement |
|     | | Data | | | | | Preventative | Upgrades to CRM, closely managed changes to CRM development. Internal audit of personal data security | CRM upgrade completed successfully in March 2019 |
|     | | Business technology | | | | | Preventative | Internal audit on GDPR compliance provided moderate assurance. | Internal audit report in March 2019. Part of ongoing Cyber and data security and SIRO reporting. |
|     | | | | | | | Preventative | Systems training forms part of the induction process for new starters | Ongoing records of all new starters trained in key business systems. New induction programme to be launched Summer 2020 |
### Insufficient, or ineffective management of financial resources

**(Risk to Deployment objective b)**

**Risk Owner:** Richard Sydee

<table>
<thead>
<tr>
<th>REF</th>
<th>INHERENT RISK PRIORITY</th>
<th>PROXIMITY</th>
<th>INHERENT RISK PRIORITY</th>
<th>EXISTING CONTROLS/MITIGATIONS</th>
<th>RESIDUAL RISK PRIORITY</th>
<th>ACTIONS TO IMPROVE MITIGATION</th>
<th>LINE OF DEFENCE</th>
<th>TYPE OF CONTROL</th>
<th>ASSURANCE OVER CONTROL</th>
<th>ASSURED POSITION</th>
</tr>
</thead>
<tbody>
<tr>
<td>8</td>
<td>5</td>
<td>Ongoing</td>
<td>5</td>
<td>Budget management framework to control and review spend and take early action</td>
<td>2</td>
<td>4</td>
<td>All</td>
<td>All</td>
<td>Budgetary control policy reviewed annually and agreed by SMT</td>
<td>Last review January 2019 - revised versions to go to SMT in July 2020</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Financial projections, cash flow forecasting and monitoring</td>
<td>X</td>
<td>Monitoring</td>
<td>Monthly finance reports to SMT and quarterly to Authority. Quarterly reports to DH</td>
<td></td>
<td>Preventative</td>
<td>Update agreed by the Authority November 2019 meeting</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Licence fee modelling</td>
<td>X</td>
<td>Preemptive</td>
<td>Monthly finance reports to SMT and quarterly to Authority</td>
<td></td>
<td>Preventative</td>
<td>This has changed in response to COVID-19 impact on licence holders - April licence fees have been deferred until September. Although we maintain a tight grip on our position the overall environment is more uncertain than normal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Rigorous debt recovery procedure</td>
<td>X</td>
<td>Preemptive</td>
<td>Update agreed by the Authority November 2019 meeting</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Reserves policy and levels reserves</td>
<td>X</td>
<td>Monitoring</td>
<td>Reserves policy reviewed annually and agreed by ARAC</td>
<td></td>
<td>Monitoring</td>
<td>Last agreed by ARAC October 2019</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Delegation letters set out responsibilities</td>
<td>X</td>
<td>X</td>
<td>Delegation letters issued annually</td>
<td></td>
<td>Preventative</td>
<td>Issued in May 2020</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Prioritisation when work requirements change</td>
<td>X</td>
<td>Preemptive</td>
<td>Agreed business plan, monthly HTA and SMT reports</td>
<td></td>
<td>Preventative</td>
<td>Last HTA and SMT report October 2019 Last SMT update January 2020</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Fees model provides cost/income information for planning</td>
<td>X</td>
<td>Preemptive</td>
<td>Annual review of fees model, reported to SMT and Authority</td>
<td></td>
<td>Preventative</td>
<td>Update agreed by the Authority November 2019</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Annual external audit</td>
<td>X</td>
<td>Detective</td>
<td>NAO report annually</td>
<td></td>
<td>Monitoring</td>
<td>Last report in June 2019 - clean opinion</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Monitoring of income and expenditure (R)</td>
<td>Ongoing</td>
<td>X</td>
<td>Monthly finance reports to SMT and quarterly to Authority. Quarterly reports to DH</td>
<td></td>
<td>Preventative</td>
<td>Last quarterly report January 2020</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Horizon scanning for changes to DH Grant-in-aid levels and arrangements (R)</td>
<td>Ongoing</td>
<td>X</td>
<td>Quarterly Finance Directors and Accountability meetings</td>
<td></td>
<td>Detective</td>
<td>FO from NHS Resolution, HRA, NICE and CQC maintain contact over common issues 2019/20 - last met July 2019 DHSC Finance wrote in September indicating confirmation of GIA funding sometime in October 2019 Confirmation of 2020/21 GIA recovered in December 2019 - no formal note of delegation at present.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Action plan to move from rudimentary to basic level of maturity on the GovS 013 Functional Standards</td>
<td>X</td>
<td>X</td>
<td>Counter fraud Strategy and Action Plan developed and presented to ARAC Oct 19: Annual training of staff completed in Q4</td>
<td></td>
<td>Preventative</td>
<td>Cabinet Office responses/feedback although fraud prevention now part of BAU for the organisation</td>
</tr>
</tbody>
</table>

**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
- Unforeseen increases in regulatory responsibilities
- 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

