ORIGINAL COMMUNICATION

The use of Fresh Frozen Human Cadaveric Material in the UK:

A questionnaire study

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A questionnaire was created to determine how Fresh Frozen human cadavers and body parts are being used in the UK, in order to aid the Anatomy Associations Advisory Committee (AAAC) produce best practice guidelines. The questionnaire was initiated following discussions at a UK Human Tissue Authority (HTA) Stakeholders Group meeting in 2015 and in the subsequent production of an HTA discussion paper on the use of fresh frozen bodies in training healthcare professionals (HTA Stakeholders Group, 2015). The questionnaire was emailed to Surgical Training Centres in the UK and to the IAS membership. The results of completed questionnaires were collated and were reported to the AAAC in May 2016. The results highlighted differences in the practices and procedures for the use of fresh frozen human material employed in UK institutions. It is hoped that the study could be used to inform the development of guidelines to set standards for the use of fresh frozen cadaveric material for Anatomical Examination.

Keywords: Fresh Frozen, Surgical training, Anatomy Associations Advisory Committee, Human Tissue Authority

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INTRODUCTION

There is increasing demand for the use of fresh frozen human tissue in surgical and other healthcare professional training. Fresh frozen material has historically been imported, but an increasing amount is now being sourced from UK donors. The increase in demand has led to discussions within the Human Tissue Authority (HTA) Stakeholders Group and the Anatomy Associations Advisory Committee (AAAC), regarding the potential risks to users of fresh frozen compared to embalmed human material.

Concerns raised in a HTA Stakeholders Group discussion paper (HTA Stakeholders Group, 2015) included inconsistencies in the practices and procedures employed in UK institutions for managing fresh frozen material and the potential need for the HTA to produce guidelines covering the use of such material. Potential risks identified in the discussion paper included: disease transmission, recovering costs for running courses, ethical review of what types of courses are acceptable, unpleasant / hazardous working conditions for staff, appropriate respectful disposal of fresh frozen human material and the increased requirement for storage space/paperwork/staff resources due to the higher throughput of cadaveric material. In the light of the above concerns, the Council of the Institute of Anatomical Sciences (IAS) decided that it would be beneficial to survey its membership and known Surgical Training Institutes, to identify the extent of the use of fresh frozen tissue in the UK, the procedures and practices followed and also whether further advice and guidance is needed.

METHODS

A questionnaire was designed to collect information and report it to the AAAC and the HTA Stakeholders Group. Ultimately the objective of the study was to inform stakeholders what practices and procedures are being used in the UK and leading to a decision whether to produce HTA Best Practice Guidelines for using fresh frozen human material in Surgical and healthcare Professional Training.

A draft questionnaire was created, for completion by any individual who manages or works in an Anatomy teaching environment e.g. Medical School or Hospital that uses human cadaveric material. The questionnaire sought to identify the institution involved, whether it uses fresh frozen material, and if so, what it is used for and how it is sourced. If an institution uses fresh frozen material, subsequent questions focused on what practices and procedures are employed to receive, prepare, use, store and dispose of the material. The questionnaire required responses in a mixture of yes / no and free text formats. The draft was then refined following review by IAS Council members and questions were added in order to acquire the maximum relevant information possible.

The completed Questionnaire (appendix) was then sent to the HTA Designated Individual for each of the 16 Surgical Training Centres identified in the UK and also to the IAS membership (approx. 140). The participants were asked to return the completed form by email or post and were allowed 9 weeks to respond. Two weeks before the deadline, a reminder email was sent out to Surgical Training Centres and IAS members that had not responded, the completed questionnaires were sorted to separate those from institutions that used fresh frozen material, from those that did not. The responses from institutions using fresh-frozen material were then collated.

RESULTS

Completed questionnaires were returned from 12 of the 16 Surgical Training Centres contacted (75% response rate) and a further 6 responses were obtained from IAS members working in other institutions. The responding institutions are listed in figure 1.

