

## Chapter 4

# Scientific matters : The sources of human tissue

## Introduction

- 4.1 In this chapter we look at the different sources of human tissue and describe some of the safeguards incorporated into current working practice to regulate the removal and acquisition of human tissue. The legal framework relating to procedures for removing human tissue is discussed in Chapter 7. Table 4.2 on p 30 gives examples of tissue from different sources and the uses to which the tissue may be put.

## Left-over tissue obtained during diagnosis or treatment

- 4.2 Most commonly, human tissue is removed from the body in the course of diagnosis or treatment. Blood or bone marrow may be drawn for diagnostic examination. Amniotic fluid or pieces of chorion villus (part of the placenta) may be taken for cytogenetic or other diagnostic tests during pregnancy. Small pieces of tissue may be taken by biopsy for pathological examination and diagnosis, and larger amounts of tissue may be removed surgically during operation for malignant or other disease. Inevitably, prudence dictates some over-collection, and there may be tissue left over after sampling or surgery once sufficient has been assured for diagnosis and therapy. This surplus is ordinarily discarded and destroyed as clinical waste. Such left-over tissue, and also material archived during the course of diagnosis and therapy may, however, be made available for scientific research, medical training and scholarship, and evaluation and review of medical procedures. The Royal College of Physicians has advised that the use of anonymised left-over tissue for research is a traditional and ethically acceptable practice that does not need consent from patients or relatives, and need not be submitted to a research ethics committee.<sup>1</sup>
- 4.3 An example of left-over tissue is the excised foreskin after circumcision, which can be used as a source of cells. Over-collection of very small amounts of blood or tissue such as chorionic villi also occurs in the course of diagnosis performed on the fetus *in utero*. Serum or plasma that has proved to be in excess of diagnostic requirements can be used, often pooled, in standardisation of tests or in quality assurance programmes.

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<sup>1</sup> Royal College of Physicians (1990) **Guidelines on the practice of ethics committees in medical research involving human subjects** Second edition, p 29

- 4.4 It must be emphasised here that there are underlying principles of professional conduct that govern such uses of left-over tissue or samples. There must be no intention to collect surpluses of tissue, not required for diagnosis or treatment, for which specific consent should be sought. The user must be a respectable, *bona fide* scientist and the use must be ethical and inoffensive. Respectful disposal of any tissue remaining after research should be afforded, with ritual burial of material from ritual circumcision (the arlot). Incidents in which human tissue is not thought to have been handled or disposed of appropriately have given rise to much concern. We recommend that bodies such as NHS trusts and independent hospitals review their practices on all handling and disposal of human parts, excised tissue and abortuses to ensure that they meet the requirements both of law and of professional standards and also to ensure that major body parts (for example, limbs, hands), and tissue subject to special public concern or scrutiny (for example, fetal tissue), are handled and disposed of in ways which show respect.

### Autopsy material

- 4.5 Autopsies are carried out to determine the cause of death. Parts of organs and tissue are taken by the pathologist for section and study, and whole or cut organs may be removed if they illustrate particular pathological processes. The thorough dissection and examination required during any autopsy examination provides invaluable opportunities to add to the body of medical knowledge through demonstration, teaching and training. Opportunities to study tissue from dead bodies are vital to medical research and scholarship and to the development of greater understanding of disease and the effects of treatment. An autopsy is often witnessed by and demonstrated to medical students and practitioners. Bodies may also be dissected by surgeons seeking new approaches to surgical problems.

### Cadavers donated for anatomical studies

- 4.6 Cadavers may be donated, by arrangements made before death, for anatomical study and teaching and, as such, are available for demonstration by dissection. Bodies donated for anatomical purposes are fixed and dissected by medical students in the course of their training. The tissue of such cadavers is not available for purposes unconnected with anatomical examination.

### Donated tissue

- 4.7 Subject to certain safeguards and some statutory control (Chapter 7), volunteers may donate, both during life and after death, organs or tissue for 'spare part' or replacement surgery. The supply of organs, and also of corneas and heart valves, for transplants is co-ordinated by the United Kingdom Transplant Support Service Authority (UKTSSA), a Special Health Authority established in 1991.<sup>2</sup> The NHS Organ Donor Register, a national register of people who wish to donate organs after their death, administered by the UKTSSA, came into effect in 1994.<sup>3</sup> Healthy volunteers may also donate tissue for research purposes. Tissue, usually blood, but sometimes biopsy specimens, may be donated during the initial trials of new medicines or therapeutic agents. Blood collected from donors (see below) that has become outdated and can no longer be used therapeutically may also be made available for research.
- 4.8 In the United Kingdom, whole blood used therapeutically comes from volunteer donors. The provision of blood and blood products in England is the responsibility of the National Blood Authority, which manages the National Blood Service and the Bio Products Laboratory. The National Blood Service organises the donation of blood and the quality assurance, storage and transport of blood and blood components. Whole blood is usually separated to produce three components of therapeutic importance: red blood cells, platelets and plasma. Plasma may be processed further by the Bio Products Laboratory to produce therapeutic products such as Factor VIII used by haemophiliacs and albumin for burns patients.
- 4.9 There has been increasing debate about the ethics of commercial transactions involving blood and blood products. One recent focus for concern was the basis on which private hospitals obtain blood (Fig 4.1). The current situation is that about 1% of all donated blood is supplied to private hospitals. This arrangement permits the central regulation of all blood donation in the UK and is seen as preferable to a situation where private hospitals would have to set up alternative systems for collecting blood. Such systems might involve payment of donors, which is widely seen as carrying the risk of affecting the safety and quality of blood donated. In the present arrangement, the same cost-recovery fees (approximately £35/unit of blood) are charged to NHS and private hospitals alike.<sup>4</sup> It is a condition of supply that private hospitals should make no profit on blood supplied to them. It has been

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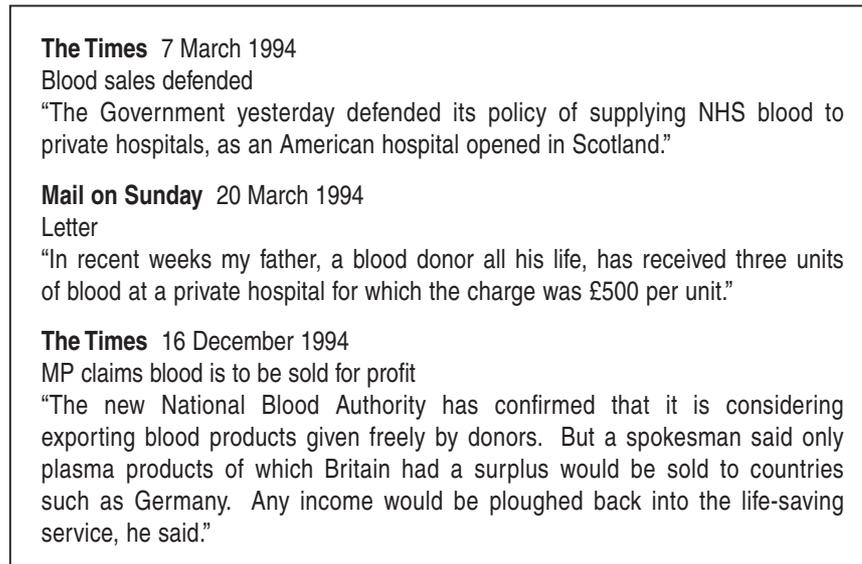
<sup>2</sup> United Kingdom Transplant Support Service Authority (1992) **The First Annual Report of the Special Health Authority 1991/2**, Bristol

<sup>3</sup> Registration forms can be obtained from Post Offices, or write to NHS Organ Donor Register, FREEPOST (BS8793), PO Box 14, Patchway, Bristol BS12 6BR

<sup>4</sup> Department of Health Circular HC(85)8

alleged, however, that a private hospital had been charging patients up to £500/unit for transfused blood (Fig 4.1).

Fig 4.1



- 4.10 The basis on which blood products are supplied to users outside the NHS has also become an issue. It has been alleged that blood products produced by the Bio Products Laboratory are being sold abroad (Fig 4.1). The policy of the National Blood Authority is to collect only enough blood from donors to satisfy therapeutic needs in the UK. This results in a surplus of some blood products, such as albumin, and these products may be sold to foreign countries. Money earned on exporting products helps the Bio Products Laboratory to recover its costs over its range of products.

## Fetal tissue and embryos

- 4.11 As we mentioned in Chapter 2, these sensitive tissues enjoy special safeguards (paragraphs 2.9 - 2.12). Research on human embryos up to 14 days old is permitted, for certain limited reasons, subject to strict licensing conditions imposed by the Human Fertilisation and Embryology Act 1990 and supervised by the Human Fertilisation and Embryology Authority, and subject also to the explicit consent of the donors. The code of practice on the use of fetuses and fetal material in research and treatment produced by the Polkinghorne Committee recommends that fetal material, which may be the result of death *in utero* or of spontaneous or induced abortion, may be used for research and also for therapy such as transplantation or

reconstructive surgery. There are recommended safeguards to prevent the management of pregnancy and decisions about abortion being influenced by the potential use of the fetal tissue. The key recommendation is that an intermediary should eliminate contact between the source and the users of fetal tissue.

### Tissue banks

- 4.12 Tissue used for medical treatment or research is often procured through local and informal arrangements with individual practitioners or with particular hospital departments. As the pace and scope of reconstructive and transplantation surgery and of research accelerates, it has become clear that *ad hoc* arrangements of this sort do not suffice to meet the needs of modern medicine. This has led to the development of tissue banks, which procure and store human tissue and make it available for further use (Fig 4.2), and of coordinating bodies such as the United Kingdom Transplant Support Service Authority (UKTSSA) (paragraph 4.7).

Fig 4.2

After Stephen Kirkby suffered burns to 95% of his body in an accident at a camping site, an appeal was launched to find live skin donors. Although donors were found and the operation was successful, he later died of a kidney infection. This incident highlighted the importance of having a national skin bank. As a result, a skin bank will open at Queen Mary's University Hospital, Roehampton, in 1995. People will be asked if they want to donate skin removed during cosmetic operations and skin will also be removed from people who donate it after their death. The skin, which can be stored for up to three years in refrigerators, will be used to treat burn victims and cancer patients.  
(Source: **Independent** 19 October 1994)

- 4.13 Many tissue banks operate within the NHS, holding fresh tissue at hospital sites chiefly for the therapeutic purposes of transplantation and reconstructive surgery. Bone, heart valves, corneas and skin are the most commonly banked tissues, since they are relatively straightforward to handle. Bone, which is removed during hip replacements and used for limb reconstruction after accidents or bone cancer, can be frozen and stored for up to five years and does not require matching to the recipient's tissue. In Scotland, and in some areas of England, bone banks have been established under the auspices of blood transfusion centres. Table 4.1 offers a survey of tissue banks supplying tissue for transplantation in the UK.

Table 4.1: The number of tissue banks in the UK, which are members of the British Association of Tissue Banks, supplying different types of fresh human tissue for transplantation.<sup>5</sup>

Tissue	Number of Tissue Banks
Cornea	5
Heart Valve	6
Bone	5
Skin	2
Brain (research)	1
Cornea/heart valve	1
Heart valve/bone	2
Heart valve/bone/skin	1
In addition to the bone banks included above, several blood transfusion centres in Scotland and England store bone	

4.14 Medical and biological research using human tissue may be undertaken in hospitals and in the laboratories of universities, medical research charities or pharmaceutical and biotechnology companies. As we describe in Chapter 5, liver tissue is especially important for researching the effects of potential new medicines and their fate in the body (paragraph 5.12). Much of this research occurs in the laboratories of pharmaceutical companies and it has been argued that dependence on informal links with hospitals for supplies of human tissue particularly hampers pharmaceutical companies and can hold back such research. The use of human tissue for research is also seen as a way of reducing the use of animals in research. For some purposes, if human tissue is available its use may be more appropriate than the use of animals (paragraph 5.14). Thus, there are reasons to improve the availability of human tissue for research.

4.15 The Medical Research Council (MRC) administers several banks which supply tissue for research purposes. Various brain banks store fixed or frozen material obtained by biopsy or post-mortem from those with disorders such as Alzheimer's disease. An MRC Fetal Tissue Bank makes fresh material available for research, acting as an intermediary organisation separating decisions about abortion from those relating to the subsequent use of the tissue as recommended by the Polkinghorne Committee (paragraph 4.11). Further guidance on the use of fetal tissue for research, diagnosis and therapy has been prepared jointly by the Department of Health and the MRC.<sup>6</sup>

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<sup>5</sup> Information supplied by the British Association of Tissue Banks

<sup>6</sup> Department of Health (1995) **Guidance on the use of fetal tissue for research, diagnosis and therapy** HMSO

4.16 Thus, the term tissue bank encompasses both institutions that handle primarily fresh tissue and those that maintain collections of preserved tissue. Pathological archives also serve as a source of preserved tissue, and we describe the important uses of such archives, in Chapter 5 (paragraphs 5.19 - 5.25). There is also a distinction to be drawn between tissue banks that supply tissue primarily for therapy, and those that supply it for research purposes. It is widely recognised that sensitive handling is required so that requests for donation of tissue for research do not undermine the motivation to donate tissue for therapy. Finally, tissue banks may operate simply as central stores, providing research workers or surgeons with access to certain tissue, or those who organise them may pursue a more active policy of organising collection and distribution. In the UK at present, tissue banks are non-profit making bodies established, funded and administered by the NHS, the Medical Research Council or medical research charities. Elsewhere, some tissue banks appear to operate on a more commercial basis. A number of foreign organisations advertise the availability of a variety of tissue and organs which can be supplied for research purposes or clinical applications.

### Conclusions

4.17 As we have seen, the source of human tissue may be tissue left over after surgery once diagnosis and therapy have been provided for. Volunteers may donate blood or other tissue for transplantation or research, or their organs or bodies after death. The people from whom tissue is removed are protected and safeguarded in a variety of ways which include professional practice arising from long established custom, specific codes of guidance for conduct, and statute and common law (Chapter 7).

Table 4.2 Sources and uses of human tissue

Source	Examples	Actual or Potential Uses
From patients following diagnostic or therapeutic procedures (includes left-over-tissue) <ul style="list-style-type: none"> <li>a) minimally invasive procedures (usually healthy tissue)</li> <li>b) invasive procedures (biopsy or surgery: usually diseased tissue)</li> </ul>	Blood or blood serum Scrapes of surface cells  Many organs or tissues	Diagnosis, archiving, research and teaching  Diagnosis, archiving, research and teaching
Autopsy specimens	Many organs or tissues	Diagnosis, archiving, research and teaching
Donations of organs or tissue from living or dead, related or unrelated volunteers	Kidney, liver, heart, bone marrow, cornea, gametes Blood Tissue (for example small skin biopsies)	Transplantation  Transfusion, manufacture of blood products Fundamental or pharmaceutical research
Fetal tissue	Many organs or tissues	Research or therapy
Body wastes	Urine, faeces, sweat Hair, nail clippings	Usually disposed of Direct commercial value (hair) Extraction of substances for therapy or research (for example erythropoietin from urine)
Abandoned tissue	Placenta	Usually disposed of Extraction of therapeutic substances (for example albumin)