HUMAN TISSUES ACT, 1974 - THE PRESENT AND THE FUTURE

I. INTRODUCTION

The main part of this paper is in respect of the Human Tissues Act, 1974. Which governs the Malaysian law relating to procurement of cadaveric organs for various purposes, including transplantation. I shall begin by considering briefly the various procurement policies concerning cadaveric organs and the principles that underpin human organs transplant schemes generally, before proceeding to the Act. The discussion that is to follow will be based on two assumptions, which might be controversial themselves, that there is a need to increase the supply of organs in order to save lives and/or enhance the quality of those lives, and that societal efforts to increase the supply of organs should remain within certain ethical boundaries.

II. ORGAN PROCUREMENT REGIME UNDERLYING THE ACT

Rapid progress in the development of surgical techniques, tissue matching and immunosuppressive drugs have increased the demand for cadaver organs. Procurement of organs from dead donors has certain advantages, even if the practical difficulties that beset the removal aspect in live donations were not to be considered. It would seem important that this source of organs is tapped efficiently and to its fullest extent.

A programme regarding human organ transplants, to be successful, requires an orderly framework, both theoretical and practical. Essential to

the programme is an acceptable procurement policy. Procurement involving the removal of organs from a deceased person raises the question of authority to remove. Central to this issue is that of dispositional authority over the body of the deceased person and its parts. The law would have to recognise various rights holders, who could be the individual himself while alive, the family after his death, or the community at large.

The general law did not have concepts or doctrines that could have formed the basis of any organ procurement policy. Special laws had to be enacted to provide a legal structure of rights that could deal with the complexities of human organ transplants. As the subject-matter involves moral and ethical issues, it has been found that for procurement programmes to be effective, they have to be based on a morally acceptable philosophical foundation, one that would reinforce rather than undermine values of both the individual and society.

Organ or tissue transfer or transplant involves at least three legal regimes, the 'natural' regime, the 'mixed' biologics and biotechnical regime and the 'artificial' regime. Unlike the other two, the natural regime is gift-based, and is characterised by an ethical basis and public policy of non-commerce, non-profit and non-property, involving not only a recipient but a donor too, and the procurement of organs in their natural state, not as manufactured products. We are concerned with just this regime, which involves dialogue between law, medicine and society.

Inherent in a gift-based policy governing procurement of cadaveric organs are certain tensions, between the automony, inviolability and integrity of the human body and the preservation and protection of life, between the respect that should be accorded to the dying, the dead and their families and the commitment to efficiency as a compelling guideline. Moral evaluations have to be made, religious norms and cultural traditions need to be modified, and the self-interest of doctors and relatives recognised and catered to.

The creation of a market for cadaver organs has been generally rejected so far, as being morally reprehensible. A market approach would involve sale and purchase of human organs, it might take some time before people learn to perceive the human body as capable of being an object of commerce, to see it being reduced to a commodity, and to tolerate human organs being auctioned off to the highest bidder. A commitment to basic notions of justice too would not admit a policy that determines accessibility to scarce human organs by the criterion of one's ability to pay for them. But national and international organ scarcity, and the need to advance life-preserving principles through the law, is likely to exert pressure on the existing organ donation system, and to prompt law reform initiatives in favour of at least a controlled form of a sales regime, at least on the side of procurement, if not distribution.

So far, the various approaches to organ procurement have been based on what is perceived as altruism.² But altruism, by itself, is not sufficient to sustain an organ procurement programme for long. Some programmes, such as the programme provided under the Singapore Human Organ Transplant Act (Chapter 131A), seem to be based on an assumption that a moral duty of beneficence exists, and that the State could take steps to see that the duty is carried out, ensuring compliance by means of punitive measures. Such an approach would have to based on an essentially paternalistic foundation, and a policy of 'one who gives shall receive'.

A survey of the laws of various countries on organ procurement from deceased potential donors, including Australia, Great Britain and other European countries, and the United States, reveals variations of the express-consent, presumed-consent and required-request models. The precise legal role that the family members should be permitted to play in the donation process is being resolved but slowly.

In practical terms, at one extreme is the policy of complete voluntarism. In the USA, for example, the law established a gift or donation framework, within which competent individuals have a right to determine what is to be done with their organs after their death. The programmes began as based on voluntarism and donor cards. At the other extreme is legislation mandating a policy of a strong presumed consent on the basis of life-saving necessity, community altruism, and a view that the dead body has no rights, although it is entitled to respect. France is one of the European countries empowering its doctors to remove organs from deceased persons without having to consult anyone, not even family members of the deceased persons, in the absence of the deceased's prior or the family's current explicit objection. These programmes involve opting out', requiring the individual or the family to take affirmative action to stop the process of donation, rather than to initiate it.

But neither extreme has been really successful. Though there are sufficient donor organs to meet the demand for cadaver organs, the potential donors fail to become actual donors. For example, it has been found that there are enough cadaver kidneys available in the US to satisfy the demand, but only one in eight potentially useful organs are obtained in practice. This type of shortfall is attribtued to the fact that autonomy of the individual is enhanced to the detriment of the social dimension to life, to the legitimate interests and expectations of others, and to the economic constraints.