Out of the 18 replies: 12 institutions use fresh frozen, 4 formalin fixed and 2 Thiel embalmed human material. The two who use Thiel prefer it to fresh frozen (although one has been asked for fresh frozen), because it is less messy than fresh frozen. The four institutions that only use embalmed material, have all been asked to use fresh frozen material, but they don't have the facilities to deal with health and safety issues of using fresh frozen human material.

Of the 12 institutions that use fresh frozen human material, 5 use imported specimens, 2 use their own donors and 5 use their own cadavers and imported material. All 12 of these institutions use the fresh frozen material for surgical training and 4 of them use it for research. 2 of the 12 institutions also use fresh frozen cadavers for training in cosmetic procedures and physio / movement therapist training courses. One institution also runs forensic training courses. The number of whole cadavers that the individual institutions use each year varies from 12 -100.

7 of the 12 institutions have a designated suite for using fresh frozen material, 6 of these freeze and use cadavers donated directly to them. Institutions without a designated facility are more likely to import fresh frozen material for use in their courses. It is not known what type of courses are more likely to use imported body parts rather than the material donated in the UK.

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Hull York Medical School
Keele University
Kings College London
Manchester Surgical Skills Centre, Manchester University
Newcastle Surgical Training Centre
Nottingham University
Royal College of Surgeons of England
Southampton University
St Andrews University
Swansea University
University College London
Vesalius Centre, University of Bristol
West Midlands Surgical centre, Warwick University

Figure 1 *List of responding institutions*

Imported fresh frozen material is screened by the US supplier prior to dispatch. The imported material is screened for Hepatitis B and C, Human Immunodeficiency Virus (HIV) and from one supplier also HCV and Meningitis and Syphilis. The material is delivered with screening certificates and in one case there is also a historical screening certificate. One institute previously received a false positive with the imported material but this was then ignored after a negative result was received from second test. It is not known what pathogen the false positive was positive for or who performed the blood test. None of the 7 institutions that use UK donated cadavers screen them for pathogens. Instead, their Bequest Officers rely mainly on verbal information from the donor's GP, family, hospital doctors and mortuary staff, who are asked for any medical history including surgery, weight and infectious diseases.

All institutions using fresh frozen material insist that their staff are immunised against Hepatitis B for working with fresh frozen material and 4 also insist on immunisation against Tuberculosis and Tetanus. However, only 2 institutions ask course delegates for their immunisation status. Pastoral care and counselling is available for staff in 9 out of 13 institutions that completed the questionnaire, however, it is unclear what the nature and level of this support is.

The time period between acceptance of a whole body for freezing and its cremation or burial varied between institutions from three months to two years. Any parts that are retained after cremation (which occurs in 3 institutions), are disposed of as clinical waste and incinerated. These results reflect the demand for the material, the storage capacity of each facility and what the cadavers and parts are used for.

Although a charge cannot be made for the fresh frozen material itself, room and facilities hire, consumables, catering, technical and administration time, storage, transport and cremation / disposal of material are included in the charges for training courses using fresh frozen material.

Of the 12 institutions that currently use fresh frozen material 9 responded that they did not want any more advice or guidelines from the HTA regarding the use of fresh frozen material. Of the 3 who wanted more advice, one asked for guidance specific to training courses, on what serology is necessary, on the acceptance of bodies for training courses, an on the importation of fresh frozen material and which overseas suppliers should be used.

DISCUSSION

The results of the current UK study reveal a variety of practices and procedures for the use of fresh frozen cadaveric material in surgical and other postgraduate training courses. The reason for this variety is unclear, but is probably due to the fact that although there is clear health and safety legislation governing the handling of non-embalmed human material (2,3), the widespread use of fresh frozen material for postgraduate training courses is relatively recent and there are not as yet any national guidelines for such use. While the production of best practice guidelines is unlikely to dramatically improve the health and safety of those using fresh frozen material, it would be expected to drive up standards and harmonise procedures and practices across the UK. Furthermore, the existence of best

practice guidelines would facilitate the development of fresh frozen training courses at additional institutions.

