Department of Health

Triennial Review of the Human Tissue Authority

Review Report

April 2017

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Executive summary

The Human Tissue Authority (HTA) is an Executive Non-Departmental Public Body of the Department of Health (the Department or DH). The Triennial Review of the HTA was conducted to provide assurance to the Department and the public that the HTA's functions are required and the body is operating efficiently.

The HTA was established under the Human Tissue Act 2004 with the aim of maintaining public and professional confidence by ensuring that human tissue and organs are used safely and ethically and with proper consent. The HTA regulates organisations that remove, store and use human tissue for research, medical treatment, post-mortem examination, teaching and display in public. It also gives approval for organ and bone marrow donations from living people.

This Triennial Review was announced through a Written Ministerial Statement on 25 June 2015. Stage One of the review considered whether the functions undertaken by the HTA are necessary and, if so, whether they could be better delivered through another organisational structure. Stage Two moved on to an assessment of the HTA's performance, efficiency and governance. The review process included gathering evidence from stakeholders, interviews and analysis of written material.

Main findings

Overall, the review team found clear evidence that the HTA performs necessary functions to a high standard. It is very highly regarded by the large majority of stakeholders from whom we received views. Where this report picks up on areas for improvement they should be seen within this context.

Stage One of the review concluded that the functions were necessary and that the current form of the HTA is most appropriate. However, there were a number of concerns raised by stakeholders about some provisions of the Human Tissue Act 2004, with a view that the Act now both imposed unnecessary burdens in some areas and also failed to provide for necessary regulation in others. Although we understand that there are no current plans for legislative change in this area, we are aware that this is an area that the Department is keeping under review. The HTA and the Department will therefore need to continue to work together to find further flexibility to tackle issues in a practical way within the current legislation.

Recommendation 1: that the functions of the HTA continue to be required.

Recommendation 2: that the HTA continues to operate in its current form.

Stage Two of the review looked at performance, efficiency and governance issues. Particular areas of focus for the review included: the potential for the HTA to further develop a coordinated approach with other regulators and inspection regimes; sharing best practice approaches to

stakeholder engagement; and delivery of the recommendations set out in the 2013 report by Justin McCracken[1]. There are a further 10 recommendations:

Recommendation 3: that the Department of Health coordinates arrangements to support the HTA and other health and care system regulators to provide an even more joined-up regulatory framework.

Recommendation 4: that the HTA, builds on its approach of working collaboratively with the other regulators to support further development of the Regulatory Advice Service for Regenerative Medicine to provide support to researchers to understand and manage the regulatory requirements.

Recommendation 5: that the HTA, working with the Arts Council and within the current regulatory framework, looks to simplify the licensing process for public display by accredited museums.

Recommendation 6: that the HTA, working with the Department of Health, shares its information and best practice with other health ALBs on how it approaches stakeholder engagement.

Recommendation 7: that the HTA seeks further opportunities to raise public awareness and understanding of human tissue regulation, particularly consent arrangements in relation to human tissue and organs.

Recommendation 8: that the HTA considers the practicalities of inclusion, within its performance measures, of an assessment of comparative performance against relevant high-performing organisations.

Recommendation 9: that the HTA further develops knowledge management plans to further mitigate the risks of loss of key staff.

Recommendation 10: that the Department of Health assists the HTA by working to better manage information and reporting requests of all arm's length bodies, having regard to proportionality and reflecting differences in the size of, and resources available to, such bodies.

Recommendation 11: that the HTA works with the Department of Health and other arm's length bodies to explore further opportunities to share services and develop implementation plans.

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[1] Review of the Human Fertilisation & Embryology Authority and the Human Tissue Authority, Justin McCracken, April 2013.

Recommendation 12: that the HTA develops proposals for the Department of Health on succession planning for non-executives that maximise knowledge transfer and stagger appointments and re-appointments as much as possible.

Next steps

The HTA, working with the sponsor team in the Department of Health, should produce a plan to take forward these recommendations over the next 12 months. The sponsor team should monitor progress and ensure that the Department of Health is actively engaged in decisions taken.

Acknowledgements

The review team would like to thank everyone who contributed to the review process. Particular thanks go to Allan Marriott-Smith and Jenna Khalfan in the HTA and to all those who took the time to meet with the review team or respond to the call for evidence.

1. Introduction and background

Aims of the Review

1.1. It is government policy that an arm's length body (ALB) should only be set up, or remain in existence, where there is clear evidence that this model is the most appropriate and cost-effective way of delivering the function in question.

1.2. In April 2011, the Cabinet Office announced that all Non-Departmental Public Bodies (NDPBs) still in existence following the first stage of public bodies reform would have to undergo a substantive review once in a three year cycle. Triennial Reviews (TRs) have two main stages:

- stage One tests the continuing need for the body, both in terms of the functions it performs and the model and approach in which they are delivered; and
- stage Two considers the body's governance, performance and capability as well as exploring opportunities for efficiencies.

1.3. The health and social care system reforms, set out in the Health and Social Care Act 2012 and the Care Act 2014, resulted in the devolution of functions and powers away from the DH to ALBs and local health and care organisations. As steward of this evolving system, the DH is using TRs to provide assurance that the system, and the ALBs within it, is fit for purpose.

1.4. Although the Cabinet Office requirement for government departments to undertake TRs currently applies only to NDPBs, the DH is including its Executive Agencies and Special Health Authorities within this process, with the reviews playing a key role in supporting effective stewardship and oversight of the Department's ALBs. The TRs are conducted in line with Cabinet Office guidance[2] so far as is appropriate and relevant. This guidance states that all reviews should be conducted in line with the following principles:

- **Challenge:** reviews must be challenging. They should take a first principles approach to whether the function of a body is still needed, and if it is what the best form for delivery of that function is. Reviews should not just seek to evidence the status quo. They should be robust and rigorous and provide evidence for all recommendations. They must consider issues of efficiency, including the potential for efficiency savings, and make relevant recommendations. They should consider the performance of the body, and whether it could provide better value for money, including in terms of the body's contribution to economic growth. A description of how the review will be structured to meet this aim should be set out clearly in the Terms of Reference, which will be agreed between the department and Cabinet Office.

[2] Guidance on Reviews of Non Departmental Public Bodies, revised in 2014.

- **Proportionality:** reviews must not be overly bureaucratic and should be appropriate for the size and nature of the NDPB being reviewed. Where appropriate, reviews of similar bodies should be combined or clustered to ensure the maximum benefit in terms of streamlining the review process, identifying synergies across departments and NDPBs, and considering efficiency.

- **Contextual:** reviews should not be undertaken in silos, but should wherever possible be integrated with other departmental policy initiatives, efficiency reviews or landscape reviews, and seek to look across departmental boundaries to cluster reviews of bodies to further enable informed discussions about potential efficiencies. Departments should consider the potential for integration when building their Triennial Review timetable and Cabinet Office will assist departments in doing this.

- **Pace:** reviews must be completed quickly to minimise the disruption to the NDPB's business and reduce uncertainty about its future. Reviews should normally take no more than six months. Timetables, including start and completion dates, for individual reviews will be agreed with Cabinet Office at the beginning of each review.

- **Inclusivity:** reviews must be open and inclusive. The NDPB being reviewed must be engaged and consulted at both an Executive and a Non-Executive level. Users and stakeholders must have the opportunity to comment and contribute. Parliament must be informed about the commencement and conclusions of reviews. Departmental Select Committees must be given the opportunity to input.

- **Transparency:** all reviews must be announced formally, both to Parliament and to the public. All review reports must be published once clearance has been given by the Minister for the Cabinet Office. The results of reviews must be announced to Parliament.

Process and methodology of the HTA Triennial Review

a) Governance

1.5. The review was conducted by a small Department of Health team working under direction of an impartial Senior Review Sponsor (SRS).

1.6. The review was overseen by a Project Board that was chaired by the SRS. The review was also subject to scrutiny by a Critical Friends Group. The Critical Friends Group looked also at the Triennial Review of the Human Fertilisation and Embryology Authority (HFEA). Details of the membership of the review team, the Project Board and the Critical Friends Group are set out in Annex A. The Project Board and Critical Friends Group each met 3 times during the review process.

1.7. The terms of reference for the review are set out at Annex B and a copy of the Written Ministerial Statement announcing the review is at Annex C.

b) Stakeholder engagement and call for evidence

1.8. Stakeholder engagement was a key element of the evidence gathering process. The review team sought to obtain views from a wide range of stakeholders to pick up key themes emerging from a variety of viewpoints. The full list of stakeholder respondents is provided at Annex D and a list of the call for evidence questions is at Annex E. Evidence was though gathered through a variety of means:

- a public call for evidence announced on the Department of Health website and open between 14 July and 31 August 2015. This included 12 questions seeking views on the HTA;
- a total of 27 stakeholder interviews (including HTA board members and staff, experts in the health and care system, regulated bodies and professional groups);
- three workshops to which stakeholders were invited to attend; and
- analysis of other published material (Annex F provides a list of the key papers used).

c) Previous reviews of the HTA

1.9. Several reviews have taken place in recent years looking at various aspects of the HTA and its functions:

- the Department of Health published a report[3] reviewing all of its arm's length bodies in 2010. This report proposed, for both the HTA and the Human Fertilisation and Embryology Authority, that the department should consider the practicalities of transferring functions to the Care Quality Commission (CQC), the Health and Social Care Information Centre and a new research regulator (now the Health Research Authority (HRA));
- this was followed by a public consultation, published in June 2012, on proposals to transfer the functions of the HTA and HFEA to the CQC and HRA. The response to this consultation process was published in January 2013[4]. There were 109 responses and a large majority were opposed to the transfer of functions; and

[3] Liberating the NHS: Report of the arm's-length bodies review - July 2010, Department of Health

[4] Government response to the consultation on proposals to transfer functions from the Human Fertilisation and Embryology Authority and the Human Tissue Authority – January 2013

- consequently, Justin McCracken (then Chief Executive of the Health Protection Agency) undertook a review[5] aimed at supporting the HTA and HFEA in delivering efficiencies in the way in which they undertake their functions. This Triennial Review considers the extent to which the recommendations made by Mr McCracken have been implemented.

1.10. It was agreed at the outset of this review that it would not reopen issues that have been covered in these other recent reviews unless there was compelling evidence to do so. For example, the review has not re-opened consideration of a possible merger between the HTA and HFEA or the transfer of functions as considered in the 2012 consultation.

d) Estimated costs of the review

1.11. The review team started planning the review in May 2015 and it formally stated on 25 June 2015. This report was drafted by December 2015 and cleared for publication by October 2016. The review team worked on other reviews simultaneously and an estimate has been made of the time allocated to this review. On this basis, the direct costs of the review, based on eight months duration, are set out in Table 1 below. There were no travel or other costs associated with the review. This estimate does not take account of indirect costs, such as the time contributed by HTA members and staff.

Table 1: Estimated cost of the Triennial Review of the Human Tissue Authority

Role	Proportion of time spent on review	Estimated cost
SRS	0.05 * 0.66	£4,126
Lead Reviewer	0.4 * 0.66	£26,644
Assistant Reviewer	0.5 * 0.66	£18,486
Assistant Reviewer	0.3 * 0.66	£8,106
Total estimated cost		**£57,362**

About the HTA

1.12. The HTA has been in existence for a little over 11 years. It was established as an Executive Non-Departmental Public Body on 1 April 2005 under powers in the Human Tissue Act 2004. Its functions are set out in three pieces of legislation:

- the Human Tissue Act 2004 (HT Act) and associated Regulations;
- the EU Tissue and Cells Directives (EUTCD), via the Human Tissue (Quality and Safety for Human Application) Regulations 2007; and

[5] Review of the Human Fertilisation & Embryology Authority and the Human Tissue Authority - Justin McCracken, April 2013

- the EU Organ Donation Directives (EUODD), via the Quality and Safety of Organs Intended for Transplantation Regulations 2012.

1.13. The HTA's remit extends to England, Wales and Northern Ireland. It also carries out some functions (such as in relation to EU legislation, regulating living donation, and keeping of registers) on behalf of the Scottish Government. From December 2015 the Human Transplantation (Wales) Act 2013 will govern consent for organ and tissue donation in Wales, for which the HTA will produce a Code of Practice and oversee compliance.