**Assurance Over Control**

- Monitoring of income and expenditure (RS)
- Horizon scanning for changes to DH Grant-in-aid levels and arrangements (RS)
<table>
<thead>
<tr>
<th>REF</th>
<th>RISK/RISK OWNER</th>
<th>CAUSE AND EFFECTS</th>
<th>INHERENT</th>
<th>PROXIMITY</th>
<th>EXISTING CONTROLS/MITIGATIONS</th>
<th>RESIDUAL</th>
<th>ACTIONS TO IMPROVE MITIGATION</th>
<th>LINE OF DEFENCE</th>
<th>TYPE OF CONTROL</th>
<th>ASSURANCE OVER CONTROL</th>
<th>ASSURED POSITION</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>Failure to achieve the benefits of the HTA Development Programme (Development objectives a-d)</td>
<td>Risk owner: Louise Dineley</td>
<td>• Uncertainty of funding</td>
<td>3</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Programme and project benefits poorly defined and understood</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Preventive</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Inadequate programme and project governance arrangements</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Preventive</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Poorly specified programme and projects</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Preventive</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Insufficient programme, project and change management skills</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Preventive</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Inadequate leadership of change</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Preventive</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Inability to access the necessary skills required at a affordable cost</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Preventive</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Lack of staff buy-in to change</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Preventive</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Management and Head stretch of delivering transformation alongside business as usual and other development activity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Preventive</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Insufficient agility in (re)deploying people to change projects</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Preventive</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Poorly specified procurement and inadequate contract management</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Preventive</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Realisation of single points of failure for DDAT and People Strategy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Preventive</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Failure to achieve the central strategic intent of the Authority</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Preventive</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Distracts senior management from operations at a time when demands have increased</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Preventive</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Insufficient leadership of change</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Preventive</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Inability to access the necessary skills required at a affordable cost</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Preventive</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Lack of staff buy-in to change</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Preventive</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Management and Head stretch of delivering transformation alongside business as usual and other development activity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Preventive</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Insufficient agility in (re)deploying people to change projects</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Preventive</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Poorly specified procurement and inadequate contract management</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Preventive</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Realisation of single points of failure for DDAT and People Strategy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Preventive</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Wasted public money</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Preventive</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Failure to achieve the central strategic intent of the Authority</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Preventive</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Distracts senior management from operations at a time when demands have increased</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Preventive</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Insufficient leadership of change</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Preventive</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Inability to access the necessary skills required at a affordable cost</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Preventive</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Lack of staff buy-in to change</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Preventive</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Management and Head stretch of delivering transformation alongside business as usual and other development activity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Preventive</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Insufficient agility in (re)deploying people to change projects</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Preventive</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Poorly specified procurement and inadequate contract management</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Preventive</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Realisation of single points of failure for DDAT and People Strategy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Preventive</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Risks: 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
- Insufficient 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

**Actions to Improve Mitigation:**
- SMIT experience of organisational change, programme and project management
- HTA approach to the management of change projects (underpinned by PRINCE2)
- A number of trained project managers among HTA staff
- Experience of procurement and contract management
- Existing mechanisms for engaging staff
- Well established corporate governance arrangements and financial controls
- Agreement to a phased delivery approach to avoid all or nothing investment and align with available funding
- Obtain external advice on programme design and implementation
- Implementation of external advice on programme design and governance
- Limited Benefits Realisation Management methodology within programme
- Introduce a Programme Management Office
- Authority approval to proceed at key Gateway decision points
- Act on the formal training needs analysis undertaken for the HTA more widely to identify and improve the level of internal capability to deliver the programme
- Training plan to encompass project and change management and HTA approach
- Development of procurement plan to deliver the DDAT Strategy
- EDROs identified for Programme and individual projects
- Schedule a regular programme of staff engagement events
- Establish an external stakeholder communications and engagement plan
- Programme to become a focus for appropriate internal audit

**Line of Defence:**
- Preventive
- Preventive
- Preventive
- Preventive
- Preventive
- Preventive
- Monitoring
- Preventive
- Monitoring
- Preventive
- Preventive
- Monitoring
- Preventive
Business Continuity- Regulatory Update

Background

1. This agenda item presents an overview of the HTA’s regulatory operating environment during quarter one of 2020/21.

2. The annexes to the paper provide details of the volume of regulatory activity over the quarter and an assessment of the current position in each of the HTA’s sectors.

Decision-making to date

3. This report was approved by SMT on 9 July 2020.

Action required

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

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

Enquiries

2. Figure 1 below displays the total number of body donation enquiries and other general enquiries received.

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

![Enquiries Received](chart.png)

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

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

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Anatomy</td>
<td>30</td>
<td>42</td>
<td>43</td>
<td>21</td>
<td>19</td>
<td>160</td>
<td>136</td>
</tr>
</tbody>
</table>

*Data period: 1st Apr – 28th Jun. May be subject to revision.
**Table 2: New licence applications, new licences offered, satellite additions and revocations in quarter one**

<table>
<thead>
<tr>
<th>Sector</th>
<th>New Licence Application</th>
<th>New Licences Offered</th>
<th>Satellite Additions</th>
<th>Revocations</th>
<th>Satellite Revocations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anatomy</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Human Application</td>
<td>1</td>
<td>0</td>
<td>4</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Organ Donation and Transplantation</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Post Mortem</td>
<td>10</td>
<td>7</td>
<td>2</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Public Display</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Research</td>
<td>1</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>12</td>
<td>10</td>
<td>6</td>
<td>3</td>
<td>1</td>
</tr>
</tbody>
</table>

5. Twelve new licence applications were received in quarter one 2020/21 (Ten were emergency mortuary licence applications in the Post Mortem sector, one application was received in the Human Application sector and one was received in the Research sector).

