Human Tissue Authority written evidence submitted to the Joint Committee on the draft Modern Slavery Bill

Date 10 February 2014

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Introduction

1. The Human Tissue Authority (HTA) welcomes the opportunity to submit written evidence to the Joint Committee on the draft Modern Slavery Bill.

2. Section 2 of the draft Bill includes the offence of human trafficking, and section 3(4) states that the meaning of exploitation includes the removal of organs. It is on this aspect of exploitation that the HTA is responding, specifically in regard to living organ donation.

3. The draft Bill refers to sections 33 and 34 of the Human Tissue Act 2004 (HT Act), which concerns commercial dealings in human material for transplantation and restrictions on transplants involving a live donor, respectively.

4. We have not made reference to deceased organ donation in our response, as in order for this to be a consideration in a human trafficking case, it is likely the offence of manslaughter or murder would have been committed.

Background

About the HTA

5. The HTA assesses each living organ donation in the UK to ensure that the donor is aware of the risks involved and the nature of the procedure they are due to undertake, that no reward is being offered or sought in exchange for the donation and that the donor is making the decision to donate free from duress and coercion. We also undertake this role for bone marrow and peripheral blood stem cell transplants from children who lack the competence to consent and adults who lack the capacity to consent.

6. The HTA also 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.

7. 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.

8. 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.

9. We help people to understand these requirements by providing codes of practice and advice, guidance and support.

Living organ donation in the UK

10. While the draft Modern Slavery Bill applies only to England and Wales, we note the intention of the Northern Ireland Assembly and Scottish Parliament to consider their respective approaches to the matters included in the Bill.

11. The HT Act covers England, Wales and Northern Ireland. The HTA also undertakes the assessment of living organ donation cases for Scotland under the Human Tissue (Scotland) Act 2006.

12. In the UK there are active living kidney and living liver lobe donation programmes.

13. The HTA approved 1243 living organ donation cases in 2012/13, of which 1200 were living kidney donations and 43 were living liver lobe donations.

14. It is possible to direct a living donation, so that it goes to a specified person. Most cases of living organ donation are directed – 87% in 2012/13. The remaining 13% were either non-directed altruistic donations, where the donor does not know who their organ or part organ will be allocated to, or a paired/pooled kidney donation, where a donor and recipient who are incompatible ‘swap’ kidneys with one or two other pairs in the same position.

15. Living organ donation constitutes 39% of all kidney transplants in the UK and 4% of liver transplants.

16. As less than 2% of South Asian and Black communities are on the Organ Donor Register, but are three times more likely to need an organ transplant than the UK

average, living donation is a particularly important option for this group as recipients are likely to face a long wait on the list.

17. The HTA's role in living organ donation falls towards the end of the donor work-up period, which tends to last about six months. The work-up period is the time it takes to assess whether the donor is suitable, whether they are a good match, and to run myriad clinical tests to ensure the transplant will be as successful as possible.

18. Independent Assessors (IAs), who are people trained by the HTA and independent of the transplant programme at the hospital in which they work, carry out interviews with the donor and recipient, separately and together, to ensure there is no duress or coercion, no reward changing hands and the donor understands the risks involved.

19. We have just 130 IAs and they include clinicians from a range of specialities, chaplains and administrative staff.

20. In the main part IAs do not receive any additional pay for carrying out this role, and time is found in their work plans to accommodate this function. A minority of IAs are paid for each assessment they carry out.

21. Once the interviews have been completed, a report is submitted to the HTA for assessment. Some types of donations (non-directed altruistic, paired and pooled donations) must be considered by a panel of three HTA Board Members, other cases can be, and mainly are, devolved for consideration to the HTA Executive.

22. A decision is then made to approve or reject the case. Very few cases are rejected (2 in 2012/13) and when this does happen there is a right to appeal.

23. In most cases the information provided allows a decision to be reached swiftly. However, in more complex cases we may need further information and this is collected in a variety of ways, including a different IA being asked to interview the donor and/or recipient with a set of specified questions, or working with Living Donor Coordinators to gain a better understanding of the specifics of a situation.

24. The HTA's role in living organ donation is becoming more complex. In 2005 when we started to regulate this activity, the vast majority of living donations were between people with close genetic or emotional relationships. Today we assess increasing cases where the relationship is distant, or there is no relationship prior to the need for a transplant arising (directed-altruistic donation). In such cases establishing that there is no duress, coercion or reward is often more difficult and requires detailed questioning.

25. It is also important to note that as the HTA's assessment comes towards the end of the process, a number of cases never reach assessment. This may because the donor is ruled out on medical grounds, or it may be because there is concern amongst the clinical team that things are not quite as they are being presented and the decision is made not to proceed.