1.14. Much has changed in the treatment of human remains over the years. The Murder Act 1752 provided for the corpses of executed prisoners to be used for dissection, while the Anatomy Act 1832 made it lawful to use unclaimed corpses. The Human Tissue Act 1961 brought in more controls but allowed human tissue to be used for treatment, education or research provided there was no objection from relatives.

1.15. The HTA was set up following events in the 1990s that revealed a culture in hospitals of removing and retaining human organs and tissue without consent. There was particular public concern when it emerged that a number of hospitals had routinely been collecting and retaining the organs and tissues of babies and children who had died at the hospitals. In some cases these were then used for research, including by pharmaceutical companies. This was all being done without the knowledge and consent of the parents. The key priority for the HTA is therefore to maintain public and professional confidence by ensuring that human tissue and organs are used safely and ethically and with proper consent.

1.16. The HTA regulates over 850 licensed premises across nearly 600 organisations that remove, store and use tissue:

- post mortem (186 licences to conduct post-mortem related activity);
- research (154 licences for storage of tissue for the purpose of research into health and illnesses using human tissue);
- human Application (149 licences to conduct regulated activities involving tissue and cells for patient treatment);
- public Display (14 licences to display human bodies and body parts from the deceased);
- anatomical examination (36 licences to use human bodies and tissue for training of healthcare professionals); and
- organ Donation and Transplantation (37 licences to conduct activities related to the donation or transplantation of organs).

2. Stage One: Function

The HTA's functions and supporting legislation

2.1. The HTA is a statutory body and its functions are set out in the Human Tissue Act 2004, which extends to England, Wales and Northern Ireland. The HTA also has limited regulatory responsibilities for Scotland by agreement with the Scottish Government. The HTA is also the UK competent authority under EU directives dealing with the quality and safety of tissues and cells used for patient treatment and organs for transplantation.

2.2. Table 2 below provides a detailed breakdown of the HTA's functions, all of which have a statutory basis.

Table 2: Breakdown of HTA functions

Breakdown of HTA Functions				
	Function/Activity	**Legislative requirement**	**Purpose (objectives, beneficiaries)**	**Approximate spend**
1	Maintaining a statement of the general principles which it considers should be followed in the carrying-on of activities within its remit.	Yes - HT Act Part 2, Sections 15 and 26. The Quality and Safety of Organs Intended for Transplantation Regulations 2012, Part 4.	To maintain public and professional confidence in the treatment of human tissue and to reinforce the legal concept of consent. Achieved through guidance, regulation, inspection and enforcement. Protects public interests and provides a clear regime within which providers operate.	Small – included elsewhere below.
2	Providing oversight and guidance in relation to activities within its remit.	Yes - HT Act Part 2, Section 15; Part 3, Sections 42 and 48; and Schedule 5.		£300k
3	Compliance with requirements imposed by the HT Act and associated codes of practice.	Yes - HT Act Part 2, Sections 15 and 16; Part 3, Section 48 and Schedule 5.		Included in 7 below
4	Providing information and advice to the public and to persons carrying on activities within its remit.	Yes - HT Act Part 2, Sections 15 and 26. The Quality and Safety of Organs Intended for Transplantation Regulations 2012, Part 3.		Included in 7 below

5	Monitoring developments relating to activities within its remit and advising the Secretary of State, the National Assembly for Wales and the relevant Northern Ireland department on issues arising. Also, advising on such other issues as they may require.	Yes - HT Act Part 2, Sections 15 and 26.	Horizon scanning to identify emerging issues and provide advice to government. Informing national policy and legislation.	£300k
6	Licensing activities associated with the procurement, storage and use of human tissue and licensing activities associated with the procurement and transplantation of organs (including Scotland).	Yes - HT Act Part 2, Sections 16, 19, 20, 22 and 23. The Human Tissue (Quality and Safety for Human Application) Regulations 2007, Part 7 and Schedule 1. The Quality and Safety of Organs Intended for Transplantation Regulations 2012	To maintain public and professional confidence in the treatment of human tissue by providing a mechanism for the continued oversight of establishments removing, storing or using human tissue. Protects public interests and provides a clear regime within which providers operate.	£1.1m
7	Maintaining records: A register recording the grant, suspension or revocation of every licence granted (including Scotland). A register of serious adverse events and reactions (including Scotland). A reporting system for serious adverse events and reactions. Traceability of organs sent to another country.	Yes - The Human Tissue (Quality and Safety for Human Application) Regulations 2007, Part 4, Sections 18 – 20. The Quality and Safety of Organs Intended for Transplantation Regulations 2012, Part 4.		

8	Inspection and audit of licensed establishments to ensure compliance with licensing conditions and directions.	Yes - HT Act Part 3, Section 48 and Schedule 5. The Human Tissue (Quality and Safety for Human Application) Regulations 2007, Part 2. The Quality and Safety of Organs Intended for Transplantation Regulations 2012, Part 4.		£1.7m
9	Preparation of codes of practice to give guidance and lay down standards.	Yes - HT Act Part 2, Section 26.		£200k
10	In certain circumstances, in the absence of consent, directing that relevant material may be used for the purpose of obtaining scientific or medical information about a person.	Yes - HT Act Part 1, Section 7.		Small – included elsewhere.
11	Regulating living donation of organs. Keeping records of the aggregate number of living and deceased donors; types and quantities of organs procured, transplanted or disposed.	Yes - HT Act Part 1, Section 33 and Regulations. The Quality and Safety of Organs Intended for Transplantation Regulations 2012, Part 13.	To create a framework for living donation of organs. Benefits patients and protects donors against unethical practices.	£400k
12	Management and Governance: such as producing annual reports and accounts.	Yes - HT Act, Part 2, Section 36 and Schedule 2. The Quality and Safety of Organs Intended for Transplantation Regulations 2012, Part 5.	Supports the effective management and oversight of the organisation.	£400k

2.3. The key areas of activity covered by these functions are:

- Regulating research: the HTA ensures that tissue is removed (from the deceased) and stored appropriately, and with appropriate consent. Its role involves licensing premises, such as tissue and brain banks, but there are exemptions for ethically approved research projects. The HTA does not license the use of human tissue in research or approve individual research projects.

- Regulating public display: any person or organisation wanting to publicly display the body of a deceased person, or tissue taken from that person, must have evidence that their consent was obtained prior to their death. The HTA licenses such premises unless the remains are from someone who died before the HT Act came into force and they have been dead for more than 100 years.

- Organ donation (living and deceased) and transplantation: under EU law, the HTA licenses organisations across the UK to ensure the quality and safety of organs that are intended for transplantation. It regulates consent requirements to ensure that valid consent has been given and that no coercion is applied and no reward is offered or made.

- Tissue used in treatment: under EU law, the HTA licenses organisations across the UK to ensure the quality and safety of tissue and cells used to treat patients.

- Post-mortem examinations: the HTA ensures that mortuaries where bodies are stored for the purpose of post-mortem examination and where post-mortem examinations take place are licensed and inspected.

- Bone marrow and peripheral blood stem cell donation from living people: the HTA regulates, through an independent assessment process, the donation of bone marrow and peripheral blood stem cells from living children who do not have competence to give consent (all children under 16 years of age in Scotland) and adults who lack the capacity to consent.

- Anatomical and surgical skills training: the HTA licenses and inspects organisations, such as medical schools, that use human bodies and body parts for training purposes.

Devolved functions

2.4. As mentioned above, the Human Tissue Act 2004 covers England, Wales and Northern Ireland. Separate legislation, the Human Tissue (Scotland) Act 2006 applies in Scotland, though the HTA regulates EU legislation in Scotland and also regulates living donation, in compliance with Scottish legislation, on behalf of the Scottish Government.

2.5. Some key areas of difference in the legislation are that the 2006 Act in Scotland:

- different requirements for the storage of tissue blocks and slides from the deceased;
- does not regulate the storage and use of tissue from living people except in the case of transplantation;
- does not cover public display, which is covered by an amendment to the Anatomy Act;
- provides (section 3) for consent to cover removal of body parts for transplantation, research, education and audit, removing any need for separate consent; and
- provides (section 38) for tissue samples removed from a deceased person during examination to become part of the medical records of that person.

2.6. On the 1 December 2015, the Human Transplantation (Wales) Act came into full effect, introducing a soft opt-out system for consent to organ and tissue donation. The main aim is to increase the number of organs available for transplantation by changing the consent requirements. If people neither register to be an organ donor nor register to opt out of donation then they will be regarded as having no objection to donation ('deemed consent').

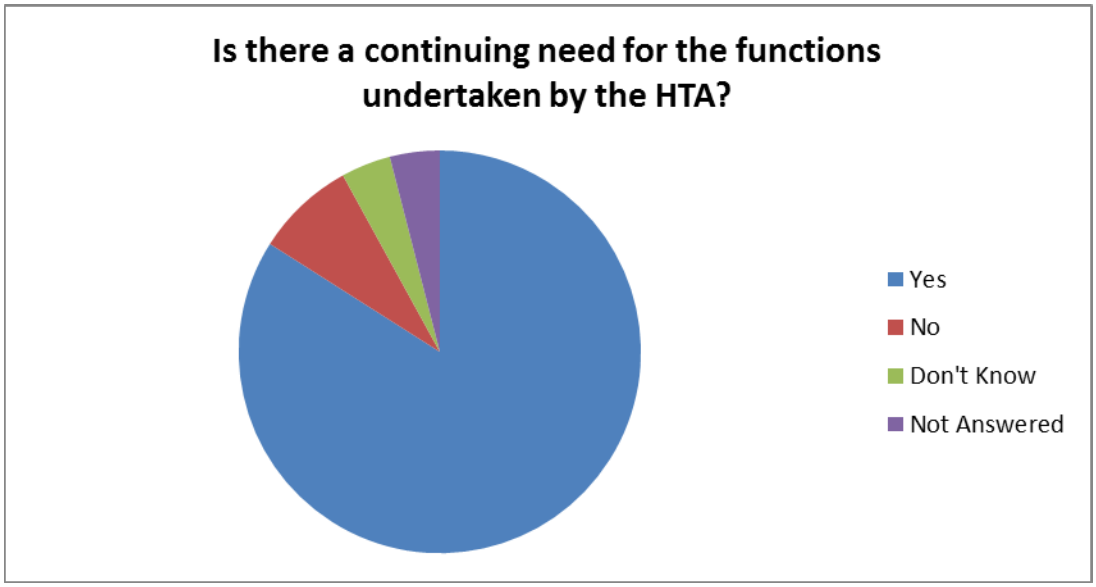
2.7. The HTA has been given responsibility, under this legislation, to produce a Code of Practice to support practitioners and to oversee compliance with the Code and the legislation. Overseeing different consent arrangements in relation to organ donation from different parts of the UK will potentially pose a greater challenge for the HTA.

Are the functions necessary?

2.8. Before the HT Act 2004, the relevant legislation was the Human Tissue Act 1961. Section 1 of that Act permitted the person "lawfully in possession of the body" (usually taken to be the hospital) to authorise the removal of parts of the body for purposes of medical education or research. Such authorisation required either the deceased person to have expressed such a wish before death or if, "having made such reasonable enquiry as may be practicable" it was established that neither the deceased person nor their relatives or spouse would have objected. The regulation of the retention, for research or education purposes, of organs or tissue after a patient's death was therefore based primarily on lack of objection rather than consent.

2.9. Stakeholders were very clearly of the view (see Figure 1 below as an example) that the functions of the HTA continued to be necessary.

Figure 1: Call for evidence responses - Functions



2.10. There were nevertheless a few areas where the review team received a number of responses calling for either a relaxation of the regulatory controls or for the regulations to be extended to activities not currently covered. Particular areas where a relaxation of the existing controls was raised by some stakeholders were:

- the legislation applies a definition of 'relevant material' regulated under the Act that covers any human tissue: "material, other than gametes, which consists of or includes human cells"[6]. Exclusions are provided for embryos outside the human body (IVF treatment) and hair and nail from the body of a living person. This definition catches 'waste' products such as urine, faeces and saliva, which a large number of stakeholders would wish to see exempted;

- some stakeholders also expressed the view that consent requirements relating to the removal of tissue for research should be simplified, particularly where consent had already been obtained for removal for transplantation or where Research Ethics Committee approval had been obtained;

- where museums hold a valid museum accreditation some stakeholders argue that the need for the HTA to license the public display of human bodies or body parts in an exhibition is unnecessary; and

- whether microscope slides and tissue block samples should be regarded as part of the medical record and so be able to be retained and used without consent.