*Data period: 1<sup>st</sup> Apr – 28<sup>th</sup> Jun. May be subject to revision.*
6. Ten emergency mortuary licence applications were received in quarter one and seven licences were offered.

7. Three new licences were offered in the Research sector in quarter one 2020/21

8. There were four satellite additions in the Human Application sector and two satellite additions in the Post Mortem sector

9. A total of three revocations took place in quarter one, one was in the Human Application sector and two in the Public Display sector. One satellite revocation took place in the Post Mortem sector.

Licensing Variations

10. Figure 2 displays the total number of licensing variations received each quarter

11. Licensing variations received by sector is displayed in Table 3.

Figure 2: Number of licencing variations received each quarter

![Figure 2: Number of licencing variations received each quarter]

Table 3: Licensing variations received by sector

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Anatomy</td>
<td>4</td>
<td>8</td>
<td>10</td>
<td>8</td>
<td>6</td>
<td>25</td>
<td>30</td>
</tr>
<tr>
<td>Human Application</td>
<td>54</td>
<td>72</td>
<td>54</td>
<td>83</td>
<td>124</td>
<td>260</td>
<td>118</td>
</tr>
<tr>
<td>Organ Donation and Transplantation</td>
<td>4</td>
<td>7</td>
<td>12</td>
<td>4</td>
<td>5</td>
<td>27</td>
<td>27</td>
</tr>
</tbody>
</table>

*Data period: 1st Apr – 28th Jun. May be subject to revision.
12. New change categories introduced during the COVID-19 period has contributed to the higher number of licensing variations received in quarter one when compared to previous quarters. This includes the Minor Change variation which is a newly added category used to collect information that organisations have been asked to send us regarding their current activities. 61 of the 278 variations received in quarter one were Minor Change variations. The majority of these Minor Change variations involve suspension of activities due to COVID-19.

Living Donation

13. Figure 3 shows the total number of living donation cases approved by the LDAT and Board panels.

14. In quarter one 2020/21, 30 cases were approved by the LDAT and one case was approved by a Board panel. The total number of cases approved also includes those using the emergency out-of-hours processes.

Figure 3: Number of living donation cases approved per quarter

*Data period: 1st Apr – 28th Jun. May be subject to revision.
15. Table 4 below shows the total number of bone marrow and PBSC cases approved (donors are children lacking competence to consent) in quarter one compared to preceding quarters.

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

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Approvals</td>
<td>15</td>
<td>19</td>
<td>15</td>
<td>17</td>
<td>16</td>
<td>71</td>
<td>66</td>
</tr>
</tbody>
</table>

Incidents – HTARIs

16. Figure 4 displays the number of reported HTARIs in quarter one compared to preceding quarters. This also includes any near misses and incidents that may, on investigation, be found not to be reportable incidents.

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

17. Figure 5 displays the number of HTARIs closed in quarter one compared to the preceding quarters.

*Data period: 1st Apr – 28th Jun. May be subject to revision.*
Figure 5: HTARI cases closed during quarter in the Post Mortem sector

Incidents – HA SAEARs

18. Figure 6 below displays the number of reported HA SAEARs in quarter one 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.

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

*Data period: 1st Apr – 28th Jun. May be subject to revision.
19. Figure 7 displays the number of HA SAEARs closed in quarter one compared to preceding quarters.

**Figure 7: SAEARs closed during quarter in the Human Application sector**

![](chart1.png)

**Incidents – ODT SAEARs**

20. Figure 8 below displays the number of reported ODT SAEARs in quarter one compared to preceding quarters.

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

![](chart2.png)

*Data period: 1st Apr – 28th Jun. May be subject to revision.*
21. Figure 9 below displays the number of ODT SAEARs closed in quarter one compared to preceding quarters.

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

![ODT SAEARs Closed](chart.png)

**CAPA Plans**

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

23. A total of 21 CAPA plans were opened in quarter one. Eight CAPA plans were opened in the Human Application sector, ten were opened in the Post Mortem sector, one was opened in the Public Display sector and two were opened in the Research sector.

24. A total of 31 CAPA plans were closed in quarter one. 16 CAPA plans were closed in the Human Application sector, one closed in the ODT sector, 11 closed in the Post Mortem sector, one closed in the Public Display sector and two were closed in the Research sector.

*Data period: 1\textsuperscript{st} Apr – 28\textsuperscript{th} Jun. May be subject to revision.*
25. Table 5 shows all open CAPA plans at the end of quarter one and the length of time they have been open.

26. There were a total of 65 CAPA open plans at the end of quarter one. 26 CAPA plans have been open for less than six months, 18 have been open between 6-12 months and 21 CAPA plans have been open for longer than 12 months.

