Human Tissue Authority’s response to the Department of Health’s Consultation on proposals to transfer functions from the Human Fertilisation and Embryology Authority and the Human Tissue Authority

28 September 2012

Introduction

1. The Human Tissue Authority (HTA) welcomes the opportunity to respond to the Department of Health’s (DH) “Consultation on proposals to transfer functions from the Human Fertilisation and Embryology Authority and the Human Tissue Authority” which it was pledged would be undertaken in the document “Liberating the NHS: Report of the arms-length bodies review”\(^1\) published in July 2010.

2. The HTA is committed to working with DH and other stakeholders to ensure that human tissue and organs continue to be stored and used safely, ethically and with proper consent, and that the bodies of deceased people are treated with respect and dignity. The HTA holds patient safety and public confidence as paramount and notes that the Ministerial Foreword to the consultation document stresses the Government’s commitment to maintaining standards.

3. This response document provides information on the HTA and the range of activities it carries out. It also provides the views of the HTA on the options proposed in the consultation document, the views of a number of stakeholders and of HTA staff.

4. The response does not comment explicitly on the proposals as they relate to the Human Fertilisation and Embryology Authority (HFEA). It should be noted that while the DH consultation concerns both the HTA and the HFEA, these are two independent organisations charged with distinct remits and working with different groups of stakeholders.

5. The HTA believes that of the options presented in the consultation document, option 3 would continue to ensure the safe and ethical storage and use of organs and tissue while delivering realisable efficiencies,

\(^1\) DH consultation document
without the risks associated with options 1 and 2. Therefore, the HTA's preferred option is option 3.
About the HTA

6. The consultation document provides an overview of the HTA at paragraph 29. As a statutory body the core of what the HTA does is laid down in three pieces of legislation. These are:

   a. The Human Tissue Act 2004 (HT Act) and associated Regulations
   b. Human Tissue (Quality and Safety for Human Application) Regulations 2007
   c. Quality and Safety of Organs Intended for Transplantation Regulations 2012

7. Since the HTA came into being in April 2005, it has established itself as an effective and successful regulator. It has achieved this by developing a distinctive style of regulation that is underpinned by close working relationships with its stakeholders, and supported by a risk-based and proportionate approach.

8. The HTA’s regulatory approach is made possible by its specialist and expert staff who provide high quality advice and guidance to licensed establishments, professionals and the public in order to raise standards more widely, ensure compliance with statutory requirements and maintain public confidence.

9. The HTA regulates establishments and activities in the following sectors, and this work is fully funded by licence fees:

   a. Post Mortem
   b. Research
   c. Human Application (the use of tissues and cells for patient treatment)
   d. Public Display; and
   e. Anatomical examination (the donation and use of bodies for the teaching of medical students)

10. The HTA also regulates establishments and activities in the transplantation sector. This work is currently funded by DH.

11. At the time of writing, the HTA has a headcount of 47, which equates to 45 full time equivalents (FTE). The majority of staff are involved directly in the licensing and inspection of establishments and activities that support regulation such as the provision of advice and guidance, the development of regulatory policy, and investigating and overseeing Serious Adverse Events and Reactions (SAEARS) and Serious Untoward Incidents (SUIs). These activities ensure continued compliance with legal requirements and HTA standards. This work is funded by
licence fees,\(^2\) which constitute 80% of the HTA’s annual income. The remaining 20% is Grant-in-aid funding from the Government, which for the year 2012/13 totals £860,000.

12. The HTA licences 543 establishments across all of its sectors, and in August 2012 issued 35 licences to transplantation establishments under the Quality and Safety of Organs Intended for Transplantation Regulations 2012.

13. A small team works on the assessment of living organ donations, of which there are approximately 1,200 a year. Of this figure about 10% are classified as complex cases and require further assessment by a panel of HTA Authority Members. Each panel consists of three Authority Members. All 12 Members sit on panels on a rotation basis and are trained annually to carry out this statutory function. This work is funded by Grant-in-aid.

14. The HTA deals with approximately 2,800 enquiries a year. Half of these enquiries come from members of the public and the remaining half from licensed establishments and professionals. Enquiries cover areas as diverse as donating one’s body to medical science to queries on the storage of tissue samples following a Coroner’s inquest. Recently, the HTA has seen an increase in the number of enquiries received on umbilical cord blood banking, illustrating how the sectors with which the HTA works are rapidly evolving.

15. It will be important that the scientific expertise and knowledge that is required to answer such enquiries is not lost under a transfer to another organisation or organisations.

16. The HTA is supported by a very small team of staff who provide high quality business support functions, including Human Resources (HR), business technology, legal, finance, administration, project management and communications. For example, the HR function is delivered by just one person, and the reduction in staff in support roles over the last two years has contributed to the 27% efficiency savings that the HTA has made.