2.11. It should be noted though that stakeholder engagement was weighted towards regulated groups (those with a strong interest in responding to the review) and that where the review did obtain the views of those for whom the regulation is in place to offer

[6] Human Tissue Act 2004, Section 53

protection there was clear support for the regulatory framework and caution at any suggestion of relaxing those controls. There was also support for adding to the regulatory controls as there were a number of functions that some stakeholders would like to see included within the HTA's remit:

- The regulation of the treatment of human remains from pregnancy loss.
- Police holdings of human remains are exempted (HT Act 2004, section 39) from the regulatory requirements where they are held for the purposes of crime prevention or detection, or relate to a prosecution.
- The regulation of the treatment of remains from cremation.
- The regulation of the treatment of human remains held by funeral directors.

2.12. The HTA and the Department of Health are aware of these issues. The HTA Strategic Risk Register[7] acknowledges the risks from a failure to meet professional and public expectations of the regulatory framework and the Department undertook a limited consultation on some aspects of possible reforms in early 2014. In addition, the HTA has taken action to assist those working under an HTA licence to work effectively within the regulatory framework by providing guidance both of the interpretation of the current legislative requirements and through the issue of guidance covering issues not directly addressed in the legislation (for example, guidance on the disposal of pregnancy remains[8]).

2.13. Some of the changes sought by stakeholders would require amendment to the HT Act 2004, or to regulations made under that Act. This is an issue that has been raised before, notably in the 2013 review by Justin McCracken, which included a recommendation that:

McCracken review, recommendation 15 – To further reduce the burden of regulation the Department of Health (DH) should review the legislation governing the use of human tissue and consult on amendments to bring it more into line with the legislation in force in Scotland. Consideration should be given (inter alia) to: reducing the scope so that microscope slide and tissue block samples and bodily products such as saliva, urine, and faeces are excluded; and exempting from the need for a licence the removal of tissue from deceased donors (where appropriate approvals are in place and where this is not part of an anatomical or post mortem examination).

[7] Strategic Risk Register, June 2015 (https://www.hta.gov.uk/sites/default/files/AuthorityJuly%202015%20papers%20%282%29.pdf)

[8] Guidance on the disposal of pregnancy remains following pregnancy loss or termination, March 2015 (https://www.hta.gov.uk/sites/default/files/Guidance_on_the_disposal_of_pregnancy_remains.pdf)

2.14. As mentioned above, the Department undertook a limited consultation on possible revisions to regulations made under the Act but there is not yet a consensus view on the content of any such changes. It would also be difficult to justify legislative change, which would require substantial resource and an extensive consultation process, at the present time. The HTA has been able to work cooperatively with stakeholders to help resolve issues that may result from interpretation of the regulatory requirements, and both the HTA and the Department will continue to work together to find any further flexibility to tackle issues in a practical way within the current legislation.

2.15. Stakeholder responses also included some concerns that suggested in certain cases there may be an incomplete understanding of the regulations (e.g., concerns were raised about the need to regulate the transportation of organs but this is covered in regulations made through a Statutory Instrument under the HT Act 2004; some concerns were expressed that the HT Act restricted the ability of coroners to retain tissue but there is a clear exemption provided in Section 11 of the Act). The HTA will continue to work with stakeholders to offer guidance on the Act to help tackle any misconceptions.

2.16. In conclusion, the review found a clear continuing need for regulation of the use and storage of human tissue. There are areas where there may be benefits in adding or removing certain regulatory requirements but the HTA has been active in addressing issues of interpretation where they have been raised and some stakeholder concerns suggest there may be some misunderstanding of existing requirements. There is perhaps more that the HTA could do in this respect and this is covered in Stage Two below. There remains active interest amongst stakeholders in the limitations of the legislation and the HTA and the Department will need to keep this under consideration.

Recommendation 1: that the functions of the HTA continue to be required.

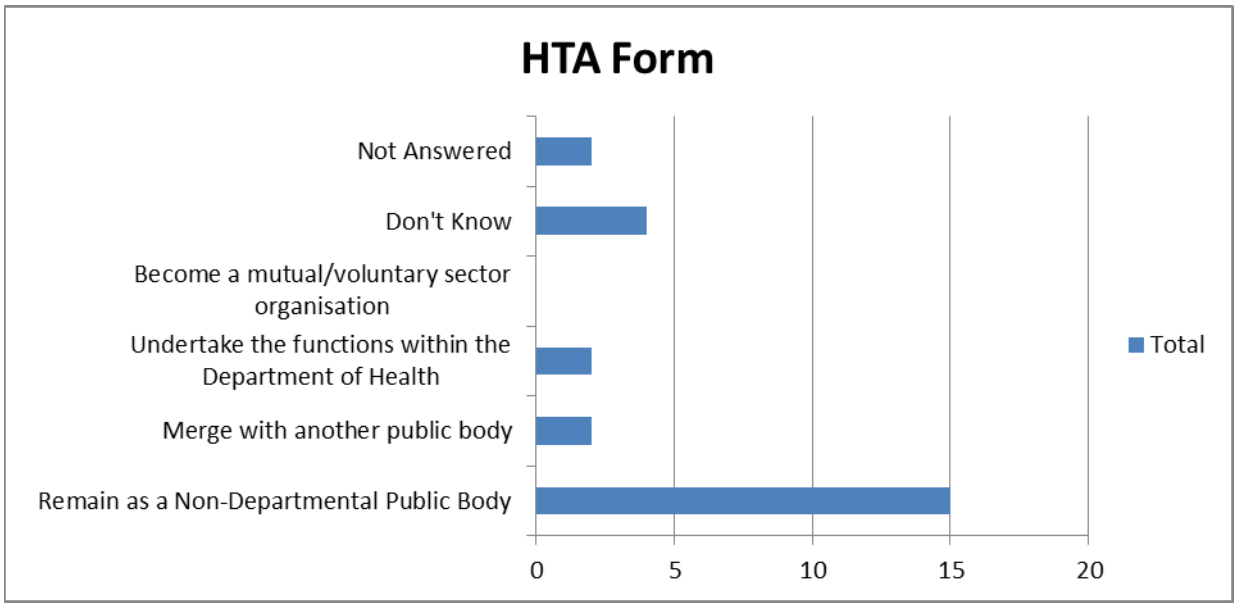
3. Stage One: Form

3.1. The HTA is an Executive NDPB of the Department of Health. Such a body operates at arm's length from the Department and Ministers but there must nevertheless be an appropriate degree of support, oversight and scrutiny.

3.2. The form of the HTA has been considered a number of times in recent years (see paragraphs 1.9-10 above). This review has considered a range of options, as set out below, but did not seek to re-open conclusions reached in recent reviews unless compelling evidence was provided to do otherwise.

3.3. The call for evidence responses, as shown in figure 2 below, were replicated in stakeholder interviews. The vast majority wanted to see the HTA retain its current independent structure. There were a small number who suggested that the HTA should either be subsumed within DH or merge with another regulator (the Medicines and Healthcare Products Regulatory Agency or the Health Research Authority), which reflect views either that the HTA was too small to operate separately or that there were potential synergies from a merger with other regulatory bodies.

Figure 2: Call for evidence responses - Form



Alternative delivery models

3.4. Triennial Reviews are required to consider whether the functions of an ALB, if still required, could be delivered more effectively through a different organisational delivery model.

3.5. In considering alternative delivery models the review team was looking for evidence that any recommended changes would deliver net benefits compared to the HTA's current

structure. The assessment was not simply whether the functions could be delivered by another delivery model but also about how well that model would support the HTA's core aims and functions. The review team consider that any changes to the delivery model should deliver clear benefits, such as reduced costs or improvements in the quality of service provision.

3.6. The review team considered and rejected a number of potential delivery models that were clearly inappropriate:

- abolition – given the conclusion that the functions were necessary then abolition would only be appropriate if those functions were moved elsewhere. The options for that are discussed below;
- commercialisation/privatisation – the HTA generates income from regulatory licence fees. Under Treasury rules[9] the HTA can only charge full cost recovery for such activities. There is some small scope to charge for other services, such as guidance material and conferences, but this is limited and could not justify any commercial status; and
- contracting out – regulated bodies, who are required to share sensitive and commercial information with the regulator, place great store in the independence, impartiality and expertise of the HTA. This would almost certainly be undermined by any contacted-out service provision. Stakeholder responses also suggested that the wider public, who are beneficiaries of the regulation, would have less confidence in an organisation operating under a commercial contract. There are no obvious providers of such a service.

Bring the functions within the Department

3.7. The core regulatory functions of the HTA are entirely appropriate for an arm's length body operating with a degree of day-to-day independence from the DH and Ministers. Stakeholders were largely supportive of the HTA remaining as an independent arm's length public body that was seen to operate independently of any direct political influence.

3.8. Regulated bodies can see what their fees are paying for in the HTA but this would be undermined if it became a part of the Department. In addition, the HTA provides a high level of expertise to support the regulatory function that could be lost within the Department.

Merge with another public body

3.9. Mergers with other ALBs have been considered before and some stakeholders again suggested that benefits might accrue from a merger between the HTA and another

[9] See Managing Public Money (https://www.gov.uk/government/publications/managing-public-money)

regulator. The review team accepted that there are potential benefits from closer ties between the HTA and some other regulators (and this is addressed further in Section Two below) but there was no evidence of overlap of functions or potential synergies that justified a merger, particularly given the risks that any merged body, with the wider remit that implies, would lose a degree of expertise and clarity of focus.

Continuing delivery by the existing NDPB

3.10. This was the option stakeholders supported. The regulatory functions of the HTA would appear to be most appropriate for delivery through an NDPB. This was the conclusion reached by Justin McCracken in his 2013 review and there is no evidence to support revising that conclusion.

3.11. The Cabinet Office set out three tests for NDPB status. A body only has to meet one test but in practice many will meet more than one. The three tests are:

- is this a technical function (which needs external expertise to deliver)?
- is this a function which needs to be, and be seen to be, delivered with absolute political impartiality? and
- is this a function which needs to be delivered independently of Ministers to establish facts and/or figures with integrity?

3.12. A strong argument can be made that the HTA meets all of these tests. The need for technical expertise to deliver the regulatory function is clear; such regulation requires political impartiality and independence from direct ministerial control; although the establishment of facts and figures is not a core HTA function it is required to maintain records and provide guidance.

3.13. A summary of the options considered is set out in Table 3 below.

Table 3: Assessment of alternative delivery models

Delivery Option	Assessment
Abolish	Rejected – functions are needed.
Commercialisation/privatisation	Rejected – income is from regulatory fees and scope to expand into other income streams is extremely limited.
Contract out the service	Rejected – could undermine independence and expertise, no obvious providers.
Bring-in house (DH takes on the function)	Rejected – not ideal for a regulatory function and may undermine independence and expertise.
Merger with another body	Rejected – no clear benefits that couldn't be achieved outside of a merger and risks to loss of

	expertise.
Continued delivery by an NDPB	Accepted – HTA meets the tests for NDPB status.

Recommendation 2: that the HTA continues to operate in its current form.

4. Stage Two: Performance

4.1. If the conclusion of Stage One is that the organisation should be maintained in its current form, then the review moves on to Stage Two and considers the scope for improving performance or delivering efficiencies, as well as adherence with the principles of good corporate governance.

4.2. The HTA is highly regarded as an effective regulator, and this review supports that view. Stakeholder responses to the call for evidence largely rated the Authority's performance as good or very good (see Annex E). This generally positive view of the HTA was also reflected in stakeholder interviews. The sections below pick out the key issues identified by the review process where it is considered that the HTA can make changes to improve performance further but they are often building upon actions that the Authority has either already planned or are in progress.