Table 5: All Open CAPA plans

<table>
<thead>
<tr>
<th>Open CAPA Plans</th>
<th>Anatomy</th>
<th>Post Mortem</th>
<th>Human Application</th>
<th>Research</th>
<th>Public Display</th>
<th>ODT</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 6 months</td>
<td>0</td>
<td>10</td>
<td>13</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>26</td>
</tr>
<tr>
<td>6-12 months</td>
<td>1</td>
<td>4</td>
<td>10</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>18</td>
</tr>
<tr>
<td>&gt; 12 months</td>
<td>0</td>
<td>3</td>
<td>17</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>21</td>
</tr>
<tr>
<td>Total</td>
<td>1</td>
<td>17</td>
<td>40</td>
<td>5</td>
<td>1</td>
<td>1</td>
<td>65</td>
</tr>
</tbody>
</table>
**Website Analytics**

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

**Table 6: Audience Size**

<table>
<thead>
<tr>
<th></th>
<th>2020/21</th>
<th>2019/20</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visits</td>
<td>50,554</td>
<td>53,793</td>
</tr>
<tr>
<td>Sessions</td>
<td>70,811</td>
<td>75,149</td>
</tr>
</tbody>
</table>

28. Overall traffic is down. This is against the trend, as in general we have seen yearly increases in audience size. For example, 2019 saw the number of users for the year increase by nearly 8% compared to 2018.

**Table 7: Engagement**

<table>
<thead>
<tr>
<th></th>
<th>2020/21</th>
<th>2019/20</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average time on page</td>
<td>2min 33s</td>
<td>2min 39s</td>
</tr>
<tr>
<td>Bounce rate</td>
<td>42.9%</td>
<td>41.7%</td>
</tr>
</tbody>
</table>

29. Engagement statistics both fell, but only by moderate amounts. There is no overall trend for engagement statistics over time, however we usually expect to see any fall in audience size to be met by an increase in engagement metrics. Bounce rate measures the percentage of site visits that arrive on a page on the website and leave without visiting another page. It is generally used as an engagement metric.

**Popular Pages**

30. There were no significant changes in which pages users were visiting on the website with two exceptions:

- the number of people visiting the body donation page increased as a proportion of overall website visitors (9.7% compared to 9.0%).
- there was a substantive increase in the number of people viewing the body donation FAQs. This increased from 0.17% of all page views last year, to 1.8% this year. This represents the continuation of increased visitors which began in October 2019 and does not represent a unique event during the period being reported.

*Data period: 1st Apr – 28th Jun. May be subject to revision.*
**Additional notes**

31. There was a significant spike in website visits on 2 April 2020 where 1497 people visited the website, compared to 932 for 2 April 2019.

32. This spike in traffic mostly originated from email referrals and coincides with a COVID-19 email sent to establishment staff which contained various links to the website.

**Conclusion**

33. Other than the spike in visits due to the COVID-19 email sent to establishment staff in April (as shown in the spike in site visits below), there is little to mark this period as being significantly different to any other.

**Comparison graph (users over time)**

*Data period: 1<sup>st</sup> Apr – 28<sup>th</sup> Jun. May be subject to revision.*
Business Continuity- Development Programme

Background

1. This agenda item provides an overview of the development plans over quarters two, three and four, including desk-based inspections. This item is supported by an annex of Power point 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 9 July 2020.

Action required

3. The Board is asked to note the content of this report.
Audit and Risk Assurance Committee Update

Purpose of paper

1. To provide the Board with an overview of the work of the Audit and Risk Assurance committee over the past 12 months.

Decision-making to date

2. This report was approved by the CEO on 8 July 2020.

Action required

3. The Board is asked to note the report and the opinions of ARAC on the governance processes within the HTA.

Background

4. The ARAC’s formal role is to advise the Accounting Officer and Authority on:
   - the strategic processes for risk, control and governance and the Annual Governance Statement;
   - the accounting policies, the accounts, and the annual reports of the HTA, levels of error identified, and management’s letter of representation to external auditors;
   - the planned activity and results of both internal and external audit;
   - the adequacy of management response to issues identified by audit activity, including external audit’s audit completion report;
   - assurance relating to corporate governance requirements for the HTA; and
• the policies on whistle-blowing and fraud prevention, including the arrangements therein for special investigations.

5. There is an annual cycle of matters to consider, with ARAC’s regular business focussing on assurance and risk management processes, as well as matters arising from internal and external audit work. At each meeting, the Committee received progress reports on all these areas.

Overview

6. This report summarises the Committee’s activity during the year and gives the Committee’s opinion on the HTA’s risk management and internal control arrangements. The report forms part of the assurance processes, which support the Accounting Officer’s Annual Governance Statement.

7. Membership of ARAC through the year has been:

• Amanda Gibbon (ARAC Chair);
• Bill Horne (Authority Member);
• Dr Stuart Dollow (Authority Member);
• Professor Andy Hall (Authority Member);
• Glenn Houston (Authority Member).
• Professor Gary Crowe (Authority Member)
• Dr Charmaine Griffiths (Authority Member)

8. During this period Bill Horne and Andy Hall stepped down from ARAC (February 2020) and Professor Gary Crowe and Dr Charmaine Griffiths joined as members of ARAC from its June 2020 meeting.

9. ARAC met three times in 2019/20. The Chief Executive, the Director of Resources, the Head of Finance and Governance and the HTA’s external and internal auditors attended all meetings. Other Directors and staff attended to discuss particular risk areas that ARAC wished to explore, or other topics depending on ARAC’s business. Colleagues from the Department of Health and Social Care also attend.

10. ARAC’s terms of reference outline the support this body provides to the Accounting Officer (the Chief Executive) throughout the year, in particular, by providing scrutiny to support the agreement of the Governance Statement.

