

## **Chapter 7**

# **Legal matters : removal of tissue**

### **Summary**

For the living, case law establishes that a person must consent to the removal of tissue. It is appropriate to distinguish between the removal of tissue in the course of medical treatment, and non-therapeutic removal which requires more rigorous safeguards, whether the purpose is a donation for transplantation or for research. Thus, the removal of organs from donors is covered by statute which makes the requirement for consent explicit. There are a few exceptions to the requirement for consent:

- 1 Children between the ages of 16 and 18 must, like adults, consent to medical treatment. Children younger than this must be asked for their consent if they are judged competent. For children who are not considered competent, the consent of the person with parental responsibility must be obtained for removal in the course of treatment. For non-therapeutic removal, the law is complicated and unclear. The important legal principles would seem to be that any child under 18 would be deemed incompetent to consent, as a matter of public policy, to anything other than a trivial intervention, for example, perhaps, the taking of a blood sample; the consent of the person with parental responsibility must therefore be obtained; such consent could then only validly be given if the removal of tissue were not against the child's interests, that is, if it posed no more than negligible risk and minimal burden, and the tissue could not equally well be taken from an adult.
- 2 Some adults may be legally incompetent to give consent: they may be too disturbed or they may be unconscious. In such cases, tissue may be removed if it is in the patient's best interests to do so. The law is unclear on whether tissue may be removed from such adults for non-therapeutic purposes.

Statutes regulate the removal of tissue from the dead for the purposes of donation for therapeutic purposes, anatomical examination as part of medical training, and autopsy to establish the cause of death. Certain activities, such as archiving and tissue banking, may lie outside these statutes. The precise legality of such activities is unclear although, being accepted as common practices, they are also probably lawful.

### Introduction

7.1 We have noted the useful analysis of the US Office of Technology Assessment (OTA) in its 1987 study.<sup>3</sup> We use the term removal to include:

- ▶ *“aspiration of bodily fluids (for example, blood) through a needle*
- ▶ *scraping of cells from a surface (for example, skin or cervix)*
- ▶ *surgical removal of tissue*
- ▶ *collection of body substances by non-invasive procedure (for example, semen . . .)”*

7.2 Consent considerations are at the heart of the law relating to the removal of tissue. The considerations depend on whether tissue is removed from the living or from the dead and if from the living, whether the person is competent or not to give consent, and on the intended purpose for the removed tissue, whether therapeutic or non-therapeutic.

### Removal of tissue from the living : general principles

7.3 The Human Organ Transplants Act 1989 regulates the removal of organs (as defined in s.7(2) of the Act) from living donors. In particular the Act makes it a crime to deal commercially in organs and, in the case of donors unrelated to the intended recipient, established a statutory Unrelated Live Transplant Regulatory Authority (ULTRA) with responsibility to authorise each donation in accordance with strict rules on consent. Thus, the Act permits removal subject to the observance of at least two moral principles; that commerce in organs is wrong and, secondly, that in the case of unrelated donors, donation is not wrong but special care to avoid exploitation must be taken, and procedures for securing explicit consent are to serve as one of the principal means of protecting potential donors. ULTRA must be satisfied *“that the donor **understands** the nature of the medical procedure and the risks, **as explained** by the registered medical practitioner, and consents to the removal of the organ in question”* (our emphasis).<sup>3</sup> To require that the donor “understands” goes further than the common law, which requires as regards medical intervention generally only that a person be capable of understanding not that he understood, which is a much more demanding standard. Equally the requirement that the doctor explain the nature and risks of the procedure<sup>4</sup> allows no room for the discretion available to doctors at common law of not informing a patient about certain risks associated with a particular treatment, if, for example, the patient is extremely anxious.

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<sup>3</sup> Office of Technology Assessment (1987) **New Developments in Biotechnology: Ownership of human cells and tissues**, Washington DC, reviews examples of the use of tissue and the uncertainty of US law which in this context is not dissimilar to English law.