Regulation and Inspection: working with other regulators

4.3. Perhaps the single most significant concern raised by regulated bodies was the view that the impact of regulation could be reduced if regulators were more joined-up in their approach. Particular concerns related to regulators apparently requesting the same, or very similar, information, the timing of inspections not being co-ordinated, and different inspection standards being applied.

4.4. Even when focusing only on those regulatory bodies within the health and care system it becomes clear that often a range of different bodies interact with the same institutions. In the case of the HTA there are quite likely to be regulatory alignments or links with the work of the Care Quality Commission (CQC), the Medicines and Healthcare Products Regulatory Agency (MHRA), the Health Research Authority (HRA) and the Human Fertilisation and Embryology Authority (HFEA). In addition, there are accreditation bodies, notably the UK Accreditation Service (UKAS) but also the Joint Accreditation Committee ICT Europe and EBMT (JACIE), that inspect and register a number of institutions that are regulated by the HTA.

4.5. This was an issue raised in the McCracken review and led to the following recommendations:

McCracken review, recommendation 16 – The HTA should continue to pursue closer cooperation with other regulators to eliminate any overlaps or inconsistencies in regulatory activities and to ensure that there are well understood and seamless regulatory pathways for organisations engaged in activities that are regulated by other bodies, notably the MHRA.

McCracken review, recommendation 18 – The HTA should prioritise its collaborative work with Clinical Pathology Accreditation (CPA)[10] to eliminate any duplication in the inspection activities of the two bodies by the end of the current financial year.

4.6. It should to be acknowledged that the HTA has done much to improve engagement with other regulatory bodies:

- it has (since 2013) Memoranda of Understanding, primarily covering the sharing of information and good practice, with the CQC and the HFEA;
- in 2013, the HFEA and HTA agreed a policy whereby ovarian tissue which is intended for transplantation, can be now be stored solely under an HTA licence;
- it has (since May 2015) a more comprehensive Memorandum of Understanding, not only covering the sharing of information and good practice but also providing for joint inspections, with UKAS. This allows UKAS to inspect mortuaries (where the establishment has agreed to a joint inspection) and assess compliance with selected HTA licensing standards; and
- it has also established joint inspections with the MHRA and provides guidance which allows that, where the storage, processing, import, export or distribution of cells or tissues for patient treatment is for use in manufactured products and these activities are regulated by various medicines and medical devices regulations, these activities will not be regulated by the HTA.

4.7. A further recommendation in the McCracken review related to risk-focused regulation:

McCracken review, recommendation 14 – The HTA should sharpen the risk focus of its regulatory approach, for example using progressively lighter touch inspections for high-performing licence holders as long as risk assessments indicate this is appropriate; reducing the intensity of regulatory scrutiny for lower risk activities such as public displays; and by reviewing the operation of the European Union Organ Donation Directive (EUODD) after the first round of audits.

4.8. The HTA responded to this recommendation by introducing a new risk assessment process (August 2013) and refining the risk profile of all licensed establishments. The HTA refines its approach to reflect the risk profile of different regulated sectors. As mentioned above, joint inspections with UKAS reflect the fact that such accredited bodies are already meeting stringent quality standards.

4.9. Despite this work that has already been undertaken, a number of stakeholders wanted to see more done to align the regulatory processes. There are limitations to what can be achieved since regulators may well be required to undertake inspections within a given

[10] Now the UK Accreditation Service.

timeframe and to apply standards appropriate to that regulated activity. However, within such restrictions, there is further potential to reduce the regulatory burden while at the same time having a positive impact on the quality of regulation. Particular issues that stakeholders would welcome include:

- regulators coordinating their information requirements and sharing information (within the requirements of legislation such as the Data Protection Act 1998) so that regulated bodies are subject to fewer requests;
- the timetable for inspections being better coordinated, where possible and appropriate, between regulators so that they can either take place together or as part of a clear process. Many regulated bodies would prefer joint inspections or, better still, one body inspecting on behalf of another also (such as the HTA has agreed with UKAS); and
- to the extent possible, the standards required by regulators of stakeholders should be consistent. It is understood that this will not always be easy and that different standards are often necessary for different activities. What is most important is that standards are mutually consistent (i.e., standards applied by one regulator will not necessarily be that same as those applied by another but the reasons for differences should be understood and they should not be contradictory).

4.10. Although it is possible for the HTA to engage further with regulators and accreditation bodies to coordinate arrangements, it is nevertheless difficult for any individual regulator to achieve this goal. The Department of Health is well placed to support this work among regulators and we recommend that consideration is given to establishing the necessary processes.

Recommendation 3: that the Department of Health coordinates arrangements to support the HTA and other health and care system regulators to provide an even more joined-up regulatory framework.

Regulation and Inspection: research and consent

4.11. As mentioned above, the HTA does not license the use of human tissue in research, but it does license the removal and storage of tissue for such purposes, as well as the provision of consent. Most stakeholders from whom we heard and who were involved in this field appreciated what they saw as a proportionate and supportive approach from the HTA but some also felt that the regulations were overly burdensome and having an adverse impact on the amount of research taking place. Particular concerns surrounded the consent requirements. Examples were given of seriously ill patients having to be asked for consent to their tissue being used for a variety of research purposes.

4.12. However, many of the concerns expressed would be addressed by following HTA guidance. The HTA Code of Practice 9 (Research)11 states that:

"To facilitate the use of valuable human tissue in research, the HTA advises, in line with the MRC and HRA that consent should be generic because this avoids the need to obtain further consents. It is still important however that consent is valid. If the intention is to store the tissue for an as yet unknown research purpose or as part of a tissue bank for research then this should be explained, setting out the types of research that may be involved, any wider implications and the circumstances under which the tissue will be disposed of."

4.13. A further issue raised in relation to research related to the regulation of research tissue banks, which provide access to tissue samples for research purposes. The HTA has previously cooperated with the Health Research Authority's National Research Ethics Service (NRES) to provide clear advice on processes for the establishment of research tissue banks. Generic ethics approval can be agreed for research tissue banks which allows them to release tissue for research without the recipients of such tissue requiring further ethics approval or a separate HTA licence for storage.

4.14. In addition, the HTA has helped to establish – through the MHRA and working also with the HRA and HFEA – the Regulatory Advice Service for Regenerative Medicine ('One Stop Shop') for research and development professionals. This offers a single point of access to expert support and advice in response to queries about the regulation of regenerative medicines. The HTA has proposed using the Regulatory Advice Service to provide wider support to researchers to help them manage within the regulatory framework.

Recommendation 4: that the HTA, builds on its approach of working collaboratively with the other regulators, to support further development of the Regulatory Advice Service for Regenerative Medicine to provide support to researchers to understand and manage the regulatory requirements.

4.15. The McCracken review included a recommendation related to the regulation of tissue aimed at developing medicinal products:

McCracken review, recommendation 17 – The regulation of tissue for applications aimed at developing medicinal products Advanced Therapy Medicinal Products (ATMPs) should be transferred from the HTA to the MHRA in order to simplify the regulatory pathway for those involved in such developments.

4.16. The HTA took this forward, including co-hosting a workshop in January 2014 to consider the options. The Regulatory Advice Service (One Stop Shop) was the agreed way of

[11] https://www.hta.gov.uk/sites/default/files/Code_of_practice_9_-_Research.pdf#page=6

addressing this recommendation. It sought to address the concerns that led to the recommendation by ensuring that the MHRA were properly engaged whilst avoiding the potential complexities that might result from transferring this function (which would have applied to only a small proportion of HTA licensed establishments).

4.17. The HT Act provides a hierarchical list of 'qualifying relationships' of persons from whom consent may be sought for storage or use of the body or tissue in the event that the deceased did not give or refuse consent, or appoint someone to represent them for consent purposes after their death. This moves from spouse/partner to parent, child, etc, right through to long-standing friend. These requirements are reflected in the HTA's guidance on consent, HTA Code of Practice 1 (Consent)[12], This was only raised as an issues by a small number of stakeholder respondents but the review team was informed of examples where people with different qualifying relationships might be in disagreement over the use of tissue in cases where it could be used to resolve other concerns (such as using DNA to prove parenthood). This is an issue that would benefit from engagement between the HTA and other parties, leading to any necessary revision to the HTA Code of Practice.

Regulation and Inspection: public display

4.18. Any premises used for the public display of dead bodies, or body parts, must be licensed by the HTA unless the remains are from someone who died before the HT Act came into force and they have been dead for 100 years or more. In many cases the premises will be a museum and the HTA Code of Practice 7 (Public Display)[13] states that the standards applied by the HTA are complementary to those of the Arts Council England Accreditation Scheme for Museums in the United Kingdom. Although any future change would require amendment to the legislation, this licensing requirement for properly accredited museums that meet the required standards is seen as unnecessary by some stakeholders.

4.19. The HTA recognises this issue and is applying consistent standards but may be able to do more to simplify the licensing process for museums that have Arts Council accreditation. Some stakeholders suggested that the format of the application forms was not tailored to public display, being more oriented towards research and clinical activity. However, the public display licence application form can be downloaded from the HTA website[14] and seems to be specifically tailored. It does look rather long, at 17 pages, although not all parts would need to be completed, and opens as a Word document that can be emailed but does not provide for direct online completion.

[13] https://www.hta.gov.uk/sites/default/files/Code_of_practice_7_-_Public_display.pdf#page=7

[14] https://www.hta.gov.uk/policies/guide-completion-public-display-licence-application

4.20. The HTA is clearly already in contact with the Arts Council to standardise requirements but might seek to agree how much further it could go to simplify the licensing process for accredited museums within the current regulatory framework.

> **Recommendation 5:** that the HTA, working with the Arts Council and within the current regulatory framework, looks to simplify the licensing process for public display by accredited museums.

Stakeholder Communication and Engagement

4.21. The HTA is extremely highly regarded by stakeholders across the board; not only for the extent of its engagement but particularly because it is thought to be responsive to feedback received and issues of concern raised. Stakeholders reported that the website is well regarded, as is the newsletter (there are around six a year), and HTA staff are felt generally to provide helpful support and guidance to queries.

4.22. Effective communication and engagement with the full range of stakeholders is vital for all of the Department's ALBs and Triennial Reviews usually receive more concerns and criticisms. The positive feedback on the HTA reflects fairly closely that received in the McCracken review also. That review did though lead to the following recommendation:

McCracken review, recommendation 4 – In order to improve transparency, both the HFEA and the HTA 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.

4.23. In 2013 the HTA conducted an independent evaluation of stakeholder views that then influenced their strategic plan 2014-17 and communications strategy 2014-17. The HTA also set up a new Stakeholder Group in response both to this and to a further recommendation in the McCracken review:

McCracken review, recommendation 5 – Both the HFEA and the HTA should establish and operate a permanent fees review group to improve accountability and facilitate dialogue with licence fee payers.

4.24. The purpose of the Stakeholder Group is to consider regulatory issues across all sectors to inform the continued development of HTA regulation and fee-setting. It first met in November 2013. Discussion with this Group led to agreement on a review of the fee structure in 2016.

4.25. Although particular approaches will not always be transferable to other organisations there does seem to be real potential for other DH ALBs to learn from the good practices of the HTA. It would be beneficial therefore for the HTA to work with the Department to share best practice.

Recommendation 6: that the HTA, working with the Department of Health, shares its information and best practice with other health ALBs on how it approaches stakeholder engagement.

4.26. There were a few suggestions for areas where the HTA could go further. A number of stakeholders indicated that they would welcome more training events and conferences (the HTA does run some already) to support better understanding of the regulation. Examples put to us included events for:

- NHS staff working in cell tissue and organ donation;
- designated Individual's to set out their responsibilities, etc; and
- Serious Adverse Events/Reactions (SAEARs), covering issues such as what should and should not be reported.

4.27. Many stakeholders indicated that they would be happy to pay for such events and so this would be self-financing as well as supporting better understanding of, and therefore adherence to, the regulation.

4.28. Stakeholders sit on three HTA committees; Stakeholder Group, Histopathology Working Group and Transplantation Advisory Group. This inclusion of stakeholders in the considerations of the HTA was strongly welcomed but it was questioned as to whether there was a tendency to seek senior executives as representatives rather than people with day-to-day frontline experience of applying the regulation at a working level. It is not easy to determine the merits of this concern from looking at committee membership but the HTA should consider this issue when making future appointments to the committees.