Review of Committee effectiveness

11. The Committee reviewed its effectiveness in the period March 2019 to March 2020. This consisted of members responding to a series of questions relevant to ARAC at this time. The questions were:
a. What does ARAC do for the Authority?
b. Does the annual cycle of business cover all that we should?
c. Do ARAC papers cover what is needed? If not, what would be better?
d. Do we have sufficient expertise on the committee and in internal/external audit attendees properly to scrutinise as we should?
e. Do we have sufficient time in meetings?
f. Are the training sessions valuable? If you feel you need more training, what would that cover?
g. Do you feel able to raise everything you would like to discuss?
h. Is there anything we could do better?

12. The responses were very positive, with some minor suggestions for further improvement made.

13. ARAC members attended Department of Health and Social Care and National Audit Office (NAO) events, including networking meetings of audit committee members.

Risk Management

14. Strategic risks are reviewed by the Senior Management Team (SMT) on a monthly basis and are reported to ARAC at each meeting with the Risk Register being presented to the Authority quarterly.

15. During the 2019/20 business year, ARAC identified risk areas to explore in greater detail and relevant staff attended meetings to provide more information and assurance on:
   a. DI Engagement;
   b. Licensing Fees review; and,  
   c. HTA Office relocation

16. The Committee reviews the strategic risk register at all meetings and discussed the updated risk register at its most recent meeting in June 2020 meeting.

Information and data security

17. Cabinet Office have required management boards to include a Senior Information Risk Owner (SIRO) since 2008, to ensure that priority is given to the protection of information and data. Within the HTA, the Director of Resources fulfils this role.

18. During this period ARAC has received regular reports on the transformation activity in this area, frequency and responses to IT and cyber incidents during the period as well as updates on the HTA’s overall data and cyber security situation and policies.
19. ARAC has agreed with the thrust of the organisation’s oversight and recommendations with regard to information and cyber security. Although the likelihood of an attack is low, the HTA continues to monitor the situation and takes all reasonable steps to protect against a cyber-attack, with an emphasis on making sure staff are aware of the risks and act accordingly.

20. Overall the SIRO considered that information risk was managed adequately. The Committee received a formal report from the SIRO at its last meeting.

**Internal audit**

21. During this period the Committee endorsed the Internal Audit strategy and plans for the year and monitored work progress. In total, five audits were undertaken across Critical Incident Management, Utilisation of Capabilities, Anti-Fraud Controls, Payroll & Expenses and Business Continuity.

22. Internal Audit gave “moderate” assurance that the HTA had adequate and effective systems of control, governance and risk management in place for the reporting year 2019/20.

**External audit**

23. NAO officials attended all Committee meetings and continued to make a valuable contribution to discussions. The NAO recommended an unqualified opinion on the 2019/20 accounts and agreed that the Governance Statement complies with HM Treasury guidelines.

**Assurance processes**

24. During 2019/20, the Chief Executive met with HTA Directors at least monthly (individually) to review the delivery of their responsibilities. Directors hold similar meetings with their staff and ensure that controls are in place on an ongoing basis. The Senior Management Team of the Chief Executive and Directors met weekly to share information, review progress against business plans, review strategic risk, and make necessary decisions.

25. The Committee believes that ongoing management review and communication, supported by the findings of audits and Departmental oversight give sufficient evidence to provide the Accounting Officer with assurance that the systems are sufficiently robust.
Governance Statement

26. The Governance Statement is a key part of the Annual Report and Accounts. It is signed by the Accounting Officer and explains how governance responsibilities have been discharged. The Committee considers that there is sufficient evidence of effective governance processes to support the signing of the Governance Statement. There are no material issues to be brought to the attention of the Accounting Officer or Authority.

Summary

27. The HTA’s governance systems are well established and there is a commitment to making continuous improvements to them. The Committee is satisfied with the arrangements for risk management and the assurance processes.
Professional Stakeholder Evaluation 2020

Purpose of paper

1. To provide an overview of the latest professional stakeholder evaluation results, conducted in quarter four 2019/20.

2. To highlight the key emerging areas of development work related to the insight received.

3. To invite feedback from Members and answer any questions they may have on the results before they publish on the HTA website.

Decision-making to date

4. This report was approved by the CEO on 8 July 2020.

Action required

5. The Board is asked to note the report and the proposed next steps.
Background

6. Every two or three years the HTA commissions an evaluation of key stakeholders to better understand what they know, think, and have experienced in relation to the HTA’s work.

7. These evaluations are a key measure of professional and public confidence in human tissue regulation, and help to inform the HTA’s strategic direction whilst ensuring transparency and an intelligence-led, consultative, approach.

8. We will use results from the recent stakeholder evaluation exercise to make sure that our regulatory approach and engagement strategies remain fit for purpose and reflect the views and experience of our regulated establishments.


10. All previous evaluations are available on the HTA website here: HTA > Corporate Publications > Evaluations.

11. In quarter three 2019/20, heads of function and the senior management team (SMT) were engaged in the tendering and selection process of the research agency who would undertake the evaluation – Savanta ComRes – and an updated draft questionnaire was agreed to go into the field in quarter four.

Evaluation Response

12. The evaluation comprised two parts:

Online Survey


14. 518 individuals out of a total sample of 3,028 contacts provided by the HTA responded to the survey, amounting to a response rate of 17.1%.