17. The Authority itself has eleven Members and a Chair. The Chair, Baroness Warwick, works two days a week for the HTA, and each of the other Authority Members work two days a month. By statute, the Chair and at least half of the membership must be lay, and Members currently include a transplant surgeon, an ethicist, a coroner, a pathologist and a Professor of Diversity in Public Health. The Authority meets six times a year and one of these meetings is held in public.

---

\(^2\) In 2011/12 licence fee income totalled £3,120,000
18. The HTA’s success to date is largely due to the manner in which it discharges its functions. The high opinion of stakeholders and the high standards of compliance throughout the regulated sectors are attributable to the specialist knowledge and skills of the HTA’s people, the quality of the relationships that have been built and the focus on advice and guidance. These combine to add value and give the HTA its distinctive style of regulation which accounts in part for the high standards of compliance throughout the regulated sectors.

Indeed, Henny Braund, Chief Executive of the charity Anthony Nolan, recently stated in BioNews that:

“We have a regulator [the HTA] whose board has learnt some pretty complicated detail about cells, laboratory techniques, medical practice, genetics, national and international law. In turn, the board is supported by an expert executive. Board members play an active role in sector working groups, for example in transplant, ensuring they can guide the organisation with a clear awareness of their stakeholders’ evolving needs.”

Similarly, Dr Archie Prentice, President of the Royal College of Pathologists (RCPPath), has stated:

“The HTA continues to reduce the burden of regulation whilst being proportionate and risk-based in its approach. The HTA’s Histopathology Working Group has made much progress in addressing the concerns of the sector, whilst balancing them with those of the public and the requirements of the Human Tissue Act.”

19. The HTA has always been committed to collaboration with other organisations, and continues to work to realise synergies with other bodies. The HTA carries out joint inspections with the Medicines and Healthcare products Regulatory Agency (MHRA) and will continue to strive to do so for the 15 establishments which are regulated by both organisations for Advanced Cell Medicinal Products. Significant work was undertaken during 2011 and early 2012 by the HTA, HFEA and the Care Quality Commission (CQC) to ensure that information held on establishments that are licensed by more than one of these regulators is available to the others. This aims to provide increased levels of protection for the public and improvements in clinical standards. Work is also ongoing with Clinical Pathology Accreditation (CPA) to scope the options available for joint working, which may initially involve a small number of establishments, to explore whether this could be expanded to include other establishments regulated by both organisations.

---

3 Biocnews article
20. The HTA is widely acknowledged to be a highly effective and efficient regulator. In addition to its core regulatory role, the HTA is regularly called upon for its expertise by a wide range of groups and organisations. In the last year the HTA has worked with and supported the groups in the table below.

<table>
<thead>
<tr>
<th>Organisations the HTA worked with and supported during 2011 and 2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Association of Chief Police Officers</td>
</tr>
<tr>
<td>Bereavement services</td>
</tr>
<tr>
<td>British Transplantation Society</td>
</tr>
<tr>
<td>Competent Authorities in other EU Member States</td>
</tr>
<tr>
<td>Coroners</td>
</tr>
<tr>
<td>Council for Healthcare Regulatory Excellence</td>
</tr>
<tr>
<td>EU Commission</td>
</tr>
<tr>
<td>Health Research Authority</td>
</tr>
<tr>
<td>Hillsborough Independent Panel</td>
</tr>
<tr>
<td>Home Office</td>
</tr>
<tr>
<td>Ministry of Justice</td>
</tr>
<tr>
<td>National Policing Improvement Agency</td>
</tr>
<tr>
<td>NHS Blood and Transplant</td>
</tr>
<tr>
<td>Nuffield Council on Bioethics</td>
</tr>
<tr>
<td>Patient organisations</td>
</tr>
<tr>
<td>Royal Military Police</td>
</tr>
<tr>
<td>Stillbirth and Neonatal Deaths charity</td>
</tr>
<tr>
<td>The three devolved administrations</td>
</tr>
</tbody>
</table>

21. The table above is not exhaustive, but gives an indication of the range of relationships the HTA has, many of which were instigated by the partner organisation as it required specialist knowledge and expertise to resolve or address sensitive and emotive issues. This is an example of the added value delivered by the HTA and diversity of the areas covered by such a small organisation.

22. Some of these relationships were established and developed by the HTA in order to ensure that tissues and organs are used safely, ethically and with proper consent. The regulatory approach taken by the HTA is based on advice, guidance and support; and through an active and ongoing stakeholder engagement program this approach has been improved and refined.