<sup>4</sup> By Regulation 3(2)(b) of the Human Organ Transplants (Unrelated Persons) Regulations 1989 (SI 1989/2480)

- 7.4 A donor of reproductive tissue, ie eggs, must as a matter of common law consent to the procedure involved. (No consent would be required for the donation of sperm). Additionally, the Human Fertilisation and Embryology Act 1990, establishes a framework of specific consents. Donors of gametes (and embryos) must explicitly consent to the use of such tissue before it may be stored or used for treatment or research, the only uses of reproductive tissue which are licensed under the Act.
- 7.5 Apart from these Acts, there is little or no law specifically concerned with the removal of tissue from the living. Clearly, as a general legal principle, unconsented interference with bodily integrity is unlawful. To remove human tissue against the consent of a competent person would ordinarily constitute both a crime and a civil wrong. In the frequently quoted dictum of the distinguished American judge, Cardozo J: “*Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient’s consent commits a [wrong] for which he is liable in damages.*”<sup>5</sup>

### Removal of tissue from the competent

- 7.6 The fact that there may be urgent need for certain tissue cannot legally justify its being taken without consent; the law’s commitment to the absolute right to ‘bodily security’ of one person cannot be abandoned in order to save the life of another person. Thus, in another US case<sup>6</sup> a court refused to order a man to donate compatible bone marrow to his cousin and so save the cousin’s life. Although the court expressed the view that the refusal was morally indefensible, “*to compel the defendant to submit to an intrusion of his body would change every concept and principle upon which our society is founded. To do so would defeat the sanctity of the individual and would impose a rule which would know no limits and one could not imagine where the line would be drawn. . .*” It is likely that these general principles would be followed in English law. (One situation where a departure from this rule was held to be justified in law was in the **very** special circumstances where a pregnant woman was said to have put the life of her unborn child at risk by refusing a caesarean section.<sup>7</sup>)

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<sup>5</sup> *Schloendorff v Society of New York Hospital* (1914) 105 NE 92

<sup>6</sup> *McFall v Shimp* 10 Pa D&C 3d 90 (1978) Pennsylvania

<sup>7</sup> In the case of *Re S* [1992] 4 All ER 671, the High Court decided that a woman should be required to undergo a caesarean section despite her objection, to prevent the death of her unborn child. Mrs S was in labour with her third pregnancy. Although the fetus was 6 days overdue and she had been in labour for several days, she refused to submit to a caesarean section on religious grounds. The fetus was in a “transverse lie” with the elbow projecting through the cervix and the head on the right side. There was a grave danger of the uterus rupturing if the caesarean section was not carried out. The medical opinion was that the fetus could not be born alive unless the operation were performed. To the extent that the fetus could be regarded as tissue, this is an example

7.7 Thus, where a person is legally competent, explicit consent, whether for therapeutic or non-therapeutic procedures, is the rule. The legal requirements necessary for a valid consent may vary between the two types of procedure. As regards therapeutic procedures, there are two levels of consent. There must be explicit consent to the nature and purpose of any proposed intervention. Thereafter, the degree of information concerning possible risks associated with the treatment, which the doctor must disclose, so as to make the consent informed and thus valid, is currently determined in English law by reference to what a reasonable doctor would disclose. In certain circumstances, for example, if a patient is extremely anxious, a doctor may decide not to inform the patient about certain risks associated with a particular treatment. Where the procedure is non-therapeutic, there are not two levels of consent and thus there is no scope for medical discretion. Consent must be explicit and all relevant information must be provided. Thus, when removal of tissue takes place in a non-therapeutic context, for example from a volunteer in a research project, not only must the removal be for a purpose which the law permits, that is, it must be in the public interest (paragraph 8.3), but it must also be consented to explicitly and on the basis of all appropriate information.

