# Eighty-First Meeting of the Human Tissue Authority

**Date**  
14 September 2017  
**Time**  
10:00 – 16:30  
**Venue**  
Scotsman Suite, Grosvenor Hotel  
101 Buckingham Palace Road, SW1W 0SJ

Research sector session (10:00 – 11:00)  
Refreshment break (11:00 – 11:15)  
Regulatory tools session (11:15 – 13:00)  
Lunch (13:00 – 13:30)  
Authority meeting (13:30 – 16:30)

## Agenda

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| 1. | Welcome and apologies  
2. | Declarations of interest  
3. | Minutes of 27 June 2017  
4. | Matters arising from 27 June 2017  

### Regular Reporting

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| 5. | Chair’s Report  
6. | Chief Executive’s Report  
7. | Delivery Report – Quarter One 2017/18  
10. | White space for non-agenda items  

### Committee and Advisory Group Reporting

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| 11. | Advisory group review  

### Policy Issues

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| 12. | Licence fees 2018/19 (CONFIDENTIAL)  

### Other Items

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| 13. | Any other business  

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

Purpose of paper

1. To provide the Authority with context for the regulatory tools session.

Decision-making to date

2. No decisions have been made to date.

Action required

3. To review the tables attached at Annex A, which will be presented by the Regulation directorate, at the morning session of the 14 September 2017 Authority meeting.

Background

4. On 19 October 2017, the Authority will consider how the HTA’s current strategic approach might be changed to better protect public and professional confidence, for the strategic period 2018-2021. To do this, the HTA is developing a proposal document to set out options for Members to consider. The proposal document will seek to answer twelve strategic questions. One of these is,

“what is the HTA's current baseline for assessing risk and deciding on the regulatory tools we use in the six regulated sectors”.

5. To assist Members in considering this question, colleagues have given Members detailed sector presentations on two of our sectors over the past year. A presentation on the research sector will be given by Christopher Birkett ahead of this presentation.
Presentations on the public display, anatomy and organ donation and transplantation sectors will be delivered at future Authority meetings.

6. In addition, Heads of Regulation have developed summary sector profiles, which they will present on 14 September. These sector profiles set out:

a. headline information about each sector licensed activities;
b. the risk profile of the sector;
c. details on how inspections are carried out;
d. how shortfalls are managed;
e. compliance update requirements;
f. other tools available to the HTA; and
g. advice and guidance we provide to the sectors.

7. The aim of this session is:

a. to create common understanding amongst Members about the risks and approaches taken in each sector;
b. for Members to ask questions that they may have in relation to that; and
c. to consider if the current approach is right, and what we might do differently, in the lead up to the October strategy away-day.
### Summary Information

<table>
<thead>
<tr>
<th>Sector</th>
<th>Inspections/Audits*</th>
<th>Compliance data**</th>
<th>Annual Activity Data</th>
<th>Reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Organ donation and transplantation</td>
<td>First round of audits in 2012/13. Second round of audits commenced October 2016. All centres to be audited during 2017/18 and 2018/19 i.e. an audit per month.</td>
<td>Every two years</td>
<td>N/A</td>
<td>SAEARs</td>
</tr>
<tr>
<td>Post-mortem</td>
<td>Originally every three to three and a half years; the interval between inspections has increased to four and five years in the last two years</td>
<td>Full set every two years. Since 2015, capacity and contingency data have been collected in between</td>
<td>NA</td>
<td>HTARI</td>
</tr>
<tr>
<td>Human application</td>
<td>As a minimum, every two years in line with legislative requirements</td>
<td>Para 35 of the ‘Guide’ requires establishments to complete a self assessment form assessing the establishment against the HTA’s compliance standards at least every 12 months. All self-assessment forms must be retained and provided to the HTA on request (for example prior to an inspection).</td>
<td>Annually</td>
<td>SAEARs</td>
</tr>
<tr>
<td>Research</td>
<td>Repeat inspection range of three to nine years</td>
<td>Every two years</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Anatomy</td>
<td>Repeat inspection range of four to nine years</td>
<td>Every two years</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Public display</td>
<td>A small number, two or three, are inspected each year on a rolling cycle, but all new licensed premises inspected on application</td>
<td>Every two years</td>
<td>NA</td>
<td>N/A</td>
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</table>

*With the exception of establishments in the human application sector, which we are required to inspect every two years, the timing of inspection of a given establishment within a sector will be based on the risk we consider it to pose.

**To support our system of continuous licensing, every licensed non-HA establishment is required to provide us with a biennial update of licensing information and to complete a concise, sector-specific questionnaire, focussed on risk and compliance with our standards. The responses are used to:

- Ensure each establishment’s continued suitability to be licensed;
- Inform the scheduling of site-visit inspections; and
- Inform the HTA’s regulatory approach to each sector.

While the core administrative checks remain the same for each round of compliance updates, the sector-specific questionnaires are adapted to keep pace with key risks and trends in activities or non-compliances. The questions – which are informed by trends, findings or concerns we have noted e.g. from inspections or reported incidents - are used to:

- assess each establishment’s compliance with our licensing standards;
- gather updated, establishment-specific information on their levels and ranges of activities;
- gather intelligence to form a snapshot of activities across sectors; and
- identify riskier establishments, primarily to prioritise inspections within sectors.

Data from the submitted compliance updates are analysed and any points requiring clarification are followed up with individual establishments; any necessary improvements are put in place with our support. Compliance data is evaluated and, along with information such as the length of time since the last inspection, is used to prioritise establishments for inspection.
Organ donation and transplantation

<table>
<thead>
<tr>
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<tr>
<td>35 establishments; consisting of 31 NHS Trusts, 4 private hospitals and NHSBT. For the purposes of licensing, there are two separate groups of activity: a. Procurement activities may include one or more of the following: • donor characterisation; • organ characterisation; • preservation of an organ; • making arrangements to transport an organ; and • retrieval of an organ. b. Transplantation activities may include one or more of the following: • organ characterisation; • preservation of an organ; • making arrangements to transport an organ; and • implantation.</td>
<td>This sector is broadly compliant so is considered low risk from a regulatory perspective. Recent experience has demonstrated that concerns around Trust governance are where the majority of minor shortfalls have been identified. However, it is an inherently high risk sector due to the nature and breadth of the activities being undertaken across both living and deceased organ donation and transplantation. In particular, regulatory non-compliance could have a serious adverse effect on patient safety and clinical outcomes for those giving and receiving organ and tissue transplants. Adverse outcomes and, on occasion, widespread media attention means there is a very real risk in terms of loss of public confidence if standards are not met and maintained across the sector. Biennial compliance updates are collected and contribute to audit prioritisation e.g. the establishment’s overall compliance score, and also provide sector oversight. This data is useful in identifying particular areas where the HTA may wish to seek assurance during the audits.</td>
<td>Inspections are referred to as audits in this sector. The HTA began regulating and licensing this sector in August 2012 as a result of the EU Directive on the standards of quality and safety of human organs intended for transplantation. The first round of audits took place in 2012/13 during which all establishments licensed under the new regulatory framework were audited. The second round of audits began in October 2016. During the 17/18 and 18/19 financial years we will undertake one audit per month. The size of the audit team and length of audit varies depending on the complexity of the activities at the establishment, for example the audit of an establishment transplanting living kidneys only will be shorter than the audit of an establishment transplanting multiple organs from deceased and living donors.</td>
<td>Shortfalls are managed through a CAPA process. Biennial compliance updates are collected and contribute to audit prioritisation e.g. the establishment’s overall compliance score, and also provide sector oversight. This data is useful in identifying particular areas where the HTA may wish to seek assurance during the audits.</td>
<td>SLA with NHS Blood and Transplant (NHSBT) sets out a number of functions that NHSBT performs on our behalf to assist us in meeting our obligations as the Competent Authority (CA) under the EU Directive. Significantly, this includes the management, reporting and investigation of Serious Adverse Events and Reactions (SAEARs), which are reported to the HTA and closed once we are satisfied that appropriate measures have been taken to prevent the SAEAR occurring again, and that shared learning has taken place where appropriate. Quarterly meetings with NHSBT to discuss SAEARs and other key topics. Transplant Advisory Group meets twice a year to discuss issues primarily relating to the living organ donation sector. HTA attends annual EU CA meetings.</td>
<td>Enquiries Website (including FAQs) During audits Webinars SAEARs management via NHSBT E-newsletter Sector specific publications</td>
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### Regulatory tools session

#### 14 September 2017 HTA Authority meeting

**Post-mortem**

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<td>248 licensed sites (127 stand-alone sites, and 53 hubs with 68 satellites) which undertake around 100,000 PMEs p.a. Majority are mortuaries within NHS Trusts; a few are on LA-owned premises. Licensed activities are: PM examination, removal of tissue from the body of a deceased person for use for a SP, storage of bodies and tissue for use for a SP. Licence emergency mortuaries for PM examination. Licensing exemptions: (i) body stores; (ii) storage for criminal justice purposes; (iii) specialist centres which undertake analysis for a licensed establishment.</td>
<td>High inherent risk: (sensitivities around dealing with the deceased; potential for media interest and public concern when things go wrong; pressures on the coroners’ service, which impact on body storage). High regulatory risk, particularly relating to premises. Some evidence to suggest that tissue traceability remains an area of ongoing risk. Inspections since the introduction of the new standards have resulted in increased numbers of critical and major shortfalls. This may be due, in part, to the interval since the last inspection, but financial problems in the NHS are also like to be a factor. Risk profiling focussed on evidence of governance or infrastructure problems and likelihood of a serious incident occurring.</td>
<td>Around 40 a year, working to a cycle of around 4 ½ years. Typically follow the two RM’s for one day format, although this may vary depending on the size and activity (including number of satellites), e.g. if research tissue is stored under a PM sector licence. Two-day inspections are becoming more frequent. Inspections prioritised according to risk. Storage for criminal justice purposes included in inspections under an agreement with the Home Office. Occasionally, undertake non-routine visits, e.g. as a result of an allegation or the incidence of HTARIs, and small number with UKAS, which includes unannounced inspections. Evidence emerging that current model provides insufficient scrutiny and consideration is being given to how approaches.</td>
<td>Shortfalls usually managed through CAPA process. For critical or major shortfalls, HoR involvement and follow-up inspection has proved effective in achieving required improvements. Very little need to resort to other regulatory tools such as licence variations, directions, etc. This may be because of the potential impact of significant regulatory action on the Coroner’s Service and loss of income if PMs were moved to other premises.</td>
<td>Every two years. Includes a scoring system that uses a system of red flags to highlight the potential for the occurrence of an HTARI based on the responses to key questions. Specific questions around capacity and contingency always included; data shared with DH and NHSE. Information gathered informs risk profiling and scheduling of inspections. Inspection timetables also informed by knowledge of the establishment (for example, tissue stored for research) and compliance history.</td>
<td>Intermittent updates on capacity &amp; contingency. HTARI system. Input to RCPA HTARI guidance. HWG, which informs regulatory approach and helps ensure compliance and proportionality.</td>
<td>Frequent and through various media: • Inspections • HTARI management • E-newsletters • Sector-specific publications • Website/FAQs • 1:1 contact • Enquiries • Attendance at others’ events, e.g. APT consent training LA events to check emergency mortuary licensing procedures</td>
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Human application

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<td>186 licensed sites (116 stand-alone sites, and 20 hubs with 50 satellites). Sector comprises a mix of public (e.g. NHSBT, hospitals, registered charities) and private (e.g. tissue banks, importers/distributors, storage facilities, hospitals, start-ups). Licensed activities: Procurement, testing, processing, storage, distribution, import and export of tissues and cells intended for human application.</td>
<td>Currently considered our highest risk sector, due in part to the potential impact that regulatory non-compliance could have on patient safety and clinical outcomes. However, it also reflects the complexity and diversity of the work undertaken in this sector and the heterogeneity of the organisations licensed, which includes many commercial organisations. In addition to inherent risk, the HTA’s assessment of risk in this sector is based on a number of factors including recent non-routine regulatory action (e.g. RDMs, issuing of Directions / Conditions), changes to a licence (e.g. change of DI, addition of new sites/activities) reports of serious adverse events and reactions (SAEARs) and complaints / investigations. A formal review of risk in the HA sector is currently ongoing.</td>
<td>Statutory requirement for inspections to be carried out at least every two years. As a result, we undertake approx. 70 HA inspections p.a., which equates to approximately 100 site visits if satellite sites are factored in. Inspections may be general system-oriented or thematic, depending on the assessment of risk for an individual establishment, and can range from one-day visits involving a single inspector for simple, low-risk establishments (i.e. a single site carrying out limited licensable activities with only one tissue type), to multi-day visits involving several inspectors for more complex sites (i.e. those carrying out the full range of licensable activities across multiple tissue types and on several sites). Our current inspection strategy in the HA sector includes joint or linked inspections with other regulators such as the MHRA, HFEA and CQC, as well as carrying out licence application assessment visits (LAAVs) prior to granting new licences. Non-routine inspections may be carried out in response to significant regulatory non-compliance (i.e. critical shortfalls), SAEARs, or in relation to any on-going regulatory action.</td>
<td>As for PM above. However, where these are not sufficient or effective at ensuring compliance, the HTA will consider the need for Directions, Conditions or other regulatory action (e.g. licence suspension/revocation).</td>
<td>HA establishments are required to report serious incidents (termed SAEARs) within 24hrs of discovery. HA establishments are also required to submit annual activity data. The Guide also requires establishments to conduct a compliance self-assessment at least every 12 months.</td>
<td>SAEARs system. Participation in expert groups (e.g. SaBTO, JPAC, EU Competent Authority meetings and biovigilance expert group meetings). Contribution to EU projects (e.g. VISTART, preparation process authorisation) RASRM MHRA/HTA technical liaison group meetings</td>
<td>As PM sector above. SAEARs Insights Guidance documents (public/professional) Position/policy statements</td>
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Research

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<td>305 licensed sites (111 stand-alone sites, and 52 hubs with 142 satellites). A growing sector, with 10-15 new applications per year. It is a heterogeneous sector with an almost equal proportion of establishments which are ‘academic’ or ‘commercial’ (making up 80% of all research sector establishments). Of the remaining 20%, half are NHS-affiliated and the remaining 10% are a mixture of others, including charities and partnerships e.g. academic and commercial. Licensed activities: • storage of research material (living and deceased) • removal of research material (deceased). We do not license the ‘use’ of tissue for research or approve individual research projects or clinical trials. Neither do we have a role in the ethical approval of research, although regulations to the HT Act allow human tissue held for a specific research project approved by a recognised REC (or where approval is pending) to be stored on premises without a HTA licence.</td>
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<td>Considered low inherent risk because of the nature of the licensable activities and consent is generally well understood. Also, there are other assurance factors in the regulatory environment, such as research ethics committees. Summary reports (of inspection and compliance update data) have confirmed that our research establishments are highly compliant with our regulation.</td>
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<td>Typically 15-20 ‘full’ inspections each year. As the research sector has been considered to be of low regulatory risk, inspections of research establishments have been scheduled across longer periods of time than in other sectors (3-9 years). Research establishments are selected and prioritised for inspection, taking into account the following factors: compliance update score (linked to level of compliance); analysis of individual responses to the compliance update questions, including the number of what we have marked as ‘red flags’ (linked to risks); time since the last inspection; and, incorporating establishments which were poorly compliant with the compliance update process or where other regulatory issues had come up in the interim. Research activities cut across into other sectors so we also undertake representative scrutiny of related research activities (e.g. research tissue banks) when inspecting relevant establishments in other sectors.</td>
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<td>Biennial compliance updates are collected and contribute to inspection prioritisation, sector oversight and strategic planning. Every licensed non-human application establishment is required to provide us with an update of licensing information and to complete a concise, sector-specific questionnaire focussed on risk and compliance with our standards. While the core administrative checks remain the same for each round of compliance updates, the sector-specific questionnaires are revised to keep pace with key risks and trends in activities or non-compliances.</td>
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<td>There is no mandatory reporting of adverse events. We have a broad-ranging MoU with HRA, which includes the sharing of information about matters of regulatory concern.</td>
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<td>Enquiries Website (including FAQs) On inspections Joint guidance (with other regulators) Sector-specific publications &amp; pieces in e-newsletter Webinars</td>
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### Regulatory tools session

**14 September 2017 HTA Authority meeting**

**Anatomy**

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| 52 licensed sites (28 stand-alone, and nine hubs with 15 satellites). Mostly academic institutions and training centres. In addition to anatomical examination, many facilities store and use human tissue for other purposes, such as surgical training and research. Licensed activities:  
- Storage of an anatomical specimen  
- Carrying out of an anatomical examination  
- Storage of a body or relevant material for a SP  
- Removal of relevant material from the deceased for a SP | Considered low risk as there is a long history of regulation and a well established culture of dignity and respect. Also, well-established and secure consent mechanisms. Summary reports (of inspection and compliance update data) have confirmed that our anatomy establishments are highly compliant with our regulation. Anatomy sector review, March 2015:  
- Data from 24 inspections (almost 4 years)  
- One major shortfall  
- 22 minor shortfalls  
- 152 items of advice  
- No shortfalls in 63% of inspections | Typically, three to five ‘full’ inspections each year. As the anatomy sector has been considered to be of low regulatory risk, inspections of anatomy sector establishments have been scheduled across longer periods of time than in other sectors (4-9 years). Anatomy sector establishments are selected and prioritised for inspection, taking into account the following factors: compliance update score (linked to level of compliance); analysis of individual responses to the compliance update questions, including the number of what we have marked as ‘red flags’ (linked to risks); time since the last inspection; and, incorporating establishments which were poorly compliant with the compliance update process or where other regulatory issues had come up in the interim. | Shortfalls managed through the CAPA process, with Head oversight. Inspections may be brought forward. Case Review and Regulatory Decision Making meetings used when required by our processes (occasional). Directions rarely used. | Biennial compliance updates are collected and contribute to inspection prioritisation, sector oversight and strategic planning. Every licensed non-human application establishment is required to provide us with an update of licensing information and to complete a concise, sector-specific questionnaire focussed on risk and compliance with our standards. While the core administrative checks remain the same for each round of compliance updates, the sector-specific questionnaires are revised to keep pace with key risks and trends in activities or non-compliances. | One unannounced site visit, as part of an investigation, has been undertaken. Attendance & participation in meetings. Collaboration e.g. with Anatomy Associations Advisory Committee. | Enquiries  
Website (including FAQs)  
On inspections  
Joint guidance (with other regulators)  
Sector-specific publications & pieces in e-newsletter  
Webinars |
Public display

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<tbody>
<tr>
<td>20 licensed sites (10 stand-alone, and four hubs with six satellites), which is the smallest of our regulated sectors. Storage of the body of a deceased person or relevant material from the body of a deceased person for use for a SIF &amp; the use, for the purpose of public display, of the body or a deceased person or relevant material which has come from the body of a deceased person. Storage and public display of tissue from the living are not subject to licensing.</td>
<td>Considered low risk because of the static nature of museum collections and the fact that many museums are accredited by Arts Council England, whose standards include many of our requirements. The exception is temporary exhibitions, which take place on premises other than those of a museum, for example Body Worlds. However, there is always an element public interest and the possibility of an adverse response from the public and the media.</td>
<td>We undertake a small number of PD inspections every year (an average, over the last 3 years, of five per year), to maintain visibility in the sector. The consent and disposal standards do not usually apply, because collections are neither being expanded nor reduced, so inspections focus on governance and quality systems, including collections management and traceability, along with premises, facilities and equipment. All newly-licensed establishments are subject to a site-visit inspection prior to material being put on show to the public. In this way we are able to assure ourselves that standards are met and provide advice and guidance, usually on matters relating to the dignity of the deceased. A small number are selected and prioritised for inspection, taking into account the biennial compliance update score (linked to level of compliance); any concerns about specific establishments and the time that has elapsed since the last inspection.</td>
<td>It is rare that we identify a shortfall, and when we do it usually relates to aspects of governance and quality, most commonly risk management. CAPA process is used to manage these. Biennial compliance updates are collected and contribute to inspection prioritisation, sector oversight and strategic planning. Establishments that are accredited by Arts Council England are required to provide less information, reducing the burden on them of this regular information-gathering exercise.</td>
<td>From compliance updates and inspection findings, we know that established museums are compliant with our standards and subject to very little change. Against this background, it is challenging to maintain a system of regulatory oversight that is proportionate and reflective of risk, whilst providing the sector with recognisable value for money.</td>
<td>Enquiries Website (including FAQs) On inspections Webinars</td>
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Regulatory tools session

14 September 2017 HTA Authority meeting

HTA meeting papers are not policy documents.
Draft policies may be subject to revision following the Authority meeting.
## Minutes of the eightieth meeting of the Human Tissue Authority

### Date
27 June 2017

### Venue
Etc. venues
One Drummond Gate, SW1W 2QQ

### Present

<table>
<thead>
<tr>
<th>Members</th>
<th>In attendance</th>
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<tbody>
<tr>
<td>Sharmila Nebhrajani, OBE (Chair)</td>
<td>Allan Marriott-Smith (Chief Executive)</td>
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<tr>
<td>Dr. Hossam Abdalla</td>
<td>Sarah Bedwell (Director of Regulation)</td>
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<tr>
<td>Amanda Gibbon</td>
<td>Vicky Marshment (Director of Policy, Strategy and Communications)</td>
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<tr>
<td>Prof. Andrew (Andy) Hall</td>
<td>Richard Sydee (Director of Resources)</td>
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<tr>
<td>William (Bill) Horne</td>
<td>Nicholas Baré (Head of Corporate Policy and Strategy)</td>
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<tr>
<td>Glenn Houston</td>
<td>Dr. Amy Thomas (Regulation Manager - Policy)</td>
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<tr>
<td>Prof. Penney Lewis</td>
<td>Sarah Kelly (Stakeholder Engagement Manager)</td>
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<td>Prof. Dame Sally Macintyre</td>
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<td>Bishop Graham Usher</td>
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<td>Dr. Lorna Williamson, OBE</td>
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<td>Prof. Anthony Warrens</td>
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### Apologies

- Dr. Stuart Dollow
- Jeremy Mean (Department of Health)
- Roger Wallis (Department of Health)

### Observers

- Rumku Basu-Owen (Department of Health)
Welcome and apologies

1. Sharmila Nebhrajani (the Chair) welcomed Members, attendees and members of the public to the eightieth meeting of the Human Tissue Authority.