In Depth Interviews

15. Stakeholders were given an opportunity to opt in for telephone interviews at the end of the online survey.

16. 30 of these individuals were interviewed between 12 March and 16 April 2020, with five interviews per sector.
17. Interviews each lasted half an hour and were designed to explore and discuss stakeholder evaluations of the HTA in greater depth and detail.

**Key Metrics**

18. Overall, respondents were positive about their knowledge, understanding, interactions with, and experience of, the HTA.

19. The HTA scored positively across the three key metrics of:

- Knowledge – 96%
- Confidence in regulation – 94%
- Favourability towards HTA – 87%

20. Communications with, and how respondents would speak about, the HTA, were also net positive:

- Communications with the HTA – 78%
- Speak highly of the HTA – 69%

21. Favourable impressions appear to be primarily driven by perceptions of the HTA’s professionalism in terms of being an effective and thorough regulator, and its perceived helpfulness in providing guidance and advice.

22. The most notable changes stakeholders had identified in their experience of the HTA in recent years were:

- More thorough regulation
- More supportive
- More accessible

23. At least nine in 10 respondents deemed the HTA to be effective in fulfilling its regulatory responsibilities.

**Other Headline Results**

24. The extent to which stakeholders understand what the HTA does is largely consistent across sectors; a majority think they know at least a fair amount from a high of 100% in the Anatomy sector, to a low of 83% in Public Display.

25. Interviews and survey data suggest stakeholders are aware of the HTA’s statutory requirements. They often make unprompted references to these, and also rate them as highly important activities for the HTA.
26. Alongside being ‘necessary’, stakeholders also associate the HTA with being ‘helpful’, ‘respectful’ and ‘thorough’.

27. Stakeholders mostly hold positive and balanced impressions of the HTA, often as a result of its professionalism, good engagement and helpful guidance.

28. The view that the HTA is authoritative and effective is more prevalent now than in 2013 although a minority suggest its approach can be inflexible:

- Professional (94%), Authoritative (84%), and Expert (84%) were the words most commonly associated with the HTA.
- Proportionate (63%), Modern (59%), and Flexible (51%) were the words least commonly associated with the HTA.

29. Favourability levels are broadly high and consistent by sector, from a high of 98% in the Anatomy sector to a low of 83% in Public Display.

30. A vast majority appear confident in the HTA as a regulator, some express uncertainty but this more often relates to regulation outside of their sector, from a high of 100% in the Anatomy sector, to a low of 91% in Public Display.

31. The scope of the HTA’s regulation is considered as reasonable by a majority of stakeholders.

32. Most stakeholders suggest it is easy to know how to comply with the HTA’s standards in their sector.

33. The revised codes of practice and standards appear to have largely had a positive impact on the tangible usage of the guidance in practice.

**Potential Areas for Improvement and the HTA’s Development Work**

34. The HTA’s Development Programme seeks to build resilience, agility, and overall sustainability through a programme of more significant organisational change activity, alongside a plan of continuous improvement.

35. There are two key areas that will be directly informed from the insight provided in the stakeholder evaluation, looking at how we develop and improve both our regulatory contact with establishments and a model for remote oversight and assessment. These are:

- Relationship Management
• Format, and type, of inspection

36. A number of questions were included in the online survey to gauge the perceived impact of potential future developments in the HTA’s approach and operating model. These were on the impact of:

• The introduction of a streamlined regulatory model with one point of contact / relationship manager for the whole organisation
• Shorter, more focused inspections
• The introduction of a publicly available rating or visible marking system to denote compliance
• Fewer onsite inspections
• More unannounced inspections

37. Respondents were most positive about the introduction of a “streamlined regulatory model” / “relationship manager” (81% positive).

38. This is something the HTA has been discussing internally and developing a model for how it might work, in particular, for a single organisation with multiple licences.

39. It also might serve to address negative feedback in the communications and engagement section of the survey, which was critical of the HTA’s responsiveness to enquiries.

40. With the HTA’s aim to be a right-touch, proportionate regulator, and engaging its authoritative voice to good effect, it is in line with the strategic aim of using the minimum necessary direct intervention to achieve compliance and improvement.

41. With the above in mind, it is key to ensure the best use of communications and engagement with establishments, as part of the HTA’s regulatory toolkit, both as a pre-emptive measure to reduce the risk of shortfalls, and to avoid on over reliance on regulatory action.

42. Areas in which the HTA are looking to strengthen our regulatory communications based on the feedback from this survey are through:

• More sector focused communications and engagement
• More sector specific guidance for establishments
• Focusing on key areas where knowledge and understanding of the HTA’s standards and guidance is reported as low
• Greater use of digital tools to engage with establishments, e.g. webinars, video meetings, Q&A sessions
43. The next most favoured option for potential future change was “Shorter, more focused inspections”. This ties in, conceptually, with “more unannounced inspections” being the least positively received (29%).

44. The concept of more focused inspection links to our work - accelerated somewhat during the COVID-19 lockdown period - exploring how the HTA might conduct and undertake remote, regulatory activity and oversight.

45. It also related to our development work assessing how onsite inspection could happen with similar, or even greater frequency, as under the current model, but would focus on known areas of risk that are only transparent when onsite.