4.29. This engagement with stakeholders includes those for whom the regulation offers necessary safeguards, the wider public. Lay members, often those who have experienced the impact of the regulation or the situation prior to the HTA being established, form part of the Stakeholder Group and are regularly invited to HTA run events.

4.30. This engagement with lay representatives is perhaps particularly important when wider public and media attention is relatively low. Although keeping out of the headlines might well be considered a measure of success in itself, the HTA might also seek opportunities

to raise the profile of the issues it covers; for example, to raise understanding of consent and organ donation issues.

Recommendation 7: that the HTA seeks further opportunities to raise public awareness and understanding of human tissue regulation, particularly consent arrangements in relation to human tissue and organs.

Innovation

4.31. As is the case for all health regulators, it is vital that the HTA is aware of new technologies and innovations, both to ensure that the regulatory framework remains appropriate and also to help support innovators and ensure that the regulation doesn't stifle innovation.

4.32. The membership of the HTA board brings in expertise from a range of relevant sectors, as does the Stakeholder Group. The HTA does not have a dedicated horizon scanning function but does have a number of internal stakeholder groups and it is involved in the HFEA's Horizon Scanning Panel and other external groups. Through such engagement with other bodies the HTA keeps abreast of new developments. An example of this is the Regulatory Advice Service for Regenerative Medicine (or the One Stop Shop), which brings the HTA together with the MHRA, HRA and HFEA.

Performance management

4.33. Key Performance Indicators should reflect and support the strategic priorities of an organisation. They help organisations understand how well they are performing in relation to their strategic goals and objectives. Below this, an organisation might use a number of further targets or measures. There are a wide variety of types of performance indicators but some core examples are:

- **Cost:** the money spent to acquire the resources.
- **Input:** the resources (staff, materials and premises) employed to provide the service.
- **Output:** the service provided, for example, in terms of tasks completed.
- **Outcome:** the impact and value of the service delivery.

4.34. The HTA's Annual Report and Accounts[15] and Business Plan[16] for 2014-15 set out four strategic aims (outcomes) supported by a large number of activities and performance

[15] HTA Annual Report and Accounts 2014-15, pages 5-6, https://www.hta.gov.uk/sites/default/files/HTA%20annual%20report%20and%20accounts%201415.pdf

indicators (largely outputs). Where targets were not met (as was the case for two of the 17 key performance indicators for 2014-15) the HTA investigates the causes and takes action accordingly.

4.35. The HTA seeks continuous improvement and value for money. To assess performance against this the HTA needs to make appropriate comparisons. It should therefore seek to benchmark performance against comparator organisations. This might include a selection of bodies from other regulators, similar organisations in other countries, and high-performing organisations in other sectors.

Recommendation 8: that the HTA considers the practicalities of inclusion, within its performance measures, of an assessment of comparative performance against relevant high-performing organisations.

[16] HTA Business Plan 2014-15, pages 21-25, https://www.hta.gov.uk/sites/default/files/HTA_Business_Plan_2014-15.pdf

5. Stage Two: Efficiency

5.1. The HTA is a very small organisation and has made significant reductions in its size and spend over recent years. Many stakeholders commented on the savings already achieved and expressed concern at the scope for such a small organisation to go much further whilst retaining sustainability and resilience. Since 2010, the HTA has reduced costs by 31% (to £4.1m) and staffing levels have fallen to 46 full time equivalents.

5.2. Table 4 below summarises HTA resources.

Table 4: HTA Income, Expenditure and Staff

(£000s)	07/08	08/09	09/10	10/11	11/12	12/13	13/14	14/15	15/16
Licence Fee income	3395	3789	5455	4141	3120	3131	2970	3288	3384
Grant-in-Aid	1647	1643	2013	1162	1143	359	773	773	740
Expenditure	4591	4704	6025	5337	4423	4237	3913	4149	4415
Staff (FTE)			71	54	46	47	45	46	46

5.3. The HTA sets licence fees to cover the costs of regulation and this income covers more than 80% of its expenditure. The HTA's licence fees are generally considered fair by stakeholders and the fact that surpluses have been refunded where income has exceeded costs by £250,000 or more was strongly welcomed. The HTA does nevertheless have a cash balance of £2.9m at present and should seek to reduce this to the minimum level necessary to meet likely cash requirements.

5.4. Some stakeholders expressed concerns that the small size of the HTA led to inherent risks that the loss of key staff could have a significant adverse impact on performance. Particular concerns related to the loss of key senior staff and to experienced inspectors. The annual rolling rate of attrition in 2014-15 was 23%, above the target of 18% or below. Pay constraints and lack of progression opportunities in a small organisation were seen as the main causes and the HTA aims to offer non-pay benefits to help improve staff retention. The issue is picked up in the HTA's Strategic Risk Register and monitored by the board.

Recommendation 9: that the HTA develops knowledge management plans to further mitigate the risks of loss of key staff.

5.5. The HTA is foremost a successful regulatory body. However, the demands placed upon a small ALB such as the HTA by the DH and other departments can be challenging, both in terms of time and cost. It would be helpful to such bodies if information requests and reporting requirements were proportionate to the ALB's size and resources wherever possible. This issue will become increasingly significant as ALBs seek to manage resources effectively under tight fiscal controls.

5.6. This will be best achieved where there is close communication with the Department. As well as the HTA responding to the priorities of the Department, the role of the sponsor team is pivotal in ensuring that the Department understands what it is possible for the HTA to achieve and the competing priorities that need to be balanced.

Recommendation 10: that the Department of Health assists the HTA by working to better manage information and reporting requests of all arm's length bodies, having regard to proportionality and reflecting differences in the size of, and resources available to, such bodies.

Accommodation

5.7. The HTA is located in a building shared with a range of other DH arm's length bodies and pays £536,000 per annum for 645sqm. Although a reduction in staffing levels means it currently has more space than it needs, part is currently being sub-let to the NHS Litigation Authority (recovering £100,000 per annum). In addition, the HTA had been discussing sub-letting further space from spring 2016 to provide for co-location with the HFEA. However, the HFEA has recently agreed to co-locate with NICE as this delivers greater direct savings. Such co-location of the HTA and HFEA was considered in the McCracken review and resulted in this recommendation:

McCracken review, recommendation 3 – The Department of Health's future estates strategy should take into account the clear operational benefits in terms of facilitating seamless regulation of co-location in one building all the bodies engaged in regulation and oversight of health care and related research.

5.8. The HTA is currently located with the MHRA, CQC, NHSLA and others; and from 2016, will sub-let more space to NHSLA. This not only provides the potential for benefits from lower accommodation and back-office costs but also provides for the wider operational benefits referred to in the McCracken review. For the HTA, co-location with other regulators would seem to offer the maximum potential for delivery of these wider benefits. Some of the other potential efficiencies referred to below would be far more difficult to achieve without co-location. The Department of Health should aim to ensure that its accommodation strategy for its arm's length bodies gives full consideration to the wider potential benefits of appropriate co-location.

Sharing back and middle-office functions

5.9. The HTA has relatively low overheads, particularly for such a small organisation, and some benchmark assessment is provided at table 5 below. The scope for further savings is relatively limited but some benefits ought to be achievable.

Table 5: HTA back-office benchmark assessment

Function	Cabinet Office Benchmark	HTA performance
HR	50:1 ratio of staff to HR employee.	49:1
Finance	Cost of the finance function equates to 1.9% of total funding	2%
IT	Cost of IT equates to 4% of total funding	5%

5.10. The current IT support contract ends in 2016 and the HTA needs to explore options for its replacement. This should include possible links to services provided by/to other ALBs, such as the HFEA or MHRA.

5.11. The posts of Director of Resources and Head of Finance are shared with the HFEA. This implements a recommendation in the McCracken review:

McCracken review, recommendation 2 – The support services of the two bodies should be combined and managed by a single Director of Finance and Resources, supporting both Chief Executives. This will facilitate further efficiency savings, estimated at £2.8m over 10 years.

5.12. It should be possible to go further as the finance teams, though small, have not been merged due to different financial software systems being used. In the short term the costs of combining these functions may well outweigh the benefits but the HTA should work with the HFEA to agree a plan to achieve this goal. This may though be more difficult to achieve without co-location with the HFEA and this could mean that other options may need to be explored.

Recommendation 11: that the HTA works with the Department of Health and other arm's length bodies to explore further opportunities to share services and develop implementation plans.

Procurement and contract management

5.13. By far the largest HTA contract relates to accommodation costs, as covered above. Other contracts total around £170,000 per annum, with the largest relating to desktop support and other IT provision and costing £144,000 per annum.

5.14. In negotiating contract replacement or renewal the HTA uses government frameworks and the Crown Commercial Service. For example the HTA intends to use GCloud7 in 2016 to re-tender current IT services.

Generating income

5.15. As mentioned above (paragraphs 4.26-4.27), a number of stakeholder responses suggested that there is a demand for the HTA to provide more training sessions and conferences. Such events could both generate income and support the needs of staff in regulated bodies but would need to be balanced against the resource risks (costs being incurred in advance of the income generated) and staff being drawn away from other issues.

6. Stage Two: Governance

Principles of good corporate governance in ALBs

6.1. Every arm's length body needs clear arrangements for overseeing its strategic direction, performance monitoring and review. The variety of organisations means that one solution will not fit all and departments, in discussion with the arm's length body, are able to decide on the precise structure of governance arrangements as long as the key principles are met. Such arrangements are then normally outlined in the Framework Agreement.

6.2. Cabinet Office guidance states that Triennial Reviews must assess the controls, processes and safeguards in place against the principles and supporting provisions set out in the Code of Good Corporate Governance. The Cabinet Office publishes a range of guidance on governance issues for public bodies[17].

6.3. The full assessment for each principle is detailed in tabular form in Annex G. It reflects both self-assessment by the Authority and analysis of the review team. Non-compliance is acceptable where this is justified by the particular circumstances and where appropriate alternative arrangements are in place.

6.4. Overall the HTA is fully compliant with all of the principles. The sections below summarise the detail in the table and pick up particular issues in relation to the principles.

Accountability

6.5. The Authority complies with the principles. The Chief Executive is formally appointed as the Accounting Officer, with the role and responsibilities clearly set out in a draft Framework Agreement between the HTA and the Department.

6.6. The Secretary of State appoints the Chair and all other non-executive board members. The relevant departmental minister holds an annual accountability meeting to review the performance and strategic development of the HTA. The Minister also approves a five-year corporate plan that sets out the HTA's longer-term aims and objectives.

6.7. The Permanent Secretary has appointed a Senior Departmental Sponsor (SDS) at Director General level to provide regular senior level contact between the Department and the HTA. In this role the SDS supports the Permanent Secretary in holding the HTA to account and providing assurance on performance. The SDS ensures quarterly accountability meetings are held with the Chief Executive and his senior management team and is responsible for agreeing the HTA's annual business plan.

[17] www.gov.uk/government/publications/public-bodies-information-and-guidance

6.8. The quarterly accountability meetings assess performance and can escalate any concerns to the Permanent Secretary if necessary. If HTA were to fail to comply with any requirement to address performance issues the Secretary of State would be able to make arrangements for another body to exercise the functions on his behalf.

6.9. This process sets out clear lines of accountability for the Chief Executive. The Chief Executive (as Accounting Officer) is accountable to the Permanent Secretary (as Principal Accounting Officer) and also directly to Parliament for the Authority's use of public funds.

Role of the sponsor department

6.10. The Authority and Department comply with the principles. In addition to the SDS, there is a departmental sponsor team which has regular contact with HTA and a team member attends board meetings as an observer.

6.11. The framework agreement between the department and the HTA sets out clear accountability arrangements and the roles and responsibilities of senior parties in both organisations. It is reviewed at least every three years.

6.12. Oversight by the Departmental Board is provided through a quarterly performance report that includes an indicator on overall ALB assurance and occasional consideration by the Audit and Risk Committee, which has an ongoing programme of inviting ALB sponsor teams and audit chairs to meetings.

Role of the Board, Chair and Non-Executive Board Members

6.13. The Authority complies with the principles. The HTA has an independent Chair who is appointed by, and can provide advice directly to, the Secretary of State.

6.14. The HTA's board is made up of 12 non-executives, who are Authority members and appointed by the Secretary of State[18] under Schedule 2 of the HT Act 2004. The Chief Executive and other staff will attend meetings but not as board, or Authority, members. Although the Corporate Governance Code recommends that non-executives make up the majority of the board it is also expected that a mixed board of executives and non-executives would normally provide the best balance. Such a structure should best ensure that the board has a full understanding of the key issues affecting the Authority, is subject to appropriate scrutiny and challenge, and is able to take forward outcomes effectively.

[18] The National Assembly for Wales and the relevant Northern Ireland department each appoint one member also.

6.15. However, the review found that the HTA board operates effectively, with good two-way communications with the executive that provides oversight, challenge and a close connection to decision-making processes. It is not clear whether a mixed executive and non-executive board structure could be established whilst meeting the requirements for the Authority as set out in legislation and without creating a complex and bureaucratic structure. As such, no change to the current structure is recommended.

6.16. The specialist nature of the HTA's responsibilities is reflected in the knowledge and expertise brought by non-executive authority members. The board reviews its composition with the Department to ensure relevant skills and experiences are covered. Non-executive appointments are made in accordance with the Commissioner for Public Appointments' Code of Practice.

6.17. Nevertheless, for a relatively small organisation such as the HTA, the loss of board members or key staff can result in a loss of knowledge and ability. There are some risks that the expected loss (as their term of appointment comes to an end) of five experienced board members in 2016 (which will mean that, apart from the chair, no non-executive will have been in post for two years) could result in a loss of knowledge and ability to offer effective scrutiny and challenge.

Recommendation 12: that the HTA develops proposals for the Department of Health on succession planning for non-executives that maximise knowledge transfer and stagger appointments and re-appointments as much as possible.

Effective financial management

6.18. The Authority largely complies with the principles. The expenses policy needs to be published and this will be done by September 2016.

Communications

6.19. The Authority complies with the principles. It publishes data on its website for all transactions above £1,000 and for Government Procurement Card transactions over £500.

6.20. Information on board members, minutes of board meetings, performance, expenditure, etc., is published online. The HTA is considered open and approachable by the vast majority of stakeholders. Public board meetings are held once a year and are valued by stakeholders.

Conduct and behaviour

6.21. The Authority complies with the principles.

7. Annexes

Annex A - Membership of the Project Board and Critical Friends Group

Review team

Senior Review Sponsor	Kathryn Tyson	DH, Director of International Health and Public Health Policy
Lead Reviewer	David Dipple	DH
Assistant Reviewer	Kim Collins	DH
Assistant Reviewer	Maxine Ward	DH

Project Board

The purpose of the Project Board was to provide oversight of the review process, clearing the approach and documentation.

Chair	Kathryn Tyson	Senior Review Sponsor (DH, Director of International Health and Public Health Policy)
Member	Allan Marriott - Smith	Chief Executive Officer, HTA
Member	Edward Webb	DH Sponsor Team
Member	David Dipple	Lead Reviewer
Secretariat	Kim Collins	Assistant Reviewer

Critical Friends Group

The purpose of the Critical Friends Group was to rigorously and robustly test and challenge the scope of the reviews, the process (particularly the robustness of the approach to evidence gathering and analysis), and emerging conclusions and draft reports.

Chair	Justin McCracken	Previously Chief Executive of the Health Protection Agency.
Member	Professor Bobbie Farsides	Professor of Clinical and Biomedical Ethics, Brighton and Sussex Medical School
Member	Hugh Whittall	Director, Nuffield Council on Bioethics

Member	Kathryn Tyson	Senior Review Sponsor (DH, Director of International Health and Public Health Policy)
Secretariat	David Dipple	Lead Reviewer

Annex B – Terms of Reference for the Review

Stage One

Stage one of the review will verify the functions of the HTA, evaluate how they contribute to the core business of the health and care system, and consider whether they are still needed.

The McCracken review looked at most aspects of the HTA's functions. This included the HTA's work to streamline regulation, increase focus on risk, cut costs and strengthen stakeholder and public engagement. The Triennial Review will take full account of the outcome of the McCracken review's assessment of functions. Within this context, the review will consider:

a) whether delivery of the functions contributes to wider government policy and constitutes a justifiable use of public money;

b) the benefits of delivering the function or activity for users and wider stakeholders;

c) the cost and effects of not delivering the function; and

d) how the functions interact with other parts of the health and care system or the wider public sector.

Where it is concluded that functions are still needed, stage one will go on to examine how this function might best be delivered including whether the function would be better delivered by any of the following delivery models:

a) to be delivered by the private sector, the voluntary and community sector, under contract by the private or community sector, or as a mutual, community interest company, or social enterprise; and

b) merged with another body, either another area of central government or another public body. (This will exclude the assessments made in recent reviews regarding merger with the HFEA or transferring functions to the CQC and HRA.)

If it were decided that the HTA should remain as a separate public body then the McCracken review has relatively recently assessed the Authority against the three tests set by the Cabinet Office and determined that NDPB status was appropriate. This assessment would be accepted.

Stage Two

If the outcome of stage one is that the HTA should retain its current status, stage two will go on to review its performance, governance and efficiency. Within this context, the review will consider the following key lines of enquiry:

a) whether the HTA makes the best use of public money and maximises revenues (where appropriate and possible);

b) whether internal processes are sufficiently lean and further efficiencies could be delivered outside of those in the McCracken review (including digitisation, shared services, etc.);

c) an assessment of the implementation of the recommendations in the McCracken review;

d) the balance between grant-in-aid and regulatory fee income;

e) whether regulatory activity is efficient and risk-based (having regard to the requirements of the legislative requirements);

f) the capacity and capability to respond effectively to changing demands or a changing regulatory/policy/scientific environment, e.g., the quality of strategic plans and horizon scanning;

g) collaboration with partners across the health and social care system, and elsewhere. Building and maintaining public confidence;

h) relations and communications with stakeholders, including understanding of regulated bodies, patients, and wider interests; and

i) whether the governance is appropriate - to whom is the HTA accountable and how is this exercised?

Annex C - Written Ministerial Statement announcing the review

Made on 25 June 2015:

DEPARTMENT OF HEALTH

Arm's Length Bodies (Triennial Reviews)

The Parliamentary Under Secretary of State for Public Health, Department of Health (Jane Ellison): I am today announcing the start of the Triennial Reviews of the Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment, the Human Fertilisation and Embryology Authority, the Human Tissue Authority, and NHS Blood and Transplant.

The Triennial Review programme ensures that all Government Departments review their Non-Departmental Public Bodies on a regular basis. In order to ensure that the Department of Health is operating as an effective system steward and can be assured of all the bodies it is responsible for, it has extended the programme of reviews over the period 2014-17 to include all of its arm's length bodies.

The reviews are conducted in two stages. The first stage will examine the continuing need for the function and whether the organisation's form, including operating at arm's length from government, remains appropriate. If the outcome of this stage is that delivery should continue, the second stage of the review will assess whether the bodies are operating efficiently and in line with the recognised principles of good corporate governance.

Copies of the reports of the reviews will be placed in the Libraries of the House.

Annex D – Stakeholder Engagement

List of respondents to Call for Evidence

The review team published an online call for evidence that was made available on the Department of Health pages on Gov.Uk and was publicised on the HTA website also. In addition, the team emailed a wide range of stakeholders to inform them of this process and encourage wider dissemination. The call for evidence opened on 14 July 2015 and ran until 31 August 2015. The respondents are listed below.

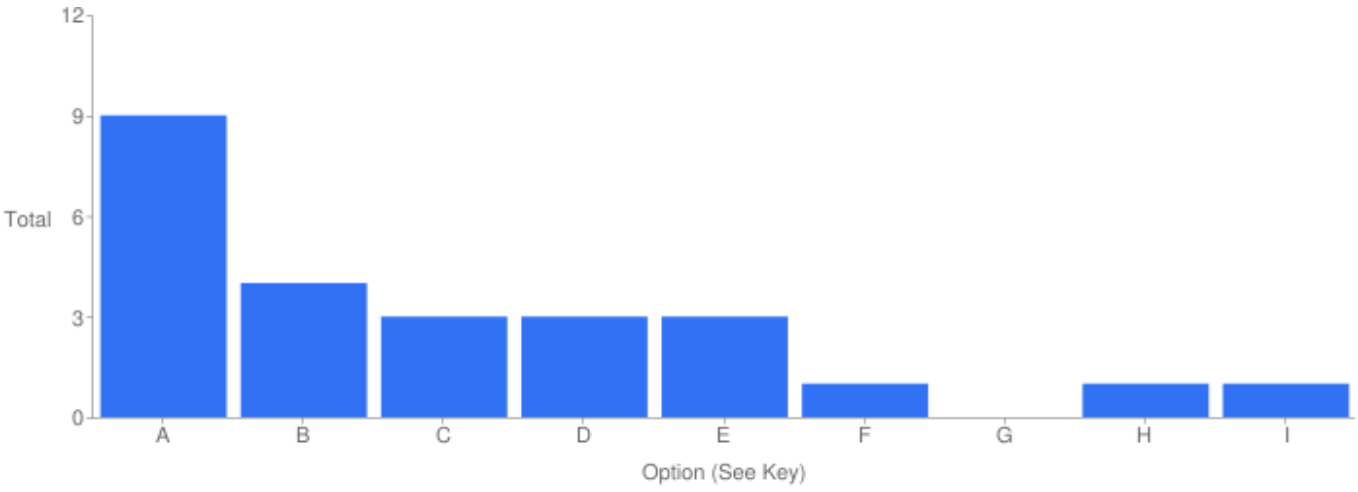
Call for Evidence Respondents

	Name	Grouping and Organisation/Individual
1	Detective Sergeant Wendy Hesmondhalgh	Individual (Human Tissue Manager, Greater Manchester Police)
2	Dean Jones	Individual (Home Office)
3	David Adams	Individual (Anatomy Department, The Robert Jones and Agnes Hunt Orthopaedic Hospital NHS Foundation Trust)
4	Keith Rigg	Individual (Nottingham University Hospitals NHS Trust)
5	K. Benes	Individual (Consultant Histopathologist in NHS)
6	Andrew Laurie	Individual (Pathology)
7	Francesco Pezzella	Research (University of Oxford)
8	Debby Gibson	Individual (Leeds Teaching Hospitals NHS Trust)
9	Dr Kenny Douglas	Public Sector (Scottish National Blood Transfusion Service)
10	Guy Singleton	Individual (Colchester General Hospital (Mortuary Manager))
11	Simon Butler	Charitable/Voluntary (Anthony Nolan)
12	Philip Adds	Academic (St George's, University of London)
13	Anonymous	Individual
14	Sarah Davis	Individual (Deputy Mortuary Manager, Birmingham Women's Hospital)
15	Angela Douglas	Public Sector (Cheshire and Merseyside Genetics Service)
16	Cecilia Brassett	Academic (University of Cambridge)
17	Sarah May	Charitable/Voluntary (Institute of Biomedical Science)

18	Don M. Wallace	Private Sector (GlaxoSmithKline R&D)
19	Jane Apperley	Academic (Imperial College London)
20	Hilary Lloyd	None (British Medical Association)
21	Margaret Wilcox	Charitable/Voluntary (Independent Cancer Patients Voice)
22	Ian Bateman	Public Sector (NHS Blood and Transplant)
23	Sarah Dickson	Research (Medical Research Council)
24		Research (Academy of Medical Sciences, Association of Medical Research Charities and the Wellcome Trust)
25	Steven Wilson	Public Sector (Healthcare Improvement Scotland)

Figure 3 below provides a breakdown of respondents self-classification of the various sectors represented.

Figure 3: Breakdown of call for evidence respondents



Key	Option	Total	Percentage
A	Individual	9	36.00%
B	Public sector	4	16.00%
C	Charitable/Voluntary sector healthcare organisation	3	12.00%
D	Clinical research	3	12.00%
E	Medical/Academic schools	3	12.00%
F	Private sector - pharma	1	4.00%

G	Private sector - other	0	0%
H	None of the above	1	4.00%
I	Not Answered	1	4.00%

A number of the respondents to the call for evidence indicated that they were representing views of a wider membership. In addition, some respondents, or their organisations, were also included within stakeholder interviews or attended a workshop. The review team took this into account but did not attempt to formally weight responses in any way.