2. The Chair noted that each year, the Authority holds one meeting in public, which is followed by the HTA’s annual conference. This year, the subject of the conference is conversations about death and dying.

3. The Chair advised that Amy Thomas (Regulation Manager - Policy) was in attendance to present Item ten – Understanding risk in the human application sector [paper HTA (26/17)]. Sarah Kelly (Stakeholder Engagement Manager) was also in attendance to present Item eleven on the agenda - Results of public evaluation.

4. The Chair noted that Rumku Basu-Owen would observe the meeting from the Department of Health.

5. Apologies were received from Authority Member Stuart Dollow. Jeremy Mean and Roger Wallis (Department of Health) also sent apologies.

Item 2 Declarations of interest – Oral

6. The Chair asked Members if they had any personal or pecuniary interests to declare in relation to items of the meeting’s agenda; none were declared.

Minutes of 4 May 2017 – HTA (21/17)

7. Ahead of the 27 June 2017 meeting, Members were asked to provide comments on the minutes for the Authority meeting on 4 May 2017.

8. Comments were provided by Stuart Dollow, Andy Hall, Amanda Gibbon, Penney Lewis and Lorna Williamson.
9. With the exception of these incorporated updates, the minutes were accepted as an accurate record of the meeting, and of the confidential session.

### Item 4 Matters arising from 4 May 2017 – Oral

10. The Chair noted that all actions from the 4 May 2017 meeting were resolved, ongoing in nature or would be addressed by the Senior Management Team (SMT) during the meeting.

11. Sarah Bedwell updated Members on the position regarding reimplantation or reallocation of an organ from a living donor when it cannot be implanted to the intended recipient. In most cases, this is discussed with the donor ahead of the operation and the decision recorded in the Independent Assessor’s report. Sarah Bedwell will discuss how well this is working with colleagues from NHS Blood and Transplant (NHSBT) when she next meets with them.

12. Amanda Gibbon, the Chair of the Audit and Risk Assurance Committee (ARAC), reported that internal auditors had observed a test of the HTA’s critical incidence response plan. The internal auditors offered limited assurance on the exercise, which Members of the Committee considered to be a severe analysis. However, the internal auditors assured the Committee that the scope of their time available for the exercise (it was not a full internal audit) was part of the reason for the limited rating.

13. Vicky Marshment updated Members on the HTA’s licensed establishment relationship programme, which is seeking to increase engagement with establishments. The HTA will shortly be launching online training materials for licensed establishments, which will be followed by the development of an online forum.

14. Sarah Bedwell reported that HTA colleagues were continuing to identify suitable inspections for Members to attend, with a view to ensuring that all Members that have not been on an inspection, would have the opportunity to do so.

15. The Chair asked Members for any further matters arising; none were raised.
### Item 5  Chair’s Report – Oral

16. The Chair highlighted meetings of note that she had attended since 4 May 2017.

17. On 30 May 2017, Members took part in their third teleconference to discuss organ donation panel cases, with the next meeting scheduled for 31 July 2017.

18. On 8 June 2017, the Chair met with Clara Swinson, Director General for Global and Public Health at the Department of Health, for an appraisal of her performance in 2016/17. The Chair noted that once she had received the report from that meeting and her objectives for the 2017/18 year, these objectives would form the basis of those for fellow Authority Members.

19. On 18 June 2017, the Chair attended the HTA’s ARAC meeting, at which Members recommended that the annual accounts and report be approved by the Accounting Officer. They will be laid in the both Houses on 6 July 2017. The Chair thanked the HTA’s finance team for producing a robust report and accounts.

20. On 21 June 2017, the Chair chaired a meeting of the Understanding Patient Data Steering Group. The Chair noted that this was an important initiative, supported by the Wellcome Trust and the Department of Health, to encourage a rigorous conversation about patient data for research.

21. The Chair noted that Bill Horne was reappointed as the HTA’s Welsh Member, by the Welsh Cabinet Secretary for Health, Wellbeing and Sport, to serve until August 2020. His tenure was due to end on 31 July 2017. The Chair thanked Bill for his continuing valuable contribution to the work of the Authority.

22. The Chair noted that the Authority’s Remuneration Committee would meet on 4 July 2017, to discuss the pay remit for HTA colleagues.

23. The Chair invited Rumku Basu-Owen to provide an update from the Department on the progress of the transposition and implementation of the Human Tissue Amendment.
Regulations 2017, which deliver the European Union Directives for Coding and Import. Rumku Basu-Owen reported that there was no update to provide on the Directives, as the new Minister had not set out how she would be proceeding on the subject. Jackie Doyle-Price, the new Minister, was due to meet with Jeremy Mean at the Department on 28 June 2017. Rumku Basu-Owen also reported that she had no update on the reappointment of four Authority Members, whose tenures are due to come to an end in October 2017.

**Item 6 Chief Executive’s Report – HTA (22/17)**

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

25. The Chief Executive noted that at standard quarterly reporting meetings of the Authority, reports are presented to update Members on the HTA’s delivery of its key performance indicators. As this was not a quarterly reporting meeting, this paper would address the main developments since the Authority’s last quarterly meeting on 4 May 2017.

26. Allan Marriott-Smith reported that the SMT had reviewed its strategic risk register in June and reduced the residual risk for risk one – *failure to regulate appropriately* – as the recruitment of new Regulation Managers has increased capacity at the HTA. The residual risk for risk five – *insufficient or ineffective management of financial resources* – also reduced during June. Although budget pressures remain tight, the quarter one expenditure plan is forecast to come in on budget.

27. Allan Marriott-Smith noted that the report provided details on deterrents to organ trafficking, and how trafficking is monitored in the United Kingdom (UK), to respond to interest expressed by Authority Members at the 4 May 2017 meeting. The HTA will continue to work with NHSBT to ensure that recommendations of a world summit of organ trafficking and tourism are implemented to address international concerns.

28. The Chief Executive noted that the report provided an update on policy areas which lie at the border of the HTA’s statutory remit, where the public may look to the HTA for confidence.
29. Allan Marriott-Smith noted that the University of Huddersfield continues to develop a proposal for a human forensic taphonomy facility. The HTA is working with the Home Office to consider how this facility and related activities might be regulated. The Authority will be provided with an update at its September meeting, setting out significant issues, and a timetable for recommendations. This will include background on how taphonomy facilities operate in other countries, particularly in regard to consent and security, to help Members to form a view on how the facility might be regulated.

30. The HTA continues to consider what information could be made available for the public on cryopreservation, and for those who may be asked to facilitate the cryopreservation process as part of their job, for example, those working in licensed establishments. Any draft information will be shared with the Authority for comment.

31. Allan Marriott-Smith reported that the delay on a decision on the transposition of the European Union Coding and Import Directives, caused by the General Election was creating uncertainty for licensed establishments in the human application sector. To ease this uncertainty, the HTA continues to advise licensed establishments on what the Directives may mean in practice for them on a case-by-case basis.

32. In June, the HTA scoped and began various projects and activities, including:
   a. establishing a formal horizon scanning function at the HTA, to respond to changes in the external environment;
   b. reviewing the sustainability of the Independent Assessor Framework and continuous accreditation of Independent Assessors; and
   c. developing the licensed establishment relationship programme.

33. The Chief Executive reported that changes were introduced to the HTA’s personal development planning (PDP) process, to address results of a survey in 2015/16, in which staff
reported that they did not feel the PDP process improved their performance. Changes to the process focus planning on development needs, which are supported by detailed guidance documents, to make PDP discussions more beneficial.

34. Allan Marriott-Smith reported that the HTA has involved staff at an early stage of the development of a strategy proposal for the period 2018-21, at an away morning on 12 June 2017. The Chair added that she had personally emphasised the importance of staff contributing to the development of the proposal, which will be considered by the Authority at its strategic away day on 19 October 2017.

35. The Authority noted the content of this report.

**Action One:** Provide Members with the minutes of the 24 May 2017 accountability meeting with the Department of Health.

**Action Two:** Provide Members with an update on taphonomy at its 14 September 2017 meeting.

**Action Three:** Provide Members with any draft information on cryopreservation for comment if necessary.

**Item 7 Audit and Risk Assurance Committee Update – HTA (23/17)**

36. Amanda Gibbon, ARAC Chair, presented this item and introduced the paper, which provided Members with an assessment of the Committee’s meeting on 18 May 2017, and overall annual activity.

37. Amanda Gibbon reported that the National Audit Office had recommended certification of the HTA’s 2016/17 financial statements with an unqualified audit opinion.

38. In addition, internal auditors had recommended moderate assurance for the HTA in their Internal Audit Annual Assurance Report for 2016/17, noting that the HTA had effective systems in place for the reporting year.

39. The ARAC Chair reported that a new Head of Internal Audit, Jeremy Nolan, had been appointed during the year, who is employed by the Government Internal Audit Agency. He will
carry out this role jointly for the HTA and the Human Fertilisation and Embryology Authority (HFEA). Jeremy Nolan presented a draft 2017/18 Internal Audit Plan for the consideration of the Committee at its 18 May 2017 meeting, which focuses on cyber security and stakeholder engagement activities.

40. The ARAC Chair reported that the Committee had considered the Director of Finance’s assessment of the 2016 Caldicott Review, and that no substantive changes would be required to the HTA’s information assurance framework.

41. The ARAC Chair reported that throughout 2016/17, the Committee had carried out deep dive reviews on areas of identified risk, to explore them in greater detail with relevant staff members. These reviews included:

   a. reduced income arising from the impact of the spending review;
   b. the HTA’s approach to staff turn-over; and
   c. risks in the human application sector and public confidence in HTA regulation.

42. The ARAC Chair expressed her gratitude for the high quality of work that members of staff had contributed to these reviews.

43. The Authority noted the content of this paper.

Item 8 Advisory Groups Update – HTA (24/17)

44. Bill Horne, Chair of the Stakeholder and Fees Group, introduced this item and presented elements of this paper, which related to the Stakeholder and Fees Group.

45. Bill Horne thanked Members of the Authority who sit on the HTA’s three advisory groups for their input throughout 2016/17. This paper provided Members with an update on their activities.

46. Bill Horne reported that the Stakeholder and Fees Group considered a number of substantive issues throughout the year, including the development of the licensed establishment...
relationship programme, mentioned earlier in the meeting by Vicky Marshment.

47. Bill Horne reported that the Group had input into a number of policy areas including:
   a. joint inspections with the Medicines and Healthcare products Regulatory Agency (MHRA), to reduce inspection burdens on licensed establishments;
   b. reviewing and updating the HTA’s representations process;
   c. reviewing proposed changes to the HTA’s codes of practice and standards; and
   d. feedback, following input from the HTA’s public review panel, on the development of lay guides for the updated codes of practice.

48. Bill Horne reported that the Group also reviewed responses to the HTA’s consultation on changes to its licensing fees, and the finalised fees proposal. The Group agreed with the proposal to increase the HTA’s budget to allow for increased staffing and information technology development.

49. Sarah Bedwell presented elements of this paper, which related to the Histopathology Working Group (HWG), and the Transplantation Advisory Group (TAG).

50. Sarah Bedwell reported that the HWG meets to maintain a strategic oversight with stakeholders across the post-mortem sector. HWG works closely with the Royal College of Pathologists to develop meeting agendas, which enable the group to consider relevant and topical issues.

51. Of particular note in 2016/17, HWG considered issues around mass fatalities. HWG has also contributed to discussions around mortuary capacity and contingency arrangements.

52. Sarah Bedwell reported that TAG meets as a forum to provide strategic oversight for issues mainly arising in living organ donation.

53. Of particular note, TAG will consider a number of issues at its meeting on 18 October 2017, including:
a. revisions to the statutory referral letter, which will be considered over the summer;
b. a potential review of revised guidance for transplant units and Independent Assessors; and
c. the sustainability of the Independent Assessor framework and review of the reaccreditation process.

54. The Authority’s Chair noted that the HTA will be reviewing its advisory groups over the summer to assess how they operate, the sectors they cover and their memberships. The review aims to identify operational best practice and any standardised processes that could improve how they deliver their respective remits.

55. The Authority noted the content of this paper.

**Item 9**  
**HTA Strategy Review 2018 to 2021 – HTA (25/17)**

56. Allan Marriott-Smith presented this item and introduced the paper.

57. The Chief Executive reported that HTA is currently in year two of a three-year strategy. At this time, a fundamental review of the strategy is being carried out, to consider if the HTA’s strategic approach is delivering optimum confidence for professionals working in the establishments that the HTA regulates and is delivering confidence to the public, by ensuring the safe and ethical removal, storage and use of human tissue and organs, with proper consent.

58. Allan Marriott-Smith noted that the findings of the two subsequent items on the agenda (Item ten: Understanding risk in the human application sector, and Item eleven: Results of the public evaluation) would form a part of a proposal that will be presented to the Authority at a dedicated strategy meeting on 19 October 2017. These findings will be considered alongside other inputs in the proposal, which are currently being developed.

59. Allan Marriott-Smith noted that the knowledge and expertise of HTA colleagues was being drawn upon in the development of inputs for the proposal, as well as through a range of all-
staff meetings, and at the monthly HTA Management Group meetings.

60. The proposal will provide an analysis of these inputs, which will facilitate Members in making a decision on the direction for the 2018-21 strategy. This direction will then be developed into a final strategy document by the end of March 2018.

61. Members identified elements that they regarded as essential to the strategy proposal. These included:

   a. public and professional feedback on confidence in the HTA’s regulation;
   b. consideration of the longer-term licensing fee structure;
   c. consideration of the HTA’s regulatory role in respect to the role of other healthcare regulators;
   d. adequate time for Members to review resources and the proposal itself, in the build-up to the October meeting.

62. Members noted the scope and timing proposed in the paper.

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<th>Item 10</th>
<th>Understanding risk in the human application sector – HTA (26/17)</th>
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63. Amy Thomas presented this item and introduced the paper.

64. In a presentation to the Authority, Amy Thomas set out details of a project to review risk in the human application sector. A sector which is complex and diverse, requiring licensing for a range of activities.

65. The project will draw its evidence from:

   a. existing data sources, including licensed establishment profiles, inspection findings and serious adverse events and adverse reaction (SAEARS) data;
   b. stakeholder input, including user surveys and focus groups; and
   c. expert feedback, from HTA colleagues and other regulators.

66. The findings of the project will include a recommendation on a future model for human application regulation, which will
form a part of the HTA’s proposal document for the Authority’s strategy meeting in October.

67. Members thanked Amy Thomas for her paper and presentation, and noted the short timeframe for what is an ambitious project.

68. It was noted that Sam Abdulla expressed his interest in contributing to the project, where possible.

**Item 11  Result of public evaluation – Presentation**

69. In a presentation to the Authority, Sarah Kelly set out details of qualitative research commissioned by the HTA, which sought public views through focus groups and in-depth interviews. The research aimed to establish:

   a. the level of public awareness of the HTA;
   b. assumptions of what the HTA does;
   c. regulation priorities of the public, by sector;
   d. levels of interest in what the HTA does; and
   e. levels of priority in what the HTA does.

70. Sarah Kelly also reported that a quantitative online survey of 10,000 respondents would be carried out in July 2017.

71. The results of the survey, will be combined with the results of the focus groups and in-depth interviews, to create a detailed report on the public’s views on the HTA and its regulation. This report will also form a part of the HTA’s proposal document for the Authority’s strategy meeting in October.

72. The Authority thanked Sarah Kelly for the presentation.

**Item 12  Question and answer session – Oral**

73. The Chair asked Members of the Authority and members of the public for questions on agenda items or general questions for the HTA.

74. Q: Lauren Savage, from Thermo Fisher, noted that when carrying out employee inductions, it is difficult for companies such as hers, which are regulated by the HTA, MHRA and the HFEA, to explain how the three regulators cross over and
interact. Does the HTA have a map to explain this? A: Sarah Bedwell responded that we do not have something that could be used by third parties, but this is useful feedback for the Regulatory Advice Service for Regenerative Medicines. The HTA does have this presentation on its website, which explains its role in advanced therapy medicinal products.

75. Q: Douglas McKechnie, from AstraZeneca, noted that former designated individual training supplied by the HTA was an excellent resource for explaining the basics of human tissue regulation. Would the HTA consider releasing something similar. A: Vicky Marshment encouraged delegates to sign-up to the HTA e-newsletter, to receive information about resources that are being released as a part of the licensed establishment relationship programme.

76. Q: Isabelle Heyerdahl-King, from the University of Sheffield, was interested to understand if there is a formal resolution process for when families wish to override consent given for body donation by deceased family members. A: Penney Lewis, Authority Member, responded that she was not aware of any formal resolution mechanisms.

77. The discussion then moved on to family objections in cases for deceased organ donation, where the person had provided consent prior to death. Bill Horne noted that numbers of family challenges in Wales since the introduction of deemed consent have been very small. Sarah Bedwell added that where there is conflict with the wishes of the deceased, medical professionals have a range of approaches that they can take with families. While families have no legal right to overturn a legal consent, the fact they do not support the donation is likely to prevent the donation proceeding in such cases.

78. Fidelma Murphy, from NHSBT, highlighted the importance of having conversations about organ donation before death, as families will be much less likely to overrule the wishes of the deceased in such cases.

79. Penney Lewis, Authority Member, added that she is involved with a European platform, Ethical, Legal and Psychosocial Aspects of organ Transplantation (ELPAT). ELPAT is
researching ethical considerations of families overriding the donation wishes of the deceased and will soon be publishing findings.

80. Q: Sam Abdulla, Authority Member, asked whether evidence was available yet regarding the impact of the change to deemed consent in Wales. A: Karen Morgan, from the Welsh Government, responded that it was still too early to know. Vicky Marshment added the qualitative and quantitative research on the changes, commissioned by the Welsh Government, was due to be published in late 2017.

81. Q: Sally McIntyre, Authority Member, asked was there a statutory reason why the human application sector was named as such, as the name is unhelpful to those from outside of the sector. A: Sarah Bedwell responded that the name “human application” came from the European regulations, but the HTA can use another term to describe the sector. The Chair asked HTA colleagues to consider this point.

82. The Chair encouraged members of the public who did not have a chance to raise questions or comments to record them on the boards that would be available after the lunch break.

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<th>Item 13</th>
<th>Any Other Business – Oral</th>
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<td>83.</td>
<td>The Chair asked Members to raise any other business.</td>
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<tr>
<td>84.</td>
<td>No further business was raised.</td>
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The meeting closed at 12:25.
Chief Executive’s Report

Purpose of paper

1. This paper provides an overall assessment of the strategic risks currently facing the HTA as set out in Annex A. The paper also reports on other issues of strategic interest emerging over quarter one, July and August 2017, that are not reported elsewhere.

Decision-making to date

2. This report was considered by the Senior Management Team (SMT) at its meeting on 7 September 2017.

Action required

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

Overview of strategic risks

4. All strategic risks (found in Annex A) were assessed to be stable as of August 2017. In June, SMT has downgraded the residual score of risk one – *Failure to regulate appropriately* from amber to green. This is as a result of the greater stability in the Regulation Manager cadre and the growing experience of the newer recruits. This risk remained stable in August.
5. All other residual risk scores were unaltered since the last report. Strategic risk five – *Insufficient or ineffective management of financial resource* – is discussed in greater detail in the Deployment Report.

**Other issues**

**Feedback from the HTA Annual Conference**

6. Each year following the Annual Conference, we seek to evaluate what went right and what may need to be developed or changed, both in the run-up and during the day itself. This year we received some helpful feedback from colleagues, which we will use to improve next year’s event.