Next Steps

46. HTA to publish the stakeholder evaluation on its website alongside previous evaluation.

47. HTA to include a news item on the front page of the website to share with visitors.

48. HTA to add a news article to the July professional e-newsletter about the evaluation results and to thank all those who took part.

49. HTA to continue to use this insight to contribute to and direct work across the Development Programme.
Living Donation Policy updates

Purpose of paper

1. The purpose of this paper is to update Board Members on three key areas in Living Donation:
   - Emergency out of hours assessments;
   - Novel cases and;
   - Proposed new process for consideration of cases requiring decision by a panel.

Decision-making to date

2. This paper was approved by SMT on 2 July 2020.

Action required

3. Board Members are asked to note and comment on the proposals described in this paper.

Emergency out-of-hours assessments

4. During the November 2019 Board meeting, in response to concerns raised by some Members about taking part in the on-call rota for out-of-hours consideration of emergency living donation cases, the Board was presented with options for alternative arrangements.
Following feedback, the Executive undertook some further work. A paper was submitted to the SMT for consideration in June 2020 which outlined a new proposed approach.

This proposal was that the provision of out-of-hours assessment would continue, but that the assessment of these cases would be undertaken by Executive staff. Living liver donation decisions are already made by the Executive in office hours, and it is these cases which drive the demand for out-of-hours assessment.

A total of 13 Executive staff members are on the rota with a possibility for additional members of staff to join the on-call rota in the future once more individuals have been trained in the assessment of living donation cases. The rota is covered by staff who are trained in the assessment of cases. For any time taken out of hours to assess a case, staff will claim time off in lieu.

The revised approach was agreed by SMT on 4 June 2020. Work has been completed to update relevant SOPs and training has been delivered to all staff that are on the rota. The new arrangements came into effect on 1 July 2020.

**Novel cases**

An outstanding action point from the November 2019 Board meeting was to develop a policy for consideration of novel living donation cases.

Following detailed legal advice our internal policy HTA-POL-102, on the assessment of living donation cases, has been updated.

These will be treated as retained panel cases; all cases that meet the criteria of “novel” will be referred to panel for consideration. Please refer to the table on page five below for further details.

Once it has been established that the novel donation can be considered routine, using agreed criteria set out in the policy, cases will be considered by the Executive team.

The Policy has been approved by the Director of Regulation.

**Proposed new process for consideration of cases requiring decision by a panel**

Regulation 12 of The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 require that for certain categories of living organ donation, the decision must be made by a panel of no fewer than three Members of the Authority.
15. Pre COVID-19, we continued to see a significant increase in the number of panel cases, leading to concern about the call this places on Members’ limited time available for HTA business. In discussion between the Chair, DHSC and Board Members there has been a strong sense that the involvement in this level of executive decision making is inappropriate to the relative regulatory risks and creates a barrier to greater strategic focus by the Board across the whole of the HTA’s regulatory remit.

16. We expect the volume of panel cases to return to pre COVID-19 levels by early 2021. This pressure may be compounded if there are delays in appointing new Members as current terms come to an end.

17. In the 2013/14 financial year, 262 cases were assessed by panel, compared to 382 cases in the 2018/19 financial year. This is an increase of almost 46% in cases requiring a decision by a panel. This figure is expected to continue to rise in line with NHSBT plans to maximise the potential of the national sharing schemes.

18. As Members are also aware, transplant centres are increasingly requiring decisions in less than ten working days, driven by factors such as theatre capacity, identifying suitable dates to meet the needs of all centres and patients, and NHSBT matching run deadlines. A reduction in time taken to assess panel cases would be welcomed by stakeholders.

19. In March 2020, we sought legal advice to ascertain whether there was any scope for the decision making by a panel of three Authority Members under regulation 12 to be delegated to the Executive. The advice confirmed there is not scope for delegation of the actual decision-making power in regulation 12(1) to the Executive. While we continue to make the case to DHSC to review this requirement, this remains unlikely in the short to medium term. However, the advice did provide alternative options for consideration of these cases to reduce the time spent by Members on assessing these.

20. The Executive has used the legal advice to develop a solution which will allow for a lighter touch and more timely approach to resolving the cases that require panel consideration but are now considered more routine, without fettering of the Board’s discretion.

21. Paired/pooled donations, for example, were once considered to be novel and of greater complexity; these donations are now routine. These cases very rarely present a greater regulatory risk than directed donations and so the need for increased scrutiny has now reduced. It is these cases that have contributed the most to the significant increase in cases requiring a panel decision, as the national sharing scheme has become so successful.
22. Legal advice confirmed that there is nothing in the Act or the Regulations to prevent the panel of Authority Members appointing a competent person(s) to advise them and provide recommendations in relation to regulation 12(1), so long as the ultimate decision is made by the panel.

What will stay the same?

23. The Executive will continue to review every case before it is referred to panel as has always been the case. This is undertaken by the most experienced members of the Executive, the two Transplant Officers or the Transplant Manager. They will continue to liaise with the Independent Assessor and members of the clinical team to ensure that the evidence from the clinical work up has properly accounted for the regulatory requirements to be fulfilled.

24. Members will continue to have access to free text boxes in the “comments” section on CRM to ensure that it is possible to record the relevant documents that have been considered as part of decision making and input reasons for their decisions.

25. Cases will continue to be referred to panel each Wednesday, though the aim will be to do so my mid-morning at the latest.

What will change?