23. The HTA has worked with the media during crisis or potential crisis situations that have had the potential to damage public confidence, or to be accountable to the public by participating in public debate. Concerns on the removal of such support have been raised by Fiona Fox, Director of the Science Media Centre. In response to a potentially significant regulatory incident it may be difficult for a large organisation to have the expertise to be able to respond to the media quickly and seek to limit the potential damage caused to public confidence and

---

4 Fiona Fox comment
the organisation’s reputation. This is particularly true of functions moving to an organisation that may have to handle such issues in parallel with a diverse and wide ranging remit.

24. The HTA is a proportionate regulatory body, and on occasion this means that robust and timely regulatory action has to be taken in order to prevent a breach of legislation or license conditions. A system of review is incorporated in procedures to ensure that there is constant learning and refinement.

25. Licensed establishments in the post mortem sector are required to report SUIs to the HTA within five working days of them having been discovered, and establishments in the human application and transplantation sectors should report SAEARs within 24 hours. This reporting allows the HTA to factor such incidents and events into the risk profile of each establishment, and allows the HTA to share knowledge to prevent such events from occurring elsewhere, or reoccurring at the same establishment.

26. The HTA has developed and is implementing an online portal to reduce the administrative burden on licensed establishments so they can view all the information relevant to their particular licence. The HTA continues to identify ways in which it can relieve the burden on those it works with, and this contributes to the organisation’s supportive regulatory approach.

27. A number of the groups the HTA works with represent patients or the public more widely. Working with such groups to make sure there is public confidence in the way in which tissues and organs are used has been a key part of the success of the HTA. Continued dialogue with these groups, for example on the development of a model paediatric post mortem consent form, will be important under any of the three options presented to realise the Government’s aim of “no decision about me, without me”.

Options for consideration

28. The consultation document gives three options on the future of the HTA’s functions. These are:

Option 1
Transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the Health Research Authority (HRA); and abolish the HFEA and HTA.

Option 2
Transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and a limited number of functions that would transfer elsewhere; and abolish the HFEA and HTA.

Option 3
HFEA and HTA retain their functions but deliver further efficiencies.

29. The HTA (and many of its stakeholders)\(^5\) believe that option 3 is, subject to clarification of the further efficiencies envisaged, by far the best option for the regulated sectors and the public as a whole. It is the view of the HTA that this option would continue the effective and efficient regulation of human tissue and organs by the HTA, minimise the risks associated with the use of human tissue and protect, maintain and improve public confidence. The HTA therefore supports option 3.

\(^5\) See page 22 for stakeholder quotes and comments
The HTA's view on option 1

30. In the ALB review document published in July 2010, the option of transferring the HTA’s functions to the CQC was detailed, and this was subsequently identified as the preferred option of the Government.

Benefits

31. Since the publication of the ALB review document in 2010, the HTA has been of the view that under any transfer arrangements, all of its functions should remain together. This is required to ensure that a consistent approach is taken to the regulation of appropriate and valid consent for the full range of activities in the HTA’s remit, and to build on the work already done on ensuring public and professional confidence. There is currently certainty on where information can be obtained on all the HTA’s functions, and separating them could cause confusion and uncertainty, undermining what has been achieved to date and increasing the risk of non-compliance.

32. It is of value to note that the HTA gives advice and guidance not only on the regulated sectors, but also on other matters relating to human tissue and organs, such as the analysis of DNA. This advice and guidance is provided to a wide range of stakeholders including members of the public, licensed establishments and the Government.

33. One of the reasons put forward in the consultation document for an overall reduction in the number of health ALBs is an envisaged reduction in bureaucracy, which will in turn reduce the burden on licensed establishments.

34. Whether or not there is a reduction in bureaucracy under option 1 will very much depend on how the transfer is undertaken.

35. The HTA believes that it is too simplistic to state that a transfer to a larger health regulator will, in itself, lead to a reduction in bureaucracy. Without knowing how the CQC will take on the functions of the HTA (for example, becoming integrated with existing functions or becoming a separate unit within the organisation), it cannot be said that transferring the HTA’s functions to the CQC will reach the stated aim of reducing bureaucracy.

36. Indeed, if the benefits of the HTA’s current regulatory approach are to continue, it is difficult to imagine how there could be a reduction in staff or major change in methodology on transfer. It should also be noted that the Government has no intention of altering the requirements of the HT Act, and therefore the burden will not be reduced by limiting the statutory obligations of an establishment. Rather it
is proposed under options 1 and 2 that the burden will be reduced by limiting the number of regulatory bodies in this area.

37. It was originally stated that a transfer to the CQC would result in cost savings, and therefore deliver greater value for money to the tax payer. This is not a discussion which is focussed on in the consultation document, and the HTA considers it important that sight of this original aim is not lost during any transfer.