What is required is not really an altruistic act, but beneficence, as the act of donating the body or part of it, though it would be in the interest and for the benefit of somebody else it is not at the expense of the interests of the donor himself.

But the system based on strong presumed consent has not registered a dramatic increase in supply, either. In France, the public itself supports organ transplantation. Nevertheless, it has been found difficult to apply the strong presumed-consent approach to the realities of clinical practice. It is the doctors who have found it psychologically impossible to proceed with removal procedures without first having obtained the consent of the next-of-kin. A coercive approach can be counter-productive in other ways. It is bound to have an adverse effect on the relationship of trust and confidence that is essential between the medical community and the general public. The practice in most countries is to consult the relatives, and to give effect to their wishes, though there may be no legal obligation to do so.

In between these two extremes are policies based on various degrees of voluntarism and consent. In certain European countries, the procurement programmes are based on what has been described as 'weak presumed consent', requiring 'opting out'. One such country is Italy. Where a potential donor has been admitted to a hospital authorised to remove organs, the relatives concerned must be informed of the need and usefulness of a planned operation. They must also be informed that failure to submit an objection in writing within the period prescribed by law shall be deemed to be consent. These programmes too have an element of coercion, based on what would seem to be an assumption that though the individual has dispositional authority over his body, his or his family's failure to dissent constitutes consent.

The Human Tissues Act 1974 provides for the use of parts of human bodies of deceased persons for therapeutic purposes and for purposes of medical education and research. The Act regulates donation of tissue for all the three purposes in the same way. It is based on both express-request or consent, and presumed consent.

A person may 'opt in' by making a legally correct request under section 2(1) of the Act, which request can be withdrawn by the deceased himself but cannot be overriden by anybody else. In any case, under section 2(2)(a), there seems to be a presumption that a person had 'opted in', unless he had expressed objection during his life-time, which objection could be communicated to the proper authorities after his death. Where there is no express request, 'such reasonable enquiry as may be practicable' is to be held by the person lawfully in possession to find out if the deceased had expressed any objection to organ removal. Other persons, such as a spouse, can express objections under section 2(2)(b), thereby rebutting the presumption of a donation arising under section 2(2).

The full impact of section 2(2) appears to be that, if the deceased has not been found to have expressed any objection, and if the spouse or

next-of-kin does not object, consent is to be presumed and the person lawfully in possession could authorise removal. It would appear that an objection would have to be an express objection. It is not to be inferred from the facts of the case, for example, the fact that the deceased belonged to a particular religious sect whose opposition to human organ transplants was well known.

The authority to remove as provided by section 2(2) would appear to be exercisable notwithstanding the lack of any form of consent. A discretion to authorise removal that requires decisions to be made as to whether it is 'practicable' to hold the enquiry, whether an enquiry is 'reasonable' enough, and finally whether there is 'no reason to believe' that there is any objection, is a wide discretion. Reasonableness here becomes a matter of a highly subjective judgment. The person lawfully in possession in a particular case could have exercised his discretion within the scope provided when deciding that it was not practicable to make enquiries to find out if there were objections, and could have accordingly authorised removal. But in such circumstances, where an enquiry had not been held, it would be fallacious to assume consent. The deceased might have, in fact, expressed an objection in writing and left the document with a member of the family. and this fact would have been easily discoverable if an enquiry had been held, but which had not been held because it was decided that it was not practicable.

Section 2(2) seems to be unduly biased in favour of the person lawfully in possession. It appears to have been drafted so as to ensure that the authority to remove would get to be exercised, rather than that the real wishes of the deceased got to be known. A person would have to be concerned more with expressly opting out rather than expressly opting in, for opting in can be presumed, but opting out has to be done expressly, and one day be made known to the person lawfully in possession.

Furthermore, the subsection places the person lawfully in possession in a position analogous to an arbiter, but at the same time, equips him with such a discretion as would enable him to exercise it in his own favour. The ambiguity inherent in the subsection could to lead to disputes resulting in litigation to determine whether in fact and in law the discretion had been exercised reasonably.

Regarding the wishes of the deceased, they are likely to be overridden in another way. Section 2(2) requires the person lawfully in possession to make an enquiry so as to find out if the deceased had expressed objection, or if the spouse or next-of-kin objects. If the whole subsection is read together, it would seem that even where it is found that the deceased had expressed no objection, and could therefore be presumed to have consented, his spouse or next-of-kin could object, thereby effectively prevent-

ing any organ being removed. The spouse or next-of-kin would appear to have a power to veto the presumed wishes of the deceased, unless the deceased had made an express request as provided by section 2(1).

Furthermore, a difficult point of law is likely to arise as to which should prevail, the right of the person lawfully in possession to authorise removal or the right of a person or his family to object to removal. If removal were to be authorised in a particular case where an express objection of the deceased or a family member would have come to light if an enquiry had been held, but which in fact had not been held because it had been decided that it was not practicable, the right to authorise removal would have been properly exercised despite the existence of an objection. If it were to be held that the right to authorise removal were to prevail, perhaps as being in the public interest, the right to object would be an illusory right.

