Published in final edited form as:

Med Law Int. 2006 ; 8(1): 1–21.

HUMAN TISSUE LEGISLATION AND MEDICAL PRACTICE: A BENEFIT OR A BURDEN?

SHEILA A.M. McLEAN,
University of Glasgow*

ALASTAIR CAMPBELL,
University of Bristol

KERRY GUTRIDGE, and
University of Bristol

HELEN HARPER
University of Glasgow

Abstract

The scandals surrounding organ removal and retention throughout the United Kingdom provoked several Inquiries and ultimately led to law reform. Although the medical professions were well represented at the Inquiries, little was heard of the voices of those at the ‘coal face’. In this scoping study, funded by the Wellcome Trust, we interviewed a number of doctors and others engaged in the uses of human tissue and organs to explore their hopes, concerns and fears about the role of the law in their practices. We found that those involved in transplantation were more aware of, and more actively involve with, the law, whereas others, such as pathologists, had less direct engagement with the law. Most of those we interviewed expressed the hope that law reform would provide much-needed clarity. Although some expressed concern that the law might be over-intrusive, most felt that the placing of authority firmly in the hands of the person him or her self to decide what should happen to their bodies was to be welcomed.

INTRODUCTION

The controversies that were exposed by the Inquiries in Bristol,¹ Alder Hey² and Scotland³ following discovery of the unauthorised removal and retention of organs at post-mortem examination raised a number of serious professional and ethical questions. However, they also raised some interesting legal ones. Most particularly, questions arose around the terms of the existing law, consideration of which also raises the further question of whether or not the law should interfere in medical practice in this area. It is relatively uncommon for legislation to intervene directly in the practice of medicine - one obvious exception being in the area of assisted reproduction⁴ - but early in the development of transplantation procedures it was felt appropriate to institute legal control over the purposes for which, and the circumstances in which, human tissue and/or organs could be used after death for transplantation and for the purpose of medical education and research. This took the form of the Human Tissue Act 1961. For 40 years healthcare professionals had worked with this piece of legislation, which the recent Inquiries have suggested was flawed, ambiguous and ultimately unhelpful.

The question as to whether or not statutory intervention is appropriate - while important - seems now to be largely theoretical in light of the responses from the Parliaments in Westminster and Edinburgh, both of which opted for the legislative route, passing the Human Tissue Act 2004 and the Human Tissue (Scotland) Act 2006 respectively. In addition, the storage and use of human tissue must now subscribe to the terms of the European Tissue Directive,⁵ although it should be noted that this Directive does not cover human organs. Like it or not, healthcare professionals who work with human organs and tissue remain subject to statutory requirements, albeit ones which have moved beyond the terms of the 1961 Act.

In a small project, funded by the Biomedical Ethics Panel of the Wellcome Trust, we interviewed a number of professionals - from both the transplant community and those who work with human organs and tissue for other purposes (such as pathologists) - in order to find out what were their experiences of the previous legal regime and what were their hopes/ fears/ expectations about the new regulatory framework. Some respondents to this study described the 1961 Act as vague, woolly and ambiguous. A prominent theme in relation to the new legislation then, perhaps unsurprisingly, was the importance of legislative clarity in relation to the future. The new legislative provisions - which will be considered in more depth later - drew clear lessons from the experiences in Bristol, Alder Hey and Scotland and sought to satisfy the concerns expressed by families, professional bodies and society as a whole.

Institutionally, the healthcare professions were well-represented in opinion forming at the time of the exposure of past practices, through membership of the various inquiries and through the evidence they submitted to them, but we were interested in what 'on the ground' professionals actually working with human organs and tissue felt about previous practices, the earlier legislative regime and their expectations of the new laws. Here, we set their views against the backdrop of the previous regime, the Inquiries themselves and the new legislation. For the purposes of this article, we will confine ourselves to the responses from the pathology and transplant communities. Although we interviewed other healthcare professionals (see below) their concerns were sometimes of a different nature, and these will be considered elsewhere.

It became clear early on in this project that this was an important effort. There is very little literature which focuses on health professionals' assessment of their experience of professional life in a legislative environment. There has been work that examines the attitudes of professionals regarding their clinical role, but not explicitly as to how this role is realised within a legislative framework. One such is work by Jenkins *et al.*⁶ who conducted a postal questionnaire study to establish pathologists' views about their professional relationship to clinicians and patients. Of the 773 pathologists who returned the questionnaire, all agreed that their primary role was diagnosis and emphasised their role as a clinician centred on patient care. The majority of these respondents associated themselves with practice rather than research. The study also concluded that there was an underlying concern amongst respondents that it is difficult to demonstrate the value of pathology in terms of its impact on clinical decision-making.