7. The HTA has a Performance Indicator (PI:17) relating to delegate satisfaction from the Annual Conference. The performance indicator is, “Feedback from the event is positive, with 80% or more attendees reporting that the day was interesting, well run, and that they would attend again (and / or recommend it to others)’’.

8. Delegates (41 in total) who kindly took the time to fill out the feedback forms on the day told us:

   a. 100% positive - I enjoyed the event (n = 41);
   b. 98% positive - The talk and discussions in the afternoon were interesting and engaging (n = 40);
   c. 90% positive - The venue was suitable for the event (n = 32);
   d. 88% positive - The event was a good way to engage with those affected by the HTA regulation (n = 40);
   e. 75% positive - The Public Authority meeting in the morning was informative and useful (n = 29); and
   f. 34% positive - The networking and drop-in session was useful (n = 41).

9. We will take this feedback into account for event planning for the 2018 Annual Conference, particularly looking at how we ensure the networking and drop-in session can be better used and more useful to delegates. This will involve consulting this year’s delegates on their thoughts for 2018 as well as our own staff.

**Development of the strategy proposal**

10. As reported at the 27 June public Authority meeting, the HTA is in the process of developing a proposal that will allow Members to consider if the HTA’s current strategy might need to be changed to better protect public and professional confidence for the period 2018-2021.
11. The Head of Corporate Policy and Strategy has worked with the Senior Management Team (SMT) and the wider HTA Management Team to develop and agree an outline plan to ensure that those involved in the production of the proposal document are aware of the required scope and milestones.

12. The proposal document will be based on an evaluation of evidence that will be derived from a range of sources, some of which have been previously considered by the Authority. While the proposal will draw on the sources of evidence being developed as a part of the HTA’s wider programme of development projects, we will not be bringing forward the dates that have already been agreed for existing projects. However, residual questions raised through the evidence gathering process that cannot be answered at the time of the strategy proposal’s completion will be identified and addressed once the Authority has agreed a direction of travel.

13. The proposal will seek to answer twelve strategic questions that will provide Members with:
   a. an introduction to the development of the strategy proposal;
   b. an evaluation of the HTA’s operating environment for 2018 - 2021;
   c. consideration of the HTA delivery model and deployment of its resources; and
   d. conclusions and next steps.

14. A first draft of the strategy proposal will be reviewed by the HTA Management Group at its meeting on 21 September 2017. Following further development, the proposal will then be considered by SMT, before being dispatched to Members on 5 October, ahead of the 19 October strategy away-day. The away-day itself will be facilitated by Jonathan Bowyer from Fiona Reed Associates: an organisation that has worked with Authority on a number of occasions.

Cyber and data security

15. There have been no reported or detected cyber security incidents or data protection breaches during quarter one.

16. The HTA last carried out an independent security assessment of its public facing internet and portal infrastructure in 2013. It is recommended that these assessments be carried out annually, with varying scope. The new Head of Business Technology will propose the scope for an assessment to be carried out this financial year and work with finance colleagues to budget for ongoing annual assessments.

17. The Head of Business Technology has signed up to receive cyber security threat notifications from NHS Digital CareCERT. He will combine this with other threat intelligence to create a threat register and work with BCC (our managed service
supplier) and other suppliers to protect the HTA information and communication technology (ICT) environment against these threats.

18. Currently, there are a number of published cyber and data security frameworks in use at the HTA, and others available to which we reference and align. The HTA also considers the Government’s response to the National Data Guardian (NDG) for Health and Care’s Review of Data Security (in particular the acceptance of the ten data security standards) in its cyber and data security standards. The Head of Business Technology will seek to draw out the commonality between the major frameworks including the NDG’s ten standards and will, without risking non-conformity or compromising security, develop a single cyber security framework for the HTA by quarter four.

Organ donation opt-out in England / Scotland

19. Dan Jarvis, MP has outlined his intention to lobby to change the law to that of an opt-out system in England. In addition, a Private Members Bill has been brought forward by Geoffrey Robinson MP. The Bill received its first reading on 19 July 2017. The second reading is scheduled for 23 February 2018.

20. At a Westminster Hall debate held on 13 July 2017, Jackie Doyle Price MP, the new Parliamentary Under Secretary of State, set out the Government’s priorities. These were:
   a. a continued focus on engagement with the Black, Asian and minority ethnic (BAME) communities;
   b. continued investment in Specialist Nurses for Organ Donation (SNODs); and
   c. consideration of an opt-out system.

21. The Scottish Government, having consulted, is proceeding with plans to introduce an opt-out system for deceased organ donation, similar to the system introduced in Wales in 2015. This will be part of a package of measures aimed at increasing the number of organs donated for transplantation.

European Union (EU) Joint Action – Preparation processes

22. The HTA recently agreed to participate in an upcoming EU Joint Action on the authorisation of preparation processes. As an Associate Partner on three of the project’s work packages, the HTA will receive funding from the project’s budget.

23. In July, the HTA was required to provide a number of documents to the Commission in order to verify our legal status. One of these, the ‘FEL Form public entity’, required the use of the HTA’s corporate seal.
24. Standing Order 87 states that the, “seal shall not be fixed to any documents unless the sealing has been approved by the resolution of the Authority”. Given the short turnaround time required by the EU agency to participate, I approved the use of seal on the condition that it would be reported to the Authority at this meeting.

Taphonomy

25. SMT has considered a paper on the proposed establishment of a Human Taphonomy Centre in the United Kingdom and the risks and issues this might pose from a regulatory and public confidence perspective.

26. Further work is now being taken to explore the risks arising in relation to consent, traceability and storage, and how regulation could mitigate these risks. This work will include exploring how such facilities are regulated elsewhere and what powers are available under the Human Tissue Act 2004. We will update on progress at the November meeting.

Cryopreservation

27. In assessing relative priorities, SMT has agreed that further work on cryopreservation guidance should be postponed until later in the business year. In line with previous Authority discussions, the HTA still intends to publish light-touch guidance for the public and licensed establishments.

Meeting with new Minister

28. On 6 September 2017, the Chair and I met with Jackie Doyle-Price MP, the new Parliamentary Under-Secretary of State at the Department of Health. The meeting introduced the Minister to the work of the HTA and the key issues we face. Topics covered included our role in relation to organ donation, regulation of mortuaries, matters at the periphery of our regulatory remit and our role in supporting the Industrial Strategy for Life Sciences.

Accountability to the Department

29. The HTA met with the Department of Health on 18 July 2017 as part of its regular accountability meetings. Items on the agenda included:

   a. the Department / HTA framework Agreement, which has been revised;
   b. 2017/18 capital requirements have been agreed (£250k in 2017/18);
   c. an update on EU Coding and Import Directives; and
   d. an update on setting the Chair’s objectives for 2017/18.
30. We also outlined our progress against key performance indicators and our current assessment of strategic risk.

31. During the meeting, the Department offered the HTA support in addressing the systemic issue of the (potentially insufficient) number of Independent Assessors in the context of NHS Blood and Transplant’s strategy to increase living transplantations by 2020.

Meeting with HFEA and HRA Chief Executives

32. I met with the Chief Executives of the Human Fertilisation and Embryology Authority (HFEA) and the Health Research Agency (HRA) on 11 July as part of a regular series of meetings to share information and identify potential areas for collaboration.

33. All three organisations are currently looking to make better use of data holdings to improve business performance. The HFEA has recently appointed to a new Head of Intelligence post. All three organisations agreed that we will look at the merits of an intelligence forum early in the new-year to share ideas and experience.

All-staff away morning

34. On 11 September 2017, HTA colleagues will come together for one of our quarterly all-staff away mornings. This meeting will have a specific focus on the preparatory work that is taking place for the development of the strategy proposal, which the Authority will be considering on 19 October 2017.

35. During the morning, those who are leading on the development of the specific elements of the strategy will be running group sessions with colleagues to seek feedback on important questions. Colleagues will also take part in an interactive sessions on horizon scanning and the post-implementation review of the Codes and Standards implementation project.

Complaints report

36. The HTA has received no complaints about the organisation in quarter one.
Overview: Risks reflect the strategy for 2016-19 (year two update published in April 2017 (2017/20 document)). Our highest risks are now the failure to manage expectations of regulation, which reflects the fast-pace of change within the sectors we regulate and the low likelihood of legislative change in the foreseeable future, and failure to utilise our capabilities effectively which is currently affected by the fact the Head of Business technology is new to the organisation.

Other notable risks: Final delivery of some of one of the HTA’s key projects (Coding and Import) remains in part in the hands of others. The HTA can deliver our part but is not in control of other actions necessary before implementation. Delays may affect the attitude of our stakeholders and the HTA’s reputation. Further uncertainty is caused by Brexit and the changes in Government following the General Election.

A number of more recently recruited Regulation Managers are now approaching sign off and recruitment to key posts has now been completed. This will increasingly have a mitigating impact.

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<th>Risk</th>
<th>Jun 2017</th>
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<th>Comments</th>
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<td>1 - Failure to regulate appropriately</td>
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<td>4 - Failure to utilise our capabilities effectively</td>
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<td>(Development a-d)</td>
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<td>(Deployment a &amp; c)</td>
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<td>5 - Insufficient, or ineffective management of, financial resources</td>
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<td>(Deployment b)</td>
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</table>

**Strategic Objectives**

**Delivery** – to deliver the right mix of activity to main public and professional confidence

- a) To deliver right-touch regulation and high quality advice and guidance, targeting our resources where there is most likelihood of non-compliance and greatest risk to the public
- b) To be consistent and transparent in our decision making and regulatory action, establishing those licence holders who are committed to achieving high quality and dealing fairly and fairly with those who do not comply with our standards
- c) To deliver effective regulation of living donation
- d) To inform and involve people with a professional or personal interest in the areas we regulate in matters that are important to them and influence there in matters that are important to us
- e) To maintain our strategic partnerships with other regulators operating in the health sector

**Development** – to make the right investment in development to continuously improve delivery

- a) To reduce regulatory burden where risks to public confidence are low
- b) To make it cleaner how to achieve compliance with new and existing regulatory requirements
- c) To make continuous improvements to our systems and processes to minimize wasted or duplicated effort
- d) To take opportunities to better inform and involve the public

**Deployment** – to make the most effective use of our people and resources in pursuit of our goals

- a) To manage and develop our people in line with the HTA’s People Strategy
- b) To ensure the continued financial viability of the HTA while charging fair and transparent licence fees and providing value for money
- c) To provide a suitable working environment and effective business technology

Risks are assessed by using the grid below
<table>
<thead>
<tr>
<th>REF</th>
<th>RISK/RISK OWNER</th>
<th>CAUSE AND EFFECTS</th>
<th>INHERENT RISK PRIORITY</th>
<th>PROXIMITY</th>
<th>REGULATORY MODELS/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>1</td>
<td></td>
<td>Failure to regulate in a manner that maintains public safety and confidence and is appropriate (Risk to Delivery objectives a-c &amp; d Development objectives a-d)</td>
<td>3 4 5 6</td>
<td>Ongoing</td>
<td>Regulatory model</td>
<td>HFA Strategy 2017 to 2020 clearly articulates the HTA's regulatory model</td>
<td>X 2 3</td>
<td>Preventative Authority developed and approved the HTA Strategy</td>
<td>1</td>
<td>Preventative</td>
<td>HTA Strategy published on 1 April</td>
</tr>
<tr>
<td>Risk Owner: Allan Marriott-Smith</td>
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<td></td>
<td></td>
<td>Regulatory decision making framework</td>
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<td></td>
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<td></td>
<td>Annual scheduled review of Strategy</td>
<td>X 2 3</td>
<td>Preventative</td>
<td>Reports to Authority of key decisions in Delivery Report</td>
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<td></td>
<td>Approved HTA Business Plan 2017/18</td>
<td>X 2 3</td>
<td>Preventative</td>
<td>Sign off of the business plan by the Chair on behalf of the Authority and by sponsor Department</td>
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<td></td>
<td>Quality management systems</td>
<td></td>
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<td></td>
<td>HFA quality management system contains decision making framework, policies and Standard Operating Procedures to achieve adherence to the regulatory model</td>
<td>X 2 3</td>
<td>Preventative/Monitoring</td>
<td>Individual staff Member responsible for QMS, estimated review reminders, management oversight of progress on updates</td>
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<td></td>
<td>People</td>
<td></td>
<td></td>
<td></td>
<td>HTA People Strategy roadmap 2017/18</td>
<td>X 2 3</td>
<td>Preventative</td>
<td>Management information and assessment presented to the Authority quarterly as part of the Deployment report</td>
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<td></td>
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<td>Training and development of professional competence</td>
<td>X 2 3</td>
<td>Preventative</td>
<td>Annual PDPs, RM proposals to SMT</td>
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<td>Specialist expertise identified at recruitment to ensure we maintain a broad range of knowledge across all sectors and in developing areas</td>
<td>X 2 3</td>
<td>Preventative/Monitoring</td>
<td>SMT assessment of skills requirements and gaps as vacancies occur, Recruitment policy</td>
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<tr>
<td>Other</td>
<td>Quality management systems</td>
<td></td>
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<td></td>
<td>Internal audit of quality management system adequacy and adherence (VM) by March 2017</td>
<td>X 2 3</td>
<td>Monitoring</td>
<td>The following to be refined when controls in place</td>
<td></td>
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<td></td>
<td>Regulatory model</td>
<td></td>
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<td>Delivery of Licensing and inspection review projects to strengthen our regulatory model (VM) 2017/18</td>
<td>X 2 3</td>
<td>Preventative</td>
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<td>Extension of reporting arrangements to adverse events in the Research sector (SB) Proposals developed by Q2 2017/18</td>
<td>X 2 3</td>
<td>Preventative</td>
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<td></td>
<td>People</td>
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<td>Fundamental review of the People Strategy Q2 2017/18</td>
<td>X 2 3</td>
<td>Preventative</td>
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<td></td>
<td>Other</td>
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<td>Strengthening horizon scanning arrangements (VM) by Q2 2017/18</td>
<td>X 2 3</td>
<td>Preventative</td>
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<td></td>
<td>Embed Better Regulation initiatives in the regulatory model (VM) by Q2 2017/18</td>
<td>X 2 3</td>
<td>Preventative</td>
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<td>REF</td>
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<td>PREVENTATIVE</td>
<td>RESIDUAL RISK PRIORITY</td>
<td>ACTIONS TO IMPROVE MITIGATION</td>
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<td>2</td>
<td>Inability to manage an incident impacting on the delivery of HTA strategic objectives. This might be an incident:</td>
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<td>5 3</td>
<td>Future, should event occur</td>
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<td>3 2</td>
<td>1 2 3</td>
<td>Preventative</td>
<td>Monthly reports to HTAMG</td>
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<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>
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<td>• caused by deficiency in the HTA’s regulation or operation</td>
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<td>• where we need to regulate, such as with emergency mortuaries</td>
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<td>• Insufficient capacity and/or capability (for instance, staff availability, multiple incidents or ineffective knowledge management)</td>
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<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>
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<td>• Failure to work effectively with partners/other organisations</td>
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<td>• IT failure or attack incident affecting access to HTA office</td>
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<td>• Loss of public confidence</td>
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<td>• Reputational damage</td>
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<td></td>
<td>• Legal action against the HTA</td>
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<td>• Intervention by sponsor</td>
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<td><strong>Preventative</strong></td>
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<td>Sarah Bedwell</td>
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**HTA meeting papers are not policy documents. Draft policies may be subject to revision following the Authority meeting.**
<table>
<thead>
<tr>
<th>REF</th>
<th>RISK/RISK OWNER</th>
<th>CAUSE AND EFFECTS</th>
<th>INHERENT RISK PRIORITY</th>
<th>CAUSE</th>
<th>EXISTING CONTROL/SIGNATURES</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>2</td>
<td>Failure to manage public and professional confidence in regulation in particular stemming from limitations in current legislation or misperception of HTA regulatory reach</td>
<td>External factors</td>
<td>4 / 4</td>
<td>Ongoing</td>
<td>Log of issues known to the HTA with respect to the legislation to inform DH and manage messages</td>
<td>4 / 3</td>
<td>Monitoring</td>
<td>Log In place and reviewed at HTAMG quarterly. New issues identified in causes and effects.</td>
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</tbody>
</table>

**Risk Owner:** Vicky Marshment

**Inherent Risk Priority:**

- Diminished professional confidence in the adequacy of the legislation
- Reduced public confidence in regulation of matters relating to human tissue
- Reputational damage

**Proximity:**

- Scope of relevant material e.g. waste products
- Implementation of the coding and import directives in light of Brexit
- Implementation of triennial review recommendations

**Existing Control/Signature:**

- Duties and its use understood by SMT and Chair
- Full year accountability meeting in May 2017 - positive.
- DNA project
- Legal advice now gives a clearer view of our Schedule 2, s. 20 powers
- Legal advice to be followed

**Actions to Improve Mitigation:**

- Duties and its use understood by SMT and Chair
- Full year accountability meeting in May 2017 - positive.
- DNA project
- Legal advice now gives a clearer view of our Schedule 2, s. 20 powers
- Legal advice to be followed

**Line of Defence:**

- Duties and its use understood by SMT and Chair
- Full year accountability meeting in May 2017 - positive.
- DNA project
- Legal advice now gives a clearer view of our Schedule 2, s. 20 powers
- Legal advice to be followed

**Type of Control:**

- Duties and its use understood by SMT and Chair
- Full year accountability meeting in May 2017 - positive.
- DNA project
- Legal advice now gives a clearer view of our Schedule 2, s. 20 powers
- Legal advice to be followed

**Assurance Over Control:**

- Duties and its use understood by SMT and Chair
- Full year accountability meeting in May 2017 - positive.
- DNA project
- Legal advice now gives a clearer view of our Schedule 2, s. 20 powers
- Legal advice to be followed

**Assured Position:**

- Duties and its use understood by SMT and Chair
- Full year accountability meeting in May 2017 - positive.
- DNA project
- Legal advice now gives a clearer view of our Schedule 2, s. 20 powers
- Legal advice to be followed
### Table: Risk Assessment and Control Measures

<table>
<thead>
<tr>
<th>REF</th>
<th>Risk/Owner</th>
<th>Cause and Effects</th>
<th>Inherent Risk Priority</th>
<th>Proximity</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>
</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 SM and Heads  
• Data holdings poorly managed and under-exploited  
• Inadequate business technology or training in the technology available | 4 4 | People | 4 3 | | | | | | | Currently in the middle of a regular review cycle |
|     | Risk to Delivery objectives a-d  
Development objectives a-d  
Deployment objectives a & c | | | | | | | | | | |
|     | Risk Owner: Allan Marriott-Smith | | | | | | | | | | |
|     | 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 | Data |  |  | X X Preventive/ Monitoring | Upgrades to CRM, closely managed changes to CMR development. Internal audit of personal data security. Actions from the audit of personal data security completed April 2016. |
|     | Business technology | • Staff training in key business systems  
• IT systems protected and assurances received from 3rd party suppliers that protection is up to date  
• HTAMG Development schedule to be part of monthly meetings throughout 2017/18 | | | | | | | | | |
|     | People | • Strengthen the PDP process by introducing structured 180 degree feedback (AMS) 2017/18 | | | | | | | | | |
|     | Data | • Range of projects within the People Strategy relating to managing and leading people, in particular more structured management and leadership training and development (AMS) by Oct/Nov 2017 | | | | | | | | | |
|     | Business technology | • Identify refresher training and targeted software specific training needs (RS) by Q2 2017/18 | | | | | | | | | |

#### Cause
- Lack of knowledge about individuals’ expertise
- Poor job and organisational design resulting in skills being under used
- Poor line management practices
- Poor project management practices
- Poor leadership from SM and Heads
- Data holdings poorly managed and under-exploited
- Inadequate business technology or training in the technology available

#### 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

#### Assured Position
- Currently in the middle of a regular review cycle

#### Actions to Improve Mitigation
- Upgrades to CRM, closely managed changes to CMR development. Internal audit of personal data security. Actions from the audit of personal data security completed April 2016.
<table>
<thead>
<tr>
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<th>RISK/RISK OWNER</th>
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<th>PROXIMITY</th>
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<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>
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<tbody>
<tr>
<td>5</td>
<td>Insufficient, or ineffective management of, financial resources (Risk to Deployment objective b)</td>
<td><strong>Cause</strong>&lt;br&gt;• Fee payers unable to pay licence fees&lt;br&gt;• The number of licenced establishments changes, leading to reduced fee income&lt;br&gt;• Management fail to set licence fees at a level that recover sufficient income to meet resource requirements&lt;br&gt;• Failure to estimate resource required to meet our regulatory activity&lt;br&gt;• Poor budget and/or cash-flow management&lt;br&gt;• Unexpected increases in regulatory responsibilities&lt;br&gt;• Unforeseeable price increases / reductions in GIA</td>
<td>4 4</td>
<td>Ongoing</td>
<td>Budget management framework to control and review spend and take early action</td>
<td>3 4</td>
<td>X X</td>
<td>All</td>
<td>Budgetary control policy reviewed annually and agreed by SMT</td>
<td>Last review February 2017</td>
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<td></td>
<td>Risk Owner:</td>
<td><strong>Effect</strong>&lt;br&gt;• Payments to suppliers and/or staff delayed&lt;br&gt;• Compensatory reductions in staff and other expenditure budgets&lt;br&gt;• Increased licence fees&lt;br&gt;• Requests for further public funding&lt;br&gt;• Draw on reserves&lt;br&gt;Leading to: &lt;br&gt;• Inability to deliver operations and carry out statutory remit&lt;br&gt;• Reputational damage and non-payment of fees</td>
<td></td>
<td></td>
<td>Financial projections, cash flow forecasting and monitoring&lt;br&gt;Licence fee modelling&lt;br&gt;Rigorous debt recovery procedure&lt;br&gt;Reserves policy and level reserves&lt;br&gt;Delegation letters set out responsibilities&lt;br&gt;Proritisation when work requirements change&lt;br&gt;Fees model provides cost/income information for planning</td>
<td></td>
<td>X</td>
<td>Monitoring</td>
<td>Monthly finance reports to SMT and quarterly to Authority. Quarterly reports to DH</td>
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<td>Last quarterly report March 2017</td>
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<td></td>
<td>Richard Sydee</td>
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<td>Preventive</td>
<td>Annual update to fees model</td>
<td>Update agreed by the Authority November 2016</td>
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<td>Monitoring</td>
<td>Reserves policy reviewed annually and agreed by ARAC</td>
<td>Last agreed February 2017</td>
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<td>X X</td>
<td>Preventive</td>
<td>Delegation letters issued annually</td>
<td>Issued in April 2016</td>
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<td></td>
<td></td>
<td>Preventative</td>
<td>Agreed business plan, monthly HTAMG and SMT reports</td>
<td>Last HTAMG report May 2016</td>
</tr>
<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Preventative</td>
<td>Annual review of fees model, reported to SMT and Authority</td>
</tr>
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<td>Detective</td>
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<td>Detective</td>
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<td>Detective</td>
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</table>
## Authority Report

### Delivery – Quarter One 2017/18

<table>
<thead>
<tr>
<th>Date</th>
<th>14 September 2017</th>
<th>Paper Reference</th>
<th>HTA (30/17)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agenda Item</td>
<td>7</td>
<td>Author</td>
<td>Sarah Bedwell</td>
</tr>
<tr>
<td>Protective Marking</td>
<td>OFFICIAL</td>
<td>Author Contact</td>
<td><a href="mailto:sarah.bedwell@hta.gov.uk">sarah.bedwell@hta.gov.uk</a></td>
</tr>
</tbody>
</table>

### Strategic Objectives (Delivery)

1. Deliver right-touch regulation and high quality advice and guidance, targeting our resources where there is most likelihood of non-compliance and greatest risk to public confidence.
2. Be consistent and transparent in our decision-making and regulatory action, supporting those licence holders who are committed to achieving high quality and dealing firmly and fairly with those who do not comply with our standards.
3. Deliver effective regulation of living donation.
4. Inform and involve people with a professional or personal interest in the areas we regulate in matters that are important to them and influence them in matters that are important to us.
5. Maintain our strategic relationships with other regulators operating in the health sector.