Even if there were to be clear guidelines on how the discretion given in subsection (2) of section 2 is to be exercised, there is a hidden bias in favour of persons in authority that would not be easy to overcome.

Under the Act, a person has a right to opt in. If he does not wish to opt in, he is obliged to express an objection of some kind, otherwise he will be deemed to have opted in. So what is important is not that a person opts in, but that he opts out by manifesting his intention in some way, and is fortunate enough to have his objection made known to the right people at the right time. Somehow, along the way, the original objective, as seemed to be envisaged in section 2(1), seemed to have got side-tracked.

The Act should provide for a organ procurement regime that is clearly based on the twin concepts of autonomy of the individual and his family and voluntarism, underlined by an assumption that altruism exists and could be appealed to in the name of community good.

It is therefore recommended that an express-consent model of organ procurement from deceased donors should be adopted as a preferred model for public policy, with the refinement that the family of the deceased may consent to donation on his behalf in the case of an undeclared potential donor.

This would be the best approach to be adopted in a multi-religious, multi-cultural and family-oriented society such as the Malaysian society, as being politically feasibly, as one that would be able to elicit co-operation from all bodies and persons concerned.³

³ At the second and third reading of the 'Bill on Human Tissues Act, 1973', Nik Abdul Aziz bin Nik Mat, PAS representative from Kelantan Hilir, seems to have given his support to the Bill on the understanding that the Bill ensures that doctors will remove eyes or any other parts of a deceased person only on the express consent of the deceased, and without any objection from the spouse or next-of-kin, to such removal.

III. PARTICULAR ISSUES ARISING UNDER THE ACT

1. Death

Death can be described both as a process and a state, as both dying and being dead. The classical signs of death, the permanent cessation of breathing and of the heartbeat, were the major detectable events that were found to trigger off a final, rapid sequence of biological changes, a dissolution of the organism as a whole. Irreversibility of breathing and heartbeat were the recognised proof of death.

But the advance of medicine and technology has made it possible to detect this attribute of death, irreversibility, at a different stage of the process of death, and manifested in a different form, where the brain stem is found to have ceased to function. Cessation of the brain stem function is now a medically recognised phenomenon of death. Brain death is based on the assumption that somatic life is impossible in the absence of a functioning brain stem. It is also based on the fact that to maintain a person who has suffered brain death would be hopelessly non-productive.

The concept of brain death has given a new dimension to human tissue transplantations programmes. It provides certain feasible options. Delays, which might jeopardise the vialibity of a transplantation operation, can be minimised. Donations from a 'beating heart donor' (that is, a donor whose breathing is being maintained artificially for the purposes of transplantation, and whose heart is still beating), for example, have certain technical advantages of living donations, especially of time, reducing the state of emergency that characterises cadaver transplantation surgeries. The ideal situation of the living donor can be achieved in a cadaver by the maintenance of the heart beat during an operation for organ donation. Legal acceptance of the concept of brain death is essential also if artificial support systems are to be removed without attracting legal sanctions.

Paradoxically, the concept of death has become more complex and its determination more complicated than before. The full implication of brain death on society as a whole, and in law in particular, will take some time to unravel. Law has a tradition of being slow, often acting after the event. It tends to give expression to the traditional attitudes and values at any one time, and to reject that which does not fit comfortably into its theorectical and practical framework. Nevertheless, the interaction between medicine and law has always been recognised. Both medicine and law have a common objective - they aim at the well-being of the citizen and the welfare of the community.

Whether a person is dead is a question of law for the courts. But regarding what constitutes death, the law has always left it to the medical profession to define. A court in making a determination will make a finding

that death occurred on the basis of medical evidence. '[T]he question of what is death ---- is a technical, professional medical matter'.

Where brain stem death is concerned, its determination has to be based on clinical judgment, supplemented, if necessary, by a number of diagnostic aids. The function of the law will be to see that the judgment in any particular case is a valid judgment, as based on criteria that has been accepted by the medical profession, and to ensure that the minimum standards of the profession have been observed.⁵

Section 3(2) of the Act provides for certification of death. It states that no removal shall be effected except by a medical practitioner fully registered under section 14 of the Medical Act, 1971, and who together with at least one other fully registered medical practitioner have satisfied themselves by personal examination of the body that life is extinct.

According to the provision, the medical practitioner who is to certify death could be any registered medical practitioner. He could be someone who is to be involved in the removal that is to be effected, giving rise to a conflict of interest situation. The provision would have to be revised to include certain safeguards against not only error, but also abuse of the system.

To ensure both the quality and the independence of the certification of death, the Act should be amended to make the following clear:

- that each one of the doctors who is to certify death shall be a registered practitioner of at least five years standing, and that one of them should be a specialist neurologist or neurosurgeon, or have such other specialist qualification as may be prescribed by regulation.⁶

⁴ Per Lord Kilbrandon, in his concluding remarks as a chairman of a symposium on Ethics in Medical Progress [1966]. But the statement was described as an oversimplification by PDG Skegg in his article "Irreversible Comatose Individuals: 'Alive' or 'Dead'?" [1974] 33 CLJ 130.

