

## THE REGULATION OF FETAL TISSUE TRANSPLANTATION

GAIL MORGAN\*

### I. INTRODUCTION

Human fetal tissue transplantation is a comparatively recent development in medical science, which may be able to treat a range of medical problems.<sup>1</sup> In comparison with adult tissue, fetal tissue is more resilient and adaptive when used for transplantation. With the advent of serious research into this medical therapy as a means of providing better alleviative treatment (if not the potential

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1 Council on Scientific Affairs and Council on Ethical and Judicial Affairs, "Medical Applications of Fetal Tissue Transplantation", *Journal of the American Medical Association* 1990; 263: 565-570.

for a cure) than existing modes of therapy, it is timely to consider how this form of transplantation could be regulated.<sup>2</sup>

The transplantation of living tissue from adults and children and tissue from deceased persons is regulated by specific legislation to be found in all Australian States and Territories.<sup>3</sup> It seems logical that this legislation should apply to fetal tissue transplantation as well. However, this legislation as currently drafted does not apply to fetal tissue transplantation, the main problem is that fetal tissue is excluded from the concept of "tissue". Thus, if human tissue transplantation legislation is to be used as a model for the regulation of fetal tissue transplantation, certain amendments would be necessary. The purpose of this article is to examine the scope of the current provisions, and to suggest what alterations would need to be made so as to incorporate transplantation of fetal tissue.<sup>4</sup> To set this analysis in context, it will commence with a brief description of this treatment and its application.

## II. FETAL TISSUE TRANSPLANTATION

Fetal tissue has four qualities that makes it a desirable source of tissue for overcoming a range of medical problems. They are: the ability to grow and proliferate, to undergo cell and tissue differentiation, to produce growth factors and, in comparison to adult tissue, not always to provoke a significant immune response from the host tissue.<sup>5</sup> The net effect of these qualities is that fetal

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2 It is not the author's intention to advocate or criticize this form of treatment, only to suggest how this medical development might be legally controlled.

3 The legislation of the States and Territories is as follows:

*Transplantation and Anatomy Ordinance 1978*(ACT);

*Transplantation and Anatomy Act 1979-84* (Qld);

*Human Tissue Act 1983* (NSW);

*Human Tissue Transplant Act 1979* (NT);

*Transplantation and Anatomy Act 1983* (SA);

*Human Tissue Act 1985* (Tas);

*Human Tissue Act 1982* (Vic);

*Human Tissue and Transplant Act 1982* (WA).

4 Although these proposals might apply equally to an IVF embryo or an anencephalic newborn, the content of this article is limited to fetuses that might be used for tissue transplantation.

Some of the legal implications of fetal tissue transplantation in Australia have been canvassed by P Kasimba and K Dawson "Can Fetal Tissue Transplantation Be Done Legally?" (1990) 12 *Sydney L Rev* 362. This article probes the issue of regulation discussed by them.

5 Council on Scientific Affairs and Council on Ethical and Judicial Affairs, note 1 *supra* at p 566.

tissue is able to adapt to and to conform with a new environment, without necessarily being rejected by the host tissue. This means that fetal tissue when transplanted into an organ enervated by disease may be able to assume some of the functions of that organ, and it may even promote regeneration of the tissue of the host organ.<sup>6</sup> The types of medical problems that may be amenable to fetal tissue transplantation may be categorised as: degenerative (eg., Parkinson's and Alzheimer's disease); post-traumatic injuries to the cerebral cortex or spinal cord; vascular disorders; endocrine deficiencies (eg., diabetes mellitus); and chronic pain states.<sup>7</sup> The clinical application of this therapy has been tried in relation to Parkinson's disease and diabetes mellitus in a number of countries, including Sweden, China, the United States, Mexico and Australia.<sup>8</sup>