### Removal of tissue from the incompetent

#### 7.8 Children

By s.8(1) of the Family Law Reform Act 1969, children aged 16 - 18 years are deemed competent in law to consent to medical **treatment**, in the absence of evidence to the contrary. This section does not, however, apply to non-therapeutic interventions.<sup>8</sup> Children under 16 may also be deemed competent to consent to medical **treatment** if of sufficient maturity and understanding.<sup>9</sup> In the case of a **child deemed incompetent** to consent, as regards removal **in the course of treatment**, the tissue may be removed if the person with parental responsibility judges it to be in the child's best interests. If removal takes place during the course of *bona fide* treatment, it will ordinarily be in the child's best interests. If **removal of tissue is not during the course of treatment**, the legal principles regulating non-therapeutic research in the past would have suggested that a child under 18 will be deemed to be incompetent to consent, as a matter of public policy, to anything other than a trivial intervention, for example, perhaps, the taking of a blood sample. Removal may be lawful, however, and therefore may be consented to by someone with parental

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of the removal of tissue without consent. This case has been widely criticised. It could well be that future courts will overrule the principle it states.

<sup>8</sup> See dicta in *Re W* [1992] 4 All ER 627

<sup>9</sup> *Gillick v West Norfolk and Wisbech HA*, [1985] 3 All ER 402

responsibility, **if it is not against the child's interests, that is, if it poses no more than negligible risk and minimal burden, and the tissue could not equally well be taken from an adult.**<sup>10</sup> Those principles relating to research have apparently been overtaken, however, by the European Code of Good Clinical Practice which regulates the conduct of research into pharmaceutical products and which provides that **non-therapeutic research** may be conducted only on those able to consent for themselves, ie only on the competent. The European Directive 91/507/EEC, which, on one reading, appears to incorporate the Code of Good Clinical Practice, is now part of UK law by virtue of the Medicines (Applications for Grant of Product Licences - Products for Human Use) Regulation 1993 (SI 1993/2538). Thus, if the analogy with research is employed, removal in a non-therapeutic context would be unlawful. The situation is further complicated, however, by the fact that the new Regulations apply only to research done with a view to making an application for a product licence for a medicine. Thus, arguably, the legal principles argued for earlier may still apply in all other non-therapeutic contexts. The law, as a consequence, appears to be excessively complex. At least, however, research on the incompetent child involving the removal of tissue would be lawful provided that it met all relevant ethical requirements, conformed to these legal principles and was not being carried out with a view to applying for a product licence.

### 7.9 Adults

In the case of an incompetent **adult**, no-one has legal authority to consent to removal. During the course of **treatment**, the attending doctor may remove tissue if it is in the patient's best interests to do so. Whether tissue can be removed in a **non-therapeutic** context from such a person is an unresolved question. The analysis drawing on non-therapeutic research on children may seem relevant. But, in the absence of anyone with authority to consent, it is debateable whether this analogy is appropriate. The lawfulness of any removal would depend on whether the law would countenance the dilution of the concept of best interests, by adopting the test of "*not against the interests*" as in the case of a child. But in the case of a child, there is, in law, someone to make that decision and to be held accountable for it. In the case of an adult, there is no such person.<sup>11</sup> Furthermore, what was said earlier about the new Medicines Regulation (SI 1993/2538) would apply equally here to the incompetent adult. The issue of medical treatment and research involving mentally incapacitated adults has been considered by the Law Commission in a report on

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<sup>10</sup> Nolan LJ in *Re W* [1992] 4 All ER 627 suggested that it may also be desirable to apply to the court for authorisation where what is contemplated is the "donation" of an organ.

<sup>11</sup> There are dicta in *Re F* [1990] 2 AC 1 per Lord Bridge (HL) and Neill LJ (CA) that the involvement of the court may be necessary, at least where the removal of tissue for transplantation was contemplated.

mental incapacity.<sup>12</sup> The report reached the conclusion that research of no therapeutic benefit to the participants would currently be unlawful. The new legislative scheme proposed by the Law Commission recommends that “*research which is unlikely to benefit a participant, or whose benefit is likely to be long delayed, should be lawful in relation to a person without capacity to consent . . .*” subject to strict safeguards. Research would be contemplated only if it would provide knowledge of the incapacitating condition with which any participant is affected; if the research could not be achieved without such persons; and if the procedure were of negligible risk and were not unduly invasive. A new statutory Mental Incapacity Research Committee is proposed that would be required to approve non-therapeutic research procedures. In addition, procedures for approving the participation of each individual in the research project are recommended.