In a number of cases in UK, the courts have referred to the practice of the medical profession. In Re A [1992] 3 Med LR 303 (Fam D), for example, the court went through the tests that had been carried out to verify whether brain death had occurred. It referred to the recommendations made by both Royal College of Surgeons and Royal College of Physicians and a working paper of the British Paediatric Association, and applied the criteria laid down by the profession, before deciding that brain stem death had occurred by a particular date. In Airedale NHS Trust v Bland [1993] 1 All ER 821, the House of Lords had to decide on the legality of withdrawal of hydration from a patient in a persistent state. It stated that in the eyes of the medical world and of the law a person is not clinically dead so long as the brain stem retains its function. Lord Browne-Wilkinson stated, regarding the condition of the patient: 'His brain stem is alive, and so is he'.

⁶ See Transplantation and Anatomy Regulation 1994 [Queensland]; Uniform Anatomical Gift Act (1987] [USA]; Uniform Human Tissue Donation Act [1990] [Canadal.

- that neither of the doctors who is to certify death, whether he is the doctor who attended the deceased or some other doctor, shall participate in the procedures for removing or transplanting an organ;

- that the doctors certifying death shall be independent of the transplant team of doctors and shall decide without regard to the possibility of a transplant.

It will have to be made clear that a certification of brain death would be valid for the purpose of registration of death under the Births and Deaths Registration Ordinance, 1957.

Special provisions should be made in respect of eyes to overcome the practical difficulties often associated with corneal transplants. The cornea has to be removed within six hours to be viable for transplantation, and the difficulty is that of accessing a qualified medical practitioner to remove the tissue.

The UK Human Tissue Act, 1961, was amended to provide for the special circumstances that exist in the case of removal of cornea or part of it, by providing for employees, for example, of the National Health Service, to effect removal of the cornea or any part of it. In the USA, a non-physician specialist, who qualifies by training and experience, is authorised to effect a removal. A technician may remove or process any donated part and an enucleator may remove any donated eyes or parts of eyes, after determination of death by a physician or surgeon. The removal of corneal tissue would have to be subject to the same requirements as generally applicable to the removal of tissue after death; for example, there has to be lawful authority to remove the tissue.

Some countries have a definition of death included in the transplant legislation itself, while others have legislated separately in respect of it. The USA Uniform Anatomical Gift Act, (1987), does not provide a definition of death. It is the US Uniform Determination of Death Act, 1980, which provides that each state medical association should develop and adopt model hospital policies and protocols for the determination of death based upon irreversal cessation of brain function that will be available to guide hospitals in developing and implementing institutional policies and protocols concerning death. But equally important was the drafting of a set of medical guidelines by a group of leading medical experts convened by the President's Commission, and which guidelines were hailed as landmarks when published. They were meant to ensure that there is little cause for division

⁷ See Uniform Anatomical Gift Act [1987]. See also the various Australian Acts, for example, Human Tissues Act 1983 [NSW].

or contention arising from misunderstanding or errors, and at the same time, they were meant to help frame the thinking of judges and others involved in the administration of justice.

Few statutes⁸ attempt to tell doctors how to make the diagnosis of death. In France, for example, it is provided that procedures used to determine death must be recognised as valid by the Ministry of Health, acting in consultation with the National Academy of Medicine and the National Council of the Association of Physicians.⁹

Death is not defined in the Act, nor in any other Malaysian statute, so as to provide for brain death as an alternative to heart-lung orientated death. The concept of brain stem death is yet to be formally adopted by our courts.

Section 3(2) implies that the moment of death ('life is extinct') can be established only by the doctors themselves, by the exercise of individual and personal judgment. It can also be construed as implying that the determination of death must be in accordance with accepted medical criteria and standards, that the judgment will be a clinical one, based on signs that signify death has occurred. To construe this provision to include cessation of brain stem activity as a condition signifying death, as something being be in accordance with medical practice, should not pose any difficulty.

But a formal recognition of the brain death criteria might be thought necessary in order for the transplantation scheme to go ahead without fear of legal action. Clearer guidance than that given in section 3(2) might be thought essential to clarify professional duties, patient rights and the limits of the civil and criminal liability, and incidently, to help facilitate organ procurement and transplantation.

If the dual character of death is to be provided statutorily, it could be done either as an amendment to the Human Tissues Act or by means of separate legislation. It might be simpler to amend the Act to include a definition of death that would help define death for the purposes of the Act.

In Australia, the legislation in all jurisdictions except Western Australia defines death as occurring when there is either irreversible cessation of circulation of blood in the body of a person or irreversible cessation of all function of the brain of a person. Except for Queensland, this definition

⁸ See s 10 of Law No 97 of 1987 of Cyprus on the removal and transplantation of biological material of human origin.

See Decree No 78-501 of 31 March 1978 for the implementation of the Law of 22 December 1976 on the removal of organs.

is expressed to apply for the purposes generally of the law of the relevant State or Territory.