### Relevant Key Performance Indicators (KPIs)

1. At least 210 site visits to take place during the business year across all sectors.
2. 100% of Corrective and Preventative Actions (CAPAs) implemented to address major and critical shortfalls are completed to the HTA’s satisfaction within agreed timescales or further regulatory action implemented.
3. 100% of non-panel cases turned around in line with the quality criteria set out in the standard operating procedure, and within five working days.
4. 100% of panel cases turned around within ten working days.
5. At least 95% of enquiries are answered within ten working days of receipt, excluding body donation enquiries.
6. Report provided to the Authority annually (in May / June 2018) on a series of measures, which provide an overview of safety in the regulated sectors.

### Related Strategic Risks

1. Failure to regulate appropriately (Objectives A-C & E)
2. Failure to manage an incident (All objectives)
3. Failure to manage expectations of regulation (Objective D)
4. Failure to utilise our capabilities effectively (Objectives A-D)

(see paper 29a/17 for detailed information)
Purpose of paper

1. To provide the Authority with standardised information on the delivery activities of the HTA and to highlight trends and any issues which require consideration by Members.

2. It is provided as a source of assurance on the delivery activities of the HTA, including statistics and background information set out in Annex A. Annex B reports Serious Adverse Events and Adverse Reactions (SAEARs), and HTA Reportable Incidents (HTARIs).

Decision-making to date

3. This report was considered by the Senior Management Team (SMT) at its meeting on 7 September 2017.

Action required

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

Directors’ summary

5. We have identified a number of significant regulatory issues in the post-mortem sector. These have arisen on inspection and / or have been brought to us third parties. We are currently reviewing these to ensure that we have appropriate resources directed towards the sector and to identify and mitigate the risks to public confidence. We increased our Regulation Manager posts by two for this financial year to increase the number of inspections we can undertake each year but have, so far, only recruited to one of these posts. We will update the Authority at the meeting in September.

6. We have also identified that the roll-out of our new Standards has led to us identifying an increased number of shortfalls. This is perhaps not surprising as our aim was to include more detail in the Standards and to raise standards. The impact, however, of agreeing and evidencing CAPA plans is to increase the workload on the Executive which may is likely to reduce the number of inspections we can undertake. We will discuss the impact of this with the Authority at this meeting.

Critical shortfalls

7. There were three critical shortfalls identified during inspections carried out in quarter one at two establishments in the post-mortem sector. Two critical shortfalls related to the premises and facilities, particularly in the post-mortem suite and one critical shortfall in relation to the premises.
Investigations

New investigations

8. There have been five new investigations in quarter one, relating to the post-mortem and human application sectors.

Investigation 01/17

9. We received an anonymous complaint about lone working practices in the mortuary of an HTA licensed establishment. We were informed that lone working had been taking place in the mortuary for several weeks and concerns were expressed about the impact of this on the staff member and the conduct of mortuary duties.

10. A letter was sent to the relevant Designated Individual (DI) summarising the outcome of our investigation and outlined our need to seek assurance that there is a suitable governance framework in place, which addresses staffing levels and mitigates the risk of a serious incident occurring as a result of lone working.

11. The investigation remains active and an update will be provided in quarter two.

Investigation 02/17

12. We were approached by bereaved parents who were unhappy with the process followed by a Trust in relation to post-mortem examination of their baby. This is one issue amongst a range of very serious allegations made against this Trust, relating to the care of the expectant mother and the baby; the Clinical Commissioners Group is conducting an independent investigation into other aspects. Our investigation has concluded and, although no breach was found, we are currently considering what advice might be offered to the Trust to improve their post-mortem consent procedures.

Investigation 03/17

13. A third investigation related to allegations by a former member of staff at a licensed establishment about historic breaches of the Human Tissue Act by a paediatric pathologist. Specifically, that tissue samples were retained for research use without appropriate consent.

14. Our enquiries are ongoing and an update will be provided in quarter two.
Investigation 04/17

15. An investigation into aspects of practice at an NHS Trust mortuary took place, following the receipt of information from a former mortuary employee (see paragraph 21 below). The concerns were in relation to the suitability of procedures governing the release of bodies and record keeping and the mechanism for recording the retention of organs following post-mortem examination.

Investigation 05/17

16. An investigation was conducted into the procurement of adipose tissue by three licensed establishment and the export / import to / from an European Institute. Appropriate authorisation and licences were not in place for this work prior to the activities being carried out. The Medicines and Healthcare products Regulatory Agency (MHRA) was contacted about the issue and it is investigating the matter separately. Our investigation has concluded and although it was agreed at an regulatory decision meeting held on 27 July 2017 that a breach of the tissues and cells legislation has been committed by both parties, SMT decided that the matter should not be referred to the police for investigation.

Update on investigations reported in previous Delivery Report [HTA 14/17]

Investigation 07/16

17. In quarter four of 2016/17, we reported on an investigation about a product intended for human application that is available for sale. A Designated Individual (DI) raised concerns that the product may contain animal products that have been subject to recall.

18. Following our investigation, there has been confirmation that only one item was manufactured from the recalled batch. Based on this information, we advised the relevant licensed establishment to conduct a comprehensive risk assessment; the case has now been resolved.

Investigation 09/16

19. In previous reporting, there was an investigation into an enquiry regarding services offered by an establishment, where an activity was being carried out on licensed premises, but not under the governance of the licence. As a result, all activities were stopped.

20. The investigation remains active and the agreed action is to let the Medicines and Healthcare products Regulatory Agency (MHRA) to take the lead, as this is a medicinal product.
Non-routine site visit inspections

21. There was one non-routine site visit inspection during quarter one.

22. The HTA conducted an unannounced inspection of an establishment in the post-mortem sector in April, ahead of an inspection that was already scheduled for May 2017. The unannounced inspection arose from concerns raised with the HTA about the suitability of procedures governing the release of bodies and record keeping and the mechanism for recording the retention of organs following post-mortem examination.

23. During the visit, the HTA:

   a. reviewed the procedures being undertaken during receipt, post-mortem examination and release of bodies;
   b. assessed compliance with the new standard operating procedures provided to the HTA as part of the CAPA process following its last routine inspection;
   c. assessed completion of the paperwork associated with receipt, post-mortem examination and release of bodies; and
   d. conducted audits of forms and paperwork associated with these activities.

24. The inspection team, which included a Head of Regulation, identified a number of actions, which the Trust was advised to take before the follow-up visit in May. At that visit, good progress had been found to have been made. Progress will continue to be monitored through the CAPA process.

Police referrals

25. This report includes:

   a. details of the cases considered by SMT that were potential breaches of human tissue legislation;
   b. factors in favour of referral;
   c. factors against referral; and
   d. the decisions made.

Police referral 02/17

26. As Members will be aware from the 2016/17 quarter four Delivery Report, in February 2017, a European Union (EU) Competent Authority in another Member State made us aware of a website, which appeared to offer a British matching donor service in exchange for a fee.
27. This was referred to the Police who in turn referred this on to the country in which the company offering the service is registered. This remains under investigation and we are liaising with the relevant Member State. We will update Members with further details at the Authority Meeting.

**Police referral 03/17**

28. SMT considered whether to make a police referral following notification by a DI that material had been removed from the body of a deceased person on unlicensed premises. The genuine efforts of the establishment to make contact with the HTA out-of-hours before the removal took place, the particular circumstances of the case, which led to the body being taken to unlicensed premises, and the fact that almost none of the factors in favour of referral applied, meant that a referral was not made. The HTA has updated its out-of-hour policy to prevent this from happening again.

**Legal notices**

29. We issued three sets of Directions in quarter one to two establishments in the human application sector, and one establishment in the research sector. For more information please see the 'Regulatory decision meetings' summary below.

**Regulatory decision meetings**

30. Three regulatory decision meetings (RDMs) were held in quarter one.

31. The first RDM was convened to discuss our approach to an establishment in the human application sector, which is proposing to start a tissue storage service. Tissue will be collected in the United Kingdom and tested under an HTA licence; the tissue will then be exported to an establishment outside of the EU for processing and storage. The HTA decided to issue Directions to make sure information is made available to prospective clients, which ensures that informed consent is in place regarding the regulatory oversight for this service. Information received by the HTA in relation to this matter resulted in the investigation referred to in paragraph 16 above.

32. A second RDM was convened to discuss another establishment in the human application sector, where there have been concerns over a failure to regularly evaluate the quality of samples to ensure the current practices and procedures continue to achieve the intended results. Directions have been issued to ensure that the services offered are appropriately validated.

33. The final RDM was convened to discuss an establishment in the research sector. During an inspection of a licensed establishment in April, the HTA identified significant concerns around consent and governance, including circumstances where material had
been stored outside the governance of the licence. Consequently, we extended the length of the inspection and returned for an additional four days in May. We are currently agreeing a CAPA plan with the establishment and have issued Directions to ensure compliance with it. The Directions also require the establishment to notify us of any further instances of tissue being stored outside of the licence and of any instances of tissue being stored or used without evidence of consent.

Reconsiderations, representations and appeals

34. No reconsiderations, representations or appeals were considered during quarter one.

Other regulatory activity

35. The HTA issued one regulatory alert during quarter one. This alert was issued to DIs of licensed establishments, which use human albumin during the processing of tissues or cells for human application. The HTA had been made aware of the recall of certain batches of human albumin due to low-level contamination, which occurred during manufacture.

Enquiries

General enquiries

36. During quarter one, we recorded 650 general enquiries, compared to 869 in the previous quarter. The enquiries included:

   a. 396 from members of the public about body donation (308 were received via email or phone, and in the post, and 88 via the website). This compares to 540 in the previous quarter; and
   b. 254 from professionals about licensing or other areas of our regulatory work, compared with 190 in the previous quarter.

37. Of these enquiries, 265 were received via the website, compared to 439 in quarter four of 2016/17. Other enquiries are usually received by phone.

38. The HTA sets itself a KPI of responding to 95 percent of general enquiries in ten working days. Of enquiries received during quarter one, 95 percent were closed in our case management system within ten working days, 95 percent in the previous quarter.

39. Typically, the cases that fell outside ten working days generally tended to involve more detailed concerns raised with us about licensed establishments, or more complex areas of regulation.
Freedom of Information Act (FOIA) requests

40. We had eight FOIA requests in quarter one, compared to six in the previous quarter. We publish FOIA responses on our website.

41. Of these, two were in relation to body donation figures; one was a request for a list of DIs at post-mortem establishments licensed by the HTA; another concerned the number of bodies recovered from the Grenfell Fire incident; and two were enquiries concerning software systems and cyber attacks.

42. The remaining two requests respectively asked for details concerning policy roles at the HTA and its business travel arrangements.

Stakeholder engagement

The HTA's 2017 Annual Conference

43. The HTA’s annual conference was held in June, focusing on conversations around death and dying. This is the major stakeholder event for the year, bringing together individuals who are affected by the HTA’s regulation.

44. At the conference, we also launched our annual review publication for 2016/17, ‘Protecting public confidence; ensuring professional standards’.

45. Feedback from attendees was very positive, with particularly positive comments received about the speakers in the afternoon session. A full report on the day and the feedback we have received is currently being compiled.

Joint Health Research Authority (HRA) / HTA research on public sentiment and ethics

46. This joint research project between the HRA and the HTA will be looking at the public’s perception on issues around consent and how personal data is used in relation to donated tissue.

47. The evaluation will be made up of a number of focus groups with members of the public, complemented by discussions via an online forum.

48. Results from the evaluation will help to inform the HRA and HTA’s guidance and development of policy in this area.

49. The joint research involves an oversight group, which of comprised of a range of other interested organisations, including:
a. Medical Research Council;
b. Genomics England;
c. Wellcome Trust;
d. Clinical Research Collaboration Centre; and
e. a range of academics.

50. We are currently finalising materials for the planned focus groups, which will take place between September and October in London, Sheffield and Birmingham. Initial findings and a draft report are expect in December.

Engagement with establishments

51. We are currently seeking feedback from licensed establishments on a number of areas of our work, including:

a. how we add value on inspection;
b. feedback for our assessment of risk in the human application sector; and
c. the HTA’s public guidance on cord blood banking.

52. As well as specific communications about the Annual Conference and requests for feedback, the we sent our professional newsletter to licensed establishments during quarter one (31 May).

Public panel

53. The HTA uses an online-based public panel as a platform for public review of its guidance, communications and other appropriate content. Recently, public panel members have been recruited, and continue to be recruited, through promoting a sign-up page via our public communication channels, including:

a. the HTA website;
b. social media accounts; and
c. the public newsletter.

54. Other organisations that share priorities or areas of interest with the HTA have also been sharing the sign-up form, after being approached to do so.

55. Public panel membership was originally ten individuals, and following a renewed effort to recruit, it now stands at 56, and is expected to continue growing.

56. Panel members will eventually be transitioned to the HTA online community, a work in progress, that will replace the panel as a place for stakeholder feedback and discussion.
Delivery KPI narrative

Performance against 2017/18 KPIs

57. Following agreement at an HTA’s Management Group meeting, the performance indicator for KPI:2 – *take appropriate action for all regulator non-compliances* – was widened from – *100% of CAPAs implemented to address major shortfalls are completed to the HTA’s satisfaction, within agreed timescales or further regulation action implemented* – to also include critical shortfalls.

58. All Delivery KPIs for quarter one were within target or tolerance and marked as **green**.
Annex A – Statistics and background information

Regulation

Table One: Site visits (including licence application assessment visits (LAAVs))

<table>
<thead>
<tr>
<th>Type of site visit</th>
<th>Q1 2017 / 18</th>
<th>Q4 2016 / 17</th>
<th>Q3 2016 / 17</th>
<th>Q2 2016 / 17</th>
<th>2016 / 17 Total</th>
<th>2015 / 16 Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routine inspection</td>
<td>42</td>
<td>39</td>
<td>29</td>
<td>32</td>
<td>136</td>
<td>164</td>
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<tr>
<td>LAAV - new application</td>
<td>0</td>
<td>4</td>
<td>3</td>
<td>6</td>
<td>18</td>
<td>15</td>
</tr>
<tr>
<td>Satellite site inspection</td>
<td>16</td>
<td>8</td>
<td>10</td>
<td>11</td>
<td>46</td>
<td>47</td>
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<td>CAPA follow up</td>
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<td>0</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
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<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>6</td>
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<tr>
<td>Total sites visited</td>
<td>59</td>
<td>51</td>
<td>43</td>
<td>50</td>
<td>202</td>
<td>234</td>
</tr>
</tbody>
</table>

Total number of site visit inspections

HTA meeting papers are not policy documents. Draft policies may be subject to revision following the Authority meeting.
Table Two: HTARIs in the post-mortem sector

59. As context: In 2014/15, mortuaries licenced by the HTA admitted around 330,000 bodies, and performed over 100,000 post-mortem examinations. The number of reported HTARIs in context is very low.

<table>
<thead>
<tr>
<th>HTARI Classification</th>
<th>Q1 2017/18</th>
<th>Q4 2016/17</th>
<th>Q3 2016/17</th>
<th>Q2 2016/17</th>
<th>2016/17 Total</th>
<th>2015/16 Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accidental damage to a body</td>
<td>10</td>
<td>13</td>
<td>7</td>
<td>10</td>
<td>37</td>
<td>34</td>
</tr>
<tr>
<td>Discovery of an additional organ(s) in a body on evisceration for a second post-mortem examination</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Disposal or retention of a whole fetus or fetal tissue (gestational age greater than 24 weeks) against the express wishes of the family</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Disposal or retention of a whole fetus or fetal tissue (gestational age less than 24 weeks) against the express wishes of the family</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Disposal or retention of an organ against the express wishes of the family</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Discovery of an organ or tissue following post-mortem examination and release of body</td>
<td>4</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Incident leading to the temporary unplanned closure of a mortuary resulting in an inability to deliver services</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Loss of an organ</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>0</td>
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<tr>
<td>Major equipment failure</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>6</td>
<td>8</td>
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<tr>
<td>Post-mortem examination conducted was not in line with the consent given or the post-mortem examination proceeded with inadequate consent</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>2</td>
<td>0</td>
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<td>Post-mortem examination of the wrong body</td>
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<td>1</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>0</td>
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<td>Release of the wrong body</td>
<td>5</td>
<td>6</td>
<td>2</td>
<td>1</td>
<td>11</td>
<td>14</td>
</tr>
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<td>Removal of tissue from a body without authorisation or consent</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>4</td>
<td>0</td>
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<tr>
<td>Serious security breach</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>4</td>
<td>4</td>
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<tr>
<td>Viewing of the wrong body</td>
<td>1</td>
<td>4</td>
<td>0</td>
<td>2</td>
<td>8</td>
<td>10</td>
</tr>
<tr>
<td>Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence</td>
<td>6</td>
<td>10</td>
<td>4</td>
<td>11</td>
<td>31</td>
<td>17</td>
</tr>
<tr>
<td>Total</td>
<td>34</td>
<td>41</td>
<td>16</td>
<td>36</td>
<td>118</td>
<td>102</td>
</tr>
</tbody>
</table>

*Since Q4 16/17 we have been reporting on the number of closed HTARIs cases rather than all cases which have been submitted during the quarter, this allows us to present a more accurate representation of incident reporting.*
Table Three: SAEARs in the human application sector

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

<table>
<thead>
<tr>
<th>Type of Event or Reaction</th>
<th>Q1 2017/18</th>
<th>Q4 2016/17</th>
<th>Q3 2016/17</th>
<th>Q2 2016/17</th>
<th>2016/17 Total Year</th>
<th>2015/16 Total Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event linked to Distribution</td>
<td>0</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>11</td>
<td>2</td>
</tr>
<tr>
<td>Event linked to End use</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Event linked to Materials</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Event linked to Preservation</td>
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<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Event linked to Processing</td>
<td>8</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>9</td>
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<td>Event linked to Procurement</td>
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<td>5</td>
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<td>21</td>
<td>9</td>
</tr>
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<td>Event linked to Storage</td>
<td>2</td>
<td>2</td>
<td>5</td>
<td>2</td>
<td>11</td>
<td>4</td>
</tr>
<tr>
<td>Event linked to Testing</td>
<td>2</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
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<tr>
<td>Event linked to Other process</td>
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<td>7</td>
<td>1</td>
<td>2</td>
<td>13</td>
<td>5</td>
</tr>
<tr>
<td>Reaction in Donor</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>3</td>
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<td>Reaction in Recipient</td>
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<td>5</td>
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<td>19</td>
<td>16</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>19</strong></td>
<td><strong>24</strong></td>
<td><strong>27</strong></td>
<td><strong>21</strong></td>
<td><strong>93</strong></td>
<td><strong>60</strong></td>
</tr>
</tbody>
</table>

*Since Q4 16/17 we have been reporting on the number of closed SAEARs cases rather than all cases which have been submitted during the quarter, this allows us to present a more accurate representation of incident reporting.
Table Four: SAEARs in the Organ Donation and Transplantation sector

61. Across the United Kingdom during quarter one, a total of 1,183 organs were transplanted; 942 organs donated by deceased donors and 241 donated by living donors.

