Human Tissue Authority
151 Buckingham Palace Road
London
SW1W 9SZ

Tel 020 7269 1900
Web www.hta.gov.uk
Email enquiries@hta.gov.uk
Date 10 September 2020

By email to [redacted]

Dear [redacted]

Freedom of Information request

Thank you for your request for information under the Freedom of Information Act (FOIA), which was received by the Human Tissue Authority (HTA) on 13 August 2020. Your email outlined the following request:

'records of the HTA's interactions with Peter Butler and the Royal Free Hospital between 2006-2010, relating to face transplant'.

Response

Following on from your request, please note that information related to the regulation of composite allografts, which was sent to you on 17 July 2020, is already in the public domain and can be found here:

https://webarchive.nationalarchives.gov.uk/20141105133253/http://www.hta.gov.uk/db/_documents/Complete_Agenda_minus_confid_updated_201103090930.pdf

A paper entitled 'HTA Policy on Composite Tissue' in the link above makes reference to the HTA's interactions with Professor Peter Butler.

In response to your request, we have undertaken a search of the HTA's electronic records, which identified the following documents that are attached:

- Brief for December ERPBB- reference to meeting with Professor Peter Butler (redacted);
- HTA's interaction with Professor Peter Butler's Team (redacted);
- HTA letter regarding facial transplants;

- Notes of HTA's discussion with Professor Peter Butler July 2009.

Please note that we have been unable to search any paper records at this time due to the restrictions in being able to access our Offices during this time.

Further information

If you are unhappy with the way the HTA has handled your request for information in this case, you may in the first instance ask us for an internal review by writing to us at the above postal or email address.

If you remain dissatisfied with the handling of your request or complaint, you have the right to appeal directly to the Information Commissioner for a decision, at the address below. There is no charge for making an appeal.

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire SK9 5AF

Telephone: 08456 30 60 60 or 01625 54 57 45
Website: www.ico.gov.uk

Yours sincerely

[redacted]

[redacted]

Composite tissue (reconstructive) transplantation

Update for ERPPB December 2009
Policy for February 2010 ERPPB

Background

In July 2009, following a communication from the Royal Free NHS Foundation Trust, the HTA initiated internal exploratory talks regarding the transplant of faces, limbs, digits and any other body parts (e.g. trachea,) that may not clearly fall within the definition of either an organ or a tissue. An interim decision was given to Professor Peter Butler at the Royal Free NHS Foundation Trust while a policy was researched and written by HTA.

Human Tissue Authority (HTA) interim viewpoint

Following the discussions, the following interim decision was reached by the HTA.

The HTA felt that the following reasons for treating a face transplant as an organ transplant were persuasive:

- the retrieval and management of the facial material pending transplant would follow the same procedures as for any solid organ, including very short procurement times (4-5 hours) following ischemic death
- the facial material had to be transplanted immediately. This rendered it more like an organ as, unlike tissue, it could not be stored for transplantation
- in terms of blood supply and vascularisation, facial material was much closer to solid organs than tissue; this includes the need to perfuse the face following retrieval
- patients receiving face transplants have to have lifelong treatment with immuno-suppressants(similar to kidney transplantation), unlike recipients of any tissue transplants
- France and the US had treated the face as an organ for transplant purposes.

In view of these reasons, and until we have considered in more depth how face transplants should be classified, we concluded that we should advise the Royal Free that they proceed on the basis that their imminent face transplant be carried out on the same basis as if it were a solid organ.

Following this decision the HTA is currently developing a policy regarding the transplant of faces, limbs, digits and any other body parts (e.g. trachea) that may not clearly fall within the definition of either an organ or a tissue.

Plan for policy

Description

Why we are writing this policy

- UK ready to go
- update on where facial and composite tissue transplantation is in the world today

Background

No clear way forward in regulation - examine

Uncertainty regarding classification of this material as tissue or organ

Definitions of tissue and organ

What material are we currently referring to - face, limbs and digits, larynx, oesophagus and uterus.

European CA members views of this

Purpose

Clarity regarding the definition of organs and tissue and a building block for future policies. Therefore clarity as to which legislation composite (reconstructive) transplantation is regulated, Human Tissue Act 2004 or Human Tissue Quality and Safety Regulations 2007.