It might be better, however, to dissociate the problems of the definition of death from those of transplantation, and to legislate purely for the latter contigency. Section 24(2) of the Human Tissue and Transplant Act 1982, of Western Australia, for example, is in the nature of an enabling provision. It provides that where the respiration and the circulation of the blood of a person are being maintained by artificial means, tissue shall not be removed from the body of the person for the purpose or use specified in the Act unless two medical practitioners qualified as required by that Act have declared that irreversible cessation of all function of the brain of the person has occurred. The Human Organ Transplant Act 1987 of Singapore states, in section 3, that for the purposes of that Act, a person has died when there has occurred irreversible cessation of all functions of the brain of the person. It also provides that the Minister concerned may prescribe the criteria for determining whether such a condition has occurred in any particular case, The Human Organ Transplant Regulations 1987 prescribed by the Minister of Health provides for the conditions for considering diagnosis of irreversible cessation of all functions of the brain of a person.

A definition of death that is to apply for all purposes would have broader implications than one meant for the purpose of transplantation only.

Problems of criminality and brain stem death are bound to arise and will have to be resolved. ¹⁰ In homicide cases, the question would be whether the brain-death criteria should be adopted to clarify the cause or time of death. In certain cases in England and Scotland, the courts have managed to avoid having to decide on a definition of death in legal terms. In two of these cases, in which persons charged with unlawful killing based their appeals on the argument that the doctors switching off the machine broke the chain of causation, the courts dismissed the appeals on the grounds that there was no such break in causation, that the doctors had followed good medical practice. ¹¹ In a Canadian case, where the court was presented with a legal question over the time and determination of death for purposes of liability for homicide, the court applied the traditional criteria to determine death. The court took a rather extreme stand. It characterised

¹⁰ See Skegg supra n 4.

¹¹ See R v Malcherek, R v Steel [1981] 2 All ER 422; Finlayson v HM Advocate 1978 SLT (Notes) 60.

brain death critera as 'a completely impractical standard to apply in the cirminal law'. 12

From the civil aspect, there are certain issues that will need judicial clarification. An inherent feature of brain death is that, it is imperceptible. Brain death has to be established by actual diagnosis. This makes the time when it is supposed to have occurred not only arbitrary to an appreciable extent, but also retrospective to an unknown degree. This element of uncertainty might make it necessary to apply the traditional criteria of death in certain cases, such as those concerning life insurance policies, commorlentes and survivorship.

In the case of a beating-heart donor it might be necessary to provide for certification of death on brain death having been determined. Such certification will be reassuring, both to the medical staff to be involved in the removal of the tissue and to members of the donor's family.

2. Tissue

The word 'tissue' has been variously defined. For example, the US Uniform Anatomical Gift Act (1987), which provides for the whole or part of the body to be donated, defines 'part' comprehensively, as meaning organs, tissues, bones, arteries, blood, other fluids and any other portions of a human body to be donated. In California, the word 'part' has been defined to include a pacemaker.¹³ In Australia, different considerations apply depending upon the type of tissue involved (generative or non-generative), and whether the donor is dead or alive. In the case of dead donors, the general comprehensive definition applies, whereas in the case of live donors, foetal tissue, spermatoza and ova are expressly excluded.¹⁴

The definition of the words 'tissue' and 'part' appearing in the Malaysian Human Tissue Act should be defined to exclude human gametes (sperm

¹² R v Greene [1988] 43 CCC (3d) 413 at 416 (BCSC), where a defendant to a murder charge claimed he could not be charged with murdering someone in the circumstances of the case, where he had fired two shots into the victim's head shortly after another defendant had first shot the victim in the head. According to the evidence, all three shots, if fired alone, would have been fatal. The court held that the traditional approach, where a person is pronounced dead only after his vital functions have ceased to operate, and where the heart has always been regarded as a vital organ, should be applied. The court told the jury that as a matter of law the victim was alive so long as any of his vital organs, which would include his heart, continued to operate.

¹³ See the Health and Safety Code, Vol 39A, s 7150.1 in respect of the Anatomical Gift Act as applicable in California.

¹⁴ See, for example, ss 4 & 6 of the Human Tissue Transplant Act, 1979, of the Northern Territory of Australia.

and ova) and human embryos. If necessary, a separate legal framework could be created in this area, as was done in UK. The UK Human Fertilisation and Embryology Act, 1990, deals particularly with payment for human gametes and embryos and their donation.

The complexities of the issues involving gametes and embryos, and the mechanism for regulation that will be required to deal with them, are best provided by separate enactment. The removal and donation of human gametes and embryos is technically more in the nature of an implant than a transplant, which involves replacement of that which existed. Furthermore, embryos would not fit into the phrase 'any part of a human body' that is used in the Human Tissues Act, 1974.