<table>
<thead>
<tr>
<th>Type of Event or Reaction</th>
<th>Q1 2017/18</th>
<th>Q4 2016/17</th>
<th>Q3 2016/17</th>
<th>Q2 2016/17</th>
<th>2016/17 Total Year</th>
<th>2015/16 Total Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Events</td>
<td>10</td>
<td>10</td>
<td>13</td>
<td>4</td>
<td>37</td>
<td>22</td>
</tr>
<tr>
<td>Reaction in Donor</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Reaction in Recipient</td>
<td>2</td>
<td>7</td>
<td>5</td>
<td>6</td>
<td>25</td>
<td>13</td>
</tr>
<tr>
<td>Total</td>
<td>12</td>
<td>17</td>
<td>18</td>
<td>10</td>
<td>63</td>
<td>36</td>
</tr>
</tbody>
</table>

*Since Q4 16/17 we have been reporting on the number of closed ODT SAEARs cases rather than all cases which have been submitted during the quarter, this allows us to present a more accurate representation of incident reporting.

Table Five: Bone marrow and PBSC cases where the donor lacks capacity/competence

<table>
<thead>
<tr>
<th></th>
<th>Q1 2017/18</th>
<th>Q4 2016/17</th>
<th>Q3 2016/17</th>
<th>Q2 2016/17</th>
<th>2016/17 Total Year</th>
<th>2015/16 Total Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approvals</td>
<td>14</td>
<td>25</td>
<td>16</td>
<td>14</td>
<td>69</td>
<td>55</td>
</tr>
</tbody>
</table>
Table Six: Living organ donation cases

<table>
<thead>
<tr>
<th>Type of case</th>
<th>Q1 17/18</th>
<th>LDAT</th>
<th>Panel</th>
<th>Q4 16/17</th>
<th>LDAT</th>
<th>Panel</th>
<th>Q3 16/17</th>
<th>LDAT</th>
<th>Panel</th>
<th>Q2 16/17</th>
<th>LDAT</th>
<th>Panel</th>
<th>17/18 Total Year</th>
<th>LDAT</th>
<th>Panel</th>
<th>16/17 Total Year</th>
<th>LDAT</th>
<th>Panel</th>
<th>Panel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Directed kidney</td>
<td>229</td>
<td>0</td>
<td>1</td>
<td>19</td>
<td>233</td>
<td>19</td>
<td>1</td>
<td>217</td>
<td>0</td>
<td>208</td>
<td>229</td>
<td>1</td>
<td>229</td>
<td>874</td>
<td>21</td>
<td>3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Directed altruistic kidney</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>15</td>
<td>31</td>
<td>37</td>
<td>37</td>
<td>2</td>
<td>32</td>
<td>25</td>
<td>51</td>
<td>51</td>
<td>91</td>
<td>113</td>
<td>46</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Directed liver lobe</td>
<td>25</td>
<td>51</td>
<td>10</td>
<td>14</td>
<td>31</td>
<td>35</td>
<td>9</td>
<td>32</td>
<td>8</td>
<td>3</td>
<td>51</td>
<td>10</td>
<td>10</td>
<td>46</td>
<td>0</td>
<td>5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-directed altruistic kidney</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-directed altruistic liver lobe</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TOTALS</th>
<th>Number of cases considered</th>
<th>Approvals by the Living Donation Assessment Team</th>
<th>Approvals by Authority panels</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>321*</td>
<td>315</td>
<td>303</td>
</tr>
<tr>
<td></td>
<td>240</td>
<td>248</td>
<td>229</td>
</tr>
<tr>
<td></td>
<td>81</td>
<td>67</td>
<td>74</td>
</tr>
</tbody>
</table>

*HTA panel considered a directed donation case (n=2), involving small bowel and liver lobe donation. This figure (n=2) has been included in the Total number of Cases Considered column and the Total approvals by Authority Panel column in the table above for Q1 17/18.
Communications

Social media

62. In quarter one, the HTA’s Twitter account had 1,687 followers, up from 1,589 in the previous quarter. Our engagement rate decreased to 1.2% from 1.3% during quarter four, with a peak rate of 6.0%.

63. On average, HTA tweets were seen by 1,100 people per day, which increased from 545 in quarter four. Our impression rate this quarter was higher than last quarter due to increased publicity around HTA events that took place during this period, for example the launch of the new Codes of Practice and the HTA annual conference.

Table Seven: Twitter impressions

<table>
<thead>
<tr>
<th>Month</th>
<th>Impressions</th>
<th>Profile Visits</th>
</tr>
</thead>
<tbody>
<tr>
<td>April</td>
<td>21.5K</td>
<td>1,570</td>
</tr>
<tr>
<td>May</td>
<td>15.5K</td>
<td>1,300</td>
</tr>
<tr>
<td>June</td>
<td>23.9K</td>
<td>1,895</td>
</tr>
</tbody>
</table>

64. Tweets with the highest reach and engagement in quarter one were about:

a. **Corporate**
   The launch of the HTA’s Codes of Practice and promoting the HTA annual conference.
   Organ donation and transplantation
   The first person in Britain to receive an artificial heart and an article on non-directed altruistic donation.

b. **Anatomy**
   Body donation information.

c. **Post-mortem**
   Essential facts about post-mortems.

65. There are 684 Facebook ‘likes’ on the HTA page, increased from 671 in quarter four. The HTA also had 482 followers for its LinkedIn company page, up from 451 in quarter four.

66. In quarter four 2016/17, we launched the HTA YouTube channel, primarily with the intention to make presentation footage from the Codes and Standards and Import and Coding webinars, as accessible as possible for those who were unable to view them on the day. In quarter one, we had 872 views of our video content. Our most popular video during this period has been the Codes and Standards webinar presentation on Code E: Research by Chris Birkett.
Digital communications and publications

67. In quarter one, we published the revised HTA Codes of Practice and Standards on the HTA website. The Codes were launched after a period of engagement with stakeholders that included a series of training webinars hosted by Heads of Regulation, tailored newsletters with key information, and clear and informative webpages on the HTA website. A post-implementation review is now underway to evaluate the effectiveness of the implementation project.

68. The annual Business Plan for 2017/18 and a refreshed version of the three-year Strategy were published on the HTA website in quarter one. The Business Plan sets out our priorities and objectives for the 2017/18 business year, and the Strategy provides a longer-term view of organisation priorities and activities, centred around our core themes of Delivery, Development and Deployment.

69. To coincide with the HTA’s annual conference, we launched our annual review document for 2016/17 ‘Protecting public confidence; ensuring professional standards’. The publication gives an overview of the variety of work the HTA carried out during the last business year.

Table Nine: Digital users

<table>
<thead>
<tr>
<th></th>
<th>Q1 2017/18</th>
<th>Q4 2016/17</th>
<th>Q3 2016/17</th>
<th>Q2 2016/17</th>
<th>2016/17 Total Year</th>
<th>2015/16 Total Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Users</td>
<td>62,191</td>
<td>53,204</td>
<td>50,568</td>
<td>41,093</td>
<td>199,226</td>
<td>165,032</td>
</tr>
<tr>
<td>Page views</td>
<td>254,369</td>
<td>217,912</td>
<td>206,910</td>
<td>185,555</td>
<td>781,047</td>
<td>729,300</td>
</tr>
<tr>
<td>Pages viewed per session</td>
<td>3.03</td>
<td>3.05</td>
<td>3.04</td>
<td>3.28</td>
<td>3.13</td>
<td>3.38</td>
</tr>
<tr>
<td>Average session duration</td>
<td>00:02:39</td>
<td>00:02:50</td>
<td>00:02:48</td>
<td>00:02:58</td>
<td>00:02:50</td>
<td>00:02:56</td>
</tr>
<tr>
<td>Online enquiries</td>
<td>234</td>
<td>460</td>
<td>270</td>
<td>298</td>
<td>1,396</td>
<td>1,448</td>
</tr>
<tr>
<td>eNewsletter signups</td>
<td>343</td>
<td>519</td>
<td>341</td>
<td>324</td>
<td>1,515</td>
<td>938</td>
</tr>
</tbody>
</table>

HTA meeting papers are not policy documents. Draft policies may be subject to revision following the Authority meeting.
Table 10: Page views

<table>
<thead>
<tr>
<th>Highest viewed pages</th>
<th>Q1 2017/18</th>
<th>Q4 2016/17</th>
<th>Q3 2016/17</th>
<th>Q2 2016/17</th>
<th>2016/17 Total Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Body donation FAQs</td>
<td>8,216</td>
<td>12,896</td>
<td>15,597</td>
<td>15,703</td>
<td>59,753</td>
</tr>
<tr>
<td>Medical school search</td>
<td>11,914</td>
<td>16,397</td>
<td>15,355</td>
<td>13,161</td>
<td>57,040</td>
</tr>
<tr>
<td>Donating your body</td>
<td>14,017</td>
<td>16,121</td>
<td>12,836</td>
<td>6,381</td>
<td>40,819</td>
</tr>
<tr>
<td>Guidance for professionals</td>
<td>4,564</td>
<td>5,009</td>
<td>6,023</td>
<td>6,335</td>
<td>22,847</td>
</tr>
</tbody>
</table>

70. The most frequently clicked top menu items on the front page are:

a. Donating your body – 2,300;
b. Guidance for professionals – 1,800; and
c. Codes of Practice and Standards – 1,031.

71. These statistics show that there has been increased traffic on our Codes and Standards webpage following the launch of the revised versions in quarter one. There has also been increased traffic from last quarter from members of the public seeking information on body donation.
Newsletters

72. The HTA sent out a Professional newsletter and an Independent Assessor bulletin in May. The HTA public newsletter was last sent out in April.

73. The government average is for 24% of subscribers to open newsletters.

Table 11: Professional newsletter

Table 12: Independent Assessor bulletin
74. We will continue to monitor and test these emails to consistently achieve high open rates.

Media coverage

75. During quarter one, coverage which directly mentioned the HTA included two cases that attracted significant media coverage

*HTA Response to the Court of Protection Judgment ‘In the matter of SW’ (HTA website)*

76. The HTA was named as the respondent in a Court of Protection case relating to a bone marrow donation involving an individual who it was claimed lacked capacity to consent to the procedure.

77. The presiding judge, The Rt Hon Lord Justice Munby, highlighted that there was no appropriate evidence submitted relating to:

   a. whether the recipient wished the procedure to take place;
   b. who would carry out the procedure;
   c. expert medical evidence relating to the nature and/or risks of the procedure; and
   d. evidence that the donor lacked capacity.

78. In his own words, The Rt Hon Lord Justice Munby concluded that “evidence on all these matters is almost wholly lacking”.

---

**Table 13: Public newsletter**

<table>
<thead>
<tr>
<th>Month</th>
<th>Recipients</th>
<th>Open rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aug-16</td>
<td>500</td>
<td>38%</td>
</tr>
<tr>
<td>Sep-16</td>
<td>600</td>
<td>40%</td>
</tr>
<tr>
<td>Oct-16</td>
<td>700</td>
<td>42%</td>
</tr>
<tr>
<td>Nov-16</td>
<td>800</td>
<td>44%</td>
</tr>
<tr>
<td>Dec-16</td>
<td>900</td>
<td>46%</td>
</tr>
<tr>
<td>Jan-17</td>
<td>1000</td>
<td>48%</td>
</tr>
<tr>
<td>Feb-17</td>
<td>1100</td>
<td>50%</td>
</tr>
<tr>
<td>Mar-17</td>
<td>1200</td>
<td>52%</td>
</tr>
<tr>
<td>Apr-17</td>
<td>1300</td>
<td>54%</td>
</tr>
</tbody>
</table>
79. The judgment was clear in striking this case out, deeming it a “scarcely coherent application”, and “totally without merit, it is misconceived and it is vexatious”. Two of the individuals involved had been struck off by the General Medical Council, and the judgment noted that “the Panel's findings make for very disturbing reading”.

80. It received some national media coverage: An Unregistered Doctor Was Stopped From Taking His Wife's Bone Marrow To Cure Her Brother's Cancer (Buzzfeed UK) | Dodgy cancer 'cure' doctor tried to get a judge to allow him to perform surgery on unsuspecting members of his own family (Daily Mail) | Disgraced doctor asked to operate on his wife (The Times)

**HTA Statement on the Retention of Human Tissue by Police Forces in the North East** *(HTA website)*

81. The HTA worked with Northumbria Police to provide advice and guidance in relation to tissue samples discovered, which had been retained longer than was necessary.

82. The tissue - retained in relation to police investigations, and categorised as “police holdings” - had been found at South Tyneside NHS Foundation Trust. Police holdings do not fall under the remit of the HTA, however, through a joint agreement the HTA do inspect and report to the Home Office on these holdings where they are held on HTA licenced premises.

83. This case received quite a lot of local as well as national media coverage: Daughter horrified to discover that her dad's heart and brain were secretly stored at hospital for over two decades (Mail Online) | Woman discovers father’s brain and heart secretly stored in hospital for 22 years (Metro) | Body parts could have been held at South Tynesian Hospital for 20 years (Shields Gazette) | Families not told about stored organs and tissue samples (BBC News) | Organ scandal inquiry calls as MP says it is an 'outrage' families weren't told about stored remains (Chronicle Live) | Heartbroken family want answers as dad's heart is found in hospital fridge almost 20 years after his death (Mirror).
### Annex B – SAERs / HTARI details

**Human Application – Serious Adverse Events**

<table>
<thead>
<tr>
<th>Case Number</th>
<th>Process Event Linked To</th>
<th>Description of Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS-37709-Z1T5</td>
<td>Testing</td>
<td>Medical screening of potential donors not comprehensive. Donors were contacted again and re-assessed; if donor could not be contacted, donated femoral heads were discarded.</td>
</tr>
<tr>
<td>CAS-34667-L9W4</td>
<td>Procurement</td>
<td>Bacterial contamination of bone marrow harvest detected; however, post-processing sampling results were negative and no reaction observed in recipient.</td>
</tr>
<tr>
<td>CAS-33848-W8Y1</td>
<td>Other</td>
<td>PBSC donor developed malignancy post-donation and was withdrawn from the registry. Transplant unit was informed -no issues reported for the recipient six months post-transplant.</td>
</tr>
<tr>
<td>CAS-37273-F8Y5</td>
<td>Storage</td>
<td>Malfunctioning fill valve resulted in overfilling of cryo-vessel. Stock moved to prevent immersion in liquid nitrogen; faulty vessel decommissioned.</td>
</tr>
<tr>
<td>CAS-36555-Q6V7</td>
<td>Other</td>
<td>Failure of second adipose tissue implant resulting in necrosis. Unable to determine root cause, but could be linked to the quality of the graft.</td>
</tr>
<tr>
<td>CAS-37378-B3Y4</td>
<td>Storage</td>
<td>Due to poor communication, an allograft which should have been disposed of was implanted into a recipient. No adverse reaction observed.</td>
</tr>
<tr>
<td>CAS-37701-Z3C7</td>
<td>Processing</td>
<td>Overwrap bags protecting bags of stem cells not correctly sealed. Staff were retrained.</td>
</tr>
<tr>
<td>CAS-33232-B0P1</td>
<td>Processing</td>
<td>Nitrogen entered a bag containing stem cells which was not properly sealed resulting in the bag ballooning when thawed prior to infusion.</td>
</tr>
<tr>
<td>CAS-33238-L4R8</td>
<td>Processing</td>
<td>Two out of four stem cell bags were observed to be damaged when thawed just prior to infusion. One infused as inner bag was intact but the other was deemed unsuitable.</td>
</tr>
<tr>
<td>CAS-36058-W0P7</td>
<td>Processing</td>
<td>Bag of stem cells leaked as it was incorrectly sealed; observed when thawed just prior to infusion.</td>
</tr>
<tr>
<td>CAS-31969-Y1DP</td>
<td>Processing</td>
<td>Small hole observed in tubing connected to a bag of stem cells. Could have occurred when excess tubing was removed following cryopreservation.</td>
</tr>
<tr>
<td>CAS-36224-C1T1</td>
<td>Processing</td>
<td>Heat sealer was incorrectly applied on overwrap bag resulting in damage to inner bag containing stem cells. Cells leaked during thawing.</td>
</tr>
<tr>
<td>CAS-35732-R3Q2</td>
<td>Testing</td>
<td>Harvesting and processing departments did not notice that donor testing results were absent. Root cause was incorrect form, which accompanied blood sample.</td>
</tr>
<tr>
<td>CAS-38601-V2T8</td>
<td>Processing</td>
<td>Due to incorrect loading of apheresis machine used for processing, cells leaked from bag containing bone marrow harvest.</td>
</tr>
<tr>
<td>CAS-38445-G9X1</td>
<td>Processing</td>
<td>Leak occurred in cord blood bag during thawing for infusion. Patient treated with prophylaxis, so no impact on care.</td>
</tr>
</tbody>
</table>
### Human Application – Serious Adverse Reactions

<table>
<thead>
<tr>
<th>Case Number</th>
<th>Donor or Recipient</th>
<th>Description of Reaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS-29816-XM5R</td>
<td>Donor</td>
<td>Systems in place to detect failure of cryo-vessel containing stem cells failed. Temperature in vessel increased and one donor had to be re-harvested.</td>
</tr>
<tr>
<td>CAS-35761-F1D9</td>
<td>Recipient</td>
<td>Due to human error, package distributed to hospital did not contain amniotic membrane product. Patient was anaesthetised in preparation for the application of amniotic membrane to their eye.</td>
</tr>
<tr>
<td>CAS-37626-P8P8</td>
<td>Recipient</td>
<td>Severe hypertension in patient following bone marrow infused into recipient overseas. Recipient well after four days. No issues with transport, but receiving centre did not provide any further information on haemolysis or microbial tests. Agreements with end-user updated to emphasise the importance of follow-up investigations in the event of an incident.</td>
</tr>
</tbody>
</table>

### Organ Donation and Transplantation – Serious Adverse Events

<table>
<thead>
<tr>
<th>Case Number</th>
<th>Incident Type</th>
<th>Brief description of incident</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS-37735-L7M8</td>
<td>ODT Event</td>
<td>Retrieval damage to liver - not transplanted.</td>
</tr>
<tr>
<td>CAS-38123-X1M8</td>
<td>ODT Event</td>
<td>Retrieval damage to pancreas - not transplanted.</td>
</tr>
<tr>
<td>CAS-38025-X5G4</td>
<td>ODT Event</td>
<td>Retrieval damage to kidney - not transplanted.</td>
</tr>
<tr>
<td>CAS-38721-C1Q5</td>
<td>ODT Event</td>
<td>Retrieval damage to pancreas - not transplanted.</td>
</tr>
<tr>
<td>CAS-38214-V8Y9</td>
<td>ODT Event</td>
<td>Retrieval damage to kidney - not transplanted.</td>
</tr>
<tr>
<td>CAS-37111-V1V8</td>
<td>ODT Event</td>
<td>Kidney and liver transplanted on incorrect test result information - Human data entry error.</td>
</tr>
<tr>
<td>CAS-38607-Z8Q5</td>
<td>ODT Event</td>
<td>Insufficient packaging of a kidney - not transplanted.</td>
</tr>
<tr>
<td>Case Number</td>
<td>Incident type</td>
<td>Brief description of Reaction</td>
</tr>
<tr>
<td>-------------</td>
<td>---------------</td>
<td>------------------------------</td>
</tr>
<tr>
<td>CAS-38680-J4Y3</td>
<td>Recipient ODT Reaction</td>
<td>Potential donor transmitted malignancy.</td>
</tr>
<tr>
<td>CAS-38716-J7C7</td>
<td>Recipient ODT Reaction</td>
<td>Aborted procedure, Liver recipient anaesthetised.</td>
</tr>
</tbody>
</table>

