Custody, ownership and confidentiality

There are many ethical concerns regarding human tissues

Eustace J. de Souza

Technology and research using human tissues raise many legal and ethical problems. Who really owns the "bits and pieces", or body tissues supplied to laboratories? What is their responsibility and to whom? Who owns the report and with what rights? What about confidentiality?

The basic principle is that the patient is at the core of the whole exercise(1,2,3). Any good that accrues must be for him.

The laboratory generally receives samples at a doctor's reference, though a patient may approach the laboratory directly, with an oral request, something which should be noted to avoid any dispute.

The ownership of tissue rests with the patient unless assigned away. The laboratory becomes its custodian. This stewardship comes with responsibilities. The report should be provided first to the treating doctor, to whom the patient has assigned his right in a fiduciary manner -- one of trust. The doctor must reveal the report in the best interest of the patient. Still, all reports of investigations paid for by a patient are his property and must be given to him on discharge.(4)

Hospital records

Hospital records, including copies of the reports, comments and notes by treating doctors and those involved by reference, are the property of the hospital and till recently could only be called for by court order.(2) A recent Indian High Court directive states that copies of hospital records should be handed over at the written request of the patient or other authorised person.

There are also ethical problems regarding ownership of tissues, fluids etc. For instance, features in a urine sample could be of interest to an independent research investigation. Can it be used in this study without informing the patient? Can blood samples sent for routine investigation be used for a research study unrelated to the condition for which the patient believes he is being treated? In ordinary circumstances, consent must be obtained.(4)

When dealing with human beings, the overriding factor is that the patient is a person,(1,2,3) with a basic right to life and liberty, whose individuality and dignity must be preserved and respected.(1,2,3) From this basic fact all other rights devolve. These would include the right to privacy and confidentiality(4) in relationships with others. Of course, in their exercise they must not conflict with the rights and dignity of another.

When a patient places himself in the care of a doctor, a contract comes into effect.(2,3,4) While usually implicit, sometimes, there has to be a spelled-out informed consent. This naturally applies to procedures where some form of general anaesthesia is employed.

On the other hand, if tissues or cell lines for instance, are being used in a research programme in which the patient has been enrolled, with his consent, and if there is any possibility that the results will be used in a commercial venture, the patient must also given the opportunity to share in any financial advantage.

There are three ethical factors to be taken into account: the need for informed consent; the need to share financial advantage with the owner of the tissue, and the ownership of a patient's tissues.

Since a patient's body is sacrosanct, (1,2,3) all tissues from that body, even if taken off that body, are part of his possession.

Ownership of tissues

A question arises with regard to tissues and other body samples obtained for a direct purpose, such as diagnosis of a patient's disease. If these samples become useful for research projects, the patient's consent should be taken, if possible. This would preempt any later claim and is also a recognition of the patient's right of ownership. Of course, if financial advantage may accrue, the patient must be afforded due opportunity to share or waive his rights.

On the other hand, in retrospective studies, where a researcher may wish to use stored tissues (for example), these tissues are presumed to have been handed over to the hospital. Since the tissues have served their original purpose, the hospital as custodian has the discretion to use them for research.

Confidentiality must be maintained at all levels. In research programmes, appropriate coding must be used to avoid recognition and identification of any individual participating in a research project and possibly suffer from the results of this identification.(1,2,3,4)

Hospital managements are often beset with demands from insurance companies for patient records. A research investigation's report may affect the claim to the patient's disadvantage.(6,7)

In the first case, no one has the right to invade a patient's privacy(6) because the records of a patient are available in a hospital or with a doctor who has treated the patient. Here too, the hospital or doctor holds these records as part of his custodianship of the patient's welfare.

Confidentiality and the implcit

Dr. Eustace J. de Souza, *Director (Research) The Bandra Holy Family Hospital & Research Centre, and Hon, Emeritus Executive Director; FIAMC Bio-Medical Ethics Centre, Bombay.*

fiduciary contract are the essence for a doctor-patient relationship(1,2,3,4) Obviously, these records cannot be revealed to anyone except with the patient's expressed consent or under specific court order. The sanctity of a patient-doctor relationship is similar to that of a penitent and confessor and any pressure to reveal the same, even by a court, can be resisted if the doctor so desires. However, there has been no clear legal acceptance of this stand at least as far as India is concerned.

