NUFFIELD COUNCIL ON BIOETHICS

Human Tissue: ethical and legal issues

Response from the Nuffield Council on Bioethics to the Human Tissue Bill

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Introduction

1 In 1995, the Nuffield Council on Bioethics examined ethical and legal issues raised by the increasing medical and scientific uses of human tissue. The Report, ***Human Tissue: ethical and legal issues***, discussed the removal, use, ownership, and protection of tissue. The Council concluded that there was an urgent need to clarify and strengthen the legal and ethical framework guiding clinical and research uses.

2 There has been wide debate about the uses of human tissue since the publication of the Council's Report. In particular, concerns of the public have been increased by two recent inquiries, at Bristol and Alder Hey, which have investigated improper retention of organs. The practice of storing organs and tissue, particularly from the deceased, without the knowledge or consent of families has been widespread, causing grief and distress to many.

3 A clear regulatory framework is necessary. The Human Tissue Bill establishes the requirement for consent as a cornerstone of new legislation to govern the storage and use of human organs and tissue. In principle, the Nuffield Council welcomes the introduction of the Bill. However, the Council is concerned that requirements for consent may be so onerous that potentially valuable research will be inhibited unnecessarily. Accordingly, we call for clarification and revision of the Bill to ensure that requirements for consent are not overly-prescriptive.

4 The importance of respect for the human body and its parts is widely acknowledged: human tissue should not be used at will or abused. However, human tissue also serves many beneficial purposes: for use in diagnosis and therapy, medical research, and education and training. It is important to maintain a balance between the potential benefits for diagnosis and treatment and the need to safeguard those from whom tissue is removed. Balance will only be achieved if specific provision is also made to facilitate appropriate access for medical research.

5 This paper discusses ethical issues which arise when human tissue is used in the context of clinical practice and research. It highlights the conclusions and recommendations of the Nuffield Council's Report which are relevant to the Human Tissue Bill.

Ethical principles

Any clarification of the legal and regulatory framework for the use of human tissue must be based on appropriate ethical principles. The ethical considerations emphasised in the Nuffield Council Report (Chapter 6, paragraph 13.5) were:

- it is, in principle, ethically acceptable to make use of human tissue for medical treatment, and for medical training, for fundamental and applied research and for other purposes that may contribute indirectly to medical treatment;
- these uses of human tissue are only ethically permissible when the tissue has been removed with the consent of those whose tissue is used or, where that is not possible, by procedures that give equivalent protection;
- uses of human tissue which injure in that they destroy, damage or degrade the tissue are unacceptable because such uses show lack of respect for human beings and their bodies. However, when action that might otherwise count as injury is undertaken for therapy, it is legitimate, provided there is appropriate consent;
- there are strong arguments against the commercial acquisition and supply of human tissue for medical and scientific purposes, however acceptable those purposes may be in themselves.

These ethical considerations can and should be reflected in the procedures used to organise and regulate the removal, storage and further use of human tissue.

Consent

6 The Human Tissue Bill is based on consent as the fundamental principle guiding the lawful storage and use of human bodies, body parts, organs and tissue and the removal of material from the dead bodies of deceased persons. The Nuffield Council welcomes this approach.

Scope and specificity of consent in the Human Tissue Bill

7 The Bill does not define the scope and specificity of the consent that will be required. It defines who will be able to give consent, but does not provide further detail about the process of obtaining consent or the form of the consent. Instead, these aspects will be determined by a new body, the Human Tissue Authority, through codes of practice.

8 These codes of practice are not yet available. It is therefore not possible to anticipate the specificity of the consent that will be required, or to assess the consequences for clinical practice and research. The Council also notes that the use of tissue without appropriate consent will be the basis of criminal liability under the Bill. The Council is concerned about the

uncertainty created by this approach. We consider the scope and specificity of 'appropriate consent', or at very least the minimum requirements, should be made more explicit in the Bill.

9 The codes of practice will be vital both to restore and maintain public confidence and to ensure that medical research can continue to provide benefits. The Human Tissue Authority must consult widely and with care. There could be benefit, as others have suggested, in greater Parliamentary accountability of the Human Tissue Authority's guidance and codes of practice.

The importance of 'genuine consent'

10 In 1995, the Council concluded that **the ethically significant requirement is not that consent be complete, but rather that it be *genuine***. Expressions such as 'informed consent' and 'fully informed consent' are somewhat misleading. Since description can never be fully exhaustive, consent will always be to action that is incompletely described; moreover the descriptions given may often be incompletely understood. This incompleteness cannot be remedied by devising more elaborate consent forms. Fully informed consent is therefore an unattainable ideal.

11 Obtaining genuine consent requires medical practitioners to do their best to communicate accurately as much as patients, volunteers or relatives can understand about procedures and risks, and to respect the limits of their understanding. The information provided must be relevant, accurate and sufficient to enable a genuine choice to be made. Much of the distress in recent cases has resulted from a lack of understanding of how tissue might be used. It is therefore important that appropriate information should be made available to ensure that families are not subsequently surprised or upset. **If all reasonable care is exercised, adequate and genuine consent may be established, although it will necessarily fall short of fully informed consent** (paragraphs 6.19 – 6.21).

12 Ensuring that consent is genuine requires care in detecting and eliminating lack of consent. The apparent genuineness of consent can be defeated by a number of circumstances, including coercion, deception, manipulation, deliberate misdescription of what is proposed, lack of disclosure of material facts or conflicts of interest (paragraph 6.20). The Nuffield Council suggests that the significance of genuine consent, which is both informed and voluntary, should be reflected in the legislation and the guidance produced by the Human Tissue Authority.

