

Medical Law

Topic 9 (of 10): Organ Transplants.

Lectures 1 & 2 (of 2):

Regulating Organ Transplants under the Human Tissue Act 2004

Aim:

To note the unsatisfactory provisions of older Acts repealed by the HTA 2004 and to outline some of the most significant provisions of the 2004 Act.

Objectives:

After careful study of the following notes and the recommended readings for this topic, together with the enhancement and refinement of your knowledge and expertise resulting from your attendance at, and your contribution to, a student-centred learning and teaching forum, you should be able to:

1. Explain why the statutory regulation of organ transplants via the Human Tissue Act 1961 and the Human Organ Transplants act 1989 needed to be reformed;
2. Explain the importance of “appropriate consent” under the 2004 Act; and
3. Discuss significant provisions of, primarily, Parts 1 and 2 of the 2004 Act.

1. Organ Transplants under Repealed Legislation

Prior to the coming into force in April 2006 of the Human Tissue Act 2004, the statutes (now repealed) governing the regulation of organ transplants were:

- The *Human Tissue act 1961* – which regulated cadaveric transplants (transplants from ‘the dead’); and
- The *Human Organ Transplants Act 1989* – which regulated organ transplants from living donors.

(I): The Human Tissue Act 1961

The HTA 1961 was a badly drafted Act: it was imprecise and it did not provide for either civil or criminal action if an organ had been taken from a cadaver, who, during his lifetime, was not known to object to such a procedure, and transplanted, only for an objection to be raised by the deceased’s next of kin when they had knowledge of the transplant.

Imprecise Drafting of the 1961 Act

Whereas *s.1(1) & (2)* of the 1961 Act contained the principal provisions, they also contained the major points of uncertainty. *s.1(1)* provided that:

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in possession of his body after his death *may*, unless he has reason to believe that the request was subsequently withdrawn, authorise the removal from the body of any part or, as the case may be, the specified part, for use in accordance with the request.

Analysis of this sub-section reveals uncertainty over the meanings of:

I. The request made by the deceased person

Here, the basic principle was that a valid request was made by a legally competent person; i.e., one who, at the time of making the decision, was capable of understanding the broad terms of the nature of the procedure to be performed on him after a registered medical practitioner had confirmed that his (the cadaver's / the potential donor's) life was extinct. No age limit was specified below which a potential donor could not make a valid request. Accordingly, it appeared that a *Gillick competent minor*, i.e. one who is old enough and mature enough to be capable of understanding the nature of the procedure which may be performed on him after his death, was capable of making such a valid request.

II. The requirement for the request to be in the appropriate form

A couple of points of uncertainty related to the request having to be made 'either in writing ... or orally in the presence of two or more witnesses' were:

(a). Whether a pre-printed donor card came within the requirement for the request to be 'in writing'. The British Transplant Society took the view that this uncertainty could have been eliminated by the insertion of a new subsection that provided:

"For the avoidance of doubt in the interpretation of the section, it is hereby declared:

... that a printed but personally signed donor card or other document, is 'in writing' for the purpose of subsection 1 of this section."

(b). However, it should be noted that *s.20* of the *Interpretation Act 1889* stated that 'expressions referring to writing shall, unless the contrary intention appears, be construed as including references to printing ... and other modes of representing or reproducing words in a visible form'. (See also Sch.1 of the Interpretation Act 1978). Furthermore, the Ontario Court of Appeal had no problem in recognising the validity of the printed card containing the express prohibition in respect of blood transfusions in *Malette v Shulman* (1990). By analogy, it is submitted that it was difficult to see an objection to the validity of a pre-printed 'donor card' on the sole ground of it being in printed form.

As to the validity, or otherwise, of an *unsigned handwritten request*, *Skegg* was of the opinion that:

‘If the deceased had written out his request by hand, it would not necessarily invalidate a request expressed by the cadaveric donor, though authority for removal of the organ(s) then may be sought under *s.1(2) HTA 1961* and not *s.1(1)*’.

III. ‘The person lawfully in possession of [the] body [must have had no] reason to believe that the request was subsequently withdrawn ...’

A request could be withdrawn orally even if given in writing. If this possibility arose, then there was no requirement that it should have been made in the presence of two witnesses. However, it appeared that the withdrawal of the request would be effective only if it was communicated to the person who was lawfully in possession of the body.