26. The Executive will provide a recommendation, supported by key facts, to the panel. This recommendation will summarise the key information required by law and suggest whether approval should be given. Panel members will be asked to review the recommendation and base their decision on this. Please see Annex A for an indicative template.

27. The recommendation will ordinarily be no more than half an A4 page in order to reduce the administrative burden. The recommendation will be uploaded to the “case notes” section of the case on CRM.

28. Relevant background documents will remain available for review, although there is no legal requirement for these to be reviewed by panel members. This proposed approach will allow Members to fulfil their statutory duty, allowing the discretion to review the full detail of a case, but generally reduce the time dedicated to this activity.

29. As mentioned at paragraph 18, a reduction in time taken to assess panel cases would be most welcomed by stakeholders. We are therefore suggesting that we reduce the time panels have to assess cases of paired, pooled and non-directed altruistic donations from ten working days to five working days. In 2019/20, 71% of panel cases were resolved within this timeframe.
30. A quality assurance check will be built into the system to provide assurance to Members that recommendations made by the Executive are supported by the documentation provided in the case. More work is required on the design of this quality assurance, but we anticipate sampling of an appropriate number of cases for checking.

For cases that require more input from Members

31. A separate process is proposed for those cases where the decision making has been retained by Members. This may be because they are more challenging, complex or novel to assess. This is to ensure we continue to focus additional scrutiny where it is most needed.

32. The table below sets out the proposed approach for each category type.

<table>
<thead>
<tr>
<th>Category of donation</th>
<th>Reason for panel consideration</th>
<th>Process</th>
<th>Time frame in which to make a decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paired and pooled</td>
<td>Panel decision required by law</td>
<td>Executive to review and make recommendation to panel. Panel to review recommendation</td>
<td>5 working days</td>
</tr>
<tr>
<td>Non-directed altruistic</td>
<td>Panel decision required by law</td>
<td>Executive to review and make recommendation to panel. Panel to review recommendation</td>
<td>5 working days</td>
</tr>
<tr>
<td>Cases the Executive is minded not to approve</td>
<td>Retained panel case</td>
<td>Executive to review and make recommendation to panel. All supporting documents available</td>
<td>10 working days</td>
</tr>
<tr>
<td>Economic dependence</td>
<td>Retained panel case</td>
<td>Executive to review and make recommendation to panel. All supporting documents available</td>
<td>10 working days</td>
</tr>
</tbody>
</table>
### Next Steps

33. Subject to views of the Board, we would propose completing the design of the new system by early August, with training and implementation by the end of September 2020 at the latest.

| Directed altruistic donation with overseas donor | Retained panel case | Executive to review and make recommendation to panel. All supporting documents available | 10 working days |
| Novel donations (as defined in HTA-POL-102) | Retained panel case (until established as routine when they will be considered by the Executive team) | Executive to review and make recommendation to panel. All supporting documents available | 10 working days |
| Donor is adult lacking capacity | Panel decision required by law | Executive to review and make recommendation to panel. All supporting documents available | 10 working days |
| Donor is a child (under 18) | Panel decision required by law | Executive to review and make recommendation to panel. All supporting documents available | 10 working days |
Annex A

The template will include a mix of pre-filled text and drop-down boxes, in addition to text copied from the IA report where helpful.

**Case TXXXX**  
**Recommendation completed by:** Choose an item.

<table>
<thead>
<tr>
<th>Information required by law</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category of donation</td>
<td>Choose an item.</td>
</tr>
<tr>
<td>Donor: Any difficulties in communicating with the donor</td>
<td>Choose an item.</td>
</tr>
<tr>
<td>Donor: Understanding of the nature of the medical procedure and the risk involved</td>
<td>Choose an item.</td>
</tr>
<tr>
<td>Donor: Understands that consent may be withdrawn at any time before the removal of the transplantable material</td>
<td>Choose an item.</td>
</tr>
<tr>
<td><strong>Paired/Pooled cases</strong> Donor: Is aware of the implications of being a donor in the paired / pooled scheme and understands the process</td>
<td>Choose an item.</td>
</tr>
<tr>
<td><strong>Non-Directed Altruistic cases:</strong> Donor: Is aware of the implications of being a non-directed altruistic donor and understands the process</td>
<td>Choose an item.</td>
</tr>
<tr>
<td>Donor: Any evidence of duress or coercion affecting the decision to give consent</td>
<td>Choose an item.</td>
</tr>
<tr>
<td>Donor: Any evidence of an offer of a reward</td>
<td>Choose an item.</td>
</tr>
<tr>
<td><strong>SCOTLAND cases - Donor:</strong> Any relevant wider</td>
<td>Choose an item.</td>
</tr>
<tr>
<td>Implications arising from the intended donation, including the effect on any children or dependent relatives</td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td><strong>Recipient:</strong> Any difficulties in communicating with the recipient</td>
<td>Choose an item.</td>
</tr>
<tr>
<td><strong>Recipient:</strong> Any evidence of duress or coercion affecting the decision of the donor to give consent</td>
<td>Choose an item.</td>
</tr>
<tr>
<td><strong>Recipient:</strong> Any evidence of an offer of a reward</td>
<td>Choose an item.</td>
</tr>
<tr>
<td>Approval recommended?</td>
<td>Choose an item.</td>
</tr>
</tbody>
</table>