

Introduction

In 1995, the Nuffield Council on Bioethics published its report *Human tissue: ethical and legal issues*. The report received widespread recognition for its analysis of the ethical concerns arising in the use of human bodily material for a range of purposes, and for the framework it provided for those working with such material.¹ Why, therefore, has the Council decided to return to this topic?

Much has changed since 1995. The regulatory landscape has altered beyond recognition, both in response to new scientific and clinical developments and in response to public opinion. Notably, two major pieces of legislation in the UK, the Human Tissue Act 2004 and the Human Tissue (Scotland) Act 2006, have attempted to respond to the public concerns first voiced in 1999 regarding widespread 'tissue retention' in UK hospitals.

The outcry in 1999 in reaction to this discovery of tissue retention, with particular distress where the material in question was from the bodies of dead children, demonstrated very clearly how in many cases 'clinical' views of bodily material differed markedly from those of the general public.² While some of the retained material, especially that at the Alder Hey Children's Hospital, was kept non-consensually in circumstances that no professional would defend,³ in other cases, material had been taken and stored with what was believed to be proper consent, with the very proper purpose of carrying out clinical research. In other cases, material had been taken with the best of intentions for research purposes without explicit consent in the belief that in such cases consent was not legally or ethically required, given that the prevailing law was couched in terms of 'absence of objection'.⁴ One significant problem, however, was that for most people, the word 'tissue' conjured up the idea of something very small, a few cells – not a whole organ, for example, and certainly not a whole heart. Thus, even where consent was sought, there was a significant disjunction between what professionals understood parents to have consented to, and what those parents themselves understood.

The particular distress caused by the retention of hearts of children who had died following surgery at the Bristol Royal Infirmary⁵ demonstrated a further distinction between a clinical approach to tissue and that of patients and their families. From a clinical or scientific perspective a heart can be seen as a piece of machinery that has a key role in a living body, and no role in a dead one. From the non-clinical⁶ perspective, however, hearts have many other meanings and associations. So do other parts of the body: it is striking that those who are willing to donate their kidneys for transplantation after death may nonetheless withhold consent for other body parts, in particular hearts and eyes (corneas).⁷ While it is unlikely that these distinctions between 'clinical' and 'non-clinical' attitudes were not also present in 1995, it was only in 1999 that the nature of these widespread misunderstandings clearly emerged. Moreover, while the events at Alder Hey and elsewhere were mainly concerned with

¹ Indeed, some of its recommendations, for example those regarding the importance of the 'respectful disposal' of bodily material (see paragraph 4.4 of the 1995 Report), were prescient of the public concerns expressed four years later when the extent of 'tissue retention' became widely known.

² Campbell AV, and Willis M (2005) They stole my baby's soul: narratives of embodiment and loss *Medical Humanities* 31: 101-4.

³ See, for example, the account of the "remorseless increase in the number of organs stored in containers", the "large majority" of which remained untouched at Alder Hey: see House of Commons (2001) *The Royal Liverpool Children's Inquiry report* (London: House of Commons), p4, paragraph 1.4.

⁴ Human Tissue Act 1961, section 1(2).

⁵ The Bristol Royal Infirmary Inquiry (2001) *The report of the public inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995*, available at: http://www.bristol-inquiry.org.uk/final_report/the_report.pdf.

⁶ The 'clinical/non-clinical' distinction is obviously not a simple one of profession: people with no link to the health professions may have 'clinical' attitudes to their bodies, and individual health professionals may assign 'non-clinical' meanings and associations to parts of their own bodies.

⁷ Eighty nine per cent of those registered on the Organ Donor Register (ODR) as at 31 March 2011 were prepared to donate all of their organs. Of those not prepared to donate all of their organs ('restricted donors'), 86 per cent were not prepared to donate their corneas, and 25 per cent were not prepared to donate their heart. In terms of the total percentage of all ODR registrants, this comprises 9.7 per cent and 2.9 per cent respectively: NHS Blood and Transplant (NHSBT), personal communication, 5 August 2011.

material retained after death – as opposed, for example, to diseased material retained after an operation – the legislative frameworks put in place in the subsequent years covered material from both living and deceased individuals. All this in turn has had an effect on public opinion. Fifteen years later, the endorsement in the Council's 1995 report of the practice of 'surplus' tissue after an operation being used for research with need for neither consent nor review by a Research Ethics Committee⁸ seems difficult to justify at the level of a general principle. Yet the demand for bodily material, whether for medical treatment or for research, remains as pressing as ever.

The present report notes some of the reasons underlying this demand for bodily material that apply both in the UK and elsewhere, including: changing patterns of diseases; the development of stem cell and regenerative medicine; the completion of the sequencing of the human genome in 2003, leading to new genomic technologies such as genome-wide association studies (GWAS) and high-throughput sequencing,⁹ and an increased need for human material for research to reduce, refine and replace animal research.¹⁰ Attitudes towards medicine and medical care have been changing as well, in the context of a general shift in society towards a greater focus on care of the self, and the role of the patient in determining how health services should be delivered,¹¹ and the increasing expectation that medicine will be able to intervene to overcome problems formerly regarded as insoluble. Consumerism is one manifestation of this, as discussed in the Council's recent report *Medical profiling and online medicine*,¹² there is also greater expectation of partnership between patients and their doctors,¹³ and a greater mixing of public and private medical care, including an increasing emphasis on partnership between the NHS and the pharmaceutical industry.¹⁴

It is, therefore, striking that, in this context of a more „consumerist“ approach to care, the traditional emphasis on the importance of unpaid and voluntary donation as the only means of obtaining bodily material for medical purposes continues to be widely upheld. While the general shift in attitudes to health care may have led to a new kind of awareness of the body and its potential value to others, there is little evidence to suggest that this has discouraged people from donating freely: we note, for example, that organ donation is on the increase. This is a delicate context, then, in which to suggest that as a society we need to do *more*; in which to say once again that, despite the generosity with which many already give, the demand for what people can give remains high.

We are dealing with an issue that does not seem to go away – the demand for bodily material for medical treatment and research. However, bodily material is not like any other, and the question of how it is obtained and used raises all kinds of further questions. This is where, for instance, the unpaid and voluntary nature of donation comes in: why is this aspect valued, and what are the ethical concerns to which this emphasis has been the response? The Working Party was asked to identify and consider the ethical, legal and social implications of transactions involving human bodies and bodily material in medical treatment and research. It was also asked to consider what limits there should be, if any, on the promotion of donation or volunteering.

It follows that this report is not seeking simply to re-visit the approach and conclusions of the Council's 1995 report in the light of the past 15 years' experience. Rather, it is attempting something broader. Its

⁸ See paragraph 4.2 of the 1995 Report.

⁹ Lander ES (2011) Initial impact of the sequencing of the human genome *Nature* **470**: 187-97.

¹⁰ Archibald K, Coleman R, and Foster C (2011) Open letter to UK Prime Minister David Cameron and Health Secretary Andrew Lansley on safety of medicines *The Lancet* **377**: 1915. See also: *Nature Immunology* Editorial (2010) Reduce, refine, replace *Nature Immunology* **11**: 971.

¹¹ See, for example, the implementation of the NHS improvement plan: Department of Health (2005) *Creating a patient-led NHS: delivering the NHS improvement plan*, available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4106507.pdf.

¹² Nuffield Council on Bioethics (2010) *Medical profiling and online medicine: the ethics of 'personalised healthcare' in a consumer age* (London: Nuffield Council on Bioethics).

¹³ General Medical Council (2008) *Consent: patients and doctors making decisions together*, available at: http://www.gmc-uk.org/static/documents/content/Consent_0510.pdf.

¹⁴ See, for example, Department of Health (2007) *Ministerial Industry Strategy Group: long-term leadership strategy*, available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_065170.pdf, and Association of the British Pharmaceutical Industry (2010) *Equity and excellence: liberating the NHS - white paper: ABPI submission*, available at: http://www.abpi.org.uk/publications/briefings/WhitePaperConsultation_ABPI%20submission_5Oct10_FINAL.pdf.

primary purpose is to seek to answer the question: *How far should society go in attempting to encourage or facilitate the donation of bodily material?* In approaching that question, our primary focus is on the issues for the donor arising around the act of donation, including questions as to the future use and governance of donated bodily material to the extent that they affect the donor's decision to donate. A consideration of broader governance issues falls outside our scope.

The possibility of donation may arise both during life and after death. The concern and distress caused by the retention of organs after death demonstrated the value very often placed on the physical body by those close to the deceased person, and it hardly need be added that, in life, too, people place value on particular aspects of their own body. Yet there is also ample evidence as to the enormous value human bodily material may have for others, in terms of lives saved, prolonged, enhanced, and even created, through transplantation, through fertility treatment and through medical research. In this report we attempt to assist deliberation on these questions, and to throw light on the tensions that arise when it comes to reconciling public need with individual feelings on the matter. As one respondent to the consultation commented: "Human biological samples can ultimately be provided only by individuals, not by organisations. If individuals do not accept that responsibility in sufficient numbers, the current system will fail."¹⁵

Although this report is primarily concerned with policy and practice in the United Kingdom (UK), we are of course aware of the global context. Patients, professionals, and indeed bodily material itself, may readily cross borders in response to demand and availability, and in accordance with differing regulatory approaches. We therefore highlight both the international dimension (for example where international statements or agreements exist) and examples of the diverse regulatory approaches taken in other jurisdictions. We note, too, the potential for regulatory changes within the UK to have an impact on others outside its national boundaries.

The first half of the report encompasses all forms of human bodily material made up of cells¹⁶ – including blood, tissue, organs and gametes¹⁷ – that may be provided by one person for the treatment of others or for research, without any expectation of personal health gain. We emphasise that our focus here is on treatment or research carried out with the aim of improving, maintaining, or limiting deterioration in health, and not on procedures carried out for cosmetic purposes alone, nor on material provided for non-health-related research or public display. We do not cover circumstances where material is taken from a person's body solely in connection with their own treatment ('autologous' donation), although we note that in day-to-day clinical practice procedures involving autologous donation will take place alongside the procedures involved in donating material for the benefit of others. Nor do we consider the specific issues raised by genetic research, although our general comments on research using bodily material will in many cases also be relevant for genetic research. Part I of the report also covers circumstances in which the living body may be 'loaned' for medical purposes: by participating as a 'healthy volunteer' in a first-in-human clinical trial (where new medicinal products are tested on healthy volunteers with no expectation of their receiving medical benefit¹⁸) or by bearing a child as a 'surrogate mother' on behalf of another person or couple.

It should be emphasised that, in setting itself such as broad remit in Part I, the Council is *not* starting with the assumption that a single approach necessarily could, or should, be used for the ethical regulation of all these forms of donation or volunteering of human bodily material. Rather, it has taken the view that much may be learned from *comparing* different forms of donation, their different regulatory structures, and the ethical assumptions that underpin these structures. Such comparisons

¹⁵ Professor Peter Furness, responding to the Working Party's consultation.

¹⁶ We include here material, made up of cells, that may subsequently be processed to create an acellular product, such as the processing of blood to separate out plasma.

¹⁷ We discuss these broad categories of bodily material further in Chapter 1, where we highlight how such categories are inevitably indistinct and overlapping.

¹⁸ Healthy volunteers in such trials (which are a small sub-section of all clinical trials) do not expect to benefit their own health, but choose to participate for other reasons (or combinations of reasons), such as financial reward or desire to help promote scientific knowledge in a particular medical field.

may help identify inconsistencies in approach that appear hard to justify; they may also help us elucidate important distinctions that lie beneath those differences in approach. Our aim, in taking this comparative approach, is first to provide a broad context in which to situate particular concerns, and then to sharpen our focus, as will be seen in the second half of the report (Part II), on a specific number of policy areas where recommendations, made on a clearly-articulated ethical basis, may usefully be made. We highlight here that there are some forms of donation covered in Part I, in particular the use of surrogacy arrangements and the donation of whole bodies for medical education and training, that are not covered separately in Part II, but which nevertheless played a very helpful comparative role in our deliberations.

If one factor that unites the many different forms of material covered in this report is that they have a single source (the body of a person),¹⁹ another is that the desired outcome of these actions is benefit to others, whether or not these others are in mind at the time.²⁰ In this report, we use the terms 'donor' and 'donation' as broad categories to cover transactions that people might think of as sacrifice, gift or loan, or as simply putting material at the disposal of others, as opposed to some form of 'taking' under coercion or even by seizure. Transactions involving buying and selling ordinarily share the characteristics of a 'voluntary act', but in the UK it is often thought that the voluntary nature of such transactions is compromised by the element of calculation or financial gain, and many people would contrast such transactions with the making of a gift. However, we follow general UK usage in keeping to the term 'donation' for all kinds of non-coerced disposal.²¹

Distinctions give rise to comparisons.²² We have already noted possible distinctions between bodily material from living individuals and bodily material from deceased individuals; and, indeed, the way the law now makes relatively little distinction between these has been the subject of complaint by some clinicians. Other key distinctions relate to the inducements or incentives that are permissible in the context of encouraging people to participate in these forms of bodily donation, and to the degree of control that the donor may have over the future use of what has been donated. To take two examples that appear to be at opposite ends of the spectrum of inducement: the National Blood Service (NBS) in the UK relies on voluntary donations of blood by altruistic donors, while the pharmaceutical industry may pay healthy volunteers significant sums to participate in the testing of new medicinal products. At first sight, there may appear to be very clear distinctions between the two cases that more than explain the regulatory differences. The National Health Service (NHS) is a public health service, from which anyone ordinarily resident in the UK is entitled to benefit free at the point of delivery, and in giving blood, donors may have the impression of giving their blood directly to another individual in need, as an act of public benefit in turn. First-in-human clinical trials, on the other hand, often operate on a commercial basis, with significant profits at stake if the product turns out to be effective; potential beneficiaries, however, seem a long way down the line – and indeed will often never materialise.²³

Yet, when more closely examined, these distinctions seem rather less clear. Blood is now rarely used 'whole' but is separated into components (red cells, white cells, platelets and plasma); plasma may be further processed to extract products such as albumin or clotting agents, although the plasma processed in this way in the UK is currently purchased from abroad because of the theoretical risk of variant Creutzfeldt-Jakob disease (vCJD) infection. Some first-in-human clinical trials are funded by the public sector, and the aim of all such trials (whether conducted on a commercial or public-sector basis) is to find new treatments, which will then be available to benefit individual NHS patients. Such

¹⁹ We use the term 'person' in this report to indicate a social being in relationship with other social beings.

²⁰ We include here basic scientific research, which has both the 'impersonal' value of the advancement of understanding but also the long-term aim of contributing to the health benefit of identifiable, albeit unknown and future, individuals.

²¹ We note here that others have taken a contrary approach: see, for example, Dickenson D (2008) *Body shopping: the economy fuelled by flesh and blood* (Oxford: Oneworld Publications). It is a matter of record that in coercive contexts, such as typify the global trafficking of organs, the term 'donation' is used as a gloss for circumstances that are far from free and voluntary: see, for example, Lundin SM (2010) Organ economy: organ trafficking in Moldova and Israel *Public Understanding of Science* (published online before print, 26 July 2010): 1-16.

²² Indeed, in drawing comparisons, the Working Party is doing what people do all the time in reflecting on their own circumstances.

²³ Approximately 11 per cent of new medicines that are the subject of first-in-human trials are finally registered: Kola I, and Landis J (2004) Can the pharmaceutical industry reduce attrition rates? *Nature Reviews Drug Discovery* 3: 711-6.

closer examination may or may not suggest new comparisons; it may also challenge us to consider more closely the ethical justification for these practices.