Human Tissue Authority written evidence submitted to the House of Commons Science and Technology Committee inquiry into blood, tissue and organ screening

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Introduction

1. The Human Tissue Authority (HTA) welcomes the opportunity to submit written evidence to the House of Commons Science and Technology Committee inquiry into blood, tissue and organ screening.

2. The HTA submission will focus on our role in ensuring the quality and safety of tissue and cells used for the treatment of patients, and organs used for transplantation. The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for the regulation of blood and blood products.

About the HTA

3. The HTA regulates more than 800 establishments that remove, store and use human tissue and organs for research, transplantation, medical treatment, post-mortem examination, education and training, and display in public. We also give approval for organ and bone marrow donations from living people.

4. The interests of the public and those we regulate are central to our work. We build on the confidence people have in our regulation by ensuring that human tissue and organs are used safely and ethically, and with proper consent.

5. As a statutory body, the core of what the HTA does is laid down in UK and EU legislation:

    - the Human Tissue Act 2004 and associated regulations;

- the EU Tissue and Cells Directives (EUTCD) via the Human Tissue (Quality and Safety for Human Application) Regulations 2007;
- the EU Organ Donation Directive (EUODD) via the Quality and Safety of Organs Intended for Transplantation Regulations 2012.

6. We help people to understand these requirements by providing codes of practice and advice, guidance and support. We also make sure that these laws are followed by setting – and inspecting against – clear and reasonable standards in which the public and professionals can have confidence. To support this process, every licensed establishment nominates a person (Designated Individual (DI) or named contact) who supervises the activities for which they are licensed.

HTA's role in ensuring the quality and safety of cells, tissue and organs

7. The HTA is a vital part of the 'value chain' that ensures cells, tissue and organs are of high quality and are used safely and appropriately. As part of this chain, the HTA works closely with and offers expert advice to the DH Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) and the Joint UK Blood Transfusion Services Professional Advisory Committee (JPAC). Where appropriate, we make sure that their recommendations are embedded in our processes.

Ensuring the quality and safety of human tissue and cells used for the treatment of patients

8. The EUTCD established a harmonised approach to the regulation of tissues and cells across Europe. The HTA acts as one of the EU Competent Authorities in the UK and has responsibility for regulating tissues and cells for the treatment of patients. The Human Fertilisation and Embryology Authority (HFEA) is the other Competent Authority in the UK and is responsible for the regulation of gametes and embryos for human application.

9. The EUTCD set a benchmark for the standards that must be met when carrying out any activity involving tissues and cells for patient treatment. The Directives also require that systems are put in place to ensure that all tissues and cells used for this purpose are traceable from donor to recipient.

10. The EUTCD were fully implemented into UK law in 2007, via the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations).

11. Licensed establishments are required to meet the standards in the HTA's 'Guide to Quality and Safety Assurance of Human Tissues and Cells for Patient Treatment' (Q&S standards).

Selection criteria for deceased donors of tissues and/or cells

12. The Q&S standards include specific guidance on exclusions. For example, deceased donors must be excluded from donation if there is a risk of transmission of diseases caused by prions. This risk applies to:

    - people diagnosed with CJD, or vCJD, or having a family history of non-iatrogenic CJD;
    - people with a history of rapid progressive dementia or degenerative neurological disease, including those of unknown origin;
    - recipients of hormones derived from the human pituitary gland (such as growth hormones) and recipients of grafts of cornea, sclera and dura mater, and persons that have undergone undocumented neurosurgery (where dura mater may have been used).

13. For vCJD, further precautionary measures may be considered. We advise any establishments that further measures should be based on an analysis of the risks related to the application of the specific tissue / cells, including:

    - exclusion of donors who have received allogeneic human tissue or organs transplanted since 1 January 1980
    - exclusion of donors who have received a transfusion of blood components (including plasma exchange), blood products or their derivatives since 1 January 1980
    - exclusion of donors who have received immunoglobulin therapy since 1 January 1980.

14. We also advise establishments that**:**
    - the medical records of any patients with bleeding disorders are checked for confirmation of their 'at risk' status; and
    - patients designated 'at risk' of vCJD for public health purposes should not donate blood, organs or tissues.