Bell *et al.*⁷ conducted a study examining the existing practice of diagnosing brainstem death amongst consultant anaesthetists. 157 consultants took part in this survey and every neurointensive care unit in the UK was represented. Respondents were sent a postal questionnaire containing open-ended questions. The authors identified a 'failure to apply existing [UK] guidelines accurately and a wide variation in practice where the recommendations are not specific.'⁸ This to an extent seems to mimic the findings of the

reports of the Bristol⁹ and the Alder Hey¹⁰ Inquiries. For example, the Interim Report from the Inquiry at Bristol noted that:

while the law was recognised as having some relevance, it was not clearly understood. This is hardly surprising. Pathologists are not lawyers and there was a distinct lack of authoritative legal expertise. As regards the specific issues which concern us, there was and remains little by way of guidance. It is no wonder that a kind of professional folklore developed which served the role of real law.¹¹

Perhaps even more worryingly, the Alder Hey report went one step further, saying:

We were surprised at the general ignorance of the medical profession concerning the provisions of the Human Tissue Act 1961. No doctor could remember having read it before preparing to give evidence to the inquiry.¹²

Lack of concern about, or awareness of, the law and/or professional guidelines may well have been a major contributor to the eventual suffering caused to families which was exposed in these Inquiries. Even the most basic rules as to which deaths required to be reported to the Coroner seem to have been poorly understood by the involved doctors at Alder Hey Hospital.¹³ Adequate training in the law therefore forms an important part of the recommendations of these Inquiries.

Before considering the responses of participants in our study it is important briefly to outline our methodology and sampling.

SAMPLE SIZE AND SELECTION

Interviewees were recruited from NHS hospitals in Bristol and Glasgow, following the obtaining of Ethics Committee approval. Both cities contain hospitals where professional practice was examined during the organ retention Inquiries. Sites were selected in England and Scotland to enable comparison between the different new legislative regimes.

Given that we aimed to examine the views of a range of professionals involved in different uses of human tissue and organs a random sample was deemed inappropriate. Respondents were therefore purposively sampled: each had specific insight into different aspects of work with human tissue and organs. Purposive sampling leads the researcher to “seek out groups, settings and individuals where ... the processes studied are most likely to occur.”¹⁴

Respondents were initially identified using organisational web pages (both NHS and University Web pages) and published reports. We were interested in interviewing personnel who were involved in the following activities:

- Practitioners involved in transplantation
- Pathologists and scientists working with tissue from living patients
- Pathologists and scientists working with tissue from deceased patients
- Professionals involved in medical education using human tissue
- Professionals involved in research using existing collections of tissue

Whether or not these individuals refused or agreed to take part, they were asked whether they knew of any other individuals who would be interested in taking part in the study. When asking for additional contacts, we emphasised the need for a broad range of professional interests. Given the relatively small number of pathologists and professionals involved in pathology and transplantation at each location we concluded that - despite using

the 'snowballing' approach - the sample is representative of the range of relevant professional interests which exist for the two geographical areas.

Approaching Interviewees

A total of 38 health care professionals were approached in Bristol and 28 in Glasgow. Potential respondents were sent a letter inviting them to take part in the project and an information sheet giving details of the study and how the interview data would be generated.

Response rates

Interviews were conducted with 15 professionals in Bristol and 17 in Glasgow. Table 1 and 2 show the response rates from the interviewees divided by specialism.

Reasons for refusal

Reasons given for refusing to take part were as follows:

19 failed to respond to the invitation

3 were too busy

1 found the subject "too complex and daunting"

1 felt the information was not relevant

2 had not had enough experience with the job

8 Cited previous negative experiences during inquiries into child organ retention which then dissuaded them from any involvement in studies into professional practice, albeit that this was academic research.

Anonymity and confidentiality

All data were anonymised: all names were removed from within the transcripts, and each respondent was given an identifying label. As discussed above, this study used purposive sampling to explore specific insights into a range of professional practices; in order for the resulting data and analysis to be meaningful, job titles were used to describe respondents. Retaining the job description and location of respondents therefore increased the chances of identification.

To address this issue, the invitation letter and information sheet stated that respondents would be given the opportunity to review their transcript, and delete any words or passages which they would not want quoted verbatim in the final report or any subsequent publications. This request was detailed on the consent form. If respondents did not choose this option, researchers ensured that they understood why that option was given to them, and were asked again at the end of the interview whether they had changed their mind.

16 of the 32 respondents requested the opportunity to review their transcripts. Out of the 9 respondents who returned the transcripts only one was substantially altered. The respondent changed the language used in parts of the transcript rather than the ideas expressed. It was concluded that these ideas were the essential outcome from the interview and so this transcript was included in the analysis.

It was decided that the respondents should be offered another opportunity to review their transcripts. This decision was made because a high number of respondents did not return their transcript. In addition, it was clear to the research team that a number of interviewees

who did not request to review their transcript were clearly identifiable. Letters were then sent to each of these groups, explaining that they could be identified and giving them another opportunity to examine their responses. This strategy was employed purely because the research team could not guarantee anonymity; however, we did not consider the data to be either sensitive or controversial.

Analysing interview data

All interviews were digitally recorded and fully transcribed. Transcripts were imported into NVivo®, a computer software programme which facilitates qualitative analysis. The analysis of interview data used tools associated with the 'grounded theory' approach to qualitative analysis, as described by Glaser and Strauss.¹⁵ This approach ensures that no preconceived analytical frameworks are imposed on the data; theory emerges through coding data, then examining the relationship between codes and exploring what conditions predetermine those relationships. In particular, grounded theory allows the researcher to trace the influence of particular phenomena, and the conditions which affect or predetermine any such influence. In doing so the patterns of interaction and the conditions affecting them can be identified and hypotheses generated.