**Post Mortem HTA Reportable Incidents**

<table>
<thead>
<tr>
<th>Case Number</th>
<th>Incident Classification</th>
<th>Brief summary of HTARI</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS-35219-M9H0</td>
<td>Major equipment failure</td>
<td>Power supply issues resolved temporarily by use of generator while mains supply fixed.</td>
</tr>
<tr>
<td>CAS-36732-Y6K5</td>
<td>Release of the wrong body</td>
<td>Human error led to the release of the wrong body.</td>
</tr>
<tr>
<td>CAS-38060-C7R0</td>
<td>Accidental damage to a body</td>
<td>Human error led to accidental damage to the deceased.</td>
</tr>
<tr>
<td>CAS-35681-H4K2</td>
<td>Discovery of an organ or tissue following post-mortem examination and release of body</td>
<td>A clerical error led to a delay in repatriation of blocks and slides.</td>
</tr>
<tr>
<td>CAS-38360-P7H1</td>
<td>Accidental damage to a body</td>
<td>Human error led to accidental damage to the deceased.</td>
</tr>
<tr>
<td>CAS-38498-J0M9</td>
<td>Accidental damage to a body</td>
<td>Human error led to accidental damage to the deceased.</td>
</tr>
<tr>
<td>CAS-39330-Q9L6</td>
<td>Release of the wrong body</td>
<td>Human error led to the release of the wrong body.</td>
</tr>
<tr>
<td>CAS-38217-D8B8</td>
<td>Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence</td>
<td>Human error led to the deceased being released without all health risks being addressed for the funeral directors.</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
<td>Description</td>
</tr>
<tr>
<td>--------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>CAS-39124-Q4W1</td>
<td>Accidental damage to a body</td>
<td>Human error led to accidental damage to the deceased.</td>
</tr>
<tr>
<td>CAS-37056-X4Q2</td>
<td>Accidental damage to a body</td>
<td>Human error led to accidental damage to the deceased.</td>
</tr>
<tr>
<td>CAS-37600-B4Y1</td>
<td>Serious security breach</td>
<td>Due to a lack of security personnel, the door into the mortuary was not closed following the admission of a body.</td>
</tr>
<tr>
<td>CAS-37257-R0H1</td>
<td>Accidental damage to a body</td>
<td>Human error led to accidental damage to the deceased.</td>
</tr>
<tr>
<td>CAS-34910-T8H4</td>
<td>Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence</td>
<td>Delay to the post-mortem, caused by lack of availability of a pathologist, led to accelerated deterioration of the deceased.</td>
</tr>
<tr>
<td>CAS-38142-K7S7</td>
<td>Accidental damage to a body</td>
<td>Equipment failure led to accidental damage to the deceased.</td>
</tr>
<tr>
<td>CAS-38426-S5P0</td>
<td>Discovery of an organ or tissue following post-mortem examination and release of body</td>
<td>Due to human error, tissue was retained following release of a body.</td>
</tr>
<tr>
<td>CAS-38325-N2K3</td>
<td>Accidental damage to a body</td>
<td>Due to a defective trolley, accidental damage occurred to the deceased.</td>
</tr>
<tr>
<td>CAS-38814-S4X5</td>
<td>Discovery of an organ or tissue following post-mortem examination and release of body</td>
<td>Due to failures in communication, a body was released to a funeral director before the organ was repatriated.</td>
</tr>
<tr>
<td>CAS-37899-T6C6</td>
<td>Viewing of the wrong body</td>
<td>Due to human error the wrong body was viewed by a family.</td>
</tr>
<tr>
<td>CAS-37912-T1D5</td>
<td>Release of the wrong body</td>
<td>Human error led to the release of the wrong body.</td>
</tr>
<tr>
<td>CAS-38413-X3Z9</td>
<td>Disposal or retention of a whole fetus or fetal tissue (gestational age greater than 24 weeks) against the express wishes of the family</td>
<td>Human error led to a fetus being retained instead of disposed of in line with the parents' wishes.</td>
</tr>
<tr>
<td>CAS-38068-H8W2</td>
<td>Release of the wrong body</td>
<td>Human error led to the release of the wrong body.</td>
</tr>
<tr>
<td>CAS-39204-L0W2</td>
<td>Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence</td>
<td>Due to human error, the results of a post-mortem report were sent to the family of the deceased instead of the clinician.</td>
</tr>
<tr>
<td>CAS-37733-G2Q3</td>
<td>Release of the wrong body</td>
<td>Human error led to the release of the wrong body.</td>
</tr>
<tr>
<td>CAS-38231-W4K7</td>
<td>Accidental damage to a body</td>
<td>Human error led to minor damage to a deceased person whilst being placed in to mortuary fridge.</td>
</tr>
<tr>
<td>CAS-37264-T4J1</td>
<td>Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence</td>
<td>Failure to release blocks and slides to a funeral director due to human error.</td>
</tr>
<tr>
<td>CAS-33889-R8P8</td>
<td>Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence</td>
<td>Delayed release of a baby from the mortuary due to lack of communication.</td>
</tr>
<tr>
<td>CAS-35083-S5N3</td>
<td>Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence</td>
<td>A failure by staff to follow procedures led to loss of traceability of a 20+5 week fetus, which had been sent away for PM examination.</td>
</tr>
<tr>
<td>CAS-35121-N9V2</td>
<td>Post-mortem examination conducted was not in line with the consent given or the post-mortem examination proceeded with inadequate consent</td>
<td>Post-mortem conducted before receipt of the coroner’s authorisation.</td>
</tr>
<tr>
<td>CAS-35279-W8Y7</td>
<td>Inadvertent disposal or retention of an organ against the express wishes of the family</td>
<td>A brain was disposed of in error due to a lack of robust procedures to check the wishes of the next of kin in relation to disposal of organs.</td>
</tr>
<tr>
<td>CAS-36858-R8Z9</td>
<td>Serious security breach</td>
<td>Police officers and family were given access to the body store in a mortuary contrary to procedures.</td>
</tr>
<tr>
<td>CAS-36047-C6X5</td>
<td>Accidental damage to a body</td>
<td>Human error led to accidental damage to the deceased.</td>
</tr>
<tr>
<td>CAS-36498-T3R9</td>
<td>Discovery of an organ or tissue following post-mortem examination and release of body</td>
<td>Unintentional retention of tissue blocks and slides.</td>
</tr>
<tr>
<td>CAS-38843-P8P1</td>
<td>Loss of an organ</td>
<td>Two tissue blocks were lost in the pathology laboratory relating to two separate post mortem examinations.</td>
</tr>
<tr>
<td>CAS-36826-S4S5</td>
<td>Loss of an organ</td>
<td>Loss of an organ following a PM.</td>
</tr>
</tbody>
</table>
## Authority Report

### Development – Quarter One 2017/18

<table>
<thead>
<tr>
<th>Date</th>
<th>14 September 2017</th>
<th>Paper Reference</th>
<th>HTA (31/17)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agenda Item</td>
<td>8</td>
<td>Author</td>
<td>Victoria Marshment</td>
</tr>
<tr>
<td>Protective Marking</td>
<td>OFFICIAL</td>
<td>Author Contact</td>
<td><a href="mailto:victoria.marshment@hta.gov.uk">victoria.marshment@hta.gov.uk</a></td>
</tr>
</tbody>
</table>

### Strategic Objectives (Development)

- To reduce regulatory burden where risks to public confidence are lowest
- To make it clearer how to achieve compliance with new and existing regulatory requirements
- To make continuous improvements to our systems and processes to minimise duplicated effort
- To take opportunities to better inform and involve the public

### Relevant KPIs (marked as red, amber, green, black or blue)

- Deliver a project to implement EU Directives on Coding and Import
- Deliver a licenced establishment relationships programme as per plan specification
- Assessment of Risk in the Human Application sector and update of processes to reflect this

### Related Strategic Risks (marked as red, yellow, amber or green)

1. Failure to regulate appropriately
2. Failure to manage an incident
4. Failure to utilise our capabilities effectively

(see paper 29a/17 for detailed information)
Purpose of paper

1. To provide the Authority with standardised information on the development activities of the HTA and to highlight any issues which require consideration by Members.

2. It is provided as a source of assurance on the development activities of the HTA.

Decision-making to date

3. This report was considered by the Senior Management Team (SMT) at its meeting on 7 September 2017.

Action required

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

Directors’ summary

5. Quarter one was impacted by the pre-election period which meant the work on the European Union (EU) Coding and Import Directives was put on hold, which allowed us to turn our focus to other priorities. While the further delay and uncertainty on the Directives was less than ideal, we communicated the hold to affected licensed establishments and used this time to move other work forward.

6. Good progress has been made on both the programme of work to increase our engagement with licensed establishments and ensure if it effective, and also the work on risk in the human application sector, which will feed into the development of the 2018-21 Strategy.

7. A good deal of work has been undertaken on scoping development projects to be delivered later this year, including formalising horizon scanning and considering the sustainability of the independent assessment framework for living organ donation; this stands us in good stead for the future.
Project updates

Core 2017/18 projects

8. The three projects below are considered core in 2017/18.

EU Coding and Import Directives implementation

9. As a result of the pre-election period, the Department of Health paused transposition of the Regulations required to implement the Directives. Subject to the necessary Ministerial approvals, we anticipate that the next opportunity to lay the Regulations will be in Autumn 2017. We will provide further advice for licensed establishments on the likely timetable and the process for re-issuing import licences, when we have received further information from the Department regarding Ministerial approval.

Licensed establishment relationship programme

10. The priority for this work so far has been the development of Designated Individual (DI) training. We have published a section on the website, which acts as a directory to useful resources for DIs. The content was produced with input from the group of volunteers at licensed establishments.

11. The next phase is to produce an online test. Draft questions for the test will be discussed at the next meeting of the external group on 1 September. The tests will be available online by 29 September 2017.

12. We are also considering the option of publishing recorded presentations online. The first step in producing these presentations is to gauge demand and topics of interest. We intend to ask for external input through the September edition of the HTA eNewsletter.

13. In addition, the group have had input into the following:

   a. development of an online forum;
   b. review of the HTA’s advisory groups;
   c. external feedback on the HTA; and
   d. new search functions for inspection reports on the HTA website.
Assessment of risk in the human application sector

14. The first phase of this project ran until July 2017 and looked at four key areas of impact in terms of both patient/donor safety and public confidence.

15. The areas we have focused on are:

   a. tissues and cells used for human application without appropriate consent;
   b. transmission of an infectious disease;
   c. contamination of product; and
   d. transplanted product does not achieve intended result.

16. Individual work packages have considered how well these risks are controlled by our routine regulatory processes within the human application sector.

17. Input has been sought from HTA staff and other regulators, stakeholders working in the sector and members of the public. We have also considered data collected from establishments through our licensing and inspection processes. Aligned to this, project outcomes will address ways in which we can make better use of this data to evaluate risk. This will include consideration of both the type of data that we hold, and the systems that we use to collect and store it.

18. An update report will be taken to the next meeting on the HTA Management Group on 21 September. This will summarise the research phase of the project. Following on from this, a series of recommendations will be developed for the future regulation of the sector. These will be delivered to the Authority at its Strategy away-day in October 2017.

Additional 2017/18 projects

19. In quarter one of 2017/18, the following projects were considered to be of importance.

   Codes and Standards post-implementation review

20. In June 2016, the HTA scoped a project to implement new Codes and Standards, which had been updated over the previous year. The Codes, which were laid at Parliament in December, were issued on 3 April, supported by comprehensive communications activity for licensed establishments.

21. A plan to review the implementation of the Codes and Standards was reviewed by the HTA Management Group at its meeting in July. The review will seek feedback from internal and external stakeholders on:
a. whether the project was well managed;
b. whether the project met its goals;
c. satisfaction with the outcomes;
d. the costs and benefits;
e. whether any further development is required; and
f. what lessons were learnt.

22. The findings of the review will be presented to the HTA’s Stakeholder Group at its meeting on 18 October.

Horizon scanning

23. The first phase in the development of a formalised horizon scanning system is to understand what we currently have in place.

24. Staff across the HTA are involved in horizon scanning – though it may not always be thought of in these terms – however, this has developed in an ad-hoc manner. The aim of this project is to move towards a systematic approach to horizon scanning, with consistent information management, sharing, and documented decision-making.

25. Understanding the current arrangements has been divided into two parts:

a. **Information mapping:** This involves mapping information sources against the type of information, their areas of influence, and the staff member leading in this area. The purpose of this exercise is to understand what is in place, where there are overlaps and where there are gaps. The mapping exercise has also helped to identify information sources, which are currently not being used. The map has largely been completed.

b. **Review of systems:** This involves understanding how horizon scanning information is currently recorded and/or shared between staff. This work is in the initial phases and will continue through group discussions, for example at the next all staff meeting. Discussions will focus on how information is shared currently, the benefits and disadvantages of each, and the barriers to using other methods.

26. At the next meeting of the HTA Management Group, the project team will report on the current systems with proposed next steps.

Review of the HTA advisory groups

27. This review is discussed separately at Item 11 – Advisory group review [HTA (33/17)].
Development of a safety KPI

28. As part of the 2017/18 business planning process, the Authority requested that a Delivery KPI and performance indicator be developed to give the Authority assurance in relation to HTA activities aimed at ensuring human tissue is used safely. It has been proposed that this KPI takes the form of an annual report summarising HTA activity relating to the safe use of human tissue, which will be submitted to the Authority in May / June of each year.

29. A paper outlining the proposed content of the report was taken to the meeting of the HTA Management Group and discussed with Amanda Gibbon, and all content was approved without further recommendations. A first version of the report will be shared with Authority Members in October 2017, to inform on progress and seek feedback on the scope and content of the report. This version of the report can also be used to inform strategy setting for the following year.

Sustainability of the Independent Assessors framework and continuous accreditation for Independent Assessors

30. The landscape of living donor transplantation has evolved hugely from when the system was set up. There has been a concern for some time that a continuing reliance on Independent Assessors (IAs) who are largely volunteers is unsustainable. There are plans set out in the NHS Blood and Transplant living donor strategy, for living organ donations to reach record levels by 2020, and this statutory role is a key function in the pathway to donation.

31. There has never been any formal agreements put in place, either between the HTA and IAs, or between the HTA and Trusts / Health Boards. Without any formal governance arrangements in place, it is felt that the sustainability of the system may be at risk longer term. Fewer numbers of people are coming forward to be trained as IAs, with a considerable drop in the numbers being trained in the last twelve months alone. Although overall numbers are reasonably stable, the system is operating with the fewest number of accredited IAs we have ever had, a total of 129, across the United Kingdom. In addition, a significant number of these are retired people who may not wish to continue with the role in the longer-term.

32. This project will allow the HTA to properly explore the opportunities that may be open to us to strengthen or formalise arrangements with a view to ensuring the system is fit for purpose moving forward.

33. Separate to the above, but closely linked, is the issue of IA reaccreditation. This strand of the project is likely to include consideration of a continuous accreditation system, perhaps with a quality check at specific points throughout the year, rather than an
annual review of each IA’s performance during the course of the previous twelve months.

**Undertake Disclosure and Barring Service (DBS) checks for Accredited Assessors**

34. In June 2015, internal auditors undertook a review of the HTA’s living organ donation systems, as part of the 2015/16 Internal Audit Plan. This was specifically to look at the key controls in place relating to both the accreditation and training of IAs. Auditors felt that the HTA had no assurance that IAs had appropriate DBS (or equivalent) checks in place and determined that this left the HTA facing significant reputational damage if it failed to have in place all relevant safeguarding procedures. A project was undertaken to ensure all IAs had appropriate, enhanced checks in place and this was completed during 2016/17.

35. We are now undertaking a similar piece of work, which will ensure that all Accredited Assessors have an enhanced DBS (or equivalent) checks in place to ensure the HTA has similar assurances around safeguarding. This was felt to be particularly important as Accredited Assessors interview very young children. This work will be completed by October 2017.

**Compliance updates from all non-human application sectors**

36. To support our system of continuous licensing, every licensed non-human application establishment is required to provide us with a biennial update of licensing information and to complete a concise, sector-specific questionnaire focussed on risk and compliance with our standards. This helps us to maintain oversight of the sectors we regulate, guide our regulatory approach to each sector, and inform the scheduling of site-visit inspections. While the core administrative checks remain the same for each round of compliance updates, the sector-specific questionnaires are revised to keep pace with key risks and trends in activities or non-compliances. Compliance updates are not sought from establishments licensed in the human application sector as they are inspected every two years and they are required to provide annual activity data.

37. Following a communication campaign, legal Directions and guidance were issued to all relevant establishments on 2 August 2017, setting out how to make their submissions via the HTA Portal. The deadline for the returns is 2 October 2017. Data from the submitted compliance updates will be analysed by the Heads of Regulation, with any points requiring clarification being followed up with individual licensed establishments.
Development KPI narrative

Performance against 2017/18 KPIs

38. All Development KPIs for quarter one were within target or tolerance and marked as green with the exception of KPI:7 – to deliver a project to implement EU Directives on Coding and Import, which is marked as red.

Projects scheduled to start in the next six months

<table>
<thead>
<tr>
<th>Project</th>
<th>Brief description</th>
<th>Start date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Development PI</td>
<td>PROJECT: Deliver recommendations from the enquiries audit</td>
<td>Q3</td>
</tr>
</tbody>
</table>
# Authority Report

Deployment – Quarter One 2017/18

<table>
<thead>
<tr>
<th>Date</th>
<th>14 September 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agenda Item</td>
<td>9</td>
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<tr>
<td>Paper Reference</td>
<td>HTA (32/17)</td>
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<tr>
<td>Author</td>
<td>Richard Sydee</td>
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</tr>
<tr>
<td>Author Contact</td>
<td><a href="mailto:richard.sydee@hta.gov.uk">richard.sydee@hta.gov.uk</a></td>
</tr>
</tbody>
</table>

## Strategic objectives (Deployment)

- To manage and develop our people in line with the HTA’s People Strategy
- To ensure the continued financial viability of the HTA while charging fair and transparent licence fees and providing value for money
- To provide a suitable working environment and effective business technology

## Relevant KPIs

- Reduce attrition rates through improved selection and targeted retention measures to retain staff
- Implement targeted retention initiatives to better maintain capacity and improve capability among the Regulation Manager cadre, through improved selection and targeted measures to retain staff
- Lead and advise on best recruitment procedures to maintain organisational capacity and capability
- Manage all development options offered to staff and evaluate courses to ensure quality delivery and learning effectiveness
- Ensure that the HTA has sufficient financial resources to fund its regulatory and policy activity, whilst continuing to provide value for money to license fee payers through limiting growth in licence fees
- Ensure that the HTA has sufficient financial resources to fund its regulatory and policy activity, whilst continuing to provide value for money to license fee payers through limiting growth in licence fees

## Related Strategic Risks

- Failure to manage an incident
- Failure to utilise our capabilities effectively
- Insufficient, or ineffective management of financial resources

(see paper 29a/17 for detailed information)
Purpose of paper

1. To provide the Authority with standardised information on the deployment of HTA resources and to highlight any issues which require consideration by Members.

2. It is provided as a source of assurance on the deployment of HTA resources.

Decision-making to date

3. This report was considered by the Senior Management Team (SMT) at its meeting on 7 September 2017.

Action required

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

Director’s summary

5. We continue to make good progress against the aspirations set out in the People Strategy. In quarter one, we introduced some well-received improvements to the performance development planning process to bring greater quality to development discussions between individuals and line managers and to align these discussion with the 70/20/10 development model.

6. The attrition rate has been relatively steady, and only one post holder has left the HTA during quarter one. Having said this, we now have three staff who are working notice and will be leaving the organisation in September. In light of our recent experience in recruiting for a Regulation Manager vacancy, we will be keeping a close eye on whether we are finding it harder to recruit to posts, than has recently been the case.

People

People Strategy

7. Earlier in the year, we conducted a survey on our annual performance development planning process. Following the feedback received, we made some changes to the process to place a greater focus on development and have seen an increase in staff identifying both on the job learning and formal training opportunities.

8. All HTA line managers attended line management training in August, with the aim of better embedding a common understanding of the benefits of good people management, in line with the aspirations set out in the People Strategy. This was a
good opportunity for our managers to identify personal barriers to good line management and reflect on their own development needs as people managers.

Leavers’ report

9. The HTA recognises that gathering feedback directly from leavers is valuable in assessing trends that lead to a decision to leave. To be able to do this effectively, we have an exit interview process in place, which provides a structured way for us to gather information from leavers. This report (Annex A) has been produced by collating the data from exit interviews that took place between January 2016 to March 2017. The results have then been analysed to outline areas for improvement and areas that the HTA are doing well.

Finance

Financial position for the three months ending 30 June 2017

10. The position as at 30 June 2017 has been arrived at after extensive work on our original budget. The Authority is aware that at the end of the review for 2017 fees (carried out in 2016/17), there was a significant under recovery of income. This affected the HTA’s forecast budget, which was compounded by increases in our rent and a failure to clawback under recoveries from the previous years.

11. This resulted in a deficit position of £205k in the first draft of the HTA budget for 2017/18. At this point, we were not certain if the income budgeted for would materialise, as in previous years, we had seen a significant drop in licence fee income due to establishments revoking between the period our fees were published and the first round of billing in April.