A minor amendment might be necessary to sections 2(1) and (2) to make it clear that a person lawfully in possession may authorise the removal of the whole body or part of it, depending on what has been donated. There should also be provision as to what is to be done with tissue which has been removed pursuant to a consent to its transplantion but which cannot for some reason be used for that purpose.¹⁵

3. Consent to removal

The Act sets out the general method of donation - it could be by express request or by the absence of express objection. However, clarification is needed on the category of persons who can donate, or who can be presumed to have donated, and the method of donation itself.

Regarding donations by express request, section 2(1) merely states that 'any person' may make a request, written or oral, at any time, that his body be used for the purposes provided in the Act. Regarding presumed donation, subsection (2) para (a) allows for a presumption of donation that would need to be rebutted by evidence of objection made by the deceased during his life-time.

It is not clear why the usual distinction between competent and incompetent persons is not made here. Where consent to an act is an essential element, as in the case of contract, 16 will 17 and marriage, 18 the

¹⁵ For example, see the Uniform Human Tissue Donation Act, 1990 [Canada] which provides for such tissue to be disposed of as if no consent has been given to use the tissue for the purpose of transplantation, unless the donor has consented to the use of the tissue for other purposes.

¹⁶ See s 2. Age of Majority Act, 1971 (Act 21).

¹⁷ See s 4 of the Wills Ordinance, 1959.

¹⁸ See, for example, a 10 of the Law Reform (Marriage and Divorce) Act, 1976 (Act 164).

law considers only persons who have attained the age of 'majority' and were of sound mind at the relevant time as being competent to enter a transaction or create a relationship that will be legally binding on them. There is a general assumption that '(P)ersons 18 years of age or more are of sufficient maturity to make the required decisions'19 There seems to be a similar assumption in the case of spouses.

Most countries specify a qualifying age. For example, section 3 of the Medical (Therapy, Education and Research) Act, 1972, [Singapore], requires the donor to be of sound mind and eighteen years of age or above at the relevant time. Though Australia does not specify a qualifying age, the Australian Code of Practice for Transplantation of Cadaveric organs and tissues. (National Health and Medical Research Council) 1989, advises against the removal of organs from a dead minor without the consent of the family, even if the minor had requested the removal.

The oral request that is provided in section 2(1) of the Act is likely to give rise to difficulties of construction. The requirements that the request should have been made in the presence of at least two witnesses, and that it should have been made during the last illness are rather ambigously drafted. For example, the part regarding the two witnesses is ambiguous. It is not clear whether the witnesses need to qualify as in the case of persons witnessing a will, that is, be competent (of sound mind). Perhaps that part of the subsection (1) should be deleted.

Ranking of relatives would provide a clearer guideline as to who should be approached first, and whose decision should prevail over whose.²¹

As section 2(2)(b) stands at present, just one relative has to object to veto the consent of any number of other relatives. Some guideline as to the rights of the relatives and the order of priority they stand in would facilitate the implementation of the Act. Taking into account the very limited time available following death for the successful removal of such critical tissues as the kidney, the liver, and the heart, it seems desirable to eliminate all possible questions by specifically stating the rights of and the priorities among the survivors.²²

What would seem to be sought under section 2(2)(b), which states that there should be no reason to believe that the spouse or next-of-kin objects, is consent of the spouse or the next-of-kin.

¹⁹ See the Comments to the Uniform Anatomical Gift Act. 1987 (USA), Legislative Responses to Organ Transplantation (WHO).

²⁰ See also the Human Organ Transplant Act, 1987 (Singapore).

²¹ See s 4 of the Medical (Therapy, Education and Research) Act, 1972, (Singapore).

²² See the Comments to the Uniform Anatomical Gift Act, 1987 (USA), Legislative Responses to Organ Transplantation (WHO).

The Act presumes a donor. The donor under sections 2(1) and 2(2)(a) would be the deceased himself. He would be the donor as well as the cadaveric source of the donation. The donor under section 2(2)(b), however, might not be the deceased himself. If the deceased had not expressed an objection, it is only the wishes of the family members that would remain to be verified. If, for example, a widow consents, though she is not sure of what her husband's wishes would have been in the matter, she would be the actual donor, though the cadaveric source would be her husband. It would seem that her dispositional authority over the body of her deceased husband would entitle her under the Act to decide for herself whether to give consent or to withhold it for the purposes of the Act.

In the absence of a valid expression of the deceased person's prior wishes, the family can decide whether to donate his organs. The family's right to decide in this instance would be a default mechanism. The default mechanism is likely to become the primary mechanism, especially if procedures were to be introduced in hospitals for routine inquiry of family members on their wishes as to donation. Where a deceased person had indicated neither consent nor objection during his life-time, it could be that he was waiving his right to choose for himself and leaving it to others to decide for him after his death, and this in itself can be an autonomous choice, by means of a proxy.

It is recommended that sections 2(1) and (2) of the Act be amended to provide:

- that the written request must be signed by the donor, but that it could include a personally signed donor card or other document of similar nature;
- that 'person' in section 2(1) or 'deceased' in section 2(2) at the time of request or objection must be a person who has attatined the age of contractual majority (which at present is 18 years of age) or is married, and is of sound mind;
- that the next-of-kin is ranked according to some accepted order of priority, such as the relationship between the family members; and
- that such next-of-kin as sons, daughters, brothers and sisters should have attained the age of majority.

