Triennial Review of the Human Tissue Authority

Previous Reviews of the HTA

The Department of Health published a report reviewing all the arm’s length bodies review in 2010. This report recommended that both the HTA and the Human Fertilisation and Embryology Authority (HFEA) should have their functions transferred to the Care Quality Commission and a new research regulator. However, the majority of responses to a consultation on this proposal in 2012 were opposed to such a move and this led to a further review by Justin McCracken in early 2013. This review considered a range of options, including merging the HTA and HFEA, but concluded that they should remain as separate Non-Departmental Public Bodies. This was agreed by the Department of Health and the Cabinet Office. The review also made a number of recommendations about the scope for efficiencies and improvements in the way that the HTA and HFEA undertook their functions.

This Triennial Review will take full account of these previous reviews and will not seek to reopen recent decisions. The Triennial Review will also include an assessment of the implementation of the recommendations in Mr. McCracken’s review.

About the HTA

The HTA is an Executive Non-Departmental Public Body of the Department of Health and was established under the Human Tissue Act 2004 (HT Act), which covers England, Wales and Northern Ireland, to regulate activities relating to the removal, storage, use and disposal of human tissue. There is separate legislation in Scotland - the Human Tissue (Scotland) Act 2006. While provisions of the Human Tissue (Scotland) Act 2006 are based on authorisation rather than consent, these Acts are essentially both expressions of the same principle.

In addition to the Authority’s responsibilities for licensing under the HT Act, the HTA is the Competent Authority in the UK under two sets of European legislation, and is thereby responsible for ensuring the safety of human tissue and cells used for human application and organs used for transplantation.

In relation to organ donation, the HTA also regulates the donation of solid organs from living people to ensure that valid consent has been given and that no reward is sought or offered. This is done through an independent assessment process carried out by trained professionals at clinical centres throughout the UK. The Authority fulfils a similar role for living donation of bone marrow and peripheral blood stem cells from children without competence and adults who lack the capacity to consent.

The HTA oversees the consent requirements of the HT Act for deceased organ donation. From December 2015, the HTA will assume this duty for the Human Transplantation (Wales) Act 2013, which will introduce an opt-out system of organ donation in Wales.

The overall strategic goal of the HTA is to maintain and further enhance public confidence in these activities by ensuring that they are undertaken safely and ethically, and with proper consent.

The HTA licenses 8,523 premises that store and use human tissue and organs for purposes such as research, human application, post-mortem examination, teaching, public exhibitions and transplantation. It publishes standards that licensed establishments must meet on consent; governance and quality systems; premises, facilities and equipment; and disposal. It also inspects and
audits organisations to ensure that they maintain good standards of practice and follow appropriate procedures.

The HTA has a number of statutory functions. It may restrict or prevent the activities of an organisation which does not meet its standards. It also has a duty to inform members of the public, professionals and the Secretary of State for Health about issues within its remit. It does this by issuing Codes of Practice, which outline the standards and provide clear guidance for licenced establishments. In addition, information is provided on the HTA website, and in response to enquiries, to help members of the public make informed decisions.

Further details about the HTA are available at: https://www.hta.gov.uk/about-us

Confidentiality

Information provided in response to this consultation, including personal information, may be published or disclosed in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000 (FoIA) and the Data Protection Act 1998 (DPA).

If you want the information that you provide to be treated as confidential, please be aware that under the FoIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this, it would be helpful if you could explain why you regard the information you are providing as confidential. If we receive a request for disclosure of the information, we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

The Department will process your personal data in accordance with the DPA and in the majority of circumstances this will mean that your personal data will not be disclosed to third parties.

Organisation: British Medical Association

Would you categorise your response as from: Professional Association

Please indicate what interactions/relationship you have with the HTA:

A number of BMA members are regulated by the HTA.

The BMA is represented on the HTA stakeholder group and on the HTA Histopathology Working Group.