12. During quarter one of this financial year, a review of the budget was undertaken which involved all areas of the business taking a hard look at proposed costs and making a decision as to whether these costs could be avoided thus allowing us to set an adjusted budget. This review was considered by the Authority at its 27 June 2017 meeting.

13. A review of our staffing numbers and possible deferment of recruitment, in addition to above, enabled us to reduce the deficit to £18k. The table below shows where savings were made.
14. The significant reduction within other staff costs relates to recruitment and training. The general view was that these reductions were manageable, in particular recruitment costs; these costs could be reduced by not using recruitment agencies.

15. Senior Managers with budget responsibility were involved in the review and were made aware of the constraints on our budget. Any spends against the various cost lines must be justified as necessary, and if unnecessary, no purchase orders will be raised against them.

Position as at 30 June 2017 post budget revision

16. **Annex B** shows the year-to-date surplus against the revised budget. Our income shows a significant variance above budget of £167k (11%). However, the Authority’s attention is drawn to the profiling of the budgeted income for both the Devolved Governments
and rent from our tenants. The profile assumed both income streams would be billed in quarter two (not quarter one).

17. This quarter has seen the first tranche of licence fees billed, which were for the human application sector. From the initial setting of fees to the billing date in April 2017, there was a reduction in our income of **£33k**. This is not unexpected and was similar to last year (**£27k**). There will be little movement in income from human application to year end.

18. We have drawn down a portion of our Grant-in-Aid based on last year. The shortfall against budget of **£24k** will be drawn down in quarter two. The **Annex C** provides an analysis of our income.

19. Our spend for quarter one of this business year is relatively close to budget, with a small overspend of **£15k** (1%).

20. We are underspending against staff cost of **£42k** due to vacancies carried at Head and Regulation Manager level. These vacancies were unfilled for the whole quarter.

21. Below are details of cost lines with significant variances to budget.

**Table Two: Expenditure variance**

<table>
<thead>
<tr>
<th>Budget</th>
<th>£</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Travel and subsistence</td>
<td>10,697</td>
<td>The budget for inspections understated and incorrectly profiled. Expectation is that we will overspend at year end by <strong>£21k</strong>.</td>
</tr>
<tr>
<td>Training and Recruitment</td>
<td>18,402</td>
<td>The budget for both areas have been profiled from quarter two hence the variance. There is work to be carried out on training requirements to ensure we have sufficient cover. Recruitment we believe will stay within budget by mediums such as NHS Jobs or Civil Service Gateway.</td>
</tr>
<tr>
<td>Conference and Project costs</td>
<td>10,697</td>
<td>An overspend on venue hire for the public Authority meeting plus budget incorrectly profiled. Forecast for the year shows overspend expected of <strong>£9k</strong>. This takes account of further meetings that may be held off site.</td>
</tr>
<tr>
<td>IT and Telecommunications</td>
<td>(7,906)</td>
<td>Underspends within maintenance contracts, software subscription and general IT consultancy.</td>
</tr>
<tr>
<td>Legal &amp; Professional</td>
<td>15,737</td>
<td>Activity levels where unanticipated after original budget was adjusted.</td>
</tr>
<tr>
<td><strong>Total variance</strong></td>
<td><strong>47,627</strong></td>
<td></td>
</tr>
</tbody>
</table>
22. **Annex E** details variances by directorate. The underspend within the Regulation directorate relates to the vacancy for a Regulation Manager and the overspend within the Chief Executive’s Office relates to training and recruitment costs where the budget profile is nil at quarter one but will even out in quarter two.

**Forecast outturn**

23. After the last reforecasting exercise conducted in early July, we are posting a forecast outturn of **£37k** (overspend). This overspend is not fixed and could be further reduced by looking at areas where spend could be reduced, but we would be mindful of the impact on delivery of our business plan if we choose to remove funding for areas of planned activity.

24. We will continue to review our forecast quarterly and keep a close eye on expenditure between quarters. Where possible, challenging spend before it is committed will be embedded in our procurement process.

25. We remain mindful that there is always a risk that we may incur further costs, such as legal costs, for unplanned work or an issue that arises within our remit.

**Other key performance indicators**

**Debtors**

26. As at 30 June 2017, our licence fee debtor balance was **£272,851** (**£147,005** in the same period 2016/17) relating to **45** (2016/17 – **29**) organisations.

27. We have collected over **80%** of licence fee billed in April and continue to pursue the remaining accounts with vigour. The table below details outstanding amounts by sector.

**Table Three: Debtors by sector**

<table>
<thead>
<tr>
<th>Sector</th>
<th>No. of orgs</th>
<th>Value</th>
<th>% value of total debt</th>
</tr>
</thead>
<tbody>
<tr>
<td>NHS</td>
<td>15</td>
<td>£136,650.00</td>
<td>50%</td>
</tr>
<tr>
<td>Devolved Governments ¹</td>
<td>2</td>
<td>£85,592.00</td>
<td>31%</td>
</tr>
<tr>
<td>Bodies external to Government</td>
<td>13</td>
<td>£6,746.00</td>
<td>3%</td>
</tr>
<tr>
<td>Private Companies</td>
<td>15</td>
<td>£43,863.00</td>
<td>16%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>45</strong></td>
<td><strong>£272,851.00</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

¹ Welsh and Northern Ireland Gov’ts (as at 31 August have since paid)
28. Not included within the above figures are outstanding amounts from 2016/17. These total £13,141, from 14 establishments. A provision was made in last year’s annual accounts as we were uncertain as to whether they could be collected.

29. There are two establishments (an NHS Hospital and a Mortuary) owing £7,200 / £5,100 respectively. We had problems getting an agreement to pay, however, we finally received payment for both in August.

30. We intend to take a view on the remaining amounts of unclaimed credits and small fees for activities taken up during the year. SMT will take a decision whether to write them off or continue to pursue them.

**Financial risks**

31. 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 amber as we have a challenging budget due to an under recovery of fees, which have been higher than previous years.

Table Four: Close proximity risks and mitigations

<table>
<thead>
<tr>
<th>Risk</th>
<th>Mitigating actions and controls</th>
</tr>
</thead>
<tbody>
<tr>
<td>An overspend may lead to a lack of stakeholder confidence in HTA’s ability to manage resources effectively.</td>
<td>Monthly review of financial position and quarterly re-forecasting. Review of activities that can be deferred.</td>
</tr>
<tr>
<td>Establishments change their profile resulting in a reduction in hubs and satellites, and licensed activities, leading to a reduction in fee income.</td>
<td>Periodic review of establishments and expected income. Budgets are then managed to reflect income.</td>
</tr>
</tbody>
</table>
Business technology and working environment

Business technology

32. The new Head of Business Technology continues to assess the technology currently in use at the HTA, including the long-term viability of critical line of business systems and the desktop and remote working environments. After observing a post-mortem inspection, he is also considering how technology might be used to help the inspection process.

33. The Head of Business Technology, with others, will be working to determine the right time to proceed with an upgrade to the customer relationship management system (CRM). He has also flagged that there is a more strategic decision to be made about the future of CRM, which needs to be linked into the aforementioned ‘right time’ decision.

Working environment

34. During July, we submitted information to the Cabinet Office in relation to the recently announced Public Sector Relocation Programme. This was part of the Conservative party manifesto commitment to move public sector organisations away from London to support the Government’s wider Industrial Strategy.

35. Current indications are that there will be an announcement in the November budget, but that the approach is unlikely to target smaller arms-length bodies at present and that we are likely to remain in our current location until our lease expires in 2021.
Deployment KPI narrative

Performance against 2017/18 KPIs

36. The attrition rate, measured by KPI:10, on a monthly rolling basis, was marked as red and was 22% at the end of June 2017, against an indicative rate of 18%.

37. Since April 2017, two new colleagues have joined the HTA; Emelie Wahlstedt (Regulation Manager) and David Thomson (Head of Business Technology). The former Head of Business Technology left the HTA in April 2017.

38. KPI:11, which measures retention in the Regulation Manager cadre was also marked as red at the end of June 2017, with 76% in post for longer than one year (16 of 21), against an indicative rate of 85%.

39. As mentioned above, KPI:14, which measures whether the HTA has sufficient financial resources to deliver its regulatory and policy activity (high equals risk if deficit is more than 10%) was marked amber.

40. All other Deployment KPIs to the end of July 2017 were within target or tolerance and marked as green.
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Introduction

The HTA recognise that gathering feedback directly from leavers is valuable in assessing trends that lead to a decision to leave. Being able to do so effectively provides a realistic and relevant insight which can be considered when reviewing recruitment and retention methods. The information also offers an opportunity to act on any concerning information which may be impacting on the health and wellbeing of staff.

To be able to do this effectively there is an exit interview process in place which provides a structured way in which to gather information from leavers. This report has been produced by collating the data from exit interviews that took place between January 2016 – March 2017. The results have then been analysed to outline areas for improvement and areas that the HTA are doing well.

The HTA has a two stage process for gathering exit interview data. This includes an initial short survey style questionnaire followed by an interview with HR. This is the fourth report to be produced using this approach and comparison with previous year’s results has taken place. As information is gathered year on year, an increased level of trend analysis will become possible.

Between 1\textsuperscript{st} January 2016 – 31\textsuperscript{st} March 2017 the HTA had sixteen leavers. Eleven leavers were able to participate in the formal exit interview process with four choosing not to do so. As such, this report reflects the views of seven people and as this is a relatively small number it should be taken into consideration when interpreting the figures presented.
This chart shows that the majority of leavers between January 2016 – March 2017 were in the Regulation Directorate. When comparing this data to the previous year, it is important to note that an organisation restructure took place during this reporting period resulting in the ‘Policy and Strategy’ Directorate becoming the ‘Policy, Strategy and Communications’ Directorate and the administration and living donation functions becoming part of the Regulation Directorate.

This is a change from the January 2015 – December 2015 reporting period where 60% of the organisation’s leavers had come from the CEO Office. Analysis of the data however does show that the majority of leavers would still have come from the Regulation Directorate for this reporting period even if the administration and communications functions had not been moved from the CEO Office into other directorates.

Further analysis shows that 70% of leavers from within the Regulation Directorate held pay band 3 (manager) level posts. Retention of people within the Regulation Manager post is a known challenge for the HTA and the risk associated with this is monitored through our monthly business reporting where we report on the percentage of Regulation Managers with 1 year or more service with the HTA. At the end of March 2017, we had 60% of Regulation Managers with more than 1 year of service.

The majority of these leavers cited ‘better career opportunity’ and ‘higher salary’ as their reasons for leaving which continues to be in line with data from previous years.

The HTA is bound by public sector pay restrictions that have been put in place for the term of this government and as a relatively small organisation; we recognise that progression opportunities can be limited. We continue to investigate and consider initiatives to address this where possible as part of the HTA People Strategy.

The table below outlines in number the job titles of those that left the HTA during the January 2016 – March 2017 reporting period:
<table>
<thead>
<tr>
<th>Directorate</th>
<th>Job Title</th>
<th>Number of Leavers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulation</td>
<td>Head of Regulation</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Regulation Manager</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Living Donation Officer</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Administration Assistant</td>
<td>1</td>
</tr>
<tr>
<td>Policy, Strategy and Communications</td>
<td>Head of Communications</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Head of Policy and Strategy</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Governance and Quality Manager</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Website and Design Officer</td>
<td>1</td>
</tr>
<tr>
<td>Resources</td>
<td>Shared Director of Resources</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Finance Manager (fixed term contract)</td>
<td>1</td>
</tr>
</tbody>
</table>

**Reasons for Leaving**

This data has been taken from the initial form, which lists the following categories that the leaver can choose from:

- Higher Pay
- Better Benefits
- Better Career Opportunity
- Improved work/life balance
- Career Change
- Closer to Home
- Conflict with Colleagues
- Conflict with Line Manager
- Family and/or personal reasons
- Instability and uncertainty within the HTA
- Relocation
- Other
The results are consistent with previous years reporting showing that the most frequently selected categories are in relation to career opportunities and pay.

Both of these continue to be raised as issues by staff through various avenues such as the staff survey and are usually in relation to the government restrictions on pay and the HTA being a relatively small organisation.

Two leavers chose ‘other’. One chose this option as their fixed term contract ended and while they would have liked to stay with the HTA there were no other opportunities that matched their skills and interests at the time. The second chose this option as while the role was what they expected, once they commenced they felt it was not the right role for them.

It should also be noted that for this question leavers could choose more than one answer.

**Length of service for leavers**

These figures show the number of leavers by the length of service for each individual.

The graph shows that the majority of leavers in the period January 2016 – March 2017 had 1 – 2 years of service.

The majority of leavers with 1 – 2 years’ service held pay band 2 (Officer) and 3 (manager) level positions and identified career progression / better opportunities and higher pay as their reasons for leaving. This is consistent with previous years reporting.

Two of the leavers with 5 years or more service held Regulation Manager posts. These two leavers chose not to participate in the exit interview process and as such did not formally select one of the reasons above for their reason for leaving. In discussions at the time of their resignations, however one indicated the decision was due to family / personal reasons and the other indicated it was for a career change.
The other two leavers with 5 years or more service held management and senior management posts. These two leavers also did not participate in the exit interview process however at the time of resignation indicated retirement and personal reasons as their reasons for leaving.

Of the three leavers who left during their first 12 months, only two were eligible to participate in the exit interview process. One left as they were employed on a 4 month fixed term contract and there were no opportunities that matched their skills and interests at the time their contract ended. The second left as while the role had been what was described at interview, they identified once in the role that it was not the right position for them and chose to leave within their probationary period.

**Salary and benefits**

The below chart outlines the responses received to the question: My salary was adequate and fair in relation to my responsibilities:

![Chart showing responses to salary adequacy and fairness](chart.png)

The chart shows that the majority of leavers felt that their salary was adequate and fair in relation to their responsibilities. Initially, this appears to be inconsistent with ‘higher salary’ being chosen as the second most frequent reason for leaving.

This was queried as part of the exit interview discussion and feedback indicated that while leavers felt the starting salary for their position was adequate and fair, their concerns related to the public sector pay restriction of 1% per annum and lack of progression pay once in post. Some leavers expressed concern that with transport and living costs continuing to rise each year beyond 1%, the public sector pay restrictions meant they were effectively taking a pay cut each year they continued to work for the HTA.
The below chart outlines the responses received to the question: My salary was supplemented with a range of good benefits:

![Bar chart showing responses to the question](chart.png)

The chart shows that the majority of leavers felt that the HTA offered a good range of benefits. Interview scripts suggest that the high annual leave balance and flexible working options were of particular value.

**Further analysis**

The following charts provide information about how the leaver felt about:

- Their role
- The HTA as an organisation
- Their relationship with their line manager
- The HTA’s senior management team
My role:

**Was challenging**

<table>
<thead>
<tr>
<th>Strongly agree</th>
<th>Agree</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

**What I expected it to be when I applied**

<table>
<thead>
<tr>
<th>Strongly agree</th>
<th>Agree</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

**Provided sufficient opportunities for progression**

<table>
<thead>
<tr>
<th>Strongly agree</th>
<th>Agree</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>4</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

**Had a manageable workload**

<table>
<thead>
<tr>
<th>Strongly agree</th>
<th>Agree</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

**Was appreciated by my colleagues**

<table>
<thead>
<tr>
<th>Strongly agree</th>
<th>Agree</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>5</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

**Allowed for my skills to be effectively used**

<table>
<thead>
<tr>
<th>Strongly agree</th>
<th>Agree</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>2</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

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The HTA:

- **Arranged a helpful and accurate induction**: 7 strongly agree, 2 disagree.
- **Is a positive environment to work in**: 7 strongly agree, 0 disagree.
- **Is efficient in its working practices**: 5 strongly agree, 2 disagree.
- **Provided adequate equipment to be able to complete my work**: 4 strongly agree, 3 disagree.
- **Promotes and allows for employees to have a good work-life balance**: 4 strongly agree, 2 disagree.
- **Is effective with internal communications**: 3 strongly agree, 2 disagree.
- **To the best of my knowledge did not discriminate against any employee**: 5 strongly agree, 2 disagree.
My line manager:

Had sufficient knowledge of my role to be able to effectively provide support

- Strongly agree: 1
- Agree: 6
- Disagree: 1
- Strongly disagree: 0

Recognised and acknowledged my achievements and contributions

- Strongly agree: 2
- Agree: 4
- Disagree: 1
- Strongly disagree: 2

Was open to my suggestions

- Strongly agree: 1
- Agree: 4
- Disagree: 2
- Strongly disagree: 0

Offered and promoted ways for me to develop

- Strongly agree: 2
- Agree: 4
- Disagree: 1
- Strongly disagree: 0

Provided constructive feedback

- Strongly agree: 1
- Agree: 5
- Disagree: 1
- Strongly disagree: 0

Clearly communicated management decisions and explained any impact these had on my role

- Strongly agree: 1
- Agree: 4
- Disagree: 2
- Strongly disagree: 0

Maintained a positive and professional relationship with me

- Strongly agree: 1
- Agree: 5
- Disagree: 1
- Strongly disagree: 0

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The senior management team:

Promoted fair and equal treatment across the HTA

- Strongly agree: 2
- Agree: 5
- Disagree: 1
- Strongly disagree: 0

Were available to discuss job related concerns

- Strongly agree: 1
- Agree: 6
- Disagree: 0
- Strongly disagree: 0

Were open to suggestions from all employees

- Strongly agree: 2
- Agree: 5
- Disagree: 1
- Strongly disagree: 0

Reviewed and maintained consistent policies and practices

- Strongly agree: 1
- Agree: 6
- Disagree: 0
- Strongly disagree: 0

Clearly communicated SMT decisions and the reasoning behind them

- Strongly agree: 1
- Agree: 5
- Disagree: 1
- Strongly disagree: 0

Provided the opportunity for employees to offer feedback on SMT decisions

- Strongly agree: 2
- Agree: 5
- Disagree: 0
- Strongly disagree: 0

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Interview Analysis

To provide a more rounded picture interview scripts are analysed to provide greater detail on the ratings chosen by leavers and identify areas for improvement as well as what the HTA is doing well.

The two areas highlighted by leavers for improvement are:

- **Providing challenging work that allows staff to utilise their skills**
  These are the same two areas identified in the previous reporting period and are consistent with feedback received from staff directly and through the staff survey.

  Changes have been made to the format of the 2017/18 performance development plan (PDP) template with the aim to encourage a greater level of discussion between line managers and their teams about each individuals development needs.

  The HTA's approach to learning and development is influenced by the 70-20-10 learning model and the template has been developed in a way that requires individuals and their managers to consider a wide range of approaches to learning and development beyond traditional training courses.

  It is hoped that this may help to identify pieces of work that will provide challenge and learning opportunities to staff in their areas of interest while addressing the feeling of some staff that they are not able to utilise their skills.

- **Opportunities for progression**
  Limited opportunities for progression continues to be a key theme in feedback received from staff. Interview scripts indicated that leavers felt that in order to progress to a role with higher levels of responsibility relatively quickly they had to seek opportunities outside of the HTA with larger organisations.

  Leavers suggested this was due to the relatively small size of the HTA, minimal number of Head and Senior Management positions as well as the low attrition rate for staff at those levels, which leads to these opportunities rarely becoming available.

  The HTA recognise this as a concern however are limited in the ways we can address this. At present, the HTA are investigating the possibility of a Senior Regulation Manager post however, this investigation is still in the early stages and it is not yet known if this would address the concerns raised by leavers relating to progression opportunities.

  In addition, the HTA continues to look at ways to create cross-organisational opportunities that staff will be able to expand their skills and experience within their current role leading to a greater level of staff retention.
The areas highlighted by leavers as areas the HTA do well are:

- **Culture**
  Leavers felt that the HTA was a supportive workplace that did not discriminate against any employee or have discriminatory practices in place.

- **Relationships**
  Each leaver highlighted good working relationships across the organisation, particularly within their immediate team and felt appreciated by their colleagues. Line management was also highly rated by the majority of leavers. It was suggested by a number of leavers that these good relationships had made the decision to leave the HTA difficult.

  In addition, leavers rated the HTA’s senior management team highly, noting that while the majority did not have day-to-day contact with the senior management team, they found them to be approachable when needed and willing to consult and consider opinions of staff. Some leavers noted that this open and transparent approach to management was vastly different from other organisations they had worked in.

- **Work-life balance**
  Work-life balance was rated highly by all but one leaver. Leavers noted that the HTA’s willingness to consider different types of flexible working options to be a key contributor to this. The one leaver who felt the HTA did not promote a good work/life balance was a Regulation Manager who had concerns about the level of workload placed on experienced employees while new starters were being trained.

- **Induction**
  All leavers felt they had received a helpful and accurate induction. Those leavers that had started within the previous 12 months noted that they had found the induction booklets and meetings with individual staff members very helpful. This feedback is particularly positive, as induction had been highlighted as an area for improvement in the previous reporting period.