Although imported fresh frozen material is screened for pathogens, none of the institutions that freeze their own donors in the UK, carries out similar screening. It is not clear why there is this difference between imported and UK frozen cadavers, do UK institutions doubt the benefits of screening or is it simply that they expect all staff and course participants to take the precautions necessary for handling pathogen containing material? If the latter, what are the responsibilities of hosting institutions for ensuring all delegates and staff take appropriate precautions and have the necessary immunisations? Preparing, using and disposing fresh frozen cadaveric material can be unpleasant and emotionally stressful. Although some form of pastoral care / counselling is available in the majority of responding institutions using fresh frozen cadaveric material, it is not available in all and therefore, careful consideration should be given to its nature and whether all institutions have a duty to provide it.

Fresh frozen cadaveric material is rarely if ever used for undergraduate training. Fresh frozen material is used for a variety of clinical training courses and although donors may anticipate their bodies being used for surgical training, they may not understand that their remains may be used for training in cosmetic procedures or in complementary therapies. It is therefore important that donor consent forms accurately reflect the purposes for which the cadavers may be used. This could deleteriously affect the number of donations, but on the other hand, some donors might prefer their cadavers being used on a fresh frozen course, because fresh frozen cadavers are typically cremated / interred sooner than embalmed cadavers.

This results of the current study reveal that some institutions have dedicated training suites for using fresh frozen cadaveric material, whilst others run training courses and teaching on embalmed cadavers in the same facility, but at different times. It is likely that those institutions that have a dedicated fresh frozen facility have a greater course and cadaver throughput than those that have a single facility for both fresh frozen and embalmed material. It would be useful to know whether this is in fact the case and whether there are any other reasons for the separation of fresh frozen from embalmed material in some institutions. Similarly it would be expected that those institutions that freeze their own donors have a higher throughput than those that import material and again it would be important to know whether this is the case and whether there are any other reasons for favouring local freezing over importation or vice versa. The current study was restricted to UK institutions and therefore, its results have a relatively narrow perspective. Other countries, e.g. the USA, may have a greater history of using fresh frozen cadavers and also fresh cadavers for training purposes and it would be useful to gain an international perspective on this topic. In a similar vein, more detailed information about what fresh frozen cadavers are used for may better inform best practice guidelines and indeed whether different types of applications warrant different guidelines.

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APPENDIX: QUESTIONS INCLUDED IN THE QUESTIONNAIRE

1. Do you use fresh frozen human cadaveric material for training courses?
    - Yes
        i. What type of courses is it used for? [Surgical training; Research; Cosmetic surgery training; Physio/movement specialists; Forensic; Other]
    - No
        i. Have you been asked for fresh frozen material?
        ii. Why do you not surrently use fresh frozen?
2. Do you import any fresh frozen human cadaveric material?
    - Yes
        i. How would you dispose of these specimens? [Cremation; Clinical waste?]
    - No
3. Approximately how many whole fresh frozen cadavers do you use at your intitute each year?
4. Do you have a designated dissection room/suite for fresh frozen material?
    - Yes
    - No
5. What precausions do you take during the acceptance process to limit/prevent any health risks?
6. Do you viral screen your accepted cadavers?
    - Yes
        i. What are you screening them for?
    - No (go to question 10)
7. Approximately how long do the results take?
8. Have you ever received false positive results from your screening tests?
    - Yes
    - No
9. What would you do if you got a positive result?
10. Are certain immunisations required for staff working with fresh frozen material?
    - Yes
        i. Please list
    - No
11. Do you ask course delegates for their immunisation status?
    - Yes
    - No
12. What PPE do staff wear when handling fresh frozen material?
13. Is there pastoral care and counselling opportunities for the staff working with fresh frozen material?
    - Yes
    - No
14. Approximately how long after acceptance is the body cremated/buried after a fresh frozen course?
15. If you retian parts, how do you dispose of them at a later date?
    - Cremation/Clinical waste?
16. What ‘costs’ are included in your total charge to run a training course?
17. Would you like more advice and/or guidelines from the HTA regarding the use of fresh frozen material for training courses?
    - Yes
        i. What specifically
    - No