The Call for Evidence Questions

For all options, you do not have to answer all of the questions – please feel free to answer as many or as few as you like. Your evidence should consist of objective, factual information about the impact or effect of the HTA’s approach to health and social care. Where possible, please give specific examples.
Where your evidence is relevant to other review reports, we will pass your evidence over to the relevant report teams.

Only information directly relevant to the areas of investigation will be considered. Information where relevance is not demonstrable will not be taken as evidence. The review team is unable to respond to individual cases or consider complaints other than as part of the evidence for the review where it falls within the terms of reference.

Complaints should be directed to the HTA at enquiries@hta.gov.uk or the complaints officer telephone: 020 7269 1900.

Patient identifiable information should not submitted.

The review team is particularly interested in evidence in support of responses to the questions set out below but does not seek to restrict responses provided they are relevant to the key lines of enquiry. If you wish to send us supporting documentation please email as an attachment to TR-HTA@dh.gsi.gov.uk.

**Form and Function**

This section seeks to assess whether there is a continuing need for the functions of the HTA and, if this need exists, to assess whether the current form is the most effective and efficient way of delivering these functions.

The questions that follow are intended to frame the Triennial Review Call for Evidence. The questions presume an understanding of the functions, form and purpose of the HTA, some of which are listed below for information:

The HTA’s principal functions are to:

- Inform the public, professionals and the Secretary of State for Health about issues within their remit by providing guidance for professionals, including codes of practice and information to the public to help them make informed decisions
- License organisations that store and use tissue for purposes such as research, human application, post-mortem examination, teaching, and public exhibitions.
- Inspect organisations to check that they maintain high standards and follow appropriate procedures.
- Ensure the safety and quality of human tissue, organs and cells used for patient treatment, in compliance with the European Union Tissue and Cells Directive (EUTCD).
- To regulate living donation, in compliance with Scottish legislation, on behalf of the Scottish Government.
- Oversee the consent requirements of the Human Tissue Act for deceased organ donation.

**Question 1**

*Is there a continuing need for the functions undertaken by the HTA?*

- **Yes**
- **No**
- **Don’t know**
- Are there any functions you believe could be dropped or undertaken by another organisation?
- Are there any functions that you think are needed but are not currently being undertaken?
- Are there gaps or overlaps in the HTA’s role which should be addressed?
- Could the function be merged with those of another public body?

Please briefly explain your answer:

The HTA undertakes an important role in helping to maintain public confidence in a range of sensitive areas of practice. It also provides support and advice for our members working within the sector.
We continue to question the need to license the storage of tissue from living individuals for use by individual researchers and believe that this is unnecessary and could have a detrimental impact on research. Tissue banks, which supply tissue to others, should continue to be regulated. There is an argument that the process for approving public display is unnecessarily onerous and that the Scottish approach should be considered whereby established collections are exempt from licensing and only temporary displays require approval. We would welcome further consideration of this option.

Question 2

How well do you think that the HTA fulfils each of its functions at present?

- Very well
- Well
- Average
- Poorly
- Very poorly
- Don’t know

Please provide reasons for your answer:

It is not possible to seek views from all of our members who are regulated by the HTA but we are not aware of any concerns amongst our membership and our overall view is that the HTA is fulfilling its functions well. When we had concerns a few years ago, the HTA responded well, taking practical steps to resolve the problems.

Question 3

A) Recent reviews have considered and rejected a possible merger of the HTA with both the Human Fertilisation and Embryology Authority and a combination of the Care Quality Commission and the Health Research Authority. Outside of the options outlined above that have previously been considered, which of the following organisational forms would you support?

- Remain as a Non-Departmental Public Body
- Merge with another public body
Undertake the functions within the Department of Health
Become a mutual/voluntary sector organisation
Don’t know

Please provide reasons for your answer:

It is important the HTA is, and is seen to be, independent from Government. The current system appears to be working well and we can see no reason to change it.

B) Are there parts of the HTA’s work that could be better done elsewhere in the public, private or not for profit sectors?