Selection criteria for living donors of tissues and/or cells

15. The Q&S standards also state that living donors must be selected following an assessment (questionnaire and interview) of their health and medical history. This must include relevant factors that may assist in identifying and screening

out those whose donation could present a health risk to others, such as the possibility of transmitting diseases.

16. Selection criteria for living donors must be established and documented by the tissue establishment (and the transplanting clinician in the case of direct distribution to the recipient), based on the specific tissue or cells to be donated, together with the donor's physical status and medical and behavioural history and the results of clinical investigations and laboratory tests establishing the donor's state of health.

17. There is a broader set of acceptance criteria for organ donation, as unlike using tissues and cells for patient treatment, organ transplantation is the only lifesaving treatment for end-stage organ failure.

The HTA inspection process

18. As part of our inspection process, we actively ensure that standards are being met and that standards operating procedures (SOPs) for donor selection exist and are being followed. We also check the donor selection criteria that establishments have for UK donors and imported tissue.

Ensuring the quality and safety of organs intended for transplantation

19. The EUODD aims to bring the quality and safety of organs used in transplantation across all EU countries up to the same high standards. The HTA was selected to be the Competent Authority for the UK, and from August 2012 has been responsible for ensuring the quality and safety standards of organ donation and transplantation are met.

20. In 2012/13, the HTA developed the first formal regulatory framework for the donation and transplant of organs, assisting with the implementation of the EU Directive into UK legislation, 'the Quality and Safety of Organs Intended for Transplantation Regulations 2012'.

21. The HTA licenses 36 establishments involved in various aspects of organ donation and transplantation.

22. We audit establishments against assessment criteria and gather evidence through a combination of visual inspection during a walk-through of the "organ pathway", a review of quality documentation, including patient notes and standard operating procedures, and interviews with staff involved in each aspect of the activity. Audits are carried out by a core team of HTA inspectors who

meet regularly to review, discuss and compare audit findings. This ensures a proportionate, targeted and consistent approach.

Reporting and investigating serious adverse events and reactions

23. Those establishments licensed by the HTA under the EUODD and EUTCD are required to report serious adverse events (SAE) and serious adverse reactions (SAR) within 24 hours.

24. The HTA has a system for reporting and investigating serious adverse events and reactions (SAEARs) which may pose a risk to the quality and safety of organs for transplantation, and tissues and cells used in patient treatment . Examples of SAEARs could be inappropriate tissues or cells being distributed which would have implications for patients or donors, or an adverse reaction in a donor or recipient which could be linked to the quality of safety of an organ or tissue.

25. As with any other potential transmission, the event would be investigated and other relevant organisations communicated with. If there is a risk that the donor might also have donated blood we would communicate with MHRA and NHS Blood and Transplant (NHSBT). vCJD is a reportable communicable disease and as such must be reported to Public Health England.

26. In certain cases, and where justified on the basis of risk to the quality and safety, the HTA may initiate an audit or a non-routine inspection of an establishment following a report of a SAEAR.

27. The HTA aims to share learning through the reporting and investigation of these incidents, to reduce the likelihood of incidents occurring again, improve standards and maintain public confidence in the storage and use of human tissue, cells and organs.

28. ***Inspections and investigating shortfalls in standards***

29. We schedule routine inspections according to the risk to the public and the likelihood of non-compliance. We focus on those that carry the highest inherent risk, owing to the nature of the activity and the impact on patients and families when things go wrong. We inspect all establishments licensed under the EUTCD at least once every two years but we may inspect more frequently if we believe it is necessary.

30. We grade shortfalls against our standards as critical, major or minor and the level of our intervention depends on the severity of the shortfalls:

    - critical shortfalls pose a significant risk to human safety and/or dignity or indicate a breach of legislation, or may be due to a number of 'major' shortfalls that, taken together, indicate a systemic failure;
    - major shortfalls pose a risk to human safety and/ or dignity, indicate a failure to carry out satisfactory procedures, breach our code of practice or other regulatory guidance, or have the potential to become critical unless addressed;
    - minor shortfalls – the vast majority of those we find on inspection – indicate departures from expected standards that need to be addressed.