The treatment of Parkinson's disease provides an example of the potential benefit to be derived from fetal tissue transplantation. The lack of muscle co-ordination associated with this disease is brought about by the death of the substantia nigra cells in the mid-brain, which are responsible for producing the neurotransmitter called dopamine. This is responsible for facilitating the transmission of information from the substantia nigra to the striatum, thus enabling movement to occur. Currently, this problem is treated by administering the drug, L-dopa, which raises the level of dopamine throughout the brain. However, with the passage of time, L-dopa becomes less effective and there may be adverse side effects.<sup>9</sup> Transplantation using adult tissue is not

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6 *Id.*

7 PF Bartlett and JV Rosenfeld, "Brain Transplantation: A Critical Appraisal" in L Gillam (ed.) *Proceedings of the Conference: 'The Fetus as Tissue Donor: Use or Abuse?'* held at the Royal Australasian College of Surgeons, Spring St., Melbourne, Wednesday, October 25, 1989 (Monash University Centre for Human Bioethics) at p 27. Both Parkinson's and Alzheimer's disease involve impairment of the functions of the brain. Parkinson's disease involves impairment of the motor functions of the brain, so that the patient displays symptoms such as decreased mobility or tremor. Alzheimer's disease involves impairment of the motor and cognitive (ie, thinking, remembering) functions of the brain. Diabetes mellitus involves an inability to digest carbohydrates brought about by impaired secretion of insulin produced by the islets of Langerhans within the pancreas, which results in an increased level of sugar in the blood.

8 For countries where clinical trials of fetal tissue have been conducted for Parkinson's disease, see Council on Scientific Affairs and Council on Ethical and Judicial Affairs, note 1 *supra* at p 568. For countries where clinical trials of fetal tissue have been conducted for diabetes mellitus, see TE Mandel "Obtaining and Using Pancreatic Tissue" *Proceedings of the Conference, ibid* at p 15. Research in Australia is being conducted at the Walter and Eliza Hall Institute of Medical Research, Melbourne, however, this team has decided to abandon the use of human fetal islet transplants for diabetes mellitus in favour of fetal islets from other species, such as the pig, *ibid* at p 17.

9 G Ferry "Remaking the Brain" *New Scientist* 1989; 124 (1690): 1-4 at p 4.

possible, because transplantation damages the axons of mature brain cells, mature brain cells do not regenerate nor can they be kept alive.<sup>10</sup>

Animal experiments have indicated that a graft of fetal substantia nigra placed directly into, or in a cavity of, the damaged striatum makes some connections with the host cells and releases dopamine.<sup>11</sup> This grafting technique has been refined by injecting dissociated cell suspensions consisting of dopamine-containing neuroblasts directly into the brain.<sup>12</sup> Operations on humans have proven less conclusive so far, but it may only be a question of time before the impact of fetal grafts is understood<sup>13</sup> and the long-term benefits can be evaluated.<sup>14</sup> Although fetal tissue transplantation does not as yet represent an established therapy for Parkinson's disease, it is considered to be one of the most promising forms of treatment being studied.<sup>15</sup>

### III. TRANSPLANTATION LEGISLATION AS A MODEL FOR FETAL TISSUE TRANSPLANTATION

The development of effective transplantation techniques in conjunction with immunosuppressive drugs (which prevent or suppress the immune response) has changed our perception of the human body. It has become a source of "spare parts": tissue might be removed from a living or dead person to be used for the benefit of someone else. Artificial life-support systems (such as mechanical respirators) have enabled tissue from a dead body to be kept alive for transplantation. Prior to the promulgation of the human tissue transplantation legislation, the absence of relevant legal principles to regulate transplantation caused uncertainty and inhibited the supply of suitable tissue. In particular, doubts arose as to whether medical personnel, who performed transplant operations using tissue from 'beating heart' bodies, might not be criminally liable for murder.<sup>16</sup> The development of this legislation to facilitate transplantation became imperative.

In 1976, the Australian Government responded to the need to develop suitable legal principles to regulate transplantation by issuing a reference on human tissue transplantation to the Australian Law Reform Commission. The common law has no specific provision facilitating the transfer of tissue, indeed there are principles suggesting quite the contrary. For example, a person cannot

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10 *Ibid* at p 2.