European Competent Authority (CA) members viewpoints from web forum October 2009

As part of the policy development, it was decided to seek the opinions of other European member states. This prompted a message from the HTA on the EUSTITE – EU forum for tissues and cells issues a web discussion has taken place with CA members regarding the definition.

Members discussed the following themes.

Timeframes (ischaemic period)/Risk benefits

- If this is taken from a donor and stored for a minimum period until the recipient is prepared for surgery then I think it is outside the scope of the T&C legislation. This is hardly a common process with multiple facial transplants being stored in the one area
- The entire process, risk/benefit and timeframes make it exactly like organ donation and transplant and nothing like tissues/cells. It just would not be appropriate at all to apply the directives.

Vascularisation

- the French define it as an organ on the basis that it is vascularised
- looking at the definitions of the EUTCD 2004/23 I agree that we should consider this as an organ, not as tissue. It contains of different kind of tissues, it is vascularised and different physiological functions
- vascularisation is a good argument difficult to neglect.

Clarification of "official transplantation" versus "facial reconstruction"

- should the term "facial transplant" be clarified before a definite decision is made. Very few full facial transplants are performed. Do we need to consider that most facial reconstructive surgery, which is relatively common for cancer, accidents or congenital deformity and usually involves some transplantation of various tissue and cells, bone, skin, nerves, blood vessels etc could fall under the facial transplant tag. Is that what we are implying? From a regulatory perspective, a legal opinion might say that facial reconstructive surgery should also fall out of the EUTCD if "facial transplant" is designated an "organ"
- facial transplants are relatively rare, in some cases utilize ATMPs as part of the "transplant", and thus will be regulated to some extent going forward. The transplant usually involves a heterogeneous group of tissues and cells

but I would also say the same applies to other solid organs – there are certainly a range of cells including stem cells (organ resident stem cells) and vessels involved in many solid organ transplants. Recently there have been a number of hand transplants, which contain skin, bone, and tendons but these should not be regulated as part of the T&C Directives but included in the organ directives

- it is true that many tissues are used in reconstructive maxillofacial surgery. However, I would see that as being quiet different from face transplant. In maxillofacial surgery, it is usually one tissue that is transplanted at a time - bone, cartilage, skin, vessel etc. The only other situation I am aware of where multiple tissues connected by vasculature etc. are transplanted together is in the case of 'muscle flap' transplants which, as far as I am aware, are always autologous and transplanted within the same surgical procedure (if there was an autologous example, I would argue that it, like a face transplant, should be considered an organ)
- the definition, somewhere, of a face transplant that specifies that it has multiple tissues that are still connected by the donor's vascular and nerve system.

The majority of members who contributed to the discussion support the categorisation of facial transplantation as an organ transplant rather than a tissue transplant.

Meeting with Professor Butler

Meeting on Wednesday 9 December following a request from [redacted] to engage with Professor Butler on this policy. The meeting was successful.
I gained

- an full understanding of what is involved in facial transplantation during the retrieval and transplant operations
- further information on the current position world wide on composite (reconstructive) tissue transplantation – this information was difficult to research as most is as yet to be published
- an insight into his understanding and acceptance of the need for regulation
- an awareness of the steps that have been taken do far by the team at the Royal free regarding facial transplantation from the donor family and recipients perspective

The way forward

Discuss further with European competent authorities where facial transplantation has taken place regarding their view point as come confusion re their stance during October 2009 meeting.

Complete policy for February 2010 ERPPB meeting.

From: [redacted]
To:
Subject: FW: UK Face Transplant Team Enquiry
Date: 25 July 2007 18:28:02

Dear [redacted]

Many thanks for your enquiry to the Human Tissue Authority. Please accept my apologies for the delay in getting back to you.

The Human Tissue Act 2004 came into force on 1 September 2006 in England, Wales and Northern Ireland. The HT Act regulates the donation by living people of solid organs, bone marrow and stem cells. The HT Act requires the HTA to approve transplants from living donors whether or not they are related to the recipient.

The consent provisions of the HT Act cover deceased donation of solid organs though the approval of deceased donation does not fall within the remit of the HTA.