The use of surplus tissue obtained from the living during diagnosis or treatment

13 Most commonly, human tissue is removed from the body in the course of diagnosis or treatment. Small pieces of tissue may be taken by biopsy for

pathological examination and diagnosis, and larger amounts of tissue may be removed surgically during operation for malignant or other disease. Inevitably, there may be surplus tissue left over which is ordinarily discarded and destroyed. Such left-over tissue, and also material archived during diagnosis and treatment, may, however, be made available for scientific research, medical training and scholarship, or for medical review and audit. These valuable uses of tissue will be covered by the Bill, and will in most cases require consent.

14 It is important to note that, in such cases, everything done to the patient would be done as part of treatment, so there is no otherwise injurious action which is not legitimated by its therapeutic intent. However, at present, patients may commonly assume that removed tissue is put to no further use other than for diagnosis and treatment and that all surplus tissue is destroyed. As described above, the tissue may in fact have considerable value for research purposes, and such potential uses should therefore be explained to patients.

15 **The Nuffield Council recommends that when a patient consents to medical treatment involving the removal of tissue, the consent should also address the possible subsequent disposal or storage of the tissue and any further acceptable use provided that this is regulated by appropriate ethical, legal and professional standards.** Consent to treatment should be in general terms, and explanations offered to patients should make clear the possibility that removed tissue, if stored, may at some time be used for diagnosis, further treatment, research, teaching or study. The consent which patients give to their treatment must be genuine and based on adequate understanding of that treatment and what it involves (paragraphs 6.29.1 and 13.12–13.13).

16 We consider that the Bill should state explicitly that obtaining broad consent for the use of tissue is, in principle, appropriate. Future needs of research, which cannot be anticipated at present, should also be covered. Patients should not have to be contacted afresh to give consent to future uses of tissue, provided those uses are appropriately regulated, for example by consultation with an appropriate research ethics committee.

Where a patient is unable to give consent

17 Questions arise when tissue is taken from those individuals who are not able to give consent for themselves. The Human Tissue Bill currently allows provision for use of tissue from children and adults with 'appropriate consent'. However, Clause 3 does not appear to allow any scope for the lawful use of surplus tissue from living adults who are incapable of giving valid consent. This may prevent the possibility of using such tissue for research into their disorder.

18 In the case of incompetent adults, the Nuffield Council concluded in its Report that the responsible physician, in consultation with relatives, will respect the interests of the patient when making decisions about medical treatment and subsequent uses of tissue. The physician's judgement would therefore provide equivalent protection to that given by consent procedures. It is however, important to ensure in such cases, that medical treatment is genuinely needed, and not a pretext for obtaining tissue for some further purpose. **We recommend that, in these circumstances, tissue may be removed *in the course of treatment* only if this is in their best interests** (paragraphs 6.24, 7.9 and 13.14)**.**

Achieving a balance

19 The Bill is intended "to achieve a balance between the rights and expectations of individuals and families, and broader considerations, such as the importance of research, education, training, pathology and public health surveillance to the population as a whole". This is a worthy ideal. We suggest that this intention should be reflected in the preamble or long title of the Bill.

20 However, for this balance to be achieved, we believe that it is crucial that regulations, guidance and codes of practice are not drawn so restrictively that they inhibit necessary and worthwhile clinical treatment and research. If the consent requirements are too onerous, research leading to potential benefits may be inhibited. The Nuffield Council strongly urges the Committee to consider ways of addressing this crucial concern in the Bill, and in the advice issued by the Human Tissue Authority. The Authority should also monitor the impact of the legislation.

21 In particular, there are concerns that the requirements of the Bill could impede research for the purpose of public health. The use of tissue for 'public health monitoring' will not require consent, as it is included in part 2 of schedule 1. However, a great deal of valuable epidemiological and public health research will, as the Bill is currently drafted, require consent. Careful thought should be given to the distinction between public health monitoring and public health research, and the position clarified accordingly in the Bill. It is important that research, which is non-intrusive, of no harm to the patient, and potentially of significant public benefit, is not inhibited by overly-prescriptive requirements for consent.

22 There are other reasons to ensure the availability of human tissue for research. The use of human tissue is seen as one way of reducing the use of animals in research. The Nuffield Council has recently held a consultation on the ethics of research involving animals. Several responses highlighted an increasing concern that new regulations were limiting the availability of

human tissue, thus creating difficulties for researchers wishing to reduce their use of animals or animal tissue. For some purposes, the use of human tissue may be more appropriate scientifically than the use of animals.

The importance of clarity

23 As the Nuffield Council concluded nine years ago, there is a need for clarity in new legislation. Uncertainty within the law could impede legitimate treatment, teaching and research, or could even encourage illegitimate uses of tissue (paragraph 13.4).

24 We are concerned that the Bill is complex and, in some places, ambiguous and difficult to follow. The new legislation must be clear and coherent.

Conclusion

25 The Nuffield Council supports the introduction of new legislation to regulate the use and storage of human tissue. We believe that it is right that consent should be the fundamental principle underlying the regulations. However, the requirements for consent must not become too bureaucratic or too onerous. The concerns outlined above must be addressed in order to restore public confidence and ensure that medical research, education and scholarship can continue to its maximum potential.

The Report, ***Human tissue: ethical and legal issues****, is available to download from the Council's website at:*
www.nuffieldbioethics.org/humantissue