- 7.10 The above discussion of removal of tissue for non-therapeutic purposes has been concerned with its use for research. What of the donation of tissue for the treatment of others? The requirement of ULTRA that there must be explicit consent to organ donation means that an incompetent person, whether child or adult, who is not genetically related to the recipient cannot be an organ donor. It may well be that a court would apply this principle equally in the case of the proposed removal of an organ from an incompetent person for transplantation into someone who was genetically related.

### Removal of tissue from the dead : statute law

- 7.11 At least four statutes regulate the removal of tissue from the dead:

1 **The Human Tissue Act 1961** provides by s.1 that:

- (1) *If any person, either in writing at any time or orally in the presence of two or more witnesses during his last illness, has expressed a request that his body or any specified part of his body be used after his death for therapeutic purposes or for purposes of medical education or research, the person lawfully in possession of his body after his death may, unless he has reason to believe that the request was subsequently withdrawn, authorise the removal from the body or any part or, as the case may be, the specified part, for use in accordance with the request.*
- (2) *Without prejudice to the foregoing subsection, the person lawfully in possession of the body of a deceased person may authorise the removal or any part from the body for use for the said purposes if, having made such reasonable enquiry as may be practicable, he has no reason to believe -*

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<sup>12</sup> Law Commission Report No 231 (1995) **Mental Incapacity** HMSO. See, in particular, pp 96-102 and Clause 11 of the draft Bill (p 228)

- (a) *that the deceased had expressed an objection to his body being so dealt with after his death, and had not withdrawn it; or*
  - (b) *that the surviving spouse or any surviving relative of the deceased objects to the body being so dealt with.*
- (3) *Subject to subsections (4) and (5) of this section, the removal and use of any part of a body in accordance with an authority given in pursuance of this section shall be lawful.*
- (4) *No such removal shall be effected except by a fully registered medical practitioner, who must have satisfied himself by personal examination of the body that life is extinct.*
- (4A) *No such removal of an eye or part of an eye shall be effected except by -*
  - (a) *a registered medical practitioner who must have satisfied himself by personal examination of the body that life is extinct; or*
  - (b) *a person in the employment of a health authority or NHS trust acting on the instructions of a registered medical practitioner who must, before giving those instructions, be satisfied that the person in question is sufficiently qualified and trained to perform the removal competently and must also either -*
    - (i) *have satisfied himself by personal examination of the body that life is extinct, or*
    - (ii) *be satisfied that life is extinct on the basis of a statement to that effect by a registered medical practitioner who has satisfied himself by personal examination of the body that life is extinct.*
- (5) *Where a person has reason to believe that an inquest may be required to be held on any body or that a post-mortem examination of any body may be required by the coroner, he shall not, except with the consent of the coroner,*
  - (a) *give an authority under this section in respect of the body; or*
  - (b) *act on such an authority given by any other person.*
- (6) *No authority shall be given under this section in respect of any body by a person entrusted with the body for the purpose only of its interment or cremation.*
- (7) *In the case of a body lying in a hospital, nursing home or other institution, any authority under this section may be given on behalf of the person having the control and management thereof by any officer or person designated for that purpose by the first-mentioned person.*
- (8) *Nothing in this section shall be construed as rendering unlawful any dealing with, or with any part of, the body of a deceased person which is lawful apart from the Act.*
- (9) *In the application of this section to Scotland, for subsection (5) there shall be substituted the following subsection -*
  - (5) *Nothing in this section shall authorise the removal of any part from a body in any case where the procurator fiscal has objected to such removal.*

The Act makes lawful the removal of parts of the body “for therapeutic purposes or for the purposes of medical education or research” (s.1(1)). Provided that the terms of the Act set out above are complied with, any part may be removed (save where the deceased has specified a particular part, in which case it appears that only that part may be removed). The part may then be used for the purposes indicated by the deceased or the person lawfully in possession of the body. Any removal must be by a registered medical practitioner (unless, exceptionally, in respect of the removal of an eye or part of an eye where s.1(4A) applies). Where an inquest or post-mortem may be required, the consent of the coroner is required before any authority may be given under the Act for the removal of any part.