38. There will be costs associated with closing an organisation and transferring its functions, and these have historically been above the level identified in scoping documents and impact assessments. The Impact Assessment for the transfer of the HTA’s functions does not yet provide the detail required to allow a full cost-benefit analysis to be carried out. A proposal to merge the HTA and HFEA was rejected as recently as 2007, and an important factor in that decision was the costs such a merger would incur.

39. It would be disappointing if any potential transfer failed to deliver the cost savings envisaged, and came at a high price to licensed establishments and the taxpayer.

Concerns

40. The HTA notes the commitment in the consultation document to ensuring that any successor organisation has the necessary expertise and resources to carry out the additional functions for which it becomes responsible during any transfer.

41. The Health and Social Care Act 2012 requires the CQC to take on additional responsibilities, and these combined with the possible transfer of HTA functions, will pose a significant challenge to an organisation in a period of change.

42. During the two years since the publication of the ALB review document the CQC has sustained damage to its reputation, culminating in the Public Accounts Committee’s Report of March 2012.

43. It will be important that any body taking on the HTA’s functions is both credible to, and has the confidence of, licensed establishments and stakeholders more widely.

44. If option 1 is chosen, it will be important for the CQC to give regular reassurance to the public, professionals and the regulated sectors that they will continue to receive the same level of support, advice and guidance; and the envisaged benefit of less bureaucracy will be realised.

---

6 Arms’ Length Bodies Review
7 Public Accounts Committee Report
8 RATE debate
45. The risks posed by option 1 require consideration and this is provided below. Steps will need to be taken to mitigate such risks, and assurances provided at each step of the transfer process. If the Government chooses to follow this option, the HTA will do all it can to ensure a successful transition and the continued effective and efficient delivery of services and functions.

46. The risk of a loss of expertise is highlighted in the consultation document and there is value in exploring a little further why this matters, and to whom. The feedback received by the HTA following inspections is consistently of a very high standard and it is regularly the knowledge and understanding of inspecting staff which is specifically commented on.9

47. The HTA has focussed on the importance of building a relationship of trust and openness between regulator and establishments, and a key facet of this has been the ability of the HTA’s staff to discuss scientific and technical matters on an equal footing. The aim of this has been to ensure establishments receive the very best level of support, advice and guidance from the HTA, and that a culture of sharing best practice exists, promoting a rise in standards in each of the regulated sectors.

48. One benefit of a small organisation (such as the HTA) is that it can quickly respond to developments, and deliver a regulatory approach that is consistent, informed and appropriate. This is due to the fact that it can be quickly identified which person or team is best placed to address the issue and a decision made at senior level on whether further work needs to be commissioned. It may be more difficult for a large organisation to be able to provide this level of focus on small but significant matters, and for decisions to be made quickly when necessary. This may be made more difficult with multiple layers of management and when an organisation is responsible for a broad range of sectors that may have a high public profile.

49. The sector using tissue and cells for treatment is one of the more complex, fast growing sectors the HTA regulates because of its rapid scientific developments. By using the expertise of HTA staff and working with other agencies, such as the MHRA, the sector has been supported to help ensure that the UK is a positive environment within which emerging regenerative technologies can flourish.

50. Any regulatory body taking on new functions and seeking to build strong and appropriate relationships faces a significant challenge, and the HTA urges DH to explore how the CQC would seek to do this under option 1, prior to making a final decision. If this option is chosen, then reassurance should be given to licensed

---

9 In Quarter 1 2012/13, 99% of respondents considered the approach used by the HTA inspection team to be excellent (79%) or good (20%)
establishments and stakeholder organisations that they will continue to be inspected and receive advice and guidance from people with the specialist skills and knowledge required to do so. Part of this will be a continuation of the HTA's regulatory approach, which is based on strong relationships, advice and guidance, and proportionate regulatory action.

51. The HTA was created in part in response to the retention of organs without consent by a number of hospitals. This caused great distress to those families affected and widespread condemnation in the media and from the public more widely. Many of those affected are still in regular contact with the HTA to ensure that the risk of similar events occurring is not forgotten, and to act as a reminder that the reasons why the HTA was established have not disappeared. The advice and guidance the HTA has recently provided to the Association of Chief Police Officers and the Royal Military Police on retained human material is a timely reminder of the need for a regulator with expert and specialist knowledge.

52. Regulation must be proportionate and adhere to the right touch regulatory principles outlined by the Council for Healthcare Regulatory Excellence yet, if there is a loss of focus on why regulation is required or the harm it is intended to prevent, the risk of non-compliance will increase. There is also a risk that the transfer of the HTA’s functions to a large and overarching body, with a different regulatory remit, such as the CQC, could lead to focus being lost.