4. 'Person lawfully in possession'

Who is 'the person lawfully in possession' and what are his functions?

The Act does not define 'the person lawfully in possession', or how such a person is to be identified. It might be easier to first examine the

functions of the person, at least briefly, before making any attempt to identify him.

The person lawfully in possession in the scheme provided by the Act is the link between the donor and the other parties who would be involved in transplantation. He is an essential part of the procurement process, as he is the only person who can authorise removal of organs. But before he can exercise his authority, he has to ensure that there is consent, whether express or presumed, to the removal.

It would seem that he has to be in physical possession of the body in question before he can be deemed to be in possession. In a hospital, the hospital will be in physical possession, but usually there will be others who will be entitled to claim the physical possession of the same body.

Common law does not recognise any right of property in a dead body, or in its organs, at least not in the conventional sense. However, it does recognise a right to possession. This right has generally been accepted as being vested in such persons as the next-of-kin, religious functionaries or public authorities, who are vested with special disposal powers or subject to role-duties in the interest of decency, sacred observance or public health, but are not clothed with ownership privileges and powers. This would appear to include any person who has the physical custody of the body, even a householder in whose house a person has died, 23 or a person who, though without physical custody, is legally required to dispose of the body, as, for example, an executor under a will, 24

Where a person has responsibility for burial, it would seem that, by parity of reasoning, he has a right to possession of the body.

The common law right to possession is for the purpose of burial only, whereas the right of possession of the person lawfully in possession under the Act is possession which is initially for the purpose of verifying consent, and subsequently of authorising removal of parts of the deceased person.

Physical possession or custody grants a prima facie lawful possession. In the case of a body in a hospital, the deceased person having died there, or where he has been brought already dead, the hospital has physical possession, and could be presumed to be in lawful possession for the purposes of the Act.

Section 4, however, would seem to give rise to a different interpretation. In the case of unclaimed bodies, it is specifically provided by section

²³ See R v Fetst [1858] Dears & B 590.

²⁴ See R v Fox [1841] 2 QB 246; Williams v Williams [1882] 20 Ch D 659.

4 that the hospital or a person designated by the hospital is to be the person lawfully in possession. The implication that arises from this is that physical possession, per se, does not give rise to lawful possession, as otherwise there would have been no need for the section 4 clarification.

Where the body remains outside any hospital, the identification of the person lawfully in possession would be even more difficult. There is also an anomaly in section 2(2) that should be noted. This is where a person such as a spouse is lawfully in possession. Under subsection (2), the person who is lawfully in possession of the body has to find out not only whether the deceased had any objections, but also whether the spouse or next-of-kin objects. In a case like this, the 'spouse', and the 'person lawfully in possession' will be one and the same, and might even turn out to be the next-of-kin.

As noted earlier, the person lawfully in possession has two functions. The main function is to authorise removal, but this is proceeded by the function of verifying consent, actual or presumed.

Authorisation to remove to be lawful has to be in accordance with the provisions of section 2, and subject to certification of death as provided by section 3(2) and the consent of a magistrate, as required by section 3(3). This is provided by section 3(1).

The consent of a magistrate is required in circumstances where an inquest has to be held to inquire into a death, such as a violent or unnatural death. The body would have to be kept intact for purposes of investigation, for the preservation of relevant evidence. Nevertheless, it might be possible for a magistrate to consent to removal of organs unconnected with the injuries of the deceased, and where the investigation of the causation of the injuries would not in any way be impeded by the removal.

The terminology 'person lawfully in possession' is bound to be problematic. It might be better to do away with it completely, and in its stead, to provide for authority to remove according to an unambiguous criterion, such as the place where the body of the deceased is to be found at the relevant time. It would be easier to operate a scheme where certain defined persons are given certain defined duties based on clearly identifiable or ascertainable facts, and to provide separately and specifically for each situation.²⁵

The UK Human Tissues Act, 1961, by means of subsection (7), provides

²⁵ See s 5(1) of the Human Tissue Gift Act, 1982, (Ontario), which provides for the consent of spouse and others, including 'the person lawfully in possession', who is ranked last in the list of all those who can consent to the removal of tissue in certain circumstances.

that, in the case of a body lying in a hospital, nursing home or other institution, any authority under the section may be given on behalf of the hospital by an officer designated for that purpose. There is no qualification that the body should be unclaimed, as there is in section 4 of the Act.

The Act should be amended to provide for specific situations. Two broad categories of situations could be identified, depending on whether the body of the deceased is at the hospital at the relevant time, or at some place other than a hospital. In the former case, it should be provided that the hospital or a person designated by the hospital shall authorise removal subject to the required consent. Where the body of the deceased is at a place other than a hospital, the spouse or any adult available next-of-kin of the deceased should be enabled to authorise removal where express consent has been given by the deceased, or in circumstances where consent can be presumed. The authorisation should be by means of an instrument in writing.²⁶

5. Criminal and civil liabilities

a. Criminal liability

The Act does not provide for any form of criminal sanction. It states what is lawful, not what is unlawful. Section 3(1) provides that removal and use of any part of the body in accordance with section 2 shall be lawful. In fact, section 5 preserves the existing law. It states that nothing in the Act is to be construed as rendering unlawful any dealing with, or with any part of, the body of a deceased which could have been lawful if the Act had not been passed.