List of workshop attendees

The review team also offered three sessions where interested stakeholders could book places. These were held on 29 July, 12 August and 17 August 2015. The attendees were:

Attendees at workshops

1	Birgit Whitman	Bristol University
2	Will Greenacre	Wellcome Trust
3	John Pitchers	Association of Anatomical Pathology Technology
4	Nathanial Cary	
5	Khaled El-Ghariani	NHS Blood and Transplant
6	Edward Dove	University of Edinburgh
7	Clare Skinner	Leeds University
8	Patricia Harnden	Leeds University
9	Christian Allmark	Patient Advocate

List of interviews

In addition, the review team conducted interviews with a range of stakeholders as set out below:

Interviews Conducted

Department of Health:

1 Director General for Public Health

2 DH Sponsor Team

Human Tissue Authority:

3 Sharmila Nebhrajani, OBE Chair

4	Allan Marriott-Smith	Chief Executive Officer
5	Sue Gallone	Director of Finance and Resources
6	Sarah Bedwell	Director of Regulation
7	Professor Susan Dilly	Non-Executive Director
8	Professor Andy Hall	Non-Executive Director
9	Amanda Gibbon	Non-Executive Director
10	Professor Gurch Randhawa	Non-Executive Director
11	Professor Anthony Warrens	Non-Executive Director

Other public and private sector:

12	Jeff Adams	Home Office
13	Ian Trenholme	NHS Blood & Transplant
14	Richard Power	British Association for Tissue Banking
15	Professor Chis Rudge	UK Donation Ethics Committee
16	Lorna Marson	British Transplantation Society
17	Dr Fiona Wilcox	Coroner
18	Sarah Dickson	Medical Research Council
19	Dr Michael Osborn	Royal College of Pathologists
20	Peter Thompson	Human Fertilisation and Embryology Authority
21	Dr Robert Forrest	Coroner
22	Janet Wisely	Health Research Authority
23	Alex Bayliss	Care Quality Commission
24	Professor Anil Dhawan	Kings College Hospital
25	Kay Wadely	Individual
26	David Thewlis	Individual
27	Lorraine Turner and Stephen Mitchell	UK Accreditation Service

Annex E - Public Call for Evidence Questions

Call for Evidence Question (Majority response shown in **bold**)	**Yes**	**No**	**Don't know**	**Not Answered**
1. Is there a continuing need for the functions undertaken by the HTA?	**21 (84%)**	2 (8%)	1 (4%)	1 (4%)
2. How well do you think that HTA fulfils each of its functions at present?	**Very Well – 9 (36%)** **Well – 9 (36%)** Average - 1 (4%) Poorly - 0 Very Poorly – 2 (8%)		2 (8%)	2 (8%)
3. a) Outside of the options that have previously been considered, which of the following organisational forms would you support?	**NDPB – 15 (60%)** Merge – 2 (8%) DH – 2 (8%) VCS - 0		4 (16%)	2 (8%)
b) Are there parts of the HTA's work that could be better done elsewhere in the public, private or not for profit sectors?	3 (12%)	**13 (52%)**	7 (28%)	2 (8%)
4. How would you rate the performance of the HTA?	Very Good – 6 (24%) **Good – 14 (56%)** Average – 0 Poor – 0 Very Poor - 2 (8%)		1 (4%)	2 (8%)
5. Do you think that the functions of the HTA, regulatory or otherwise, impose burdens that are:	**Proportionate – 12 (48%)** Disproportionate – 7 (28%)		0	6 (24%)
6. How effectively does the HTA operate within and support the rest of the health and care system?	Very Well – 2 (8%) **Well – 6 (24%)** Average – 1 (4%) Poorly - 0 Very Poorly – 2		9 (36%)	5 (20%)

Call for Evidence Question (Majority response shown in **bold**)	**Yes**	**No**	**Don't know**	**Not Answered**
	(8%)			
7. How well does the HTA communicate and engage with stakeholders?	Very Well – 7 (28%) **Well – 9 (36%)** Average – 3 (12%) Poorly – 1 (4%) Very Poorly – 0		3 (12%)	2 (8%)
8. Could the HTA do more to support innovation and new approaches in the area of human tissue and organs?	**11 (44%)**	2 (8%)	9 (36%)	3 (12%)
9. Are there any measures you believe the HTA could take to deliver further efficiencies (whether reduced costs or improved use of resources)?	**10 (40%)**	3 (12%)	9 (36%)	3 (12%)
10. How effectively does the HTA maintain public confidence that human tissue is regulated appropriately?	Very Well – 5 (20%) **Well – 8 (32%)** Average – 3 (12%) Poorly – 0 Very Poorly – 1 (4%)		5 (20%)	3 (12%)
11. Is the HTA sufficiently forward-looking and responsive to new challenges and opportunities?	**9 (36%)**	3 (12%)	9 (36%)	4 (16%)
12. Does the HTA follow best practices in its governance arrangements?	**10 (40%)**	3 (12%)	9 (36%)	3 (12%)

Annex F – Other Sources of Evidence

The review team referred to a range of published documents and other material as part of the evidence gathering and analysis process. The key documents are listed below:

Published sources of information and evidence	
1	HTA Website (https://www.hta.gov.uk/)
2	HTA Annual Report and Accounts 2014-15 (https://www.hta.gov.uk/sites/default/files/HTA%20annual%20report%20and%20accounts%201415.pdf)
3	Human Tissue Act 2004 (http://www.legislation.gov.uk/ukpga/2004/30/section/1)
4	Liberating the NHS: Report of the arm's-length bodies review - July 2010 (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/216278/dh_118053.pdf)
5	Government response to the consultation on proposals to transfer functions from the Human Fertilisation and Embryology Authority and the Human Tissue Authority - January 2013 (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/212742/Consultation_HFEA_and_HTA_government_response.pdf)
6	Review of the Human Fertilisation & Embryology Authority and the Human Tissue Authority - Justin McCracken, April 2013 (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/216947/Justin_McCracken_report_of_review_of_HFEA_and_HTA.pdf)
7	Human Tissue (Scotland) Act 2006 (http://www.legislation.gov.uk/asp/2006/4/pdfs/asp_20060004_en.pdf)
8	Human Transplantation (Wales) Act 2013 (http://gov.wales/legislation/programme/assemblybills/organdonationbill/?lang=en)
9	HTA Strategic Risk Register – June 2015 (https://www.hta.gov.uk/sites/default/files/AuthorityJuly%202015%20papers%20%282%29.pdf)
10	Managing Public Money – HM Treasury (https://www.gov.uk/government/publications/managing-public-money)

11	Who's accountable? Relationships between Government and arm's-length bodies - House of Commons, Public Administration Select Committee, First Report of Session 2014–15 (http://www.publications.parliament.uk/pa/cm201415/cmselect/cmpubadm/110/110.pdf)
12	Corporate governance in central government departments – HM Treasury & Cabinet Office (https://www.gov.uk/government/publications/corporate-governance-code-for-central-government-departments)
13	Joint Accreditation Committee ICT Europe and EBMT (JACIE): http://www.jacie.org/
14	Clinical Commissioning Policy: Haematopoietic Stem Cell Transplantation – NHS Commissioning Board, April 2013 (https://www.england.nhs.uk/wp-content/uploads/2013/10/b04-p-a.pdf)
15	UK Accreditation Service (UKAS): http://www.ukas.com/
16	Guidance on the disposal of pregnancy remains following pregnancy loss or termination – HTA, March 2015 (https://www.hta.gov.uk/sites/default/files/Guidance_on_the_disposal_of_pregnancy_remains.pdf)
17	HTA Codes of Practice (https://www.hta.gov.uk/codes-practice)
18	HTA Business Plan 2014-15 (https://www.hta.gov.uk/sites/default/files/HTA_Business_Plan_2014-15.pdf)

Annex G - Compliance with the Principles of Good Corporate Governance

PRINCIPLES OF GOOD CORPORATE GOVERNANCE **Accountability**			
Statutory Accountability		**Compliant (Yes/No)**	**Review Findings**
Principle	**The public body complies with all applicable statutes and regulations, and other relevant statements of best practice.**		
Supporting Provisions	The public body must comply with all statutory and administrative requirements on the use of public funds. This includes the principles and policies set out in the HMT publication “Managing Public Money” and Cabinet Office/HM Treasury spending controls.	Yes	
	The public body must operate within the limits of its statutory authority and in accordance with any delegated authorities agreed with the sponsoring department.	Yes	
	The public body should operate in line with the statutory requirements and spirit of the Freedom of Information Act 2000. It should have a comprehensive Publication Scheme. It should proactively release information that is of legitimate public interest where this is consistent with the provisions of the Act.	Yes	
	The public body must be compliant with Data Protection legislation.	Yes	

	The public body should be subject to the Public Records Acts 1958 and 1967.	Yes	

Accountability for public money		Compliant (Yes/No)	Detail
Principle	**The Accounting Officer of the public body is personally responsible and accountable to Parliament for the use of public money by the body and for the stewardship of assets**		
Supporting Provisions	There should be a formally designated Accounting Officer for the public body. This is usually the most senior official (normally the Chief Executive).	Yes	
	The role, responsibilities and accountability of the Accounting Officer should be clearly defined and understood. The Accounting Officer should have received appropriate training and induction. The public body should be compliant with the requirements set out in “Managing Public Money”, relevant Dear Accounting Officer letters and other directions. In particular, the Accounting Officer of the NDPB has a responsibility to provide evidence-based assurances required by the Principal Accounting Officer (PAO). The PAO requires these to satisfy him or herself that the Accounting Office responsibilities are being appropriately discharged. This includes, without reservation, appropriate access of the PAO’s internal audit service into the NDPB.	Yes	
	The public body should establish appropriate arrangements to ensure that public funds: • are properly safeguarded; • are used economically, efficiently and effectively; • are used in accordance with the statutory or other authorities that govern their use; • deliver value for money for the Exchequer as a whole.	Yes	

	The public body's annual accounts should be laid before Parliament. The Comptroller and Auditor General should be the external auditor for the body.	Yes	

Ministerial Accountability		Compliant (Yes/No)	Detail
Principle	**The Minister is ultimately accountable to Parliament and the public for the overall performance of the public body.**		
Supporting Provisions	The Minister and sponsoring department should exercise appropriate scrutiny and oversight of the public body.	Yes	
	Appointments to the board should be made in line with any statutory requirements and, where appropriate, with the Code of Practice issued by the Commissioner for Public Appointments.	Yes	
	The Minister will normally appoint the Chair and all non-executive board members of the public body and be able to remove individuals whose performance or conduct is unsatisfactory.	Yes	This is a duty of the Secretary of State under the Human Tissue Act 2004.
	The Minister should be consulted on the appointment of the Chief Executive and will normally approve the terms and conditions of employment.	Yes	
	The Minister should meet the Chair and/or Chief Executive on a regular basis.	Yes	Meetings between the Public Health Minister take place as needed rather than to a prescribed schedule.