11 *Ibid* at p 2-3.

12 *Id.*

13 *Ibid* at p 4.

14 Council on Scientific Affairs and Council on Ethical and Judicial Affairs, note 1 *supra* at p 568.

15 "Fetal Nerve Grafts Show Promise in Parkinson's" *Science* 1990; 247: 259.

16 Australian Law Reform Commission *Human Tissue Transplants* (1977) at [124].

direct by will how his or her body is to be disposed of, because the executor has only a limited right to possession of the body for the purpose of effecting the duty of proper burial.<sup>17</sup> Although the States had taken the initiative by providing regulation of cadaver tissue transplants,<sup>18</sup> this legislation was neither uniform between states nor did it encompass living donors. Given this lack of specific common law principles and uniform legislation, the Australian Law Reform Commission concluded that uniform "clear rules" were required. Otherwise, "[u]ntil specific laws governing the transplantation of human tissue are provided, the community will lack certainty, and the supply of tissue will continue to be deficient or non-existent".<sup>19</sup>

The model legislation drafted by the Commission is concerned with facilitating the supply of human tissue by specifying who can give tissue, and when it can be given. The Commission did not believe it appropriate for legislation to refer to other supply issues, such as storage of tissue by a tissue bank or maintaining an adequate supply through a register of donors.<sup>20</sup> The Commission also believed that this legislation could raise problems (such as privacy protection).<sup>21</sup> Similarly, the Commission made no recommendations concerning the demand for tissue: the "selection of individual recipients of tissue for transplant should not be the subject of legislation", nor should there be specific legislation concerning the consent of legally competent or incompetent recipients.<sup>22</sup> The person authorised by legislation to allow tissue removal should determine the recipient, and the common law requirement of consent provided adequate protection.<sup>23</sup> For these same reasons, if human tissue transplantation legislation is to regulate fetal tissue transplantation, then only certain issues concerning supply need to be addressed.

The Australian Law Reform Commission chose to exclude fetal tissue from its reference. The Commission was reluctant to deal with the issue of abortion,<sup>24</sup> which is unavoidable when the preferred source of fetal tissue is from elective abortions.<sup>25</sup> The issue of abortion was being considered by the Legislative Assembly of the Australian Capital Territory at the time of the

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17 *Williams v Williams* (1882) 20 Ch D 659 at 665.

18 Note 16 *supra* at [65]-[66].

19 *Ibid* at [61] and [60].

20 *Ibid* at [194]-[198].

21 *Ibid* at [194]-[196].

22 *Ibid* at [172]-[173].

23 *Ibid* at [172].

24 *Ibid* at [48].

25 GJ Annas and S Elias "The Politics of Transplantation of Human Fetal Tissue", *New England Journal of Medicine* 1989; 320(16): 1079-82 at 1081. However Mandel states in his article that viable tissue was obtained from spontaneous abortions, see note 8 *supra* at p 14.

Commission's deliberations. Moreover, the Commission believed the legal problem raised by use of aborted fetuses were "formidable".<sup>26</sup>

In the absence of constitutional power to establish Commonwealth legislation on transplants, the Australian Law Reform Commission provided model legislation in its 1977 report entitled, *Human Tissue Transplants*.<sup>27</sup> Some degree of uniformity has been achieved by the states and territories adopting the model legislation to varying degrees. For the purposes of this discussion, the provisions of the *Human Tissue Act* 1982 (Vic) (hereafter "the Act") will be the basis of discussion, and any discrepancies with legislation in other jurisdictions will be noted.

## A THE CONSENT PROVISIONS OF THE ACT

The considerable emphasis in the Act on the requirement of consent before any living or cadaver tissue is removed for transplantation reveals the importance given to respect for the autonomy of the donor. One has only to refer to the report of the Australian Law Reform Commission to find it stated that: "[t]he recommendations in this report for the donation of the tissues of living persons are made entirely on the basis of consensual giving, and for the donation of tissues of dead persons, largely on that basis".<sup>28</sup> The emphasis on providing tissue only by donation is in keeping with the prohibition on trade in human tissue.<sup>29</sup>

A person may donate living tissue and his or her body after death. Living tissue is classified as either regenerative or non-regenerative tissue. The former is defined to mean "tissue that, after injury or removal, is replaced in the body of a living person by natural processes".<sup>30</sup> Proof that one consents to the donation of living tissue must be evidence by written consent and supported by a written certificate by an attending doctor.<sup>31</sup> There is an additional precaution

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26 Note 16 *supra* at [48].