The Act should be amended to include provisions that make contravention of the Act an offence. It should be expressly provided that any removal of any part of a body not in accordance with the provisions of the Act shall be unlawful and an offence punishable under the Act by fine and/or imprisonment. There should also be a provision prohibiting disclosure of information of a confidential nature, such as the identity of the donor, contravention of the provision being made punishable under the Act.

Commercial dealings in bodies or part of bodies should be expressly

²⁶ See, for example, ss 21 & 22 of the Transplantation and Anatomy Act, 1983. of South Australia.

prohibited, contravention of the provision prohibiting such dealings to constitute an offence punishable under the Act.

b. Civil Liability

The unauthorised removal of cadaveric part or material would not give rise to an action in conversion or detinue, as the body of a cadaver or any part of it is not considered as property in the conventional sense. However, as there is a right of control or possession vested in certain persons, an unauthorised removal of the body or part of the body could constitute unauthorised interference with this right. The tort of negligence would seldom be applicable, as it would be difficult to establish a duty of care owed to the person in possession, breach of that duty and damage arising from the breach. A dead body does not constitute 'goods', nor is it something that is capable of being the object of injury or damage, thereby causing a loss of a pecuniary nature to the possessor. But a cause of action for nervous shock might be available to relatives, where, for example, the conditions of reasonable enquiry have not been met.²⁷

An agreement to sell human organs whether from living persons or cadavers would most probably be held void under section 24 of the Contracts Act, 1950. The consideration, human organs, would be regarded as unlawful on grounds of public policy.

IV. CONCLUSION

The Act needs to be amended, if not structurally, at least in respect of matters such as definitions, to facilitate its implementation. Regulations would have to be made to prescribe for such matters as are found necessary or convenient for the proper administration of the Act, or to achieve the objects and purposes of the Act. Such regulations could be used to help in the implementation of the Act even in its present form, and would in any case be necessary to control the practical aspects of procurement, removal and transplantation.

Of immediate concern should be the setting up of a task force under the auspicies of the Ministry of Health, to operate within a specific time-frame. The task force would have to conduct surveys to obtain cross-section views on medical, legal, ethical, economic and social issues arising or likely to arise from the implementation of the programme, to

²⁷ But see I Kennedy, "Further Thoughts on Liability for Non-Observance of the Provisions of the Human Tissues Act" [1976] 16 Med Sct Law 49; PDG Skegg, "Liability for the Unauthorised Removal of Cadaveric Transplant Material: Some Further Comments" [1977] 17 Med Sci Law 123.

consider the practical effects of implementing the programme, and to make recommendation, if necessary, and generally to keep the government well informed, and to advise the government from time to time on how best the human organ procurement and transplantation programme can be implemented both fairly and efficiently. The task force would enable the government to follow the process of implementation of the transplantation programme, and if necessary, to modify it to accommodate new developments and ease unforseen tensions.

A permanent body would have to be set up at the same time to oversee and assist in the implementation of the programme, to take over from the task force one day. An administrative unit in the Ministry of Health would be necessary to administer the Act, amongst other things, to designate certain agencies and to co-ordinate their activities, to provide technical assistance to the agencies, and to conduct public awareness programmes on the need for organ donations, and generally to set up an organ procurement and transplantation network.

A procurement organization, bank or storage facility would need to be set up to facilitate the procurement, distribution or storage of organs for the purposes of the Act. Another essential agency would be a central co-ordinating registry for the receipt and storage of information on potential donors and waiting donees. Hospitals would have to build up computerised banks containing comprehensive national tissue information.

The Act and any regulations in respect of it are meant to provide the legal and practical framework. The medical profession itself would have to play the major role in setting up a transplant organisational structure, and in continuing to provide firm guidance to its members in matters pertaining to it. Human organ procurement would need to be considered as an area for specialisation. Doctors and other medical staff would need to be equipped with the necessary medical knowledge and experience that would enable them to perform such complex functions as verifying brain death, and to carry out such sensitive duties as approaching bereaved relatives to discuss with them the possibility of donation. Though the government will be required to play a part, the medical profession will have to bear the major burden of the successful implementation of the organ procurement programme provided by the Act.

Public educational programmes, too, will have to be initiated so as to bring about a change that is both cognitive and attitudinal. Brain stem death will have to be explained if it is to be understood and accepted. A programme which may look feasible on paper may in fact prove to be ineffective and perhaps even counter-productive because inadequate attention had been paid to psychosocial factors. Special attention would have to be paid to intermediate communities, especially religious bodies, who

have great influence on the way an individual organises and lives out his life.

The Act was passed more that twenty years ago. It is time a serious attempt was made to implement it.

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