**Actions**

The HTA People Strategy continues to be committed to addressing the areas for improvement that have been highlighted by leavers as part of the exit interview process as well as by staff through other various feedback channels.

Please refer to the HTA People Strategy and roadmap for a list of the initiatives currently underway and those planned for the 2017-18 business year.
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Human Tissue Authority

Summary - Income & Expenditure

For the Three Months Ending 30 June 2017

<table>
<thead>
<tr>
<th></th>
<th>Year to Date</th>
<th>OUTTURN</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Actuals</td>
<td>Budget</td>
</tr>
<tr>
<td>Income</td>
<td>(1,680,087)</td>
<td>(1,513,204)</td>
</tr>
<tr>
<td>Less: Expenditure</td>
<td>1,131,558</td>
<td>1,116,397</td>
</tr>
<tr>
<td>Net (surplus)/deficit of income over expenditure</td>
<td>(548,529)</td>
<td>(396,806)</td>
</tr>
</tbody>
</table>

INCOME & EXPENDITURE SUMMARY

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Human Tissue Authority

Income Summary

For the Three Months Ending 30 June 2017

<table>
<thead>
<tr>
<th></th>
<th>Actuals</th>
<th>Budget</th>
<th>Variance</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grant In Aid</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GIA</td>
<td>176,000</td>
<td>200,000</td>
<td>(24,000)</td>
<td>-12.00%</td>
</tr>
<tr>
<td>Sub-Total</td>
<td>176,000</td>
<td>200,000</td>
<td>(24,000)</td>
<td>-12.00%</td>
</tr>
<tr>
<td>Licence Fees</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Application Fees</td>
<td>9,150</td>
<td>12,050</td>
<td>(2,900)</td>
<td>-24.07%</td>
</tr>
<tr>
<td>Anatomy</td>
<td>292</td>
<td>0</td>
<td>292</td>
<td>0.00%</td>
</tr>
<tr>
<td>Post Mortem</td>
<td>8,708</td>
<td>0</td>
<td>8,708</td>
<td>0.00%</td>
</tr>
<tr>
<td>Public Display</td>
<td>1,875</td>
<td>0</td>
<td>1,875</td>
<td>0.00%</td>
</tr>
<tr>
<td>Research</td>
<td>7,210</td>
<td>0</td>
<td>7,210</td>
<td>0.00%</td>
</tr>
<tr>
<td>Human application</td>
<td>1,258,865</td>
<td>1,291,900</td>
<td>(33,035)</td>
<td>-2.56%</td>
</tr>
<tr>
<td>ODT</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0.00%</td>
</tr>
<tr>
<td>Sub-Total</td>
<td>1,286,100</td>
<td>1,303,950</td>
<td>(17,850)</td>
<td>-1.37%</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other income (Rent)</td>
<td>77,534</td>
<td>0</td>
<td>77,534</td>
<td>0.00%</td>
</tr>
<tr>
<td>Other income (Secondees)</td>
<td>10,488</td>
<td>9,254</td>
<td>1,234</td>
<td>13.33%</td>
</tr>
<tr>
<td>Devolved Assemblies</td>
<td>129,964</td>
<td>0</td>
<td>129,964</td>
<td>0.00%</td>
</tr>
<tr>
<td>Sub-Total</td>
<td>217,986</td>
<td>9,254</td>
<td>208,732</td>
<td></td>
</tr>
<tr>
<td>Total Income</td>
<td>1,680,086</td>
<td>1,513,204</td>
<td>166,882</td>
<td>11.03%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Forecast</th>
<th>Budget</th>
<th>Variance</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grant In Aid</td>
<td>800,000</td>
<td>800,000</td>
<td>0</td>
<td>0.00%</td>
</tr>
<tr>
<td>Sub-Total</td>
<td>800,000</td>
<td>800,000</td>
<td>0</td>
<td>0.00%</td>
</tr>
<tr>
<td>Licence Fees</td>
<td>57,350</td>
<td>60,250</td>
<td>(2,900)</td>
<td>-4.81%</td>
</tr>
<tr>
<td>Application Fees</td>
<td>89,142</td>
<td>88,850</td>
<td>292</td>
<td>0.33%</td>
</tr>
<tr>
<td>Post Mortem</td>
<td>1,070,658</td>
<td>1,061,950</td>
<td>8,708</td>
<td>0.82%</td>
</tr>
<tr>
<td>Public Display</td>
<td>17,775</td>
<td>15,900</td>
<td>1,875</td>
<td>11.79%</td>
</tr>
<tr>
<td>Research</td>
<td>594,560</td>
<td>587,350</td>
<td>7,210</td>
<td>1.23%</td>
</tr>
<tr>
<td>Human application</td>
<td>1,258,865</td>
<td>1,291,900</td>
<td>(33,035)</td>
<td>-2.56%</td>
</tr>
<tr>
<td>ODT</td>
<td>248,000</td>
<td>248,000</td>
<td>0</td>
<td>0.00%</td>
</tr>
<tr>
<td>Sub-Total</td>
<td>3,336,350</td>
<td>3,354,200</td>
<td>(17,850)</td>
<td>-0.53%</td>
</tr>
<tr>
<td>Other</td>
<td>309,444</td>
<td>309,213</td>
<td>0</td>
<td>0.00%</td>
</tr>
</tbody>
</table>
| Other income (Secondees) | 38,249 | 37,015 | 1 | 0.00%
| Devolved Assemblies  | 129,964  | 116,000 | 13,964   | 12.04%     |
| Sub-Total            | 477,657  | 462,228 | 15,429   | 3.34%      |
| Total Income         | 4,614,007| 4,616,428 | (2,421) | -0.05%  |
Human Tissue Authority

Summary - Expenditure

For the Three Months Ending 30 June 2017

<table>
<thead>
<tr>
<th></th>
<th>Year to Date</th>
<th></th>
<th></th>
<th>OUTTURN</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Actuals</td>
<td>Budget</td>
<td>Variance</td>
<td>Forecast</td>
<td>Budget</td>
<td>Variance</td>
</tr>
<tr>
<td></td>
<td>£</td>
<td>£</td>
<td>£</td>
<td>£</td>
<td>£</td>
<td>%</td>
</tr>
<tr>
<td>Staff Costs</td>
<td>711,946</td>
<td>753,592</td>
<td>(41,646)</td>
<td>-5.53%</td>
<td>2,962,043</td>
<td>3,005,992</td>
</tr>
<tr>
<td>Non Staff Costs</td>
<td>419,611</td>
<td>362,805</td>
<td>56,806</td>
<td>15.66%</td>
<td>1,689,362</td>
<td>1,628,255</td>
</tr>
<tr>
<td>Total Expenditure</td>
<td>1,131,558</td>
<td>1,116,397</td>
<td>15,160</td>
<td>1.36%</td>
<td>4,651,405</td>
<td>4,634,247</td>
</tr>
</tbody>
</table>

17/08/2017
17:22
## Human Tissue Authority

### Directorate Summary

#### For the Three Months Ending 30 June 2017

<table>
<thead>
<tr>
<th></th>
<th>Year to Date</th>
<th>OUTTURN</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Actuals £</td>
<td>Budget £</td>
</tr>
<tr>
<td>Policy, Strategy &amp; Communications</td>
<td>152,662</td>
<td>147,036</td>
</tr>
<tr>
<td>Regulation</td>
<td>448,914</td>
<td>473,624</td>
</tr>
<tr>
<td>HTA Board</td>
<td>55,696</td>
<td>43,809</td>
</tr>
<tr>
<td>Resources</td>
<td>390,119</td>
<td>388,256</td>
</tr>
<tr>
<td>Chief Executive's Office</td>
<td>84,167</td>
<td>63,673</td>
</tr>
<tr>
<td><strong>Subtotal</strong></td>
<td><strong>1,131,558</strong></td>
<td><strong>1,116,398</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Total Directorate(s) Expenditure</th>
<th>Year to Date</th>
<th>OUTTURN</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Actuals £</td>
<td>Budget £</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1,131,558</td>
<td>1,116,398</td>
</tr>
</tbody>
</table>

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

**Purpose of paper**

1. To provide Members with a proposal on the future of the HTA's advisory groups.

**Decision-making to date**

2. A discussion paper on the review was considered by the HTA Management Group at its July meeting. In addition, this report was considered by the Senior Management Team (SMT) at its meeting on 7 September 2017.

**Action required**

3. The Authority is asked to:
   a. note the content of this paper; and
   b. provide feedback on, and agree, the proposal below.

**Background**

4. The HTA currently has three advisory groups:
   a. Histopathology Working Group (HWG);
   b. Transplantation Advisory Group (TAG); and
   c. Stakeholder and Fees Group (SFG).

5. The HTA membership of each Group is included at Annex C.
6. HWG and TAG were established by the HTA in order to engage and build relationships with the post-mortem and living organ donation sectors. HWG first met in January 2011. TAG, which was formerly known as the Transplantation Working Group, first met October 2005. It was renamed TAG in October 2013. At this time, the constitution of the group was changed to reflect the introduction of the European Union Quality and Safety of Organs Intended for Transplantation Regulations in 2012. Changes to the constitution established TAG as a discussion forum for both living and deceased organ donation.

7. The SFG was established following an independent review of the HTA and the Human Fertilisation and Embryology Authority by Justin McCracken, in April 2013. The review recommended that both regulators, “should review and strengthen their arrangements for consulting with stakeholders on their approach to regulatory activities, and should ensure that issues raised with them and their responses are publicly available and discussed regularly in open Authority meetings”.

8. The SFG first met in November 2013, with the core functions of providing and ongoing communication channel with stakeholders, to discuss regulatory issues and to consider fees proposals annually.

9. As the three groups have developed somewhat organically to respond to specific needs, the HTA does not have an advisory group for all of the sectors it regulates. To ensure that the current arrangements remain appropriate, it was agreed that there was value in undertaking a review of the groups, to consider whether any changes or additions were required during 2017/18 (Business Plan Performance Indicator: 30).

10. This review also forms a part of the HTA Development Programme to engage with licensed establishments (Business Plan Key Performance Indicator: 8) by considering whether there are changes which could be made that would increase both the amount and quality of engagement with our professional stakeholders.

Proposal

11. Based on Annexes A and B, it is proposed that:

   a. the existing groups remain in place; and
   b. no new standing groups are created. However, that we actively consider ad-hoc groups as and when the need arises.

12. In regard to the existing groups, it is proposed that:
a. An Authority Member becomes Chair of TAG (as is the case with SFG), which frees-up the Executive to contribute as members of the group and also makes good use of the expertise we have on the Authority.

b. Membership of TAG is revisited to ensure we have representation from those affected by both our assessment of living donations and regulation of the organ donation and transplantation sector.

c. A survey of TAG members is undertaken and steps are taken to make improvements where necessary.

d. Work is undertaken to further improve the functioning of SFG, as per the outcome of the survey of it members.

e. The Authority membership of SFG is made permanent, rather than being on a rotational basis. It is recommended two Authority members become standing members of SFG.

f. More broadly, consideration is given to rationalising the number of Authority Members on each group. Feedback from the Executive and members of HWG and SFG suggests that two or three Members is an ideal number, to ensure that the group does not feel HTA-dominated. As we have moved to having greater Member involvement in project boards, membership of the advisory groups is just one of the ways in which Members are able to contribute to the activity of the HTA. It is proposed that in future not all Members sit on an advisory group.

13. In regard to ad-hoc groups, it is proposed that:

a. Ad-hoc groups are formed when the need arises. This may be because there are new requirements (for example, a group was convened when Process Preparation Dossiers were introduced to engage with the human application sector) or a particular issue has been identified, which will be best addressed through collaborative working. These groups may be sector-based or the members may come together due to a shared interest or concern.

b. Ad-hoc groups will have a clear (and succinct) terms of reference. Once the identified tasks have been completed, the group will be disbanded.

c. Ad-hoc groups may meet face-to-face, virtually via Skype / teleconferencing, and / or via the online forum once it is established (paragraph 34). The mode of meeting will be chosen to deliver the most effective outcome in the most efficient manner.
Annex A - Existing groups

14. Both the SFG and HWG have undertaken reviews of their effectiveness by surveying group members. SFG reported the finding of its review at its October 2016 meeting; HWG at its May 2017 meeting.

15. The SFG survey found that members were of the view that the group added value to the work of the HTA and that they valued engaging with us in this format. It also established that more could be done to assist the group to function at the very highest level. The Executive considers that having a standing group, which can be consulted on fees each year (in addition to its discussion of regulatory issues), is of a significant benefit to the HTA. There is agreement that more work should be done to support this development of this group.

16. In its survey, HWG members were asked whether:

   a. the group was fulfilling its functions;
   b. the group’s objectives are clear and still appropriate;
   c. it has the right mix of skills and expertise;
   d. its secretariat service and timetable functions well; and
   e. the group communicates effectively with stakeholders.

17. Feedback was very positive in all areas. From the group’s point of view, very little needs to be changed. The Executive’s view is that HWG is valuable asset both in terms of engagement and relationship building with the sector, and in informing policy and process development, including horizon scanning.

18. TAG members have not been asked their views on the functioning of the group since its terms of reference were updated in 2013. HTA colleagues that run the secretariat function for TAG will run a survey of this nature in October / November 2017 to capture TAG members’ views.

Group terms of reference

19. In March 2015, a common terms of reference was established across the three groups, which sets out shared governance and recruitment requirements. Within the terms of reference, each group sets out a separate constitution, duties, functions, objectives and membership requirements.

20. HWG is chaired by the Head of Regulation for the post-mortem and public display sectors, TAG is chaired by the HTA’s Director of Regulation, and SFG is chaired by an Authority Member (Bill Horne). Authority Members are appointed to each group by the Authority Chair. The groups currently have a different numbers of appointed Authority
Members (HWG – four Members, TAG – five Members, SFG – one Member, with the Authority Chair attending if required).

21. Following each advisory group meeting, the common terms of reference set out that an Authority Member who was present at that meeting will provide the following Authority meeting with a verbal summary of the issues discussed.

22. In 2016, thought was given as to whether the three groups should be run by the same secretariat function. It was agreed that by keeping the secretariat functions separate, this gave staff across the organisation the chance to develop their secretariat skills, and the value delivered by centralising the functions did not outweigh the development opportunities. Despite this conclusion, the HTA remains committed to delivering a more coordinated approach for the setting of agendas for the three groups. Some steps have been taken in this area, but more can be done.

23. In summary, while some governance efficiencies can still be made, particularly to the SFG and TAG, the groups have effective governance arrangements. There was thought to be value in considering whether moving to an Authority Member being Chair of TAG would be a better use of resources.
Annex B – Approach to the review and current engagement by sector

24. The approach we have taken to considering the possible need for additional groups is three fold:

   a. Firstly, to define the roles and functions that advisory groups undertake.
   b. Secondly, to assess how these roles and functions are currently undertaken in the sectors in which we do not have an advisory group, and if they are not undertaken, whether that raises any issues.
   c. Thirdly, to use this information to make a decision as to whether establishing an advisory group in a given sector is a proportionate step, which will deliver tangible benefits. This includes consideration of whether there is alternative to establishing a new group, which would be more efficient and effective in delivering the roles and functions identified in the first step.

Roles and functions of advisory groups

25. The advisory groups fulfil a wide range of roles and functions. These are:

   a. Communication: The advisory groups provide a channel for communication with members of the group and indirectly to the relevant sector. This allows us to maintain an effective working relationship with those we licence and other interested stakeholders. The groups also allow the HTA to understand the concerns of members and those they represent to ensure that we understand the demands stakeholders are facing, and that they have confidence in our decisions.
   b. Consultation: A key objective for SFG is for the HTA to consult with the group on fees proposals in October, before recommendations are made to the Authority in November, for the following year’s fees. Consultations on other corporate and regulatory policy issues are also considered by the groups, such as the Codes and Standards review and joint regulatory inspections.
   c. Relationship building: The groups allow us to build relationships with members within a small group setting, which gives us a valuable network to draw upon should we need to get our messages out further. HWG has been particularly successful at working with stakeholders in this way on specific topics (for example, mortuary capacity) to achieve identified outcomes.
   d. Horizon scanning: The groups act as a horizon scanning tool for the HTA by informing us about changes that they see across their sectors, which helps us to form a view about the future and to plan effectively.
   e. Informing policy and process development: The groups identify and help us to develop advice and guidance in areas that are needed in each sector. They also help us to review advice and guidance that is in place to ensure it remains fit for purpose.
   f. Feedback: The groups discuss arising policy and legislative issues and difficulties experienced by each sector, to enable us to develop suitable guidance or
solutions. They also provide us with valuable feedback on our performance, so we can ensure that we can be our best as an organisation.

How we undertake these functions at present

26. Over the summer, there was input from colleagues in the Regulation Directorate to this review, particularly for the sectors that do not have a dedicated advisory group (anatomy, research, human application and public display). There was also discussion of the fact that TAG only covers the assessment of living organ donations, whereas the HTA’s remit now includes the licensing of establishments undertaking organ donation and transplantations. It was also noted that the bone marrow donation community is not represented on TAG.

27. A summary of comments has been provided below, by sector.

Anatomy

28. The HTA is already very engaged with those we regulate in the anatomy sector. A sector association, the Anatomy Associations Advisory Committee (AAAC), is already active in this area. Colleagues believe that by developing an HTA-run advisory group, we would be duplicating the efforts of others.

Research

29. The HTA has a presence on a number of groups in this sector. These include: the Health Research Authority Steering Group; the Medical Research Council Brain Banks Group; the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3R); and the Regulatory Advice Service for Regenerative Medicines (RASRM). With the limited regulatory role we take in this sector, colleagues believe that our current engagement approach is appropriate.

Human application

30. The HTA already participates in wide range of sector-specific groups, which facilitate horizon scanning for the human application sector. These include: the advisory group on the Safety of Blood, Tissues and Organs (SABTO); the Stem Cell User Group (SCUG); the Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Service Professional Advisory Committee (JPAC); the Standing Advisory Committee for Tissues and Cellular Therapy Products (SAC TCTP); and the UK Stem Cell Bank Steering Committee (UKSCB). The HTA also takes a leading role in the RASRM and has a technical liaison group with the Medicines and Healthcare products Regulatory Agency (MHRA). A new group is currently being set up with the MHRA, which will consider policy issues that affect both regulators. At the European level, the HTA participates in regular Competent Authority meetings.
31. In the past, a Tissues and Cells Working Group existed after Regulations came into effect in 2007. The group was discontinued, in part, due to the sector’s diverse nature and the resulting difficulty of agreeing on an appropriate agenda on a rolling basis.

Public display

32. Compared to other sectors, the HTA has very little engagement with the public display sector. While a standing advisory group for public display might not be required, the HTA could consider how we could engage more closely with the sector through our licensed establishment engagement programme, and through convening ad-hoc meetings where appropriate.

Organ donation and transplantation and the assessment of living bone marrow donations

33. Changes to the constitution of TAG in 2013 established that it was a forum for discussing issues arising from living and deceased organ donation. While deceased organ donation can be discussed, there is no specific member to advise on these matters, which has meant in practice they have not been discussed. Although a member of the group is a transplant surgeon (who has expertise in this area), there is a question as to whether we should seek to add a Specialist Nurse – Organ Donation (SNOD) to the group’s membership. Similarly, there is no member to advise the group on bone marrow donation. As the HTA’s role has increased in these areas, consideration should be given to expanding the membership of TAG.

Development of an online forum

34. There was support from colleagues across the organisation (as well as the licensed establishments we have spoken with on this issue) that an online forum would be an excellent way of supporting intra-establishment and sector dialogue, as well as being a mechanism for communication, consultation and seeking input.

35. The development work on the online forum is underway as part of the licensed establishments engagement programme, which will provide us with a platform for hosting ad-hoc groups when the need arises, as well as a new channel for communicating with establishments. Once the online forum is up and running, all establishments will have an account by default, and will therefore automatically be a member of their sector group.
Feedback from licensed establishments

36. We asked representatives from the small group of licensed establishments currently involved in the programme of work on engaging with establishments their views on advisory groups; there were no strong views expressed. However, when the suggestion was made that establishing ad-hoc groups, as and when required, may be a better use of resource and lead to effective outcomes, there was general agreement that this would be a good way forward.
Annex C – Current membership of groups

<table>
<thead>
<tr>
<th>Group</th>
<th>Chair</th>
<th>Authority Membership*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Histopathology Working Group (HWG)</td>
<td>Head of Regulation - Post Mortem (Caroline Browne)</td>
<td>Andy Hall, Bill Horne, Graham Usher, Lorna Williamson</td>
</tr>
<tr>
<td>Stakeholder and Fees Group (SFG)</td>
<td>Authority Member (Bill Horne)</td>
<td>Rotating Authority membership</td>
</tr>
<tr>
<td>Transplantation Advisory Group (TAG)</td>
<td>Director of Regulation (Sarah Bedwell)</td>
<td>Sam Abdalla, Amanda Gibbon, Penney Lewis, Anthony Warrens, Lorna Williamson</td>
</tr>
</tbody>
</table>

* The Authority Chair has the right to attend all meetings as needed