53. In focussing entirely on the Human Tissue Act and Quality and Safety Regulations, Members of the Authority have been able to develop a level of expertise about the issues at stake. This in turn allows them to provide effective advice and challenge to the executive to continuously drive up standards and provide improved value for money. The HT Act also mandates that certain decisions relating to living organ donation can only be made by the Authority. There are approximately 120 living organ donation cases each year that must each be assessed by a panel of three Authority Members.

54. It is not yet clear what type of structure of governance the CQC would adopt if it were to take on the functions of the HTA. In order to ensure that the value derived from the current Authority is not lost, the HTA believes it is essential that a mixed professional and lay governance structure for human tissue matters continues within the CQC.

55. The consultation document notes that the CQC is an England-only regulator, whereas the HTA has responsibilities across the UK (with the HTA undertaking some functions on behalf of Scottish Ministers). It is not clear how a cross-UK solution would be delivered after the transition of functions.

\[CHRE\] principles
Under option 1 (and option 2) there will be a transitional period. This will be the period after the announcement of a transfer of functions, and before these functions actually being transferred. As work will need to be done to effect the transfer, there is a risk that focus will be lost on the primary duty of ensuring that human tissue and organs are stored and used safely, ethically and with proper consent. During this period work will need to be done by DH, in conjunction with CQC and HTA, to ensure that standards are maintained and there is clarity as to which organisation has responsibility at any given time.

The year following the date of transition will also pose risks as licensed establishments and the new organisation or organisations will need to forge strong working relationships, as well as rebuilding and inspiring confidence. If there is any confusion as to which organisation is responsible for a function, there will be an increase in the risk of non-compliance as advice and guidance may not be sought or accurately given, and SUIs and SEARS under-reported.

For option 1 to be successful the HTA believes the following reassurances would need to be in place:

a. That there is sufficient focus by the CQC on the specialised regulatory remit of the HTA and access to expert advisors.

b. That effective governance arrangements are in place to oversee the effective provision of HTA functions, particularly board-level assessment of living donation cases, and accountability for these functions.

c. That there is sufficient strategic and operational expertise to support robust regulation.

d. That the regulatory approach of the HTA, based on advice and guidance, is maintained following the transfer of functions.

e. That the identity of the HTA is maintained to support public and professional confidence and their ability to access advice and guidance easily.

f. That the impact on licensed establishments and stakeholders is minimal and the transfer is seamless.

g. That there is the resource and expertise required to address challenging issues as they arise, and the ability to adapt processes and procedures accordingly.

Conclusion

Although this option keeps the HTA’s functions together and therefore goes some way to ensuring public and professional confidence, the HTA is not able to support this option due to the risks it would incur.
60. If this option was chosen by the Government, the HTA would strive to ensure the successful transition and support future provision of functions in order to maintain public and professional confidence in the safe and ethical use of human tissues and organs. The HTA seeks additional reassurances about the effective and efficient provision of functions and how the risks of transition will be mitigated.
The HTA’s view on option 2

Benefits

61. The HTA notes the view of a small number of stakeholders that there may be benefit in one organisation becoming the single regulator for the European legislation on blood and tissues and cells, meaning that the Human Tissue (Quality and Safety for Human Application) Regulations 2007 would become the responsibility of MHRA. While this might appear logical, questions have already been raised as to the likely change in the regulatory approach, and whether real benefits would be delivered.

62. It is of value to note that there are only 15 organisations currently regulated by the HTA and MHRA to develop regenerative therapies.

63. There are a small number of establishments which are regulated by both the HTA and MHRA for other purposes, including NHS Blood and Transplant (NHSBT), which is licensed by the MHRA for the work it does on blood donation, and the HTA for tissue and organ donation.

64. In June 2011 the HTA and MHRA worked together to draft a position statement on this proposal and concluded that there was not a strong case for such a transfer.

65. There does not appear to be a case for any of the other transfers of functions proposed under option 2.

Concerns

66. The HTA has maintained the position that its functions should remain together under any transfer, and believes the risks associated with fragmenting them are too great. For example, the risk of non-compliance due to confusion or uncertainty about regulatory remit and transition timescales.

67. Fragmentation would lead to an increased number of organisations having responsibility for consent provisions, and could give rise to inconsistencies and differing standards being applied.

68. This option is likely to prove most confusing to stakeholders and the regulated sectors. A benefit of both options 1 and 3 is that functions will be kept together, which gives the public, professionals and patients confidence on where to go for advice and guidance.
69. Although a number of transfer options are discussed in the consultation document, it is unclear whether these have been fully explored with the possible successor bodies, for example Arts Council England. Indeed, some of the bodies do not currently have the remit to take on all the functions identified under option 2. When it has been suggested that there may be a transfer to an organisation outside the DH family, there is a risk that there will be a lack of consistency in the regulation of consent and this should be considered seriously if this option is to be taken forward.