We asked those who agreed to participate to explain their experiences under the previous legal regime, which is briefly outlined below. Although the Human Tissue Act is the main focus of what follows, it is worth bearing in mind that it was not the only piece of legislation with direct relevance to our respondents.

THE PAST

The Human Tissue Act 1961

This legislation, which applied throughout Great Britain, was passed at a time when transplantation was in its early stages. Its terms related to the removal of organs/tissue from cadavers for medical purposes, such as transplantation, research and education. It should be noted that the Act made no specific provisions about consent to post mortem examinations themselves; rather, it was concerned to deal with the use(s) to which removed organs could lawfully be put and with whose authority. Its most important provisions can be found in s.1, which states that:

1. If any person 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 the 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.
2. 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 purpose 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.

The Human Tissue Act 1961 applied both to hospital post mortems and cadaveric organ transplantation (this will be discussed later). Hospital post mortems are conducted by

pathologists for medical or scientific reasons at the request of the hospital. To conduct a hospital post mortem and to retain material after its conclusion the hospital needs to comply with the wishes of the deceased, establish the deceased's lack of objection to procedures by questioning a relative or to meet the test in s 1(2)(b) above. The purpose of the autopsy is to look for patterns of disease, co-morbidities and the impact of medical interventions and to evaluate procedures.¹⁶ It functions as part of the hospital audit cycle by providing a mechanism for checking ante-mortem diagnosis against post mortem findings. It was revealed in the *Inquiries* that a general permission for hospital autopsy was often taken as "carte blanche" to retain organs after the body was released for burial.¹⁷ Post mortem examinations may be undertaken either at the behest of legal authorities or on the initiative of doctors with the agreement of relatives. Hospital post mortem examinations are generally conducted in an effort to establish cause of death and have always required that consent is offered by appropriate persons - generally the nearest relative(s) of the deceased. 'Legal' post mortem examinations rest on a different authority and do not require the consent of the person concerned or their relatives.

The Coroner (England and Wales)

Human organs and tissue can be removed from the body as a result of a post mortem conducted in the public interest at the request of the coroner.¹⁸ Doctors issuing a death certificate must send a copy of this to the registrar, and in some cases it is necessary to notify the coroner so that an inquest may be held. Coronial post mortems are conducted to determine the cause of death and to check for irregular practice or unlawful error.¹⁹ The registrar is 'specifically obliged to inform the coroner of deaths that occur without the attendance of a doctor during the last illness, or during an operation, or while the effects of an anaesthetic persist.'²⁰ Coroners 'must hold an inquest where there are reasons to suspect that there has been a violent or unnatural death, or a sudden death due to an unknown cause.'²¹

The post mortem is usually completed by a pathologist acting as an agent for the coroner (specifically a forensic pathologist); however, other sub-specialisms within pathology are also involved in coronial autopsy, for example neuropathology. It has been stated that approximately 93% of post mortems are conducted on behalf of the coroner,²² and it should be noted that the events at Bristol Royal Infirmary and Alder Hey Children's Hospital mainly concerned coroners' post mortems.²³

Coroners' post mortems are governed by the Coroners' Act 1988, the Coroners' Rules 1984 and The Coroners (Amendment) Rules 2005. The Coroners' Act 1988 provides the statutory authority for the coroner to hold an inquest without consent. The Coroners (Amendment) Rules 2005 requires that '[a] pathologist shall make provision, so far as possible, for the preservation of material which in his opinion bears upon the cause of death or the identification of the deceased'²⁴ and permits retention of material until cause of death is established and the coroner's authority expires. After the completion of the inquest the use of human organs and tissue is governed by the Human Tissue Act 1961. The *Inquiries* highlighted confusion over the coroner's role in relation to long-term retention of tissue.²⁵ Human material was often retained after an inquiry was closed and there was usually no formal instruction from the coroner's office about disposal after post mortem. The Minister for Constitutional Affairs recently announced that changes will be made to the Coroners' Service, particularly in light of the deaths attributed to Dr Harold Shipman.²⁶

The Procurator Fiscal (Scotland)

In Scotland, responsibility for conducting inquiries into certain deaths rests with the Crown Office under the direction of the Lord Advocate. The officials who will normally instruct

post-mortem examinations are known as Procurators Fiscal. The Procurator Fiscal has a duty to investigate all sudden, suspicious, accidental, unexpected and unexplained deaths. S/he also has responsibility for investigating any deaths occurring in circumstances which give rise to serious public concern. Where a hospital doctor or GP is unable to determine the cause of death, he or she will report the death to the Procurator Fiscal. If the Fiscal decides that a post-mortem examination is necessary to determine the cause and circumstances of death, he or she can instruct the carrying out of that examination. The authorisation of the relatives is not required, and this distinguishes the Fiscal post-mortem examination from the hospital post-mortem examination. These post-mortem examinations are carried out by pathologists acting on the instructions of the Procurator Fiscal.²⁷ As in England, the majority of contested organ retentions related to Fiscal post mortem examinations, and some confusion about what was to be done with retained organs was also evident.