[Further restrictions were placed on the person ‘lawfully in possession of the body’ by subsections (5) and (6) which prevented that person authorising the removal of parts of the cadaver when the coroner required the body for a post-mortem examination (5); or if the person was entrusted with the body for the purpose only of its interment or cremation (6)].

IV. ‘The person lawfully in possession of [the] body’ for the purpose of sub-sections (1) and (2) had been expressed to be the person with a right to possession of the body, i.e. the next of kin; or, alternatively, the person who had physical possession of the body. If the latter explanation is preferred, then, in practise, it would mean that if the deceased died in hospital the person ‘lawfully in possession of the body’ was the hospital administrative officer. *Mason & McCall Smith* noted that: This ... interpretation is supported by the wording of other sections of the Act [see *s.1(7)*] and is now widely accepted by the administration, the legal profession, and the British Medical Association but the point has not been tested in the courts’. Moreover, that the ‘person lawfully in possession’ of the body *may* ‘authorise the removal from the body of any part’ meant that there was no compulsion to do so. Indeed, permission may have been withheld even if it was contrary to the expressed wishes of the deceased.

In essence, *Davies*¹ summarised this sub-section by noting that: “The innate vagueness of many of the preconditions for the invocation of *s.1(1)* of the Act [wa]s exacerbated by the fact that there [was] no directly applicable case law that [could] be utilised. One ... therefore [had] to proceed carefully by way of legal analogy.”

Whereas *s.1(1)* focused on the authority of the person lawfully in possession of the body of a deceased person who ***had expressed a request that his body or part of it be used after his death***, *s.1(2)* focused on the authority of the person lawfully in possession of the body of a deceased person when it appeared that the deceased person had not expressed any ‘objection to his body being so dealt with after his death’ nor had certain relatives of the deceased objected to ‘the body being so dealt with.’

In full, *s.1(2)* provided that:

¹*Davies, M. Textbook on Medical Law.* London: Blackstone Press, 1998, p396.

Without prejudice to the foregoing subsection, the person lawfully in possession of the body of a deceased person may authorise the removal of 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-

- (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.

In relation to this sub-section, *Kennedy* (1991) noted that:

“The objections are many, but fall into two categories. First, from the legal point of view, the subsection is vague; for instance, it is not clear who is in lawful possession, or what ‘reasonable enquiry’ is, or how far ‘any surviving relative’ extends. Second, from a social-political viewpoint, the subsection embodies a policy, that of ‘contracting in’, which prejudices the living, but sick, in favour of the dead. Parliament has been made aware of these criticisms, but has not seen fit to act. The recommendations of the *Maclennan Committee* have gathered dust ever since [their] report appeared in 1969.”

With reference to the ‘social - political viewpoint’, an ‘opting in’ provision is regarded as one in which it is not possible to remove parts of a body unless the deceased had requested or indicated that parts of his body could be used for transplant purposes or at least he would not object to such use; whereas under an opting out scheme, parts of a body could be removed unless the deceased had requested or indicated that this should not be the case. *s.1(1)* and *(2)* are both characterised as ‘opting-in’ provisions. [There still tends to be debate as to whether this policy should be reversed and have an opting-out policy as in, e.g., Spain, Italy and Belgium].

According to *Skegg*, as to what constituted ‘such reasonable enquiry as may be practicable’, might have depended on whether the person lawfully in possession of a body was a hospital authority or a private individual. Both have limited resources, but the potentially greater limitations of the individual may have to have been given extra weight in determining whether ‘such reasonable enquiry as may be practicable’, had, in fact, been made.

With regard to the deceased *not having* ‘expressed an objection’ in *s.1(2)* there was no reason to suppose that the same criteria as specified in sub-section 1 applied. In *s.1(1)*, Parliament clearly specified ‘... in writing’ and ‘orally in the presence of two or more witnesses’. If the same criteria were applicable in sub-section 2 they could have been provided for.

As for ‘... the surviving spouse or any surviving relative of the deceased’ *Skegg* noted that:

“The Act d[id] not provide any definition of ‘relative’, but the separate reference to ‘any surviving spouse’ [lent] support to the view that in this context ‘relative’ [did] not include persons to whom the deceased was related only by marriage.”