- 2 **The Human Organ Transplants Act 1989** extends the prohibition on commercial dealing in organs noticed earlier (paragraph 7.3) to organs removed from the dead.
- 3 **The Anatomy Act 1984** regulates the conduct of an “*anatomical examination*” in circumstances where a deceased person has bequeathed his body for such a purpose. Such an examination is relevant here since it involves the removal of tissue in that an “*anatomical examination*” is defined (in s.1(1)) as “*the examination by dissection of a body . . . and where parts of a body are separated in the course of its anatomical examination . . . examination by dissection of parts.*” It should be noted:
  - a an examination under the Act must be carried out on licensed premises by someone licensed to do so (not, it seems, necessarily a registered medical practitioner) or by someone in “*the course of teaching or studying or researching*” (s.3(3)) who has permission from a licensed person; and
  - b if an anatomical examination is carried out in accordance with the terms of the Act, removal of tissue is lawful.
- 4 **The Coroners Act 1988.** By this Act, coroners, or, at their request, registered medical practitioners, are authorised to carry out post-mortem examinations. A necessary feature of such examinations is the removal of parts of the body if this is necessary to ascertain the cause of death.

### Removal of tissue from the dead : common law

- 7.12 These statutes do not cover all the circumstances in which tissue might be removed from a dead body: they address certain intended uses and stipulate what must be done if tissue **for those purposes** is to be removed. Is there any residual power **at common law** to remove tissue **for other purposes**?

- 7.13 There is certainly a range of criminal law offences which have been employed over the years to convict persons who have dealt ‘improperly’ with corpses. Older common law prosecutions were for “*exhuming corpses for indecent display*” or “*with intent to dissect*” and “*unlawfully and indecently mutilating corpses*”. More recent prosecutions have been for “*unlawfully removing a corpse from a grave*”, “*interfering with and offering indignities to the remains of a body*”, “*conspiracy to prevent burial*” and for “*preventing a burial and obstructing a coroner*”. In 1985 a clergyman was convicted of the common law offence of mutilating a corpse: for sexual gratification he had cut off the genitals of corpses awaiting burial in his chapel.<sup>13</sup> Clearly, in most of these cases, the defendants acted for “*improper purposes*”; although in one or two of them, even though the motives of the defendants were worthy, they were regarded as irrelevant.
- 7.14 Could it be argued, though, that the common law today might react differently if some conduct relating to a corpse was carried out for some “*good reason*”? There is no clear law on this point. It is open for the courts to accept that removal of parts of a body, outside the terms of the various statutes, can be justified at common law where such removal is for the advancement of the public good. This would be of importance, for example, in the case of tissue removed for retention in an archive: unless archiving can be regarded as “*teaching or studying or researching*” within the terms of s.3(3) and s.6 and of the Anatomy Act 1984 and its statutory regulations (and, on one reading of the Act it may be so regarded), it could be unlawful to remove tissue for these purposes in the absence of a common law justification. The same consideration would appear to apply to tissue banks. Another example may be the removal for examination of parts of the body by a pathologist during the course of a post-mortem examination requested by the deceased’s relatives (rather than ordered by a coroner). This matter is crucial in every situation when removal of tissue from the dead cannot be brought within the statutory language. Clarification of the law, or the acceptance of a common law justification, would be desirable. We have described in Chapter 6 how the scope of that justification might be delimited (paragraphs 6.13 – 6.16). Clearly, in any such clarification of the law, attention will have to be given to the need for consent by the deceased or next-of-kin. Bearing in mind the importance attached to consent in, for example, the Human Tissue Act 1961, it would undoubtedly be regarded as a requirement also at common law.

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<sup>13</sup> For a detailed and scholarly discussion of this area of law, see White, (1993) “An End to D-I-Y Cremation?” 33 *Med.Sci.Law* 151.