Lately insurance companies request medical data on previous medical disorders or such as hypertension or diabetes before agreeing to issue a policy. Can they also insist on information from genetic tests? There are differng opinions on this issue.(1,6,7) I holdthat the researcher has a confidential contract with the patient, and cannot reveal research-based data to an insurance agency without the person's consent.

Investigation reports of patients who approach a pathology laboratory should be handed to the person investigated, or to an authorised agent. Sometimes an employee or friend is sent to pick up the report. The laboratory should exercise due discretion in handing over such a report, as it can have complications and medico-legal implications.

Sometimes a bill or written receipt may serve as evidence of authorisation. However, the bill could have been stolen. It may be discreet to recheck with the patient, though strictly the bill can be considered proof of appropriate agency. Still, this fact should be recorded and the recipient's signature obtained.

The results of HIV testing

AIDS has brought in its train a whole new perspective. For instance, blood for traansfusion must be tested for HIV, and blood testing positive destroyed.

Though there is no statutory obligation, there is social and moral responsibility to inform people whose blood shows evidence of HIV infection, after counselling them.

In addition to this obligation to the person whose blood tests positive (2), one should consider sex partner/s in the wider social interest. On the other hand, such disclosures impinge on the individual right to privacy.

The Supreme Court of India recently ruled that the HIV-positive status of a patient may be revealed without breach of ethics or privacy or confidentiality, without rendering the hospital or doctor liable. Further, the person who knowingly infects another with a life-threatening disease is liable to prosecution.(@)

When results vary

The question of ownership in certain laboratory investigations raises several difficulties. A patient may demand the slide or tissue block (i.e. from which paraffin sections are made). Can the laboratory hand over the tissue without informing the referring doctor and reporting pathologist?

Since the patient is really asking for a second opinion, the doctors involved should give their consent to handing the tissue block over.(9)

Here the ethics of referral have to be balanced with those of ownership. (9) The patient had entered into an implied contract with the doctor for diagnosis and treatment. This doctor involved a specialist consultant to get this information and institute correct treatment. New sections made from the same block may have a significantly different appearance, even yielding a conflicting report. This can lead to serious litigation.

In one instance, a tumour removed from a lady operated for a pseudo-mucinous cystadenoma was first reported as benign. When she was later admitted for pneumonia, an unrelated research study of bronchial cytology found cells of mucinoadenomatous nature but with suspicion of malignancy.

When the tumour was re-examined. it first confirmed the diagnosis of the original slides, but when the block was cut further, sections showed definite malignant cells and even invasion into vascular spaces.(10)

Since all this occurred in the same public hospital, the various participants could confer regarding this patient. One can imagine the repercussions if the surgeon, the first pathologist and a second opinion were all in the private sector with no communication.

One should mention that confidentiality is only for the benefit of a patient and to prevent any invasion of privacy. I do not propose that it be used to cover up or only to preserve reputations. Confidentiality is essential for respecting a patient's privacy and acknowledges a patient's unique autonomy as a person.(1,2,3)

References

1. Haring, B. : *Medical Ethics.* St. Paul Publications, Slough England. 1996.

2. Dunn, H.P. : *Ethicsfor Doctors, Nurses and Patients.* Alba House, New York.

3. Lobo, G.V. : *Current problems in medical ethics,* Better Yourself Books Bombay, 1980 (reprint 1989).

4. Lele, R.D.: *The Medical Profession and the Law.* Sajjan and Sons on behalf The Medical Association (Bombay Chapter) Bombay 1992.

5. High Court of Judicature at Bombay: Writ No. 3720 of 1991 with Chamber Summons No.2 of 1996. Raheja vs Maharashtra Medical Council et al 1996.

6. Lucassen, A.: *Ethical issues in genetics of mental disorders.* (Commentary) *Lancet 352:* 1004-5. *1998.*

7. Thomson, B.: Time for reassessment of use of all medical information by U.K. insurers. (Viewpoint) *Lancet 352:* 11216-18, 1998.

8. Times of India News Service: AIDS patients have no right to marry: SC. Quoting a Supreme Court directive in the case of a Nagaland doctor vs Apollo Hospital, Madras. *The Times of India,* November 17, 1998.

9. de Souza, E.J.: The Ethics of Referral. *Issues in Medical Ethics* Vol. 5: No. 3 July/ Sept 1997.

10. de Souza, E.J.: Personal notes of unpublished data.