The Anatomy Act 1984 (England, Wales, Scotland)

This is of relevance only to the dissection of the human body for morphology. The unsavoury practices of some late 18th and early 19th century anatomists (dissecting unclaimed bodies of the poor and the mentally ill) led to the passing of the Anatomy Act 1832. Regulation of anatomy includes a requirement for whole bodies to be specifically bequeathed for use in medical education.²⁸ Bodies bequeathed under the Anatomy Act 1984 cannot be used for surgical skills training or for research.

The Corneal Tissue Act 1986 and Human Organ Transplants Act 1989 (England, Wales, Scotland)

These two statutes deal directly with other aspects of transplantation. The Corneal Tissue Act 1986 established that enucleation can be performed by suitably trained NHS staff who are not medical practitioners. The Human Organ Transplants Act 1989 covered live organ donation and was designed primarily to prevent commercial dealing in organs. The Act established that living donation should generally take place only between people who are genetically related, although permission for unrelated donation could be obtained from the Unrelated Live Transplants Regulatory Authority (ULTRA)

COMMON LAW

By default, the common law deals with all issues not covered in statute. This included the retention and use of tissue from living individuals (with the exception of certain aspects of transplantation which were covered by the Human Organ Transplants Act 1989). 'Ownership' of such tissue was also a subject of considerable interest to the Inquiries, especially in light of past practice. In pathology it was commonplace to archive tissue that was removed and retained initially for diagnosis without specifically informing the patient. Archived material usually takes the form of tissue fixed in paraffin blocks or on slides. Subsequent use of the tissue included medical education and audit. However, whatever the method or purpose, once retention of material from the living was considered the law became unclear. For example, it was not evident whether surplus tissue removed during surgery could be viewed as being abandoned,²⁹ belonging to the pathology department or still belonging to the patient.

There are rulings in common law which address whether there can be ownership of cadaveric human tissue. It is often stated that there is no property in a corpse. The Royal College of Pathologists has, however, indicated that slides and paraffin blocks can be fairly claimed as attracting property rights,³⁰ although in a judicial ruling³¹ it was established that preservation techniques (such as fixing in paraffin or chemicals) are insufficient for the exception to apply, since the alteration needs to be something which enhances value or

utility. In addition, it has been said that, following events at Alder Hey and Bristol '[i]t would take a peculiarly insensitive doctor to assert today that a pathologist had a possessory right to a part of a body over and above the right of a parent.'³² However, it is plausible that the uncertainty surrounding any property or quasi-property rights contributed to the practices which were ultimately to cause such distress to bereaved families. Indeed, in the case of *AB and others v Leeds Teaching Hospital NHS Trust and another*,³³ which concerned children's organs which had been removed without the consent of their parents, the claimants raised an action against the hospital Trusts and sought damages resulting from the nervous shock, or psychiatric injury, caused as a result.

A hospital post mortem was considered in this case to be one that is decided to be desirable by clinicians or relatives, '[t]he principal reason ... [being] that the relatives may know the cause of death and be advised of any points of significance arising from the cause of death.'³⁴ In this case the claimants contended first, that damages were due on the basis of unlawful interference with the bodies of their children. This is a tort not recognised in English law, although it is recognised in other countries such as Scotland, Canada and the USA.³⁵ To establish such a tort, it was submitted as being necessary that the claimant established a duty/right to 'possess the body of his or her deceased child' and that 'the defendant interfered with that duty/right by retaining and/or disposing of body parts without lawful authority.'³⁶ As to the first of these, the judge in this case indicated that 'the most appropriate place to start the analysis of the law is from the firm ground of a proposition which is not disputed. This is the principle that there is no property in the body of a deceased person.'³⁷ Nonetheless, the judge also accepted that parts of a body may become property 'by virtue of the application of skill, such as dissection or preservation techniques, for exhibition or teaching purposes ...'³⁸ In this case, the judge held that the 'work and skill applied to the parts of the body removed at the post-mortem is sufficient ... They are therefore capable of being subject to rights of possession.'³⁹

THE TRANSPLANT COMMUNITY

Almost without exception, difficulties facing respondents in the field of transplantation centred on the process of obtaining consent - for donation and use of tissue. The following interrelated issues impacted on these processes:

- changes in medicine, society and public expectations
- professional training
- the media and organ retention controversies

Professionals involved in all aspects of transplantation described a close link between legislation and their professional practice. For example, both a Consultant Anaesthetist and a Transplant Coordinator in Bristol described it as impacting "*all the time*" when carrying out their day-to-day work. A transplant surgeon in Glasgow echoed this view: "*I can't actually envisage practice without the law.*" In fact, their professional identity and development was sometimes characterised as inextricably linked with knowledge of relevant legislation.

In addition to describing the relationship between law and practice in more general terms, respondents in this community identified specific aspects of their practice which were affected by old and new legislation. Legislation was identified as having a role to play in:

- obtaining consent from families of deceased donors
- providing protection against external threats to professional integrity

Discussion around these aspects - particularly in relation to obtaining consent - concentrated on the shortcomings of the 1961 Act, and the predicted impact of new legislation.