70. Under this option (and option 3) the functions of the HTA that relate to research remain with the other functions, rather than transferring to the newly formed Health Research Authority (HRA). Since the HRA was established in November 2011 the HTA has worked closely with it on a multi-agency programme of work to shape an effective national role for the HRA, within its remit to provide a unified approval process for research projects and to promote consistent, proportionate standards for compliance and inspection.

71. It may seem that the natural home for all regulatory responsibilities for research is the HRA. However, the HTA’s function in relation to research (which is to ensure that premises at which human material for research is removed from the deceased and subsequently stored are licensed and meet the standards required by the HT Act, and that consent is in place) finds its best fit with other activities licensed by the HTA such as post mortem examination and transplantation, rather than with the HRA’s primary aim of protecting and promoting the interests of patients and the public in health research.

72. Option 2 would prove even more complex than option 1 in regard to the jurisdiction of successor bodies in comparison with the HTA. Option 2 would require a great deal of exploratory work to be done with a range of organisations and it is questionable whether this could be done in the expected two year transition period.

73. There is also a concern about regulatory fit. Questions have been raised as to whether a hospital or other licensed establishment would consider themselves to be aligned to a number of the organisations suggested, and therefore be confident in seeking advice and guidance from them.

74. Such a significant change as proposed under option 2 is likely to increase the regulatory burden on establishments, if this is in part defined by the number of organisations they are required to work with.

75. The consultation document makes it clear that there are, as yet, no clear plans as to where the assessment of living organ donations should be transferred. The HTA runs this process effectively and efficiently, and has built strong relationships...
with the transplant community and the 150 Independent Assessors who carry out interviews with donors and recipients on the HTA’s behalf. Without HTA approval, living donations cannot take place; therefore, any disruption to this process could directly affect outcomes for patients.

76. A discussion of the possibility of NHSBT taking on this function is included in the consultation document, but quickly dismissed. The HTA shares the reservations about the possible perception of conflict associated with the independent check that a living organ donor’s consent is freely given being undertaken by the same body responsible for increasing organ donations. This could damage public confidence in this important process.

Conclusion

77. Option 2 appears to create a less streamlined regulatory landscape, which is more complex for establishments and increases bureaucracy. In light of these factors and the increased risk of a decline in standards and reduced public and professional confidence, the HTA does not support option 2.
The HTA’s view on option 3

78. Option 3 is the HTA’s preferred option. The reasons for this are detailed in paragraphs 87 to 95 and this option is supported by many professional and patient groups as detailed below.

79. Option 3 retains all of the benefits of the HTA’s current regulatory regime as set-out in earlier paragraphs of this response, while realising further efficiencies.

Efficiencies

80. It is not yet determined what scale of efficiencies are envisaged under option 3. The HTA has made efficiencies of 27% from 2010/11 to 2012/13 and continues to review how it regulates and operates to provide value for money to licensed establishments and tax payers.

81. Further efficiencies are planned for 2013/14, and by 2015 the HTA will have refined regulatory processes further. This will include having reviewed the regulatory activity required from the Quality and Safety of Organs Intended for Transplantation Regulations in the light of experience over two years, and identified ways of operating that would lead to further efficiency savings. With the support of DH on more significant changes, further efficiency savings would be possible.

82. The HTA estimates that savings of 5 to 10% could be made in 2015, compared to 2013/14 levels (which already include savings of more than 30%, a saving of up to 37% from the 2010/11 baseline, as well as absorbing inflation). If the HTA remains a standalone body, it will continue to review ways of working and make efficiencies. This approach is embedded in the HTA’s culture and there is a good track record.

83. The HTA has not focussed only on financial efficiencies, but has also sought to reduce the burden on regulated sectors. There has been a streamlining of the inspection process over the last two years and a move towards themed inspections. Themed inspections enable the HTA to focus resources on areas of higher risk in order to maintain and increase public confidence in the regulation of human tissue and organs, while also reducing the bureaucracy faced by licensed establishments.

84. Further efficiencies can be made by working even more closely with the CQC, HFEA, HRA and other regulatory bodies and agencies, to build on the HTA’s reputation for collaborative work. The HTA is actively exploring different collaborative models with other regulators and agencies to assess whether there
is scope to provide even greater efficiency savings while still safeguarding the effective delivery of HTA functions.

85. For example, the HTA is working with the HRA to ensure researchers are supported in their work. The HTA has previously taken similar action with the National Research Ethics Service (NRES) through a Memorandum of Understanding, to ensure that advice and guidance on research regulation is clear, coordinated and consistent. This also ensures that mechanisms are in place to put researchers in touch with the most appropriate regulatory expertise.