27 Note 16 *supra*.

28 *Ibid* at [23].

29 *Human Tissue Act* 1982 (Vic) s 38; *Transplantation and Anatomy Ordinance* 1978 (ACT) cl 44; *Human Tissue Act* 1983 (NSW) s 32(1); *Human Tissue Transplant Act* 1979 (NT) s 24(1); *Transplantation and Anatomy Act* 1979-84 (Qld), buying and selling respectively ss 40(1) and 42(1); *Transplantation and Anatomy Act* 1983 (SA) s 35(1); *Human Tissue Act* 1985 (Tas) s 29(1); *Human Tissue and Transplant Act* 1982 (WA) s 29(1).

30 *Human Tissue Act* 1982 (Vic) s 3(1); *Transplantation and Anatomy Ordinance* 1978 (ACT) cl 4(1); *Human Tissue Act* 1983 (NSW) s 4(1); *Human Tissue Transplant Act* 1979 (NT) s 4(1); *Transplantation and Anatomy Act* 1979-84 s 4(1); *Transplantation and Anatomy Act* (SA) 1983 s 5(1); *Human Tissue Act* 1985 (Tas) s3(1); *Human Tissue and Transplant Act* 1982 s 3(1).

31 *Human Tissue Act* 1982 (Vic) ss 7 and 8; *Transplantation and Anatomy Ordinance* 1978 (ACT) cl 8; *Human Tissue Act* 1983 (NSW) s 10; *Human Tissue Transplant Act* 1979 (NT) s 8; *Transplantation and Anatomy Act* 1970-84 (Qld) s 10; *Transplantation and Anatomy Act*

for the donation of non-regenerative tissue. This allows the would-be donor time to change his or her mind during a 24-hour time lapse between the written consent being given and it being acted upon.<sup>32</sup> The intention to donate one's body after death must be evidenced by written or oral consent (the latter stated before two witnesses).<sup>33</sup>

Living tissue may also be donated by proxy consent. A parent may provide written consent to the removal of specified regenerative tissue from a child to be transplanted only into a sibling or parent of the donor child.<sup>34</sup> The *Human Tissue Act 1982* distinguishes between donor-children capable of understanding the nature and effect of the removal of tissue and the nature of the transplantation from those incapable of such comprehension by reason of age.<sup>35</sup>

1983 (SA) s 9; *Human Tissue Act 1985* (Tas) s 7; *Human Tissue and Transplant Act 1982* (WA) s 8. Donations of living regenerative tissue and tissue from deceased bodies may be used for transplantation or "other therapeutic purposes or for medical or scientific purposes": see, e.g., *Human Tissue Act 1982* (Vic) ss 7 and 26(1). Thus, when consent is sought from the donor or next of kin, it should be made clear to what purpose the consent pertains.

32 *Human Tissue Act 1982* (Vic) s 8(1); *Transplantation and Anatomy Ordinance 1978* (ACT) cl 9; *Human Tissue Act 1982* (NSW) s 8; *Human Tissue Transplant Act 1983* (NT) s 9; *Transplantation and Anatomy Act 1979-84* (Qld) s 11; *Transplantation and Anatomy Act 1983* (SA) s 10; *Human Tissue Act 1985* (Tas) s 8; *Human Tissue and Transplant Act 1982* (WA) s 9.