Many respondents described the detrimental impact of shortcomings in the 1961 Act, and anticipated that new legislation might positively achieve the following:

- Public trust and confidence in transplantation (which in turn impacts on conversations with relatives)
- Using the term 'consent' in place of 'lack of objection'
- Establishing a hierarchy of representatives able to give consent
- Stipulating the primacy of donor wishes, whilst taking into account the views of relatives
- Establishing an 'opt out' system of voluntary consent to donation, instead of 'opt in'.

Clear legislation, taking account of these expectations, was identified by respondents as an important way to encourage and maintain public confidence in transplantation. Many respondents felt that public confidence in cadaveric transplantation had a clear impact on the relationship between professionals and relatives being asked to give consent. Specifically, a number of respondents took issue with the language of the 1961 Act, which required evidence of a 'lack of objection', stating that this language was confusing, could lead to misunderstanding and could ultimately stop transplantation from going ahead. A primary expectation of the new laws, therefore, was that this position would be clarified, thus enabling professionals and patients/relatives alike to be confident as to their legal position.

PATHOLOGISTS

While transplant coordinators and 'front-line' doctors seemed to be reasonably familiar with the law, and on balance valued its contribution for the clarity it could bring, others were less positive. For one pathologist, for example, the law was seen as an external threat to the beneficial use of human tissue, particularly in respect of cadaveric material. Another expressed the view that the law's impact would depend on the kind of pathology in which the doctor was engaged. There was also a perception that, as pathologists are further removed from patients than, say, transplant surgeons, the issue of obtaining consent did not directly impact on the pathologist, so that - presumably - changes in the law in this respect would not affect their practice. However, although there were some concerns that the new laws would have a negative impact (as the prior regime was seen as more flexible) it was also the case that practice had changed in anticipation of the new regulatory framework.

THE NEW REGIMES - HOPES AND FEARS

Broadly, the new legal regimes in England and in Scotland share some fundamental characteristics. Although the language employed is different (and this will be returned to later), each regime takes a clear and unequivocal approach to the rights of individuals and their next of kin. A valid agreement is therefore necessary for post mortem examinations which are not legally required, and the transplantation programme rests on the same basis. The anger and distress caused to families by not being actively engaged with the fate of parts of their loved one's body certainly seemed to mandate reinforcement of their role in removal and retention for research and other purposes. However, some had hoped that transplantation would be dealt with differently. Some commentators, and organisations like the British Medical Association,⁴⁰ favour a weak opting-out system, which would mean that organs could be harvested for transplantation unless an objection from the person him or herself was recorded, or relatives objected. This, it is suggested, would allow more organs to be harvested, thus enhancing the transplantation programme itself. In addition, transplantation was not implicated in the practices which formed the basis of the Inquiries,

and arguably - as no negative connotations clung to transplantation practice - it might have been possible to emphasise consent in the post mortem context, while at the same time making different provision for transplantation. However, given the limited availability of Parliamentary time, and the emphasis on the consensual use of organs and tissue removed at post mortem examination, the new laws conflated the two issues; the opting out system for transplantation was, therefore, doomed (at least for the present).

The outcome, then, is that both legislatures have enacted rules which require a conscious decision to agree to posthumous uses of the human body, except where a post mortem examination is required by law, and to donate organs or tissue. In England and Wales this is encapsulated in the traditional legal concept of consent. In respect of adults, 'appropriate consent' is described as:

(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.⁴¹

If the person has left no directions, consent may be offered by someone in an appropriate relationship to the deceased; either because s/he was nominated by the deceased or because they stand in a qualifying relationship to the deceased.

In the case of children, in England and Wales, 'appropriate consent' can be given by a child when alive to 'an activity involving the body, or material from the body, of a person who is a child or has died a child'.⁴² This will be subject to the competence test outlined in the Gillick case.⁴³

Where a child has died, '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 had parental responsibility for him immediately before he died, or
 - ii. where no person had parental responsibility for him immediately before he died, the consent of a person who stood in a qualifying relationship to him at that time.⁴⁴

In Scotland, the relevant concept is 'authorisation'; a term specifically selected by the Independent Review Group on Retention of Organs at Post-Mortem in relation to the parents of young children who are unable to agree on their own behalf. This term was chosen because, after consideration of both the evidence and the law, it was felt that the traditional concept of consent was inappropriate in the case of babies and young children and might be unduly burdensome for relatives. In law, the right of parents to consent to interventions is limited by the requirement that it be in their 'best interests'.⁴⁵ It seemed at best inelegant and at worst simply false to suggest that a post-mortem examination could be said to be in the 'best interests' of the child on whom it was performed, calling into doubt the legal standing of parental agreement. Second, a number of those giving evidence to the Review Group expressed a wish to be permitted to authorise intervention without being required to receive distressing information. Since the concept of consent generally requires the provision of information,⁴⁶ it might prove counter-productive to the ability of grieving parents (or other relatives) to act either altruistically or in the interests of other members of their family. 'Authorisation', therefore, seemed better to satisfy the reality of the request for permission to perform post-mortem examinations, and to avoid the need for the provision of

information that grieving relatives do not want to receive, while at the same time permitting any such relatives to allow the use of their child's body and organs. In extrapolating the concept to everyone (not just parents of young children) the Scottish Executive has extended its ambit to all individuals including adults (and relatives, where appropriate).

Under the terms of the Human Tissue (Scotland) Act,⁴⁷ adults may offer their own authorisation for specified uses of their body after death,⁴⁸ and their nearest relatives may also provide authorisation where no such declaration exists.⁴⁹

Children over the age of 12 can also authorise the removal of parts of their own bodies after their death for the purposes of transplantation, research, education or training or audit.⁵⁰ Where no such authorisation has been provided, 'a person who, immediately before the death, had parental rights and parental responsibilities in relation to the child (but who is not a local authority) may, subject to subsection (4), authorise removal and use of any part for one or more of the purposes referred to in section 3(1).'⁵¹

THE NEW REGIMES

It would seem, therefore, that clarity about who has authority to make a decision for those who cannot make their own has been achieved, but it will be interesting to see whether or not there is a real, as opposed to a perceived, difference between 'consent' and 'authorisation'. Although some respondents doubted that the difference would be real, by and large professionals on both sides of the border preferred the concept of authorisation, seeing it as being stronger than that of consent.

We have already seen that the 1961 Act had caused problems in situations where third party consent was sought (even if not legally required). The Scottish Inquiry was very clear that where a person is legally competent, his or her own views about the disposal of their body parts post mortem should be definitive. Even although some respondents were unclear about whether it would be right not to discuss this with parents/relatives, they broadly welcomed the clarity that this new approach could bring. In both jurisdictions, under the new legislation, a significant emphasis has been placed on the views of the individual him or her self, the only exception being where post-mortem examinations are required by the Coroner or Procurator Fiscal. In England, Wales and Northern Ireland no age limit is specified in the legislation, but the common law presumption presumably remains that a mature child can make his or her own decisions.⁵² The clarification of the legal rights of the mature child is a major step forward, both in respecting young people and also in assisting members of the healthcare team to understand their legal rights and responsibilities, although it might have been better had the age issue been directly tackled by the new law in England, Wales and Northern Ireland.

In both jurisdictions, the expressed views of adults will also be respected where body parts are desired or needed for the specified purposes. There is no legal need to identify the views of relatives where a declaration has been made in the approved form. Whether this will become common practice, however, remains to be seen. After all, this was, of course, technically the case under the prior legislation, but hopefully the clear restatement in the new law of this position will encourage doctors to act directly on the wishes of the deceased when these have been appropriately provided during life. One of the concerns of those of our respondents involved in transplantation, for example, was the difficulty of obtaining consent/authorisation at the time it was needed. It is obviously difficult to approach grieving families in the immediate aftermath of their bereavement to ask that they donate organs. The new regimes, with their emphasis on respecting the deceased's views, reinforce the fact that there is no need to ask relatives. These provisions were welcomed by respondents, some of

whom were concerned that, in the past, relatives might have been given the practical, if not legal, right to override the wishes of the individual.

Some participants expressed concern about the extent to which the new legislation might impact on medical research, and expressed their hope that this would be facilitated rather than impeded by the new regime. Again, the new laws seem to have satisfied this concern. Indeed, this is very much in line with the wishes of at least some of the families affected by the unauthorised removal and retention of body parts and tissues. Many of them expressed their firm support for medical research and were convinced of its importance. In Scotland, the provision that tissue blocks and slides become part of the medical record and can be used for legitimate purposes without requiring additional authorisation⁵³ may further assist in facilitating good quality medical research.

Further concerns were that the Human Tissue Authority (HTA) created by the Human Tissue Act 2004 might just become another layer of bureaucracy. For respondents in Scotland this may be less of a problem as its role is likely to be more limited given the terms of the Human Tissue (Scotland) Act 2006. Nonetheless, Scottish Ministers are empowered to 'make arrangements with a public authority in the United Kingdom for the authority to assist them (directly or indirectly) in relation to any of their functions....'⁵⁴ Since the 2006 Act repeals the Human Organ Transplants Act 1989 which covered live donation, '[b]y agreement with the Scottish Ministers, the HTA will have responsibility for approving all forms of living donation involving Scotland.'⁵⁵ In any case, it is not yet clear how intrusive the Human Tissue Authority will be.

CONCLUSION

In England, Wales and Northern Ireland implementation of the Human Tissue Act 2004 commenced in April 2006, and the transplantation provisions came into effect on 31 August 2006. The Human Tissue (Scotland) Bill was introduced to Parliament in June 2005 and was ratified in February 2006. It came into effect on 1st September 2006. The new laws repeal the Human Tissue Act 1961, the Human Organ Transplants Act 1989 and the Corneal Tissue Act 1986. The Anatomy Act 1984 is repealed in the Human Tissue Act 2004 and amended in the Scottish legislation.

Although the law reform has reached the statute books in England, Wales and Northern Ireland many fine details of the legislation have been left to the Human Tissue Authority.⁵⁶ The Authority, established in April 2005, has a remit that includes the preparation of codes of practice for professionals working with relevant material. It is expected that the details of the legislation will be fully elucidated within these codes of practice including details on storage, disposal of tissue and communication with the families of the deceased. At the time of writing, six codes of practice have received parliamentary approval (on 4 July 2006). These Codes relate to issues of consent, donation of organs, cells and tissues for transplantation, post mortem examination, anatomical examination, removal, storage and disposal of human organs and tissue and donation of bone marrow and peripheral stem cells for transplantation.⁵⁷

It is clear that the Inquiries conducted in various sites throughout the United Kingdom have had an impact on professionals involved with human tissue and organs, as have the media comments which followed them. Indeed, one - perhaps surprising - finding from our project was the extent to which the media featured as driving professional concerns and behaviour. When combined with European-driven controls on the use of human tissue, the new regimes seem likely to have a major impact on professional practice. Although some respondents were anxious about this, many craved the certainty which they hoped the new laws would

provide. This was particularly true of those involved in transplantation. The pathologists by and large saw the law as being less directly relevant to their practice, presumably because the process of obtaining consent/authorisation is often conducted at a distance from them. However, some pathologists did express concern that they might inadvertently act outside of the law and anxiety about possible legal liability in such circumstances.

The responses to our study highlight in some cases an interesting potential tension between professional practice and the law. As we have said, it is relatively unusual for the practice of medicine to be constrained by statute rather than the common law, but the state has a legitimate interest in the use of human bodies and their parts. In the case of post-mortem examinations, this interest flows from the benefits of accurate diagnosis, the interests of justice (in some cases), respect for the deceased and the benefits to be derived for society as a whole from medical research and education. In the case of transplantation, the very real benefits to member of society from a successful and efficient system also support state involvement. Unlike in other situations,⁵⁸ the law here is not regulating morality; rather it is seeking to facilitate these very real benefits, while at the same time clarifying the rights and responsibilities of those involved in working with human organs and tissue. One possible remaining problem, however, relates to the extent to which Coronial and Fiscal post mortem examinations are untouched by the new law. The Coroners review currently being undertaken may change this, as may the new guidance developed by the Crown Office in Scotland, but whether or not this will happen remains speculative. Yet, it was these post mortem examinations that generated most of the problems. While the issue of consent (authorisation) based uses of human organs and tissue has undoubtedly been clarified and reinforced, we must wait to see the outcome of revised practices in post mortem examinations where consent or authorisation is not required.

What is clear from our research is that those most closely involved with human tissue and organs had mixed views about the role of the law and its terms. While some felt that the law was threatening, and some that it was not directly relevant, others - most notably those involved in transplantation - were both aware of its terms and welcoming of the reforms, which strengthen and clarify the legal position. It is as yet unclear what will be the effect of law reform, and in particular whether or not the different regimes will result in divergent practices within the United Kingdom. However, it will be important to follow up this study to ascertain the experiences of the relevant professionals and, of course, the affected individuals and families. Laws which are unsuited to purpose, or which do not have the desired effect, serve little purpose, and may even be counter-productive, as we have seen with the Human Tissue Act 1961. It is to be hoped that the clear recognition of where authority appropriately lies in respect of the use of human tissue and organs that is found in both new Acts of Parliament will ensure that professionals, individuals and families can find the clarity they have sought.

NOTES

1. Bristol Inquiry Interim Report . Removal and retention of human material. 2000. The Bristol Royal Inquiry. Learning from Bristol: the Report of the Public Inquiry into Children's Heart Surgery at the Bristol Royal Infirmary 1984-1995. London: HMSO; Jul. 2001
2. The Royal Liverpool Children's Inquiry. London: HMSO; Jan. 2001
3. Independent Review Group on Retention of Organs at Post-Mortem. Final Report. Edinburgh: HMSO; Nov. 2001
4. Human Fertilisation and Embryology Act 1990.
5. Directive 2004/23/EC of the European Parliament and of the Council on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissue and cells (Tissue Directive).

6. Jenkins D, Philips Z, Grisaffii K, Whynes DK. The boundaries of cellular pathology: how pathologists see their clinical role. *Journal of Pathology*. 2002; 196(3):356–363. [PubMed: 11857501]
7. Bell MDD, Moss E, Murphy PG. Brainstem death testing in the UK - time for reappraisal? *British Journal of Anaesthesia*. 2004; 92(5):633–640. [PubMed: 15033886]
8. Bell MDD, Moss E, Murphy PG. Brainstem death testing in the UK - time for reappraisal? *British Journal of Anaesthesia*. 2004; 92(5):633–640. at p. 633. [PubMed: 15033886]
9. Bristol Inquiry Interim Report . Removal and retention of human material. 2000.
10. The Royal Liverpool Children's Inquiry. London: HMSO; Jan. 2001
11. Bristol Inquiry Interim Report . Removal and retention of human material. 2000. para 11B.58
12. The Royal Liverpool Children's Inquiry. London: HMSO; Jan. 2001 p. 361para 7.2
13. The Royal Liverpool Children's Inquiry. London: HMSO; Jan. 2001 p. 4para 10, Recommendations
14. Denzin, N.; Lincoln, Y., editors. *Handbook of Qualitative Research*. London: Sage Publications; 1994. , quoted in *Doing Qualitative Research: A Practical Handbook*. London: Sage; 2000. at p. 104
15. Glaser, B.; Strauss, A. *The discovery of grounded theory: strategies for qualitative research*. Chicago: Aldine; 1967.
16. MacLean M. Doctors, patients and the law - organ retention after paediatric cardiac surgery at the Bristol Royal Infirmary. *Child and Family Law Quarterly*. 2001; 13(4):399–404.
17. Brazier M. Human tissue retention. *Medico-Legal Journal*. 2004; 72(Pt 2):39–52. [PubMed: 15239573]
18. The Procurator Fiscal in Scotland.
19. MacLean M. Doctors, patients and the law - organ retention after paediatric cardiac surgery at the Bristol Royal infirmary. *Child and Family Law Quarterly*. 2001; 13(4):399–404.
20. Montgomery, J. *Health Care Law*. 2nd Ed. Oxford University Press; 2003. p. 481
21. Montgomery, J. *Health Care Law*. 2nd Ed. Oxford University Press; 2003. p. 481-482.
22. Brazier M. Human tissue retention. *Medico-Legal Journal*. 2004; 72(Pt 2):39–52. [PubMed: 15239573]
23. Liddell K, Hall A. Beyond Bristol and Alder Hey: The Future Regulation of Human Tissue. *Medical Law Review*. 2005; 13:170–223.
24. 3 (1).
25. Bauchner H, Vinci R. What have we learnt from the Alder Hey affair? That monitoring physicians' performance is necessary to ensure good practice. *British Medical Journal*. 2001; 322(7282):309–10. [PubMed: 11159638]
26. accessed on 28/06/06available at <http://news.bbc.co.uk/1/hi/uk/5068496.stm>
27. Taken from the Final Report of the Independent Review Group on the Retention of Organs at Post-Mortem Examination. Edinburgh: HMSO; 2003.
28. Jones DG. The use of human tissue: an insider's view. *New Zealand Bioethics Journal*. 2002; 3(2): 8–12. [PubMed: 15587492]
29. See, Nuffield Council on Bioethics. *Human Tissue: Ethical and Legal Issues*. London: Nuffield Council on Bioethics; Apr. 1995
30. Price D. From Cosmos and Damian to Van Velzen: the human tissue saga continues. *Medical Law Review*. 2003; 11(1):1–47. [PubMed: 14606471]
31. Dobson v. North Tyneside H.A. 1996. p. 4784 All E.R. 474
32. AB and others v Leeds Teaching Hospital NHS Trust and another. 2004. p. 17877 BMLR 145
33. AB and others v Leeds Teaching Hospital NHS Trust and another. 2004. 77 BMLR 145
34. AB and others v Leeds Teaching Hospital NHS Trust and another. 2004. p. 15477 BMLR 145
35. AB and others v Leeds Teaching Hospital NHS Trust and another. 2004. p. 17777 BMLR 145
36. AB and others v Leeds Teaching Hospital NHS Trust and another. 2004. p. 17777 BMLR 145
37. AB and others v Leeds Teaching Hospital NHS Trust and another. 2004. p. 17877 BMLR 145
38. R v Kelly. 1998. p. 15151 BMLR 142

39. R v Kelly. 1998. p. 18551 BMLR 142
40. British Medical Association. Medical Ethics Today. 2nd Ed. London: BMJ Publishing; 2004. p. 434
41. Human Tissue Act 2004 s. 3.
42. Human Tissue Act 2004 s. 2(1) and s 2 (2)
43. Gillick v West Norfolk and Wisbech Area Health Authority. 3 All ER 402.
44. Human Tissue Act 2004 s. 2(7)
45. Gillick v West Norfolk and Wisbech Area Health Authority. 3 All ER 402
46. see, McLean, SAM. A Patient's Right to Know. Dartmouth: Aldershot; 1989.
47. which came into effect on 1 September 2006.
48. Human Tissue (Scotland) Act 2006, s 6
49. Human Tissue (Scotland) Act 2006 s. 7.
50. Human Tissue (Scotland) Act 2006 s.8.
51. Human Tissue (Scotland) Act 2006 s.9.
52. This is specifically mentioned in the explanatory notes to the Act, available at <http://www.opsi.gov.uk/acts/en2004/2004en30.htm> (accessed on 12/07/06); see also the case of *Gillick*, *supra cit*, which established that competent young people can make their own decisions
53. Human Tissue (Scotland) Act 2006 s. 38
54. Human Tissue (Scotland) Act 2006 s. 54.
55. accessed on 04/08/06 Available at http://www.hta.gov.uk/guidance/codes_of_practice.cfm
56. Human Tissue Act 2004 ss. 13-15
57. accessed on 01/09/2006 Available at http://www.hta.gov.uk/guidance/codes_of_practice.cfm
58. For example, in the area of assisted reproduction.

Table 1

Response Rates Bristol

Profession	Interview requested	Accepted	Refused
Pathologists	11	5	6
Transplant	24	7	17
Anatomists	2	2	0
Research *	1	1	0
Total	38	15	23

* Those individuals identified as researchers worked in academic departments or biobanks. The sample includes 2 academic researchers, a biobank research nurse and a biobank manager

Table 2

Response Rates Glasgow

Profession	Interview requested	Accepted	Refused
Pathologists	15	8	7
Transplant	10	6	4
Anatomists Research *	3	3	0
Total	28	17	11

* Those individuals identified as researchers worked in academic departments or biobanks. The sample includes 2 academic researchers, a biobank research nurse and a biobank manager