31. Where we find critical shortfalls, we take immediate action and are directive about what needs to be done. Where we find major or minor shortfalls, we work with establishments to achieve full compliance through the development and management of corrective and preventive action (CAPA) plans.

32. As a specialist regulator, we are also able to react quickly when we receive information that causes concern. This may be, for example, from a whistleblower, a serious incident report, or where changes in circumstances justify a review of licensed premises.

Supporting effective research

33. Human tissue can be studied to improve our understanding of diseases such as vCJD. The HTA supports this process by ensuring that human tissue is removed and stored in an appropriate and well managed way.

34. We license organisations for removal and storage for research in England, Wales and Northern Ireland. Our licensing role in research is limited to licensing premises - such as tissue and brain banks - storing tissue from the living and deceased. We also license establishments - including post mortem establishments - where tissue is removed from the deceased for research.

35. We do not license the 'use' of tissue for research or approve individual research projects or clinical trials. Neither do we have a role in the ethical approval of research. We do, however, work in partnership with other organisations to ensure that the regulatory environment is easy for researchers to navigate and understand.

36. The HTA is currently advising the Department of Health on its review of human tissue legislation, which is focussed on how changes to the legislation could

reduce the ‘legal’ burden of regulation. The HTA is committed to maintaining our role in overseeing a world-class regulatory environment, where high quality and ethical research can flourish.

Checking the knowledge and understanding of living donors

37. In addition to our role under the EUTCD and EUODD, we are also responsible for considering all cases of living donation in the UK, predominantly kidney donation, but also liver lobes. In order to approve a living organ donation, we must be satisfied that the donor is giving their consent freely. To give valid consent, the donor must have the mental capacity to give consent and they must demonstrate an understanding of the nature of the medical procedure and the risks involved – including the risk of the transmission of disease.

Collaborative working and support for the sector

38. The HTA works with a number of other organisations and individuals with responsibility in this area, including the SaBTO, JPAC, Public Health England, NHSBT, MHRA and other regulators and government agencies as necessary. Our aim is to strengthen regulation by working together so that standards are applied consistently, without unnecessary duplication or burden, whilst maintaining the quality and safety of products and/or procedures. For example, we provide advice and support to the MRC UK Brain Bank Networks Steering Committee, which includes representation from researchers working on vCJD.

39. We also work with other EU competent authorities. For example, in February 2013, we hosted the final meeting of the recently completed three-year Substances of Human Origin: Vigilance and Surveillance (SoHO V&S) Project co-funded by the European Commission Public Health Programme. The project’s focus was to establish effective EU-wide system for tracing tissues and cells used in transplantation and assisted reproduction, and to reach consensus on how information exchange is used to manage incidents involving cross-border distribution of tissues.

Conclusions and recommendations

40. Cells, tissue and organs are needed every day to save and transform lives. The HTA and others in the regulatory chain do all we can to ensure the safe supply of organs, tissues and cells. We work with, and take advice from scientific organisations like SaBTO and JPAC and make sure that their recommendations are embedded in our processes.

41. Based on current evidence we believe that the current regulatory system is proportionate to the risk presented. In our experience, a robust combination of setting standards, inspecting against them, following up on non-compliance, collaborating with others and offering guidance and sharing learning minimises the risk to the public without adding unnecessary burdens. Feedback from a recent Ipsos MORI survey showed that regulation by the HTA is seen as much less of a burden than health regulation in general.

42. There are also a number of safeguards in place to ensure that we react appropriately to cases of vCJD and developments in this area, and our processes and standards are flexible enough to allow this.

43. We welcome the recent advances in the development of a blood test which has the potential to improve the diagnosis of suspected human prion diseases.

44. However we believe that it is important to understand the risk of any measure that could potentially lead to a reduction in the amount of blood and tissue and number of organs in the supply chain.

45. To help to assess this, we would suggest that it is important to have a clear understanding of how consent should be sought for life enhancing tissue and cell treatments, or for lifesaving organ transplants. This would include explaining what information should be provided and how the patient can be supported to give informed consent with a clear understanding of any risks involved.

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