Yes
No
Don’t know

Please provide reasons for your answer

See above

Performance and Efficiency

This section seeks your views on how well the HTA performs in delivering its services.

Question 4

How would you rate the performance of the HTA?

Very good
Good
Average
Poor
Very poor
Don’t know

In what areas, if any, could the HTA improve its performance?
What key indicators should be used to effectively measure the HTA’s performance?

Please provide specific examples of areas that would benefit from improvement:
The HTA covers a diverse range of activities and therefore has a very large number of stakeholders. It manages its communications and liaison well and, in particular, worked well with the transplantation sector to ensure the regulatory system put in place was proportionate and not excessively onerous.

Question 5
Do you think that the functions of the HTA, regulatory or otherwise, (as outlined in Annex B) impose burdens that are:

- Proportionate
- Disproportionate
- Don’t know

- Are risks managed appropriately?
- How does the HTA’s approach compare to that of other regulators?
- Are they proportionate in their focus and application?
- Do they go too far or not far enough?

Please provide reasons for your answer

No answer

Question 6
How effectively does the HTA operate within and support the rest of the health and care system?

- Very well
- Well
- Average
- Poorly
- Very poorly
- Don’t know

Please provide reasons for your answer:

Whilst guidance is provided and directed to those who work within the remit of the HTA, it would be helpful if there was some way to develop a broader understanding amongst NHS staff about what is covered by the legislation and what is not. For example, we are aware of some staff being reluctant to agree to the storage of tissue for less than 48 hours from living individuals for their own use, because of concerns that this may breach the law or require a licence.
Question 7

How well does the HTA communicate and engage with stakeholders?

- Very well
- Well
- Average
- Poorly
- Very poorly
- Don’t know

- Are relationships with stakeholders (including regulators and professional bodies and other organisations in the health and care system) effective?
- How effective is engagement with the public and wider stakeholders?
- How well does the HTA influence nationally and internationally?

Please provide reasons for your answer:

The HTA is proactive about distributing information and seeking input into its work, including through its regular email update. In the past we had concerns about the level of specialist input in the pathology sector but this has now been addressed through the establishment of the Histopathology Working Group on which we are represented.

Question 8

Could the HTA do more to support innovation and new approaches in the area of human tissue and organs?

- Yes
- No
- Don’t know

Please provide reasons for your answer:

No answer

Question 9

Are there any measures you believe the HTA could take to deliver further efficiencies (whether reduced costs or improved use of resources)?

- Yes
- No
The HTA has made significant savings over the last few years. It is important, however, that it continues to have the resources it needs to effectively carry out the role it has been given.

Question 10

How effectively does the HTA maintain public confidence that human tissue is regulated appropriately?

- Very well
- Well
- Average
- Poorly
- Very poorly
- Don't know

Please provide reasons for your answer

See our response to Question 2

Resilience

This section seeks your views on whether the HTA is well placed to respond and adapt to current and future changes.

Question 11

Is the HTA sufficiently forward-looking and responsive to new challenges and opportunities?

- Yes
- No
- Don't know

- Does the HTA have the capability and capacity to carry out its functions and respond to future challenges?
- Does the HTA have a robust and effective strategy for responding to the changing demands and technologies?
- Do you believe that the HTA is well-placed to respond to future challenges?
Governance

This section explores the governance of the HTA and whether there are good governance and effective accountability structures in place.

Question 12

Does the HTA follow best practices in its governance arrangements?

- Yes
- No
- Don't know

- How effective are the Board and Senior Management Team?
- Are the skills and levels of experience of the Board appropriate?
- Is the HTA open and transparent where appropriate?
- Are effective financial management processes in place?
- Does the HTA recruit the best people through open and fair processes?

Please provide reasons for your answer.

No answer

Other Comments

Are there any other issues or evidence you think the review team should take into account? Please submit your answer here:

None

Thank you for taking the time to respond to this Call for Evidence.

Please return completed forms by 31 August 2015:

Email to: TR-HTA@dh.gsi.gov.uk

Or write to: