

## **TITLE**

Why Does It Matter How We Regulate the Use of Human Body Parts?

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## INTRODUCTION

Human tissue and body parts have been used in one way or another for millennia. They have been preserved and displayed, both in museums and public shows. From gross anatomical studies to research at the cellular level, they have been minutely examined to reveal how the human body works. In Roy Porter's words

... the western medical tradition explains sickness principally in terms of the body itself ... and from the Renaissance the flourishing anatomical and physiological programmes created a new confidence among researchers that everything that needed to be known could essentially be discovered by probing more deeply and ever more minutely into the flesh.[1]

Real human hair is used for wigs, while some artists even use human tissue in their works. Blood, bone marrow, whole organs and a host of other structures and human substances are all transplanted into living persons to treat illness. New life can be created from gametes through IVF, while the creation of cell lines keeps tissue alive indefinitely.

These uses create significant challenges for the legal system in the United Kingdom. Some, such as research and transplantation use have been addressed through a consent-based legislative scheme, while others, like the sale of human hair fall outside the regulatory framework. That framework also operates alongside a developing body of case law that has taken a quite different approach to regulation, namely by increasingly applying property principles to detached human tissue and body parts. Up until the 20<sup>th</sup> century, the human corpse and its parts (and arguably those taken from the living) could not be legally owned, but this changed with the decision in *Doodeward v Spence*, that allowed for limited possessory rights to arise if tissue was preserved through the lawful application of work and skill.[2] In 2009, the law shifted further towards accepting a property approach, with the English Court of Appeal in *Yearworth v North Bristol NHS Trust* finding that six men whose sperm had been negligently destroyed held sufficient proprietary rights to found a claim based on a bailment arrangement.[3]

The major challenge for the law is to balance the competing demands of those groups who have vested interests in human tissue—researchers, medical practitioners, patients, families, the community, and the police, amongst many others. It must provide sufficient control to users of tissue, but also take account of the fact that our bodies hold psychological, social and emotional importance for us while we live and, after we die, for those we leave behind. To some degree the law has been successful, but we still lack a comprehensive, coherent approach to the regulation of human tissue. Partially as a reaction to this lack of a wholly comprehensive approach, some commentators have turned in some cases to the idea of applying the concept of property to human tissue. For some, such an approach is also a means to achieve regulatory outcomes they support.

The papers in this issue explore the application of property principles to human tissue and body parts. In this paper, I contextualise the debate by outlining in more detail the

ways we use human tissue, the interests people have in it and the conflicts that arise as a result. In doing so, I draw out some of the ethical issues that must inform debate over the regulation of human tissue to ensure that we arrive at an ethically defensible regulatory framework.

## **TYPES OF TISSUE**

Not all tissue has the same qualities, and this affects the issues raised by its use. Some tissue yields more information than other tissue. Compare a sufficiently large blood sample used for pathology testing that yields much information with a fingernail clipping or hair without a follicle, which yields relatively little.

Biologically active tissue has different uses to non-active tissue. Cells kept alive in culture are active and have much wider uses than non-active preserve tissue like slides of brain matter. Gametes are active, and can in combination create new life through IVF. A living organ can be transplanted and become part of other person, while a non-viable one can only be preserved and observed.

## **HOW DO WE USE HUMAN TISSUE AND BODY PARTS?**

### **Education and Training**

One highly important use of human tissue is in education and training of medical practitioners and researchers. The study of gross anatomy has been an integral part of medical training for nearly two centuries. Many institutions teach anatomy through dissection of cadavers. In England and Wales, bodies for anatomy training are obtained through consensual donation, regulated through the Human Tissue Act 2004 (the Human Tissue (Scotland) Act 2006 applies to Scotland in these and other tissue regulation areas). Students studying to become medical practitioners and researchers also need access to all kinds of tissue as part of their studies.

### **Research**

It is almost trite to state that human tissue is a crucial input into medical research. Scientists have examined tissue, from large structures to tiny cells, for centuries. By the 1980s, human tissue use was ubiquitous in medical research; in a United States survey during this decade, more than half the responding medical schools replied that they used human tissue for research,[4] and use has continually expanded since this time. Human tissue research has led to profound benefits for society. For example, the analysis of autopsied lung tissue taken from smokers assisted in establishing tobacco smoking as a cause of lung cancer. Studies of vaginal tissue samples containing precancerous lesions led to the routine use of cervical smears and consequently earlier diagnosis and treatment of cervical cancer. A simple search of PubMed will yield tens of thousands of current research projects that employ human tissue samples, from tumours to blood to skin to nerve tissue, using tissue to learn more about its structure, its workings, how the body responds to a particular drug, how disease works and the myriad other crucial questions that we must answer to continue building the body of medical knowledge.

Sometimes researchers obtain samples through links with clinicians, particularly in hospitals with research facilities. Samples taken for pathology testing also find their way into research and tissue banks. To further facilitate research, there has been an increasing move to create large research 'banks' of tissue. A good example is BioBank UK, which holds tissue samples of various kinds from around half a million people, as well as large amounts of medical information. Researchers are granted access for a wide variety of projects under BioBank's Human Tissue Authority licence. Any residual sample after the research is complete must be destroyed or returned to BioBank; they may not be transferred to third party premises without approval.

## **Treatment and Transplantation**

Whole organ donation is a well-known use of tissue as a treatment. Other bodily structures, such as corneas, heart valves, lobes of lung and skin are all transplanted to improve a patient's health. In some cases, cord blood is used to produce therapeutic substances that can help to treat some blood cancers. Similarly, the urine of menopausal women is used as a source of human chorion gonadotrophin, which may have a role in the treatment of AIDS-related Kaposi's Sarcoma,[5] while Factor VIII, an essential blood clotting protein used in the treatment of haemophilia, is derived from fractioning human blood plasma. Organ and tissue donations may be made during life or after death.

As medical science develops, the use of both embryonic and adult stem cells may also offer hope for treatments. One example is their use in the treatment of spinal cord injuries, currently under development by Geron Corp. However, as yet no embryonic stem cell treatments have been approved for widespread application.[6] Recent successes with growing replacement tracheas are a good example of how adult stem cells have been used to have a profound impact on treatment options.[7]

## **Information**

Particularly since a series of scientific breakthroughs in the 1950s, we have been able to use human tissue to discover a considerable amount of information about the person from whom it was taken (and his relatives). Tissue analysis is a fundamental part of pathology testing, which itself is one of the vital means by which medical practitioners make diagnoses. A good example is testing of blood taken by heel prick from newborns shortly after birth to detect conditions such as phenylketonuria, a genetic disorder that leads to progressive mental retardation if left untreated. The analysis of genetic material can be used to diagnose inherited disorders both currently experienced as well as those that may manifest later in life. Such analysis can also yield information about an individual's predisposition to certain diseases, while carriers of genetic mutations that can be passed to offspring and potentially result in disease can also be detected through similar analysis.

Very often, this information is generated in a medical context to aid in diagnosis and treatment or to inform reproductive decision-making. However, this information can be used in other contexts, or tissue itself can be used specifically to generate information for such non-medical purposes. Obvious uses include testing for paternity and forensic use, but the information in tissue might also be of interest to insurers and employers.

## Commercial Dealings

Some tissue is used, supplied, or stored for commercial purposes. Some private research ventures use tissue to undertake research, test products and produce therapeutics. Commercial tissue banks operate to supply researchers with specific types of tissue for research, which are processed and ready for use and supplied at a price. Some firms will perform tissue-based tests for researchers and then report the results. For example, United Kingdom company Bioptra offers drug testing services on its own collection of human tissue culture systems.[8] Biopharmaceutical company Crucell will licence its 'PER.C6' cell lines to researchers and companies. Licencees are provided with these cells for the establishment of new cell lines, which can then be used in research and the production of therapeutic substances.[9]

A relatively recent way in which commercial entities have found a way to exploit tissue is the collection and storage of cord blood. 'Cord blood' refers to blood collected from the umbilical cord just after a baby is born. It is rich in stem cells, including hematopoietic stem cells, which are multipotent stem cells from which all blood cell types develop. Since the late 1980s cord blood has become useful in treating some conditions that affect the immune system and blood production.[10, 11] It may also be valuable for treating a wider range of conditions if current research into regenerative medicine comes to fruition, and of course until that time access to the blood is crucial for research.[12–15]

Cord blood is banked publically and distributed along the same principles as organs and tissue for transplant, but private storage services also collect and store umbilical blood, keeping it available for the storing party if their child or family needs it for treatment. Such blood is demonstrably valuable to many parties—the child, the family and the commercial bank. These operate alongside publically maintained cord blood banks to which individuals donate altruistically and which make blood available on the basis of need. Private banks capitalise on the unique characteristic of cord blood—that, like organs and bone marrow, it is most effective as a treatment if obtained from a matched donor. Clearly, if one were to fall ill with a condition for which cord blood was a treatment, a supply from one's own birth or that of a close relation could be highly beneficial. Further, if current research in regenerative medicine produces treatments for other conditions in the future, then such a supply will only increase in value.

## 'Miscellaneous Other'

Research and medicine are the major contexts in which tissue is used, but there are other, sometimes more esoteric uses to which tissue is put. In the case of *R v Kelly*, [16] the artist Noel Kelly used dissected body parts as part of his creative process, while Mark Quinn, also an artist, forms huge sculptures of his head using his own blood, titled *Self*. He makes a new sculpture every five years. The first *Self* was originally displayed in the Saatchi Gallery in London. The most recent *Self* was bought by the National Portrait Gallery for £300,000.[17]

Quite a different use of tissue is the creation of wigs from real human hair. One can in fact purchase hair extensions online. For example, the online store *HairTrade* will sell you an "I&K Human Hair Silky Weave (LIGHTEST BLONDE)" made from "Grade A" human hair at a price of £41 (incl. VAT) for 14 inches.

In both these examples, there is a commercial dimension to the use of tissue, with both seller and purchaser having an interest in the transaction, as well as the person from whom the tissue was originally obtained. In the case of Quinn, they are one and the same, but for the sale of hair, a third party intermediary is involved.

## **WHO HAS AN INTEREST IN HUMAN TISSUE AND BODY PARTS?**

What makes human tissue and organs particularly difficult to regulate is that they have different significances depending on the type of tissue, how it is used, from whom it is taken and why. People have very complicated interests in tissue, and the intersection of these interests can itself be tremendously complex. It is well beyond the scope of this paper to explore these interests and intersections on much depth, but it will briefly outline the major interests in tissue here and then draw out some of the intersections in the context of the tissue uses described below.

### **Individuals**

First, and most obviously, individuals have a range of interests in what is done with their tissue, body parts and organs once removed. We gain health benefits from diagnosis via tissue testing, as well as from treatments derived from tissue or from transplanted organs. Medical research using tissue leads to better understanding of disease, which also improves our health outcomes. We therefore have an interest in our tissue, as well as that of others, being put to good use in research. In the case of gametes, individual's reproductive interests are engaged, and like the men in the case of *Yearworth*, they may suffer serious psychological injury if these interests are adversely affected, quite apart from the ongoing impact on their lives some misuses may have. Given the informational content of tissue, individuals have an interest in protecting their privacy.

Some people also have a profound interest in how their bodies are dealt with after death, and their parts while living. This sensitivity derives from the emotional significance of the body for their sense of self-identity, as well as beliefs about the relationship of the physical body to the notion of 'self'.<sup>[18]</sup> People exist as a unified mind and body, but while life, as C Don Keyes states, 'is defined in terms of brain function' body image and the integrity of that image are vitally important to the mental life.<sup>[19]</sup> Empirical studies have demonstrated that external aspects of the body like hair, eyes, hands, legs play an important part in defining and maintaining a person's sense of self.<sup>[20]</sup> This extends even to how we respond to the bodies of others, even strangers. For example, medical students studying anatomical dissection also report that some body parts have stronger significance and have stronger emotional effects. For example, one stated that 'I stared at the eyes and forgot to cut...I was lost'; another that cutting the face of a cadaver felt like 'ripping somebody's self'.<sup>[21]</sup> This dimension to the significance of tissue is reflected in social mores that demand tissue, body parts and corpses are treated with respect both in life and after death. Individuals may also hold religious beliefs that lead them to want their tissue and body to be treated in particular ways. In many religions, it is important that the body is buried whole. As Margaret Brazier has explained, the failure to respect such beliefs can cause the holder of them pain which is 'acute and

life-destroying' and so arguably carry significant moral weight when we consider how we ought to treat tissue.[22]

Given all of these reasons why how we treat human tissue can have such profound impacts on an individual, we very likely have an interest in our tissue *not* being used, even if it is for beneficial purposes, because we find that particular use objectionable, or simply that use of our tissue in and of itself offends us in a subjective way.

## **Family Members**

Family members have varied interests in the tissue of their relatives. When someone dies and the cause is not clear, an autopsy can bring closure and peace of mind. In some situations, a family member may need access to a relative's tissue to aid in their own diagnosis, particularly when suffering from an inherited genetic condition. In other situations, like those in the cases of *Dobson v North Tyneside Health Authority* and *Roche v Douglas*, families may want access to legal purposes such as to use as evidence in support of a claim.[23, 24]

Relatives left behind after a family member dies may also invest the tissue, parts and entire body of their loved one, with significance. The statements of parents whose children's organs had been retained at Alder Hey provide stark, heart-rending evidence of the emotional and psychological importance these body parts to family members. One parent stated 'I feel that B is not complete and therefore not in heaven. I feel as [as though] my daughter is not at peace', another that '[as] a Catholic I believe all children go to heaven and grow up there, this cannot be so for my daughter ... having been robbed of her heart. I [believe] she ... won't rest until her heart, organs are interred with the rest of her body'.[25]

## **Community**

As a collective of such individuals, the community shares some of these interests. As a society we place value on ensuring bodies and body parts are treated with respect. Across cultures, the human corpse has almost always held an important place in death rites, as a means to express this respect. Some, such as Thomas Murray, also point to the binding effect of altruistic donations of tissue on us as a community. By giving of our bodies to one another, we affirm the ties that hold us together as a society. As Murray has put it, '[g]ifts of the body are one of the most significant means that mass societies have to affirm the solidarity, or community, that humans need in order to mature and to flourish as individuals'.[26] Similarly, Renée Fox and Judith Swazey argued in 1978 that in fact 'the giving and receiving of a gift of enormous value...is the most significant meaning of organ transplantation'.[27]

Additionally, we benefit collectively from medical research when it results in better health across the community. Those museums who resisted repatriation of indigenous remains further pointed to the community's educational benefits from their collected displays. It might also be said that the community has an interest in the cultural uses of tissue, as in the *BodyWorlds* exhibition created by Gunter von Hagens and the artistic works of Mark Quinn. Artists such as Quinn therefore have an interest themselves in access to tissue for their work.

## **Researchers**

Many medical researchers use tissue in their work. They have interests in access and also in the security of the samples they use. Much work would be undermined if tissue could be arbitrarily withdrawn from research use. Medical Practitioners not only use tissue to obtain information about patients and to treat them, they also use stored tissue for clinical audits and training purposes. Many doctors will study anatomy through the dissection of donated cadavers.

## **The State**

Some organs of the state also have an interest in bodies. The coroner investigates cause of death through post-mortem examination of a body, which can benefit the family as well as the community. Similarly, forensic use of tissue by police investigators can aid in apprehending criminals, which protects both individuals and the community.

## **Indigenous Groups**

For some indigenous groups, human bodies and their parts have special significance and the community as a whole is affected by the mistreatment of remains. For example, in Australia, the Aboriginal community has a deeply spiritual interest in the remains of its ancestors and it is profoundly important that the remains of its members be treated with proper respect.

Cultural and indigenous groups sometimes also have an interest in research because its wider implications will affect them either directly or indirectly. As one example, one of the major objections made by such groups to the Human Genome Diversity Project was that it would potentially enable the Western researchers to rewrite their histories and violate cultural beliefs. As a member of the Lakota tribe, a Sioux tribe of the Great Plains of the United States, stated, 'we never asked science to make a determination as to our origins'.[28] The experience of the Native American Havasupai tribe of Arizona is a telling example. They claimed in 2004 that 4,000 samples provided for diabetes research by the tribe were used in studies on inbreeding and schizophrenia, which they allege violated their religious beliefs and led to their members experiencing stigmatization. The Havasupai claim they would not have consented to the research had they known their samples would be used for these purposes, and have brought a \$50 million claim against the Arizona Board of Regents of the Arizona State University for the emotional distress and trauma caused by the alleged misuse.[29] Indigenous groups may therefore have an interest in maintaining control over the fate of their tissue.

## **Commercial Organisations**

Commercial organisations have interests in human tissue in a variety of contexts, and their obvious interest is in the generation of profits from their dealings with it. They need to protect their investments and, in the case of public companies, provide a return to their shareholders. In many cases, the community benefits to some degree from the commercial use of tissue, for without investment from the private sector many drugs and therapeutics would not have been developed and would not be available for treatment.



## WHY MUST WE REGULATE: THE CLASH OF INTERESTS

It becomes apparent when we tease out the varied interests in tissue that in many cases they are potentially in conflict with one another. Where such conflicts arise, the law has a role to play in determining how tissue should be used and how the adverse implications of these conflicts can be minimised. The areas of potential conflict are many; here we will examine just a few to give context to the discussions in the papers later in this issue.

### Research Use and Individual Control

In the context of research, the potential conflict of interests lies between the individual whose tissue is used, and the researcher who uses it. If the research leads to downstream products, such as tests, the individual might have an interest in the commercialisation of the research results and so their interests may clash with those of the patent-holder (the *Moore* and *Greenberg* cases are examples of such conflicts.[30, 31] In both, the researchers had patented the results of research using tissue samples, to which the suppliers of that tissue subsequently objected). In the very great majority of cases, no profit is made from medical research using tissue; most tissue is used in publicly funded primary research. Product development and patenting occur much further downstream and result usually from many years of research on the part of huge numbers of researchers that is built upon by commercial ventures such as pharmaceutical companies.

In the England and Wales the Human Tissue Act does much to regulate the interaction between donors of tissue and researchers. The Act takes a consent-focused approach, requiring researchers to obtain consent for many uses to which tissue is put. An exception is made in some cases for research for which ethical approval has been obtained and the tissue is anonymised.[32] This approach is arguably justified on the basis that the ethics committee that considers the application will have considered the ethical concerns raised by the use of the tissue without consent and determined that the research is still justified or that the concerns can be adequately addressed.

For the most part, the consent model adopted by the Human Tissue Act enables the individual to determine how his or her tissue is used, and to withdraw it from research if they no longer wish to take part. In this way, individuals have a large amount of control over their tissue and their interests are fairly well protected. Similarly, the need for ethics committee approval and de-identification in cases where there are privacy concerns can also deal with many potential concerns about protecting an individual's information.

Five years ago, the Washington University biorepository that was the subject of litigation in *Washington University v Catalona*. [33, 34] The biorepository held samples of blood, prostate tissue and DNA that had been donated for research into prostate cancer, and came mostly from patients being treated for the disease.[27] The samples were used in research studies both at Washington University and other institutions, sometimes being transferred in accordance with a Materials Transfer Agreement (MTA). In that case, conflict arose over who had the right to control the use of the stored samples—the university or William Catalona, the researcher who

had been instrumental in establishing and maintaining the collection. Such a collection of samples taken from a large cohort of patients suffering the same disease and on whom useful information was held is a tremendously valuable research tool that could not be easily replicated.

The conflict here was over who had control of the tissue—Catalona or the university—and what that control meant. Who could control access? Who could transfer the collection elsewhere? Effectively, who stood in the position of owner? The factor that sets the *Catalona* situation apart and raises questions to be addressed in the use of tissue is the involvement of the donors. The repository was created with the assistance of many donors, and when Catalona was denied control over the resource (he wanted to move it to another institution), he directly involved the donors in the dispute by asking their consent to move their samples. When the matter came to court, one of the issues was whether the donors still had a say in how their tissue was used.

The court found that while they retained certain rights, such as to withdraw it from research use, they did not have the right to direct that the tissue be moved to another institution. Many of the donors felt they had donated their tissue to Catalona, rather than the university or for research generally, but the terms of their consent were interpreted as a donation to the university. Their latterly expressed wishes about what was done with their tissue were therefore not followed. The court appeared to be concerned to protect the security of such collections and to promote research, which would be undermined if individuals could exert this kind of control over their tissue. The result, therefore, was that the interests on individuals were subordinated to those of research.

Depending on how much value is placed on protecting their autonomy, we might see this decision as deeply concerning, particularly given the significances of bodily tissue noted above. Alternatively, we might say that here the men's welfare were not adversely affected by the court's decision and that the tissue in this case did not have such significances—it was different to the hearts and brains retained at Alder Hey, and was not of the kind that persons find it offensive to be retained. For example, John Harris has commented:

Consider that toilet-paper, soiled bandages, plasters and 'band-aids', not to mention hospital 'sharps' (needles and blades etc) all have human blood and tissue and hence the whole genome attached and are usually discarded and disposed of without any clamour for respect and reverence.[35]

The same can probably be said of small samples of tissue, but this may not always be the case if we recall that for some people how we deal with even the smallest pieces of tissue have psychological or religious significance. The problem here was the infringement on their autonomy, and the question then is which should trump in such conflicts—individual autonomy or medical research? There are moral claims to be made on both sides, and Harris is mistaken (as Brazier has ably pointed out) to suggest that some tissue can be safely regarded as not needing to be treated with respect. Context and individual beliefs, as well as the need to undertake research, will always require considered balancing.

The further issue raised by the case is a more legal concern, and one at which some of the papers in this issue are directed. The court conceptualised the giving of the tissue

to the university as an unconditional gift. But problematically, the court also considered that they retained some rights to direct what might be done with it (specifically, to require that it no longer be used for research). The legal problem lies in the conflict between this retention of rights and the legal treatment of gifts. When property passes, it passes entirely and the giver retains no rights in relation to it. To therefore conceptualise the donations as a 'gift' does not sit well with the legal approach to gifts. This is an area in which work needs to be done to determine what precisely happens in the legal sense when donations of this kind are made.

Finally, this situation, like many in which donations are made for long-term research projects or to tissue banks, raises the question of whether an individual can give valid consent to unknown future uses. To re-contact all participants in such a large bank would be burdensome to the researchers, as well as often irritating to the participants. Yet, can it really be said that proper consent has been given to unknown uses? Researchers have an interest in their tissue samples being secure, but respect for persons and their autonomy demands that we ensure tissue is used only with real consent. This issue is further complicated where donations are made to large tissue banks like BioBank as that they may be used by many researchers in a variety of combinations, in different types of projects over time that might raise very different ethical issues.

## **Indigenous Remains and Repatriation**

During the 19<sup>th</sup> century, interest in determining the origins of humankind grew, fuelled particularly by the influence of Charles Darwin's *Origin of Species*.<sup>[36]</sup> With this interest came a desire for specimens to examine, as many early anthropologists sought to identify what they believed would be crucial distinctions that marked out the different races. Consequently, the skeletons of indigenous peoples were particularly sought after in both Britain and the United States. Researchers collected large quantities of indigenous remains for study, generally through grave-robbing.<sup>[37, 38]</sup> Some collectors established links with Australian settlers who would supply them with the remains they sought.<sup>[39]</sup> For example, Sir William Turner had the remains of more than 150 Aborigines to examine following the return of the HMS Challenger after its 1873–6 voyage to Australia.<sup>[40, 41]</sup> Remains of indigenous people were also taken and retained in the United States and many other countries. Many of the specimens obtained were put on display in museums in the United Kingdom.<sup>[42]</sup>

Over the past decade, repatriation efforts have grown and many remains have been returned to the indigenous communities of which the deceased were a part.<sup>[43]</sup> The Working Group on Human Remains in Museum Collections, established by the United Kingdom House of Commons to consider the issues surrounding retained Aboriginal remains, found that 18 British museums held Aboriginal remains. In total, 132 of 146 organisations responding to a survey conducted by the Group held human remains. Of these, 18 held Australian Aboriginal remains, 21 held remains from New Zealand, and 25 held 1,074 remains from the Americas.<sup>[44]</sup> It rejected the need for legislation to mandate the return of remains, opting instead to recommend that institutions develop their own procedures for returning remains. A number of museums have voluntarily returned them.<sup>[45–49]</sup> In the United States, the passage of the *Native American Graves Protection and Repatriation Act* has gone some way to addressing the similar concerns of Native Americans.

The ongoing retention of indigenous remains highlights three major interests in tension—that of a particular community, the interests of researchers and museums in access to materials for study, and the wider community's interest in the cultural and educational value of collections. For indigenous communities, perhaps the words of Aboriginal activist Michael Mansell best describes the damage done by museums retaining remains when he calls it 'astronomical', stating '[t]he spirits of our dead are disturbed by being separated from their bodies'.<sup>[41]</sup> Another Aboriginal activist, Bob Weatherall, put the matter even more strongly, explaining that Aborigines 'believe that no one has the right to violate the fundamental rights of the dead. Scientists think that when somebody dies it's finished. It's not finished. Because death to us isn't death. It's another phase of life. Life is continuous'.<sup>[50]</sup> If we are balancing interests, as the law must do, then these are weighty indeed for those who hold these beliefs, compared with the limited research interest in these remains. Similarly, while the community has some interest in the matter, this interest can be met in other ways. Compared to the cultural offence caused by ongoing retention, the case for continuing is weak, particularly when compared to the sensitivity we show in the context of organ donation, where lives are at stake yet family members will often successfully object to donation because of the distress it causes them.

These and other retentions, such as those at Alder Hey and the continuing retention of the body of Charles Byrne (the 'Irish Giant' held in the Hunterian Museum against his dying wishes), also raise a difficult question for the law—who should lawfully control them?<sup>[51]</sup> The court in *Kelly* found that the museum had sufficient possessory interest for a charge of theft to be brought when preserved body parts were removed from the museum's collection without authority. But can we extrapolate this to museum collections of indigenous remains when the communities demand their return? And what of the bodies of Byrne and others—does the museum have the strongest possessory right, defensible against all others? These questions remain unanswered in the absence of legislation, clear legal status for tissue and analogous cases.

## **Transplantation**

The Human Tissue Act 2004 regulates organ donations in England and Wales, and for the most part does so very well. But one recent United States case raises an interesting issue in relation to directed donations. *Colavito v New York Organ Donor Network*, concerned a conversion claim over a donated organ.<sup>[52–55]</sup> The claimant, Robert Colavito, suffered end stage renal disease and needed a donor kidney. When his friend Peter Lucia died, Lucia's wife attempted to donate her husband's kidneys directly to Colavito. She consented to removal of both kidneys and indicated her consent to a 'directed donation' to Colavito on the relevant donation consent form. Following their removal, only one kidney was received by the transplant team treating Colavito, and on examination it proved to be unfit for transplantation due to the presence of an aneurysm. Meanwhile, the other kidney had been transferred elsewhere and successfully transplanted. It emerged much later that in fact both kidneys were not a compatible match for Colavito after all.