	A range of appropriate controls and safeguards should be in place to ensure that the Minister is consulted on key issues and can be properly held to account. These will normally include: • a requirement for the public body to consult the Minister on the corporate and/or operational business plan; • a requirement for the exercise of particular functions to be subject to guidance or approval from the Minister; • a general or specific power of Ministerial direction over the public body; • a requirement for the Minister to be consulted by the public body on key financial decisions. This should include proposals by the public body to: (i) acquire or dispose of land, property or other assets; (ii) form subsidiary companies or bodies corporate; and (iii) borrow money; • a power to require the production of information from the public body which is needed to answer satisfactorily for the body's affairs.	Yes	
	There should be a requirement to inform Parliament of the activities of the public body through publication of an annual report.	Yes	

PRINCIPLES OF GOOD CORPORATE GOVERNANCE Roles and responsibilities			
Role of the Sponsor Department		**Compliant (Yes/No)**	**Detail**
Principle	**The departmental board ensures that there are robust governance arrangements with the board of each arm's length body. These arrangements set out the terms of their relationship and explain how they will be put in place to promote high performance and safeguard propriety and regularity.** **There is a sponsor team within the department that provides appropriate oversight and scrutiny of, and support and assistance to, the public body.**		
Supporting Provisions	The departmental board's regular agenda should include scrutiny of the performance of the public body. The departmental board should establish appropriate systems and processes to ensure that there are effective arrangements in place for governance, risk management and internal control in the public body.	Yes	The Audit and Risk Committee (a committee of the Departmental Board) has an ongoing programme of inviting ALB sponsor teams to meetings. The aim of these discussions is to obtain assurance on how that ALB manages internal risks and contributes to system-wide risks, how it works with DH in doing so, and how the sponsor team itself manages any risks. The ALB audit chair is invited to attend alongside the sponsor team. The HTA will be discussed at a meeting in January 2016. Additionally, the Integrated Performance Scorecard, part of a quarterly performance report to the Departmental Board, includes an indicator on overall ALB assurance.

	There should be a Framework Document in place which sets out clearly the aims, objectives and functions of the public body and the respective roles and responsibilities of the Minister, the sponsoring department and the public body. This should follow relevant Cabinet Office and HM Treasury guidance. The Framework Document should be published. It should be accessible and understood by the sponsoring department, all board members and by the senior management team in the public body. It should be regularly reviewed and updated.	Yes	
	There should be a dedicated sponsor team within the parent department. The role of the sponsor team should be clearly defined.	Yes	
	There should be regular and ongoing dialogue between the sponsoring department and the public body. Senior officials from the sponsoring department may as appropriate attend board and/or committee meetings. There might also be regular meetings between relevant professionals in the sponsoring department and the public body.	Yes	

Role of the Board		Compliant (Yes/No)	Detail
Principle	**The public body is led by an effective board which has collective responsibility for the overall performance and success of the body. The board provides strategic leadership, direction, support and guidance.** **The board – and its committees – have an appropriate balance of skills, experience, independence and knowledge.** **There is a clear division of roles and responsibilities between non-executive and executives. No one individual has unchallenged decision-making powers.**		
Supporting Provisions	The board of the public body should: • meet regularly; • retain effective control over the body; and • effectively monitor the senior management team.	Yes	
	The size of the board should be appropriate.	Yes	
	Board members should be drawn from a wide range of diverse backgrounds.	Yes	
	The board should establish a framework of strategic control (or scheme of delegated or reserved powers). This should specify which matters are specifically reserved for the collective decision of the board. This framework must be understood by all board members and by the senior management team. It should be regularly reviewed and refreshed.	Yes	The HTA has Standing Orders.
	The board should establish formal procedural and financial regulations to govern the conduct of its business.	Yes	
	The board should establish appropriate arrangements to ensure that it has access to all such relevant information, advice and resources as is necessary to enable it to carry	Yes	

	out its role effectively.		
	The board should make a senior executive responsible for ensuring that board procedures are followed and that all applicable statutes and regulations and other relevant statements of best practice are complied with.	Yes	
	The board should make a senior executive responsible for ensuring that appropriate advice is given to it on all financial matters.	Yes	
	The board should establish a remuneration committee to make recommendations on the remuneration of top executives. Information on senior salaries should be published. The board should ensure that the body's rules for recruitment and management of staff provide for appointment and advancement on merit.	Yes	
	The Chief Executive should be accountable to the board for the ultimate performance of the public body and for the implementation of the board's policies. He or she should be responsible for the day-to-day management of the public body and should have line responsibility for all aspects of executive management.	Yes	
	There should be an annual evaluation of the performance of the board and its committees – and of the Chair and individual board members.	Yes	

Role of the Chair		Compliant (Yes/No)	Detail
Principle	**The Chair is responsible for leadership of the board and for ensuring its overall effectiveness.**		
Supporting Provisions	The board should be led by a non-executive Chair.	Yes	
	There should be a formal, rigorous and transparent process for the appointment of the Chair. This should be compliant with the Code of Practice issued by the Commissioner for Public Appointments. The Chair should have a clearly defined role in the appointment of non-executive board members.	Yes	

	The duties, role and responsibilities, terms of office and remuneration of the Chair should be set out clearly and formally defined in writing. Terms and conditions must be in line with Cabinet Office guidance and with any statutory requirements. The responsibilities of the Chair will normally include: • representing the public body in discussions with Ministers; • advising the sponsoring Department and Ministers about board appointments and the performance of individual non-executive board members; • ensuring that non-executive board members have a proper knowledge and understanding of their corporate role and responsibilities. The Chair should ensure that new members undergo a proper induction process and is normally responsible for undertaking an annual assessment of non-executive board members' performance; • ensuring that the board, in reaching decisions, takes proper account of guidance provided by the sponsoring department or Ministers; • ensuring that the board carries out its business efficiently and effectively; • representing the views of the board to the general public; and • developing an effective working relationship with the Chief Executive and other senior staff.	Yes	
	The roles of Chair and Chief Executive should be held by different individuals.	Yes	

Role of Non-Executive Board Members		Met (Yes/No)	Detail
Principle	**As part of their role, non-executive board members provide independent and constructive challenge.**		
Supporting Provisions	There should be a majority of non-executive members on the board.	Yes	The HTA has no executive members on its Board. The Chief Executive, Directors, and other staff as appropriate, will attend meetings but not as formal members.
	There should be a formal, rigorous and transparent process for the appointment of non-executive members of the board. This should be compliant with the Code of Practice issued by the Commissioner for Public Appointments.	Yes	
	The duties, role and responsibilities, terms of office and remuneration of non-executive board members should be set out clearly and formally defined in writing. Terms and conditions must be in line with Cabinet Office guidance and with any statutory requirements. The corporate responsibilities of non-executive board members (including the Chair) will normally include: • establishing the strategic direction of the public body (within a policy and resources framework agreed with Ministers); • overseeing the development and implementation of strategies, plans and priorities; • overseeing the development and review of key performance targets, including financial targets; • ensuring that the public body complies with all statutory and administrative requirements on the use of public funds; • ensuring that the board operates within the limits of its statutory authority and any delegated authority agreed with the sponsoring department; • ensuring that high standards of corporate governance are	Yes	The duties, roles and responsibilities of members are set out in the information pack issued to applicants. Terms and conditions are set out in offer letters and must be accepted by the individuals concerned before their appointments are confirmed.

	observed at all times. This should include ensuring that the public body operates in an open, accountable and responsive way; and • representing the board at meetings and events as required.		
	All non-executive Board members must be properly independent of management.	Yes	
	All non-executive board members must allocate sufficient time to the board to discharge their responsibilities effectively. Details of board attendance should be published (with an accompanying narrative as appropriate).	Yes	
	There should be a proper induction process for new board members. This should be led by the Chair. There should be regular reviews by the Chair of individual members' training and development needs.	Yes	

PRINCIPLES OF GOOD CORPORATE GOVERNANCE Effective Financial Management			
Effective Financial Management		**Compliant (Yes/No)**	**Detail**
Principle	**The public body has taken appropriate steps to ensure that effective systems of financial management and internal control are in place.**		
Supporting Provisions	The body must publish on a timely basis an objective, balanced and understandable annual report. The report must comply with HM Treasury guidance.	Yes	
	The public body must have taken steps to ensure that effective systems of risk management are established as part of the systems of internal control.	Yes	
	The public body must have taken steps to ensure that an effective internal audit function is established as part of the systems of internal control. This should operate to Government Internal Audit Standards and in accordance with Cabinet Office guidance.	Yes	
	There must be appropriate financial delegations in place. These should be understood by the sponsoring department, by board members, by the senior management team and by relevant staff across the public body. Effective systems should be in place to ensure compliance with these delegations. These should be regularly reviewed.	Yes	
	There must be effective anti-fraud and anti-corruption measures in place.	Yes	

	There must be clear rules in place governing the claiming of expenses. These should be published. Effective systems should be in place to ensure compliance with these rules. The public body should proactively publish information on expenses claimed by board members and senior staff.	Partly	There is an expenses policy in place but this is not published (plans are in place to do so by September 2016). Claims are checked by line managers and the finance team before payment to ensure compliance with rules. Information on expenses claimed by board members and senior managers is published on the HTA's website.
	The annual report should include a statement on the effectiveness of the body's systems of internal control.	Yes	
	The board should establish an audit (or audit and risk) committee with responsibility for the independent review of the systems of internal control and of the external audit process.	Yes	
	The body should have taken steps to ensure that an objective and professional relationship is maintained with the external auditors.	Yes	

PRINCIPLES OF GOOD CORPORATE GOVERNANCE Communications			
Communications		**Compliant (Yes/No)**	**Detail**
Principle	**The Public Body is open, transparent, accountable and responsive.**		
Supporting Provisions	The public body should have identified its key stakeholders. It should establish clear and effective channels of communication with these stakeholders.	Yes	
	The public body should make an explicit commitment to openness in all its activities. It should engage and consult with the public on issues of real public interest or concern. This might be via new media. It should publish details of senior staff and boards members together with appropriate contact details.	Yes	
	The public body should consider holding open board meetings or an annual open meeting.	Yes	
	The public body should proactively publish agendas and minutes of board meetings.	Yes	
	The public body should proactively publish performance data.	Yes	
	In accordance with transparency best practice, public bodies should consider publishing their spend data over £500. By regularly publishing such data and by opening their books for public scrutiny, public bodies can demonstrate their commitment to openness and transparency and to making themselves more accountable to the public.	Partly	The HTA publishes data on transactions above £1,000 on its website.

	The public body should establish effective correspondence handling and complaint procedures. These should make it simple for members of the public to contact the public body and to make complaints. Complaints should be taken seriously. Where appropriate, complaints should be subject to investigation by the Parliamentary Ombudsman. The public body should monitor and report on its performance in handling correspondence.	Yes	
	The public body must comply with the Government's conventions on publicity and advertising. These conventions must be understood by board members, senior managers and all staff in press, communication and marketing teams.	Yes	
	Appropriate rules and restrictions must be in place limiting the use of marketing and PR consultants.	Yes	
	The public body should put robust and effective systems in place to ensure that the public body is not, and is not perceived to be, engaging in political lobbying. This includes restrictions on board members and staff attending political conferences in a professional capacity.	Yes	

PRINCIPLES OF GOOD CORPORATE GOVERNANCE Conduct and behaviour			
Conduct and behaviour		**Compliant (Yes/No)**	**Detail**
Principle	**The board and staff of the public body work to the highest personal and professional standards. They promote the values of the public body and of good governance through their conduct and behaviour.**		
Supporting Provisions	A Code of Conduct must be in place setting out the standards of personal and professional behaviour expected of all board members. This should follow the Cabinet Office Code. All members should be aware of the Code. The Code should form part of the terms and conditions of appointment.	Yes	The HTA is in the process of updating, and then publishing, its Standing Orders. The Standing Orders contain the Code of Conduct for members. It also publishes policy on handling complains about maladministration and inappropriate conduct of Board Members and Staff
	The public body has adopted a Code of Conduct for staff. This is based on the Cabinet Office model Code. All staff should be aware of the provisions of the Code. The Code should form part of the terms and conditions of employment.	Yes	The HTA has published HTA values and HR polices which highlight the standards required for all staff. Information about relevant HR policies is included in a staff induction pack.
	There are clear rules and procedures in place for managing conflicts of interest. There is a publicly available Register of Interests for board members and senior staff. This is regularly updated.	Yes	
	There are clear rules and guidelines in place on political activity for board members and staff. There are effective systems in place to ensure compliance with any restrictions.	Yes	Information is in the HTA Standing Orders (Board Members) and HR policies (staff).

	There are rules in place for board members and senior staff on the acceptance of appointments or employment after resignation or retirement. These are effectively enforced.	Yes	Senior staff have a duty of confidentiality in their contracts which applies both during employment and after employment has ended. Board Member contracts are issued by the Department.
	Board members and senior staff should show leadership by conducting themselves in accordance with the highest standards of personal and professional behaviour and in line with the principles set out in respective Codes of Conduct.	Yes	