26. The HTA is required to make a decision on the balance of probabilities.

Living organ donors from outside the UK

27. It is not unusual for those awaiting a transplant to enquire of family members and friends living abroad whether they would consider becoming a living donor. This is especially true when the potential recipient has extended family outside the UK and it is considered that someone from this group may be a good match.

28. Colleagues at NHS Blood and Transplant and the Home Office have developed protocols for living donors from outside the UK to enter the country for this purpose.

29. The HTA's experience suggests that in most cases where the donor is from overseas there is no evidence of duress, coercion or reward. However, often these cases require further investigation as the need to use a translator in many instances means it can be harder to get a detailed understanding of the donor's reasons for donating. This often goes a long way towards ruling out duress, coercion and reward. It is also difficult for an IA to fully understand a nuanced or hesitant response when a translator needs to be involved. This is especially true when a telephone translation service is used, which is increasing often.

Key points for the Committee's consideration

Duress and coercion

30. The legislation under which the HTA works in this area requires us to establish there is no evidence of duress and coercion.

31. As our experience grows and our understanding of these concepts in regard to living organ donation deepens, it is clear that they exist on a continuum. The continuum ranges from pressure an individual may place on themselves to help a family member or friend, to covert familial pressure perhaps expressed as admiration for what the potential donor is doing, to overt statements that it is expected that the donor go ahead whatever their own wishes. It is the middle 'grey' area which poses the greatest challenge to those seeking to establish whether a person is acting with free will.

32. It may be of interest to the Committee that the HT Act and associated Regulations do not make an offence of duress or coercion being placed on a potential donor, but require that the Authority is satisfied that these are not a factor when approving a living organ donation.

33. It is our understanding of the draft Bill that no offence is created in regard to duress and coercion being placed on a person to become a living organ donor. This means that, where a transplant does not go ahead, no offence would have been committed under the draft Bill or the HT Act even if duress or coercion had occurred. Similarly, if the duress or coercion comes to light after an approved transplant, no offence would have

been committed. Clearly that is a decision for Parliament, but we thought it helpful to draw this to your attention.

Family

34. The HTA's experience of the regulation of living organ donation suggests that concerns regarding duress, coercion and reward occur most frequently when the donor and recipient have a familial relationship. We note that the potential for involvement of family members or connections is included in the preface to the draft Bill and believe it will be important that this is reinforced through guidance and training.

35. It had previously been considered that directed-altruistic donations posed the greatest risk in regard to duress, coercion and reward. However, our experience of such cases (albeit limited, as there have been only 19 to date) suggests that they pose little if any increased risk of duress, coercion or reward. It is more often cases where the donor is a family member from overseas that there are concerns which require careful consideration.

Convictions for trafficking for organ donation

36. The HTA first met with colleagues from the Serious and Organised Crime Agency (SOCA) in 2012 when the first cases of human trafficking potentially involving living organ donation came to light.

37. We remain in contact and provide them with advice and guidance as necessary. However, as yet there have not been any charges brought which include the offence of trafficking for organ donation and this remains untested.

38. We support the aim in the preface to the draft Bill that charges and ultimately convictions are brought to act as a deterrent, and believe that a successful prosecution for trafficking for organ donation, suitably publicised, would deter some individuals.

Outside the system

39. It should be noted that we only have experience of living organ donations occurring within the established programmes within the UK, whether these be public or private. There is no evidence of organs being removed for transplantation in the UK outside of these programmes, and an offence would be committed under the HT Act if an organ was removed for the purpose of transplantation from a living person without HTA approval.

40. However, it would be naïve not to imagine the possibility of the existence or development of an illegal system for the removal of organs for transplantation outside of the approved programmes, and there may be value in considering placing increased focus on the prevention and detection of any such system.

Support and development for those working within living organ donation

41. We note from the preface the draft Bill that the Department of Health (DH) will roll out training to raise awareness of modern slavery amongst NHS professionals. This will provide valuable support to those who may encounter victims of modern slavery face-to-face and be in a position to help them.

42. We would suggest that particular focus is given to those working with living organ donors, as removal of an organ for transplantation will become a header of exploitation under section 3 of the new legislation. We will work with the DH to ensure that HTA IAs have access to this training, as in the past they have provided potential donors with the opportunity to state they do not wish to proceed as they feel they are being placed under undue pressure.

Conclusion

43. While this response largely highlights the potential for human trafficking for living organ donation, it is important to remember that in most cases when someone enters the UK to be an organ donor, they do so willingly and without the promise of reward.

44. In this particular aspect of human trafficking, there is a strong case to be made for a balanced approach to be taken; while exploitation must not be tolerated, unduly high barriers should not prevent donors entering the UK and recipients getting their much needed transplants.

45. Not only does a transplant dramatically improve or save the life of the recipient, it is also a cost effective treatment and can allow the recipient to live a full life for a number of years.

46. We hope the information above supports the Committee in their pre-legislative scrutiny of the draft Modern Slavery Bill.

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