Clearly, *s.1(2) HTA 1961* attached no rights to cohabitants who raised objections ‘to the body being so dealt with’.

However, probably the most remarkable observation of *s.1(2)* was made by *Skegg* who noted that apart from the provisions dealing with coroners' inquests and post-mortems (see: *s.1(5)*), *there was no recognised tort which would have created liability for unauthorised removal of tissue*; nor did there appear to have been anything but the most tenuous possibility of *criminal liability*. *Kennedy* described this as 'both a startling and a disturbing conclusion, and one which, if valid, should provide the stimulus to provoke Parliament into prompt consideration of the Act in all its aspects'. Until the Act and its provisions were repealed, however, *s.1(2)* remained the law.

{For what is now a matter of historical interest, only, see *Kennedy's* observations in: *Further Thoughts on Liability for Non-observance of the Provisions of the Human Tissue Act 1961*, Ch.11 in his book *Treat Me Right*. (Revised edition). Oxford: Clarendon Press 1991; and of the possibilities of actions in tort under 'nervous shock' and the slim possibilities of a criminal action for 'disobedience of a statute'}.

(II): The Human Organ Transplants Act 1989

In essence, the focus for objection to provisions of the 1989 Act was on the wholly unwarranted presumption that a commercial transaction between donor and recipient was in place unless there was a genetic relationship between them. Specifically, *s.2(1)(a)* prohibited *the removal* of an organ from the body of a living person not genetically related to the prospective donee; and *s.2(1)(b)* prohibited *the transplantation* of an organ from a living person who is not genetically related to the prospective donee. (The prohibitions of *s.2(1)* were subject to the provisions of *s.2(3)*). *s.2(2)* provided that:

(2) For the purposes of this section a person is genetically related to-

- (a) his natural parents and children;
- (b) his brothers and sisters of the whole or half blood;
- (c) the brothers and sisters of the whole or half blood of either of his natural parents;
- and
- (d) the natural children of his brothers and sisters of the whole or half blood or of the brothers and sisters of the whole or half blood of either of his natural parents;

but persons shall not in any particular case be treated as related in any of those ways unless the fact of the relationship has been established by such means as are specified by regulations made by the Secretary of State.

{See: *Human organ Transplants (Establishment of Relationship) Regulations 1989*}

As noted by *Price & Mackay (NLJ 27/9/91)*:

'The assumption ... seems to be that where the parties are not related within the terms of the statute, a *prima facie* presumption of financial gain is raised even in the absence of any actual evidence to that effect. Such persons, therefore, would seem to have to *prove their eligibility* to make and receive such a donation. (This requirement) seems to be unfair and unnecessary when applied to, say, spouses or even long-standing cohabitantes. Nevertheless, regulations made under *s.2(3)* provide the requirements to be met for organ donation from a donor genetically unrelated to the donee: *regulation 3 Human Organ Transplants (Unrelated Persons) Regulations 1989*'.

Ensuring Altruistic Donation, only: No Commercial Trading; and the Intervention of ULTRA

One of the principal aims of the 1989 Act was to make the commercialisation of organ donation a criminal offence (*s.I*), and it was thought that one way of outlawing such trade was by way of requiring a genetic relationship between donor and donee. However, it was also stated that there was no intention of preventing an individual who was unrelated to the prospective donee from donating an organ for altruistic purposes.

Organ donation from a living donor became subject to the approval of a Statutory Authority, the *Unrelated Live Transplant Regulatory Authority (ULTRA)*. This meant that both the donor and the donee had to be interviewed by a person approved by ULTRA; and that that person had to report to ULTRA any difficulties in communicating with, or obtaining consent from, the donor or donee. Furthermore, ULTRA had to be satisfied that no payment had or would be made in connection with the transplant and that the registered medical practitioner who had caused the matter to be referred to ULTRA has clinical responsibility for the donor: *regulation 3 Human Organ Transplants (Unrelated Persons) Regulations 1989*. Where any difficulties could not be surmounted, the transplantation would not proceed.

The unnecessary(?) prohibition of a commercial trade in organs

It may be contended that a prohibition on permitting autonomous person to buy or sell human organs for transplants is an unwarranted and unnecessary restriction. Indeed, in an article published in 2003², the authors expressed the opinion that:

There is a lot of hypocrisy about the ethics of buying and selling organs and indeed other body products and services – for example, surrogacy and gametes. What it usually means is that everyone is paid but the donor. The surgeons and medical team are paid, the transplant co-ordinator does not go unremunerated, and the recipient receives an important benefit in kind. Only the unfortunate and heroic donor is supposed to put up with the insult of no reward, to add to the injury of the operation.