33 *Human Tissue Act 1982* (Vic) s 26. Only Victoria specifies how the consent is to be evidenced. The legislation of other jurisdictions provides that if an individual expressed the wish for or consented to the use of their body after death, that has not been withdrawn or revoked, then a designated officer of a hospital may authorise tissue removal pursuant to the wish or consent. *Transplantation and Anatomy Ordinance 1978* (ACT) cl 27(1); *Human Tissue Act 1983* (NSW) s 23(1); *Human Tissue Transplant Act 1979* (NT) s 18(2); *Transplantation and Anatomy Act 1979-84* (Qld) ss 31(1) and 33; *Transplantation and Anatomy Act 1983* (SA) s 21(2); *Human Tissue Act 1985* (Tas) s 23(1); *Human Tissue and Transplant Act 1982* (WA) s 22(2)(a).

34 *Human Tissue Act 1982* (Vic) s 15(1); *Transplantation and Anatomy Ordinance 1978* (ACT) cl 13(1); *Human Tissue Act 1983* (NSW) s 10; Northern Territory - no provision in relation to donations by children, which would necessitate incorporation of such a provision; *Transplantation and Anatomy Act 1979-84* (Qld) s 12B-E; *Transplantation and Anatomy Act 1983* (SA) s 13; *Human Tissue Act 1985* (Tas) s 12; *Human Tissue and Transplant Act 1982* (WA) s 13.

35 *Human Tissue Act 1982* (Vic) s 15(2)(c) and 15(2)(d) respectively. This differentiation only otherwise occurs in Queensland pursuant to the *Transplantation and Anatomy Act 1979-84*, but s 12D also requires that the risk to the child be minimal. In all of the other jurisdictions (except the Northern Territory), regenerative tissue may only be removed if the child is capable of understanding (by reason of age) the nature and effect of the tissue removal and of the transplantation, and the child agrees to the tissue removal: *Transplantation and Anatomy Ordinance 1978* (ACT) cl 13(2); *Human Tissue Act 1983* (NSW) s 11; *Transplantation and*

This suggests that when a parent is giving proxy consent for a child capable of understanding the nature and effect of transplantation, the parent's decision is based on the standard of substituted judgment.<sup>36</sup> In other words, the parent is implementing the choice of the child, who presumably would be capable of conceptualising his or her preferences about transplantation. By contrast, when a child is incapable of this comprehension, the parent makes a proxy consent on the basis of the child's best interests by deciding how a reasonable child in his or her child's position might decide. Regardless of the basis of the parent's decision, there is the inference that the donor-child will receive a reciprocal benefit from helping a parent or sibling.

The extent of parental authority to consent to tissue removal allowed in the two Territories merits special mention. In the Northern Territory, the *Human Tissue Transplant Act* 1979 does not empower a parent to consent to the removal of any living tissue from his or her child. By contrast, the *Transplantation and Anatomy Ordinance* 1978 (ACT) enables a parent to consent to the removal of non-regenerative tissue from a child to be used for another family member if the child is capable of comprehending tissue removal and transplantation.<sup>37</sup>

When the views of the deceased are unknown, the Act respects the wishes of the next of kin (who can be located) as to how the body is to be respectfully treated.<sup>38</sup> The senior available next of kin of the deceased person may consent to the removal of tissue from the deceased, although not if it is known that the deceased objected to the removal of tissue.<sup>39</sup> The senior available next of kin may also give consent to the removal of tissue while a relative is unconscious, but this consent may only be acted upon after the death of the relative.<sup>40</sup> In the

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*Anatomy Act* s 13(2); *Human Tissue Act* 1985 (Tas) s 13; *Human Tissue and Transplant Act* 1982 (WA) s 13(2).

36 For a discussion of proxy decision making, see JA Robertson "Organ Donations By Incompetents and the Substituted Judgment Doctrine" (1976) 76 *Columbia L Rev* 48.

37 *Transplantation and Anatomy Ordinance* 1978 (ACT) cl 14(1).

38 The Hon Mr Roper, Minister of Health, second reading speech on the Human Tissue Bill, *Parliamentary Debates* 49th Parliamentary Session 1982-83, Legislative Assembly, at 2259.