86. The HTA notes the guidance issued by the Cabinet Office in 2011 on reviews of Non Departmental Public Bodies. The triennial approach outlined in this guidance is welcomed by the HTA.

Benefits

87. The HTA considers that option 3 presents an opportunity to engage with DH with the aim of achieving efficiencies that are currently outside the HTA’s control and are therefore in addition to those that would have happened anyway, notwithstanding the report of the ALB Review.

88. The HTA fulfils a valuable role in regulation that avoids other bodies taking on additional work by identifying areas which are suitable for collaborative working, and this results in efficiencies elsewhere. An example is how the HTA has absorbed the work arising from the Organ Donation Directive at minimal additional cost.

89. The joint working that the HTA is developing with other regulators, while not leading to cost reductions for the HTA, may help others to make efficiencies and pilots indicate that there are less tangible, but nonetheless significant, benefits for those being regulated, such as less disruption to their existing working practices.

90. Over the seven years of the HTA’s existence, it has developed expertise and systems that have helped licensed establishments and led to efficiencies and increased standards in those establishments. The continuation of the HTA preserves this and avoids establishments needing to make costly changes to their processes.

91. There has been detailed discussion of the strengths of the HTA which may be lost in transition and it is of value to revisit these:

---

11 Cabinet Office report
a. A supportive and proportionate regulatory approach, based primarily on advice and guidance to ensure compliance with relevant standards.

b. Specialist staff, with a strong commitment to their area of expertise and pride in the organisation, who are responsive to the requirements of the regulated sectors.

c. A supportive and diverse Board, which provides strategic leadership and shapes the approach of the executive.

d. A collaborative approach based on engagement and communication, as well as a strong record of joint working to reduce regulatory burden and costs.

e. A clear and consistent focus on the primacy of consent.

f. The ability and willingness to establish and maintain relationships with other government departments and organisations to ensure the safe and ethical storage and use of human tissue and organs, with proper consent.

g. A continued aim of increasing public and professional confidence in the storage and use of tissue and organs by using the media and other communication channels to raise awareness of regulation in this often highly sensitive area.

h. A strong track record of identifying and realising efficiencies.

i. Developing a culture of confidence and trust in human tissue regulation amongst licensed establishments and other stakeholders.

92. Option 3 ensures these strengths are not lost, and can be built on. Any transition would be likely to lead to these diminishing and possibly disappearing, which would mark a backward step in the regulation of human tissue and organs.

93. The HTA continues to strive to increase the level of collaborative working it is engaged in with other regulatory bodies to reduce the burden on licensed establishments and the tax payer. Option 3 allows this to be delivered and refined, without the demands of a transition detracting from this.

94. This collaborative approach is already delivering tangible benefits in the form of information sharing and joint inspections, and more are planned for the next year.

95. The HTA’s determination to deliver value for money, both to licensed establishments and the tax payer, is outlined at paragraphs 80 to 86 above, and this goal continues to be a key part of the HTA’s objectives.

Concerns

96. It is noted that this option does not contribute to the stated aim of reducing the number of health ALBs. However, it would reduce the cost to licensed establishments and the taxpayer, as well as ensuring the regulation of tissue and organs remains transparent. The HTA believes that if it is possible to:
a. maintain standards; and
b. increase public, patient and professional confidence; and
c. deliver further efficiencies,

without incurring the risks inherent to options 1 and 2. This must be given serious consideration.

97. The HTA is of the view that, if the efficiencies required by the Government under option 3 are so great that the organisation would in reality be unable to function effectively, then this option is not a realistic one. This is due to the fact that regulation would be weakened and there would be greater risk that the public’s confidence in the safe storage and use of human tissue and organs with proper consent could not be maintained.

98. The HTA seeks further information from DH about the extent of the efficiencies required under this option.

Conclusion

99. The HTA supports option 3 as it ensures the safe storage and use of human tissue and organs with proper consent, while still delivering efficiencies for licensed establishments and the taxpayer.
Views of stakeholders

100. As identified above, the HTA has a wide range of stakeholders including licence holders, professional bodies and patient groups. It is acknowledged that there will be a range of views and opinions amongst stakeholders, which are likely to be detailed in the responses to the consultation. There has, however, been a significant number of representations made to the HTA directly expressing strongly held views on the options presented.

101. All the stakeholders who have contacted the HTA have been in favour of option 3, for a wide range of reasons. At the root of these has been the fact that the HTA is regarded as an efficient and effective regulator, which places consent and public and professional confidence at the centre of everything it does.