1. The HTA became responsible for approval of living organ donation from 1st September - therefore our data only extends back to this date. As the HTA provides approval for donation we only have figures for the number of cases we approved, not whether the transplant went ahead or not. Since September 1st 2006 - 1st July 2007 589 solid organ donations have been approved and 80 bone marrow donations have been approved by the HTA.

2. The HTA does not keep records these records. The HTA is not responsible for promoting organ donation - this responsibility lies with UKT.

3. As above.

4. As above.

As face transplants relate to deceased donation, this kind of case would not be referred to the HTA for approval.

I hope this helps.

Best wishes,

Human Tissue Authority
Finlaison House
15-17 Furnival Street
London EC4A 1AB
Tel 020 7211 3400
Email enquiries@hta.gov.uk
Web www hta.gov.uk

-----Original Message-----
From: [redacted]
Sent: 18 July 2007 13:37
To: HTA Enquiries
Subject: Re: UK Face Transplant Team Enquiry

Dear Sir/Madam,

I am Peter Butler's [redacted] working on the

face transplant project. I obtained your address from [redacted] at UKT, who has been helping us complete a piece of work which will hopefully give us an estimate of how many facial grafts we can expect in a year.

We have also received data from the four regions we shall accept donations from (N & S Thames, Oxford & Cambridge), but we do need some data regarding tissue donation rates, both regionally and nationally, which we hope your organisation could provide. We understand that ITU units sometimes approach you directly.

The data should be relatively easy to get and essentially comprises the following:

1. Last two financial years (April 2005-April 2007) to be looked at
2. Total no. of tissues donated (and no. of people asked to donate)
3. No of corneas donated (and no. of people asked to donate)
4. No. of skin/bone donated (as above)

That should give us enough information to be able to extrapolate how many face donors we might expect in the region. We have devised a statistical method for this purpose, using Guttman scaling.

I look forward to hearing from you.

Kind regards,

[redacted]

[redacted]

Human Tissue Authority
Finlaison House
15–17 Furnival Street
London EC4A 1AB

Tel [redacted]
Email [redacted]
Web www.hta.gov.uk

Date 10 July 2009

Dear [redacted]

Procurement of tissue on unlicensed premises

As we discussed today, there are certain provisions that need to be put in place before the procurement of composite tissues for facial transplant can take place on unlicensed premise. As I understand it, the procurement of these tissues will be organised via the NHSBT Organ Donor Co-ordinator service. The procurement could take place at any hospital within the UK, and the procedure would be undertaken by a team of medical staff who would travel to the donating hospital to undertake the procurement of both solid organs and, in this case composite facial tissues.

As you are aware the procurement of solid organs does not fall within our remit, but the procurement of tissues that are to be used in human application does. For this reason it is necessary to ensure that the procurement of the tissues takes place either on licensed premises or alternatively under a third party agreement with a licensed establishment.

We discussed what this would mean in practical terms. I suggested that a template third party agreement could be developed and employed for these rare procurements. Rather than re-inventing the wheel, it would be worth liaising with NHSBT who have put in place a similar arrangement with staff who procure tissues such as corneas on unlicensed premises.

The third party agreement ensures that statutory obligations regarding (for example) donor selection, record keeping and traceability, reporting of serious adverse events or reactions are complied with by the third party undertaking the procurement.

There will be other matters to consider, for example you will need to ensure that the donor is tested in accordance with the regulations. The donor selection and testing criteria are available in our Directions 001/2006 – Annexes A & B.

Further information on third party agreements is available on our website Third Party Agreements.

We can take the opportunity to discuss this further at the report back meeting on Tuesday 14 July, but please feel free to contact me at any time if you feel that I can be of assistance

Yours sincerely

[redacted]

[redacted]

Notes of discussion on 28 July to consider if a face to be transplanted should be treated as an organ or tissue

Professor Peter Butler phoned the HTA on 27 July to discuss the impending face transplant at the Royal Free. The message he left was that he wanted to discuss the regulatory issues relating to this planned procedure.

I assumed that he wanted to discuss how a face used in this way should be classified. I chose to phone him the next day (28 July) because I wanted to establish what our position was: I understood that [redacted] and others had been in touch with the DI about the requirements of the EUTCDs as they applied to face transplants.