One of the claims he later brought against the New York Organ Donor Network was for conversion, that is for the violation of his proprietary interest in the kidneys. Colavito argued that upon Mrs Lucia's directed donation, the kidneys became his property and hence the defendants' direction of one of them to another recipient constituted conversion. Much of the debate in the case turned on whether

such rights could be held over the kidney, and by whom. Over a series of appeals, the courts considered these questions, but the decision from the New York Court of Appeals was ultimately quite unsatisfactory from the perspective of setting a clear precedent. The Court declined to speculate on when someone might have actionable rights to a body part because for present purposes Colavito could have no such right as a directed donee of an incompatible kidney. Without explaining further, the Court held that therefore no conversion action could arise.[54] On the possibility of legislatively founded rights, the Court of Appeals considered the relevant section of the New York Public Health Law[50] in some detail but concluded that it was irrelevant to the case as it applied only to recipients who needed the organ in question—Colavito did not need the kidney that had been diverted elsewhere because it was later found to be incompatible. The Court hence declined to answer the question of rights arising on the grounds that it was merely ‘academic’.[54]

The case is a good example of the complex web of interests that can arise in donation situations—the donor, the recipient, the donor’s family, and other potential donors. In the context of this issue, the particularly interesting point is the lack of a clear position on the status of the donated organs at law. To whom did they belong? Did it matter? That the various courts through which the case proceeded found these questions so vexed (just as the English courts no doubt would have done had the case come to them) demonstrates the need to clear determination of the status of tissue and whose interests should be paramount.

## **Cord Blood Banking**

Many interests are potential in tension in relation to banked human cord blood. The child has a clear interest in the health potential of the cells in the blood, particularly if her or she suffers an illness for which they will provide a treatment. There is, however, only a very small chance that an individual will ever need access to their own cord blood. One survey showed that of 460,000 units of cord blood privately banked in the United States, only 99 had been used for personal treatment.[57] Arguably, the resource would be better utilised if publicly stored and distributed across the community on the basis of need as organs are. On this view, the community’s interest is greater and more likely to be served by public distribution, particularly as the source individual would have equal access to stored blood if needed.

Such an approach conflicts with the commercial interest of banks, which seek to make money from promoting the need to store blood for the needs of oneself and one’s family. This pressure to store blood for personal purposes may also undermine the efforts of public banks, with blood that could be useful being stored away to benefit no-one. Giving parents the choice to donate altruistically or retain blood for their own and their child’s use also pits individualistic interests against those of the community, reducing the bonding effect of altruistic giving on us as a society.

From a legal perspective, the status of cord blood remains unclear. Following the *Yearworth* decision in 2009, it is now arguable that the source of the blood may have some claims to it and might be able to assert some proprietary interest in it. However, one can easily foresee vexed questions about who should hold those interests—mother or child—and what they should be permitted to do with it. Given its usefulness for other family members, in cases of disputed rights, the answer to who

may decide what is done remains unclear. And what of unclaimed blood? Does it revert to relatives, or will the commercial bank be able to assert some claim, particularly relying on the legal exception that one can gain a possessory interest in tissue if one has preserved it through the application of work and skill?[2] If cord blood and the stem cells that can be obtained from it gain greater value in the future, such questions will become all the more acute.

## CONCLUSION

In many ways, we have managed to effectively regulate human tissue and in general the interests of the individual are given paramount importance where significant harm would otherwise result. In other situations and contexts, these interests yield to those of medical research, crime prevention and medical treatment. But there remain many situations that either fall outside these well-regulated areas, as well as other scenarios that challenge the current framework. Cord blood banking, and *Colavito* and *Catalona*-type situations are good examples of these challenges. They, like the retention of Aboriginal remains exemplify both the complex tensions between interests, but also the difficulties the law faces when situations come before it that are neither akin to previous cases nor covered by legislative provisions.

It matters how we regulate because as we have seen there is potential for harm and confusion, the chilling of research or the undermining of medical treatment if we do not regulate with an eye to the many and varied interests held in tissue. While the legal system in England continues to avoid the question of the precise status of human tissue and body parts, these and other situations will remain challenging. The current common law position, explored in some of the papers in this issue, lacks a clear, principled approach to tissue use. The legislative coverage is highly-specific and hence many situations fall outside its scope. Individual interests are often clearly important, but should often yield to the needs of the community. In the face of these issues, there is still much work to be done on how to proceed. The papers in this issue go some way towards exploring how we might do so.

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