102. The HTA has received feedback from stakeholders that they are concerned at the prospect of being regulated by the CQC, with the following comments providing examples of this:

“We do not have the same confidence in CQC. It has not yet mastered its current remit. It does not listen and act on maternity issues in the same way that we have found you do.”
National Childbirth Trust

“The HTA has greatly increased public confidence in the proper collection, storage and use of human organs and tissue for public benefit. Independent Cancer Patients Voice members do not think it appropriate to de-rail the regulatory process by re-organisation or [relocating] the functions of the HTA. We are concerned that the high level of acceptance to researchers will be undermined and public confidence eroded if the process was managed by the CQC in which public confidence is very low.”
Independent Cancer Patients Voice

“I agree that being part of the CQC may create a very bureaucratic organisation, which could create conditions, which could allow another Alder Hey situation to occur, problems which other parts of the world continue to experience, with the usual attendant adverse media storm.
“I fully support the independence of the HTA if only because of the legal ramifications of the [Human Tissue] Act, some organisation has to enforce the laws embodied within the Act and I think this is best dealt with in the tolerant way, that it has been, by the present and independent HTA. Problems are more easily dealt with and accounted for by an independent HTA.”
Public Group Stakeholder
103. It is noted that in the consultation document DH commits to working with stakeholders during any transition. However, it will be important to consider how concerns about the CQC will be addressed particularly.

104. The HTA has been encouraged by the number of stakeholders who have been in contact to state their support for option 3 and for the HTA to remain an independent body, while realising further efficiencies. Comments of particular note include:

“The changes being proposed in the consultation document seem to create costly and cumbersome processes, and inevitably bring with them the risk of misinterpretation by transferring all or some of the HTA’s responsibilities to other bodies.”

British Neuroscience Association

“The potential adverse effects, on the UK’s ability to contribute to (and generate income from) vital medical research, of a further failure of public confidence in regulation of human tissue storage and use is unquantifiable. The visibility and unambiguous purpose of the HTA since its inception have been invaluable in ensuring such confidence.”

Confederation of Cancer Biobanks

“The abolition of the HFEA and HTA could hinder progress and investment in research and development in life sciences in the UK and could adversely affect the country’s reputation as global leader in the emerging bio-science and medical fields these bodies regulate.

“In GE Healthcare’s experience, as a major commercial organisation that operates in areas regulated by both the HTA and HFEA, we have found both these regulators to be efficient, knowledgeable, transparent, and above all extremely helpful to us maintaining compliant operations.”

GE Healthcare

“Over the years I have witnessed and experienced the ethos and culture of the HTA. It strives for excellence, is dynamic and responsive to human need, in ways that few institutions can emulate.”

HTA Independent Assessor

---

12 British Neuroscience Association response
Views of staff

105. The staff of the HTA have met to discuss the options presented in the consultation document on more than one occasion. The primary focus of staff has been that the HTA’s functions continue to be delivered efficiently, effectively and economically and that the high quality regulatory approach they have been part of creating is not lost.

106. HTA staff also recognise the risks of transition and the delivery of functions by either the CQC or other organisations, and that this may compromise the safe storage and use of human tissue and organs and undermine public confidence.

107. Option 3 gained the support of the HTA’s staff, and the focus was very much on the service which would be provided in the future by a successor organisation or organisations. The staff of the HTA do not believe they are the only people who can deliver a high quality service. However, they do wish to be assured that any transfer of functions would not lead to the loss of confidence and trust that has been so hard won.

108. The staff of the HTA are very proud of the work they do, how they do it, and the organisation they work for. Even if the Government’s aim was to transfer every member of staff to the successor organisation, it is unlikely such a transfer would be realised and a certain amount of rebuilding would be required.

109. Maintaining a core of motivated, expert staff during any transition period may also prove challenging and, if either option 1 or 2 is chosen, it is recommended that DH makes provision for higher levels of staff turnover.
Conclusion

110. The HTA believes that of the three options presented, option 3 is the one which offers the greatest assurance to members of the public that their tissue and organs will be stored and used safely, ethically and only when there is proper consent in place. This is the reason why the HTA was established and the harm it was intended to prevent was that such activities took place without the consent of the person or their family. The risks associated with options 1 and 2, as outlined above, mean that sight of this could be lost and the confidence of the public would fall away.

111. There are many other benefits associated with option 3 and these are rehearsed throughout this document, alongside the risks associated with options 1 and 2. When balancing these risks and benefits it becomes clear that option 3 can realistically maintain public and professional confidence, while also ensuring that standards in the regulated sectors continue to rise, alongside realising greater efficiencies. The HTA believes therefore that option 3 is the best option for the public, professionals and licensed establishments. The HTA supports option 3.