In [redacted] and [redacted] absence I asked [redacted] and [redacted] to search for any papers relating to the classification issue. The material we found was from the TWG, whose advice was that faces were tissue (NB this was advice, not a decision, because the TWG are not empowered to make decisions. The advice was the result of an initial discussion rather than informed debate). We also found brief reference to the matter in the notes of an ERPPB meeting which indicated the commissioning of an RM to prepare a policy paper for ERPPB in June or July. No RM appeared to have been asked to take on this work as yet. We found no evidence of legal advice, save a reference in TWG papers to [redacted] phoning a cardio-thoracic surgeon to ask for his views. This conversation was inconclusive and indicated that there would be differing views on this.

[redacted] and [redacted] initial views, based primarily on biological and anatomical criteria, were that a face transplant should fall under the Q&S Regs. But after further consideration – including taking advice from [redacted] (whose background is in organ transplantation) – we all moved towards treating a face as an organ, based on its properties in a medical and surgical sense. I had asked [redacted] to contact the French CA to ascertain how they had treated their two face transplants and the Germans their limb transplant last year.

The French called back to say that their face transplants had been treated as organ transplants because they fitted the definition of an organ in French law. This is:

An organ is the entirety of tissues which converge to fulfil one physiological function. The next higher level of organisation to an organ is a system, which

fulfils a group of complimentary functions, and the next lower organisational level of an organ is a tissue.

The French also said that the arm transplant done in Germany and a hand transplant in Italy had all been treated as organ transplants and they knew that both the Germans and Italians regarded face transplants in the same way.

We then called Professor Butler to hear what he had to say. He concentrated from the start on the classification issue. He had been researching face transplantation for 14 years and had encountered no professionals in this or other countries (US, France) who thought that the procedure was anything other than an organ transplant. The RCS and the DH had all previously indicated to him that a face should be treated as an organ for purposes of a transplant.

It had been drawn to his attention, only a few weeks ago, that the HTA took the different view that a face transplant fell under the Q&S Regs. In his view this was not right and he gave several reasons, all of which we had recognised from our earlier research and discussion during the day and which are described below. His prime reason for contesting this was because testing for syphilis – as required by the Q&S Regs – would introduce a delay (at least 24 hours) that was not sustainable. He recognised that the procedure could go ahead without the results of this test under an appropriate risk assessment, but he did not want any suggestion that the transplant team were conducting the procedure 'at risk' – even if the risk was, in practice, minimal. His abiding fear seemed to be that the details of the procedure would be requested under FOI and that the "at risk" status would be revealed. For the future of face transplants in this country, he wanted the whole procedure to be seen as "squeaky clean". We also had some sense that the profiling of families of potential donors has been based on this procedure being an organ transplant. Therefore the need to explain that testing for syphilis would be required had never been raised with the families. Introduction of an additional test presented a further risk, however small.

I said I would call him back after we had considered the matter further.

In further internal discussion, we felt that the following reasons for treating a face transplant as an organ transplant were persuasive:

- the retrieval and management of the facial material pending transplant would follow the same procedures as for any solid organ, including very short procurement times (4-5 hours) following ischemic death

- the facial material had to be transplanted immediately. This rendered it more like an organ as, unlike tissue, it could not be stored for transplantation
- in terms of blood supply and vascularisation, facial material was much closer to solid organs than tissue; this includes the need to perfuse the face following retrieval
- patients receiving face transplants have to have lifelong treatment with immuno-suppressants, unlike recipients of any tissue transplants
- France and the US had treated the face as an organ for transplant purposes.

In view of these reasons, and until we had considered in more depth how face transplants should be classified, we concluded that we should advise the Royal Free that they proceed on the basis that their imminent face transplant be carried out on the same basis as if it were a solid organ.

I phoned Professor Butler on 29 July to let him know of our conclusion. I pointed out that we needed to do more work on this, so our conclusion this week should not be seen as covering all face transplants in the future. We wanted to be absolutely certain that future full or partial face transplants should properly be classified as organ transplants. This would require a working definition of an organ that we could apply to transplants of faces, limbs and other parts of the body such as hands, feet and digits. Professor Butler said he would be happy to help and advise us.

I made clear that the consent provisions of the HT Act should be assiduously applied in this novel procedure. If the deceased had not clearly consented to his or her face being transplanted, the family of the deceased should be asked for their consent for this specific purpose.

HTA
30 July 2009