39 *Human Tissue Act* 1982 (Vic) s 26(1)(d) and (3); *Transplantation and Anatomy Ordinance* 1978 (ACT) cl 27(2); *Human Tissue Act* 1983 (NSW) s 23(1); *Human Tissue Transplant Act* 1979 (NT) s 18(3); *Transplantation and Anatomy Act* 1979-84 (Qld) s 22(2); *Transplantation and Anatomy Act* 1983 (SA) s 21(3); *Human Tissue Act* 1985 (Tas) s 23(2); *Human Tissue and Transplant Act* 1982 (WA) s 22(2).

40 *Human Tissue Act* 1982 (Vic) s 26(5); *Transplantation and Anatomy Ordinance* 1978 (ACT) cl 22(4); *Human Tissue Act* 1983 (NSW) s 23(4); *Human Tissue Transplant Act* 1979 (NT) s 18(4); *Transplantation and Anatomy Act* 1983 (SA) s 21(4); *Human Tissue and Transplant Act* 1982 (WA) s 22(4); there are no comparable provisions in Queensland or Tasmania.



absence of either the views of the deceased or next of kin being known, the Act creates a presumption that the deceased has no objection to tissue removal.<sup>41</sup>

## B HOW THESE CONSENT PROVISIONS MIGHT APPLY TO FETAL TISSUE

Despite the fact that the Act specifically excludes fetal tissue from its ambit,<sup>42</sup> it could be modified to include fetal tissue if tissue removal from a dead fetus or living abortus is comparable to the removal of tissue from a dead person or a living adult or child. It will be argued here that the consent provisions pertaining to the removal of tissue from a dead person should be applied to the removal of fetal tissue. This view will be supported by reference to the fact that most abortions result in the death of the fetus, and that the policy behind donations of tissue from children is not applicable to fetuses.

Even if there is no comparison, ethical guidelines would still apply to the use of fetal tissue, such as those issued by the National Health and Medical Research Council.<sup>43</sup> The Council advocates that the consent of the mother, and if practicable the father, should always be sought for the use of the fetal tissue for transplantation.<sup>44</sup>

The most common situation would be transplantation using fetal tissue from a dead aborted fetus. The vast majority of abortions in Australia occur under 14 weeks of gestation,<sup>45</sup> and the most frequently used method of abortion is by vacuum aspiration.<sup>46</sup> There is considerable ethical disagreement as to the status of the unborn fetus. However, the safe legal approach would be to acknowledge the dead fetus as the remains of a conceptus having had the potential to be a human being, rather than being comparable to excised tissue or an organ from a person's body. On this basis, tissue removal from the dead aborted fetus could be considered as comparable to the removal of tissue from a dead adult or child. This suggests that one or both parents could be consulted as the next of kin of the fetus as to whether or not use may be made of the fetal tissue. Preference

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41 Note 38 *supra* at 2260; *Human Tissue Act 1982* (Vic) s 26(1)(e).

42 *Human Tissue Act 1982* (Vic) s 5; *Transplantation and Anatomy Ordinance 1978* (ACT) cl 6; *Human Tissue Act 1983* (NSW) s 6; *Human Tissue Transplant Act 1979* (NT) s 6; *Transplantation and Anatomy Act 1979-84* (Qld) s 8; *Transplantation and Anatomy Act 1983* (SA) s 7; *Human Tissue Act 1985* (Tas) s 5; *Human Tissue and Transplant Act 1982* (WA) s 6.

43 National Health and Medical Research Council *Ethics in Medical Research Involving the Human Fetus and Human Fetal Tissue* (1983) at [2.28]-[2.31].

44 *Ibid* at [2.29]

45 The only reliable source of abortion statistics is kept in South Australia, where they are a notifiable operation. See *Eighteenth Annual Report of the Committee Appointed to Examine and Report on Abortions Notified in South Australia for the Year 1987* (1988), Table 6A at p 5.