{For further support for allowing commercial trade in organs see: (1998) *The Lancet*, 351; for a counter-argument, see the publications of Professor Alastair Campbell, written during his time as Professor of Ethics in Medicine at Bristol University.}

2. The ‘Organ Retention Scandals’ and more reasons for Reform

The perceived need for a change in the law became evident following the ‘organ retention scandals’ at Bristol Royal Infirmary and the Royal Liverpool Children’s Hospital at Alder Hey. For years, organs and tissue had been removed from children’s bodies on which post-mortems had been performed at the Bristol Royal Infirmary and used ‘.. for a variety of purposes, ... or had simply been stored’. Following the publication of the Kennedy Report

² *Erin, C* and *Harris, J*, ‘*An ethical market in human organs*’, (2003) 29 J Medical Ethics, p.137

on the Bristol inquiry, *Removal and Retention of Human Material*, it was reported that an even larger collection of children's hearts had been retained at *Alder Hey*. This led to another, separate, inquiry under the chairmanship of *Michael Redfern QC*.

The Redfern Report published details of what had become established practices of removing and retaining children's organs without consent or even any knowledge of the parents. This was compounded by withholding this information when the bodies of babies – minus many organs - were returned to the parents for burial.

Notwithstanding the value attached to the taking and retaining organs after post-mortem examination for specific and warranted research purposes, it was evident that the law was in urgent need of reform. Indeed, the Bristol Interim Report had noted that:

‘ ... we have no doubt that the complexity and obscurity of the current law will be manifest to all. Equally we have no doubt that there will be general agreement that this state of affairs is regrettable and in need of attention’.

That reform of the law was prompted more by the ‘organ retention scandals’ than by the perceived need to increase the number of organs harvested and save lives prompted Mason & Laurie to remark that ‘the 2004 Act was born under the wrong star’.

At least, the reforms brought in by the HTA 2004 gave prominence to the need for appropriate consent and such provisions were enacted in ss.1 to 3 of the Act.

Common issues in the harvesting of organs

Irrespective of whether organs are taken (or ‘harvested’) from cadavers or living donors they:

- a. Must overcome problems of tissue immunity;
- b. The organs must be ‘normal’; and
- c. The organs must be viable [viability being dependent on the time between removal of the organ from the donor to transplanting to the recipient].

Lecture 2:

{Lecture 1 covered:

1. Elements of two repealed Acts: (I) the HTA 1961; and (II) the HOTA 1989; and
2. The ‘Organ Retention Scandals’, leading to reasons for reform}.

This lecture focuses on the third and final part for this topic:

3. The Human Tissue Act 2004

The *Human Tissue Act 2004* is in three parts and has seven Schedules. Schedule 7 notes the statutes repealed by the HTA 2004, viz;

Human Tissue Act 2004

Schedule 7 REPEALS AND REVOCATIONS Part 1 REPEALS [abridged version]

Short title and chapter	Extent of repeal
Human Tissue Act 1961 (c. 54)	The whole Act.
Anatomy Act 1984 (c. 14)	The whole Act.
Corneal Tissue Act 1986 (c. 18)	The whole Act.
Human Organ Transplants Act 1989 (c. 31)	The whole Act.

Part 1 of the 2004 Act

Part 1 of the Act is principally concerned with consent – “*appropriate consent*”, as it is termed in the Act. Of the 12 sections in Part 1, **ss.1-4** are of the utmost importance.

ss.1-4 deal with:

- Activities that are lawful if done with appropriate consent (**s.1**);
- Interpreting “appropriate consent” in relation to activities involving the body, or material from the body, of a person *who is a child or has died as a child* (**s.2**);
- Interpreting “appropriate consent” in relation to activities involving the body, or material from the body, of a person *who is an adult or has died as an adult* (**s.3**);
- A person who may represent a deceased adult in relation to consent for the purposes of s.1; (**s.4**).

s.1 HTA 2004 in detail:

1 Authorisation of activities for scheduled purposes

- (1) The following activities shall be lawful *if done with appropriate consent* –
- (a) The storage of the body of a deceased person for use for a purpose specified in Schedule 1, other than anatomical examination;
 - (b) the use of the body of a deceased person for a purpose so specified, other than anatomical examination;
 - (c) the removal from the body of a deceased person, for the purpose specified in Schedule 1, of any relevant material of which the body consists or which it contains;
 - (d) the storage for use for a purpose specified in Part 1 of Schedule 1 of any relevant material which has come from a human body;
 - (e) the storage for use for a purpose specified in Part 2 of Schedule 1 of any relevant material which has come from the body of a deceased person;
 - (f) the use for a purpose specified in Part 1 of Schedule 1 of any relevant material which has come from a human body;
 - (g) the use for a purpose specified in Part 2 of Schedule 1 of any relevant material which has come for the body of a deceased person.

The ‘Appropriate consent’ of a child is provided for in s.2 HTA 2004, viz;

2 ‘Appropriate consent’: children

- (2) Subject to subsection (3), where the child concerned is alive, ‘appropriate consent’ means his consent.
- (3) Where –
- (a) the child concerned is alive,
 - (b) neither a decision of his to consent to the activity, nor a decision of his not to consent to it, is in force, and
 - (c) either he is not competent to deal with the issue of consent in relation to the activity, or though he is competent to deal with that issue, he fails to do so, ‘appropriate consent’ means the consent of a person who has parental responsibility for him.
- (7) Where the child concerned has died and the activity is not one to which subsection (5) applies, ‘appropriate consent’ means –
- (a) if a decision of his to consent to the activity, or a decision of his not to consent to it, was in force immediately before he died, his consent;
 - (b) if paragraph (a) does not apply –
 - (i) the consent of a person who has parental responsibility for him immediately before he died, the consent of a person who stood in a qualifying relationship to him at that time.

Thus, s.2 HTA 2004 provides clear, statutory authority for a ‘*Gillick competent*’ minor to consent to organ donation. Moreover, this is not qualified by the need for supplemental parental consent. This contrasts with the position at common law, where it had been said that:

It is inconceivable that [a doctor] should proceed in reliance solely upon the consent of an under-age patient, however ‘*Gillick competent*’, in the absence of supporting parental consent and equally inconceivable that he should proceed in the absence of the patient’s consent. In any event he will need to seek the opinions of other doctors and may be well advised to apply to the court for guidance ... (*per Lord Donaldson in Re W* (1992)).

The ‘Appropriate consent’ of an adult is provided for in **s.3 HTA 2004**, viz;

3 ‘Appropriate consent’: adults’

(2) where the person concerned is alive, ‘appropriate consent’ means his consent.

(3) where the person concerned has died and the activity is one to which subsection (4) applies, ‘appropriate consent’ means his consent in writing.

(5) Consent in writing for the purposes of subsection (3) is only valid if –

(a) it is signed by the person concerned in the presence of at least one witness who attests the signature,

(b) it is signed at the direction of the purpose concerned, in his presence and in the presence of at least one witness who attests the signature, or

(c) it is contained in a will of the person concerned made in accordance with the requirements of –

(i) section 9 of the Wills Act 1837 (c.26).

Of course, **s.3** does nothing to indicate if an organ can be taken from a mentally incapacitated adult. This is provided for under **s.6 HTA 2004** and **SI 2006/1659**, and such a patient may be deemed to consent to donate material from his body providing it is in his best interests to do so.

An example of an organ donation being deemed to be in the best interests of a mentally incapacitated patient in English law was provided in:

Re Y (Mental Patient: Bone Marrow Transplant) [1997] Fam 110

25-year-old Y, mentally and physically handicapped from birth, lived in a community home where she had been regularly visited by members of her family. Her mother's health was precarious and her older sister, P, who suffered from a serious illness, required a bone marrow transplant from a healthy compatible donor. By reason of her disabilities, Y was unaware of P’s illness and unable to consent to the operations required for a donation. P applied for declarations that they were lawful nonetheless.

Held, the declarations were granted. The operations were in Y’s best interests as they would tend to prolong the life of both P and the mother, and Y would receive emotional, psychological and social benefit, by way of continued regular visits, with minimal detriment to herself.