46 *Ibid*, Table 7 at p 5.

might be given to the wishes of the mother,<sup>47</sup> but the father could be consulted if practicable.<sup>48</sup>

Careful consideration needs to be given as to when tissue removal may occur from a living abortus. Some abortion methods may result in a living abortus. These methods would be preferred for some types of fetal tissue transplantation, as it may be desirable to extract tissue from an intact fetus. For example, the Islets of Langerhans are extracted from the fetal pancreas to transplant into patients suffering from diabetes mellitus. The preferred method of abortion is one that results in an intact fetus, as it is almost impossible to identify the Islets of Langerhans when the abortion is performed too early.<sup>49</sup>

In the absence of legal criteria, the National Health and Medical Research Council has specified when it is ethically acceptable to obtain tissue from an aborted fetus for medical research.<sup>50</sup> For this purpose, the Council categorizes the fetus biologically as: dead; previable- "showing signs of life but not having the capacity to survive after the separation from its mother"; and viable- "having a capacity to survive and reach the point of sustaining independent life".<sup>51</sup> To ensure that an aborted viable fetus is not mistaken as previable, a fetus can be regarded as previable when "*under 20 weeks gestation and weighing less than 400 g*".<sup>52</sup> The Council concludes that tissue may be obtained from a previable fetus, provided a heart beat is not apparent.<sup>53</sup> Most aborted fetuses would fall into the category of previable,<sup>54</sup> hence these guidelines suggest that fetal tissue for transplantation could not be removed until the heart beat ceases.

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47 Some people argue that if a woman decides to undergo an abortion, her complicity in the death of the fetus precludes her having any further decision making role in relation to that fetus, such as giving consent to the use of the fetal tissue for transplantation (see, for example JT Burchaell "University Policy on Experimental Use of Aborted Fetal Tissue" (1989) 9 *Bioethics News*, Ethics Committees, A Special Supplement, 2 at p 3). However, a counter argument can be made that the woman decides to undergo an abortion, because she is unable to provide for that potential child. She believes it is not in the interests of that potential child to exist. Thus, she should retain authority to decide what becomes of the fetus after the abortion.

48 National Health and Medical Research Council, note 43 *supra* at [2.28].

49 TE Mandel, note 8 *supra* at p 13.

50 National Health and Medical Research Council, note 43 *supra* at [2.12]-[2.19]. The Council refers to abortion, whether induced or spontaneous, as a separation: *ibid* at [2.12]. For a discussion of these guidelines, see P Kasimba and K Dawson, note 4 *supra*.

51 *Ibid* at [2.13].

52 *Ibid* at [2.14]. The Council acknowledges that medical technology may in future be able to sustain a separated fetus at earlier stages of gestation, so that the definition of previability must be kept under review: *ibid* at [2.15].

53 *Ibid* at [2.16].

54 See South Australian statistics, note 45 *supra*, Table 6B at p 5.

The previable fetus could be considered as comparable to an unconscious adult or child. In both situations, death is a relative certainty. On this basis, one or both parents could be consulted as the next of kin as to the removal of tissue before death, but this consent could not be acted upon till death occurred.

A living fetus might be considered comparable to a child for the purposes of the Act. The Act defines "child" to mean a person who has not attained the age of 18 years.<sup>55</sup> This makes clear the upper age limit. The lower age limit could be derived from a number of legal sources, which indicate that legal status begins at birth. In relation to a charge of murder of an infant, Barry J held in *R v Hutty*<sup>56</sup> that,

[m]urder can only be committed on a person who is in being, and legally a person is not in being until he or she is fully born in a living state ... the child should have an existence separate from and independent of its mother, and that occurs when the child is fully extruded from the mother's body and is living by virtue of the functioning of its own organs.