Decision-Making on behalf of the deceased

An adult who has not made a decision for himself, may, under **s.4**, nominate a representative to make a decision for him after his death; but failing that, a hierarchy of qualifying relationships is provided for in **s.27**, and this ranges from (a) a spouse, civil

partner or partner to (h) a friend of long standing. The provisions should provide the basis for decision-making that is more likely to reflect the wishes of the deceased rather the uncertainty attached to ‘the person lawfully in possession of the body’ (HTA 1961).

Offences

By contrast with the HTA 1961, criminal sanctions are provided for in the 2004 Act. Indeed, s.5 provides that:

s.5 Prohibition of activities without consent etc.

(1) A person commits an offence if, without appropriate consent, he does an activity to which subsection (1), (2) or (3) of section 1 applies, unless he reasonably believes—

- (a) that he does the activity with appropriate consent, or
- (b) that what he does is not an activity to which the subsection applies.

(7) A person guilty of an offence under this section shall be liable—

- (a) on summary conviction to a fine not exceeding the statutory maximum;
- (b) on conviction on indictment –
 - (i) to imprisonment for a term not exceeding 3 years, or
 - (ii) to a fine, or
 - (iii) to both.

See, also, s.33 for the possibility of an offence being committed (infra).

Part 2 of the 2004 Act

Part 2 of the Act, entitled: ‘Regulation of Activities Involving Human Tissue’, focuses on the creation of the **Human Tissue Authority** as a body corporate, the remit of the Authority and the regulatory system in general. Part 2 of the Act spans *ss.13-41*.

The principal provisions are:

- *ss.13-25*, relating to the *Human Tissue Authority*;
- *ss.26-29* on *Codes of Practice* [& note, in particular, the provisions of s.27];
- *s.32*, prohibiting commercial dealings in human material for transplantation; and

ss.33-34 on transplants. In particular, s.33 begins with the offence of removing ‘transplantable material’ from a living person for the purposes of transplantation unless the Human Tissue Authority is satisfied ‘that no reward has been or is to be given in contravention of section 32, ...’: **s.33(3)(a)(i)**

Part 3

Part 3 of the Act, i.e., *ss.42-61*, covers *Miscellaneous and General* provisions. Perhaps the most significant provisions for examination purposes are: *ss.43, 46* and *53*.

In more detail:

s.43 provides that it is lawful for (essentially) the management of a hospital to retain a cadaver (the body of a dead person) and preserve the organs in it which may be suitable for transplantation, while consent to the use of the organs is sought, provided that the preservation involves ‘the taking of the minimum steps necessary’ and use is made ‘of the least invasive procedure’: **s.43(2)**. Once consent has been refused, the authority to retain the body for the purpose of preserving the part(s) of the body shall cease.

s.46 provides the power to give effect to Community obligations. In essence, the immediate purpose of this section was to provide for the 2004 Act to be amended to accommodate the requirements of *EC Directive 2004/23* on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. **s.46** provides for any necessary amendments to be made by regulations.

s.53 defines the ‘relevant material’ that may be *removed* from a *cadaver* and *stored* and *used*; or which come from a *living donor* who has given “appropriate consent” and be *stored and used*.

References

Brazier, M and Cave, E. Medicine, Patients and the Law, 4/e. London: Penguin, 2007, Ch.s 18 and 19;

Mason, K & Laurie, G. Mason & McCall Smith’s Law and Medical Ethics, 7/e. Oxford: OUP, 2005, Ch.14;

McHale, J and Fox, M. Health Care Law: Text and Materials, 2/e. London: Sweet & Maxwell, 2007, Ch.15;

Pattinson, S. Medical Law and Ethics. London: Sweet & Maxwell, 2006, Ch.13;

Stauch, M, Wheat, K, and Tingle, J. Text, Cases & Materials on Medical Law, 3/e. London: Routledge-Cavendish, 2006, Ch.11.

Workshop / Potential Examination Questions

1. Critically evaluate the assertion that:

The *Human Tissue Act 2004* is “a broad piece of legislation. It governs the use of human material from both the dead and living subjects ... It also operates alongside the common law where applicable”.

(Quotation extracted from: *McHale & Fox, Health Care Law: Text and Materials, 2/e. London: Sweet & Maxwell, 2007, p1121.*)

2. To what extent, if at all, would you agree with the assertion that the issue of consent is at the essence of the Human Tissue Act 2004?