Similarly, in *Watt v Rama*,<sup>57</sup> the majority of the Supreme Court of Victoria held that legal rights (in this case, the right to sue for negligence) could only be acquired upon birth.<sup>58</sup> Similar support may be derived from the definition of "child" (born alive, not still-born) in legislation of the states and territories concerning the registration of births, deaths and marriages. The child must be completely expelled or extruded from the mother, and that he or she also breathe or have a beating heart (except in Western Australia).<sup>59</sup>

The criminal law does provide protection of a child before its birth is completed by the offence of child destruction, that is, destroying the life of a child capable of being born alive.<sup>60</sup> However, this offence does not provide

55 *Human Tissue Act* 1982 (Vic) s 3(1); *Transplantation and Anatomy Ordinance* 1978 (ACT) cl 4(1); *Human Tissue Act* 1983 (NSW) s 4(1); *Human Tissue Transplant Act* 1979 (NT) s 4(1); *Transplantation and Anatomy Act* 1979-84 (Qld) s 4(1); *Transplantation and Anatomy Act* 1983 (SA) s 5(1); *Human Tissue Act* 1985 (Tas) s 3(1); *Human Tissue and Transplant Act* 1982 (WA) s 3(1).

56 [1953] VR 338 at 339.

57 [1972] VR 353.

58 *Watt v Rama* [1972] VR 353 at 360-61.

59 *Registration of Births, Deaths and Marriages Ordinance* 1963 (ACT) cl 5(3), which refers to breathing; *Registration of Births, Deaths and Marriages Act* 1973 (NSW) s 4(3), which refers to breathing; *Registration of Births, Deaths and Marriages Act* 1963 (NT) s 5(3), which refers to breathing; *Registration of Births, Deaths and Marriages Act* 1967 (Qld) s 5(1), which refers to heart beat; *Births, Deaths and Registration Act* 1966 (SA) s 5, which refers to heart beat; *Registration of Births and Deaths Act* 1985 (Tas) s 1A(1), which refers to heart beat; *Registration of Births, Deaths and Marriages Act* 1959 (Vic) s 3, which refers to breathing or any other sign of life, but it does not refer to the child being expelled or extruded from the mother; *Registration of Births, Deaths and Marriages Act* 1961 (WA) s 3(1), which refers as well to a child being of a prescribed gestation or weight at birth.

60 *Criminal Code Act* 1899 (Qld) s 313 provides that:

clear guidance as to when the law recognises that a child's existence begins for all purposes.

The authorities previously referred to indicate that live birth marks the beginning of the legal existence of a child. Birth is a process whereby the fetus is separated from the mother, which may occur naturally or through surgical intervention. The termination of a pregnancy induced by a method of abortion which results in a live fetus could be regarded as giving rise to the birth of the fetus. One such method is hysterotomy, which is comparable to a caesarian operation. A fetus that survives the abortion is a child born alive if it is evident that he or she has a separate existence to the mother evidenced by the fetus *ex utero* breathing or having a beating heart.<sup>61</sup> The guidelines issued by the National Health and Medical Research Council suggest that a viable fetus could be defined as at least 20 weeks gestation and 400 grams in weight. Very few abortions are conducted at this stage, but the living abortus could be considered a child if he or she met the foregoing criteria.

The policy behind the provisions allowing the use of tissue from children suggests that even if the abortus can be considered a child, any tissue removal could not occur until the abortus dies. The provisions of the Act that permit a parent to consent to the removal of tissue from his or her child emphasize that the child should be able to receive some reciprocal benefit from the donation of tissue to a parent or sibling. The short-term survival rate of the abortus means that he or she could not live long enough to enjoy any reciprocal benefit from the donation of tissue.

Moreover, the only tissue that can be extracted from children is "specified regenerative tissue".<sup>62</sup> This would preclude the removal of tissue from the living abortus suitable for transplantation for the range of medical problems outlined earlier in this article.

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"Any person who, when a woman is about to be delivered of a child, prevents the child from being born alive by any act or omission of such a nature that, if the child had been born alive and had then died, he would be deemed to have unlawfully killed the child, is guilty of crime, and is liable to imprisonment with hard labour for life";

*Criminal Code Act 1924 (Tas)* s 165; *Crimes Act 1958 (Vic)* s 10(1) provides that:

"Any person who, with intent to destroy the life of a child capable of being born alive, by any wilful act unlawfully causes such a child to die before it has an existence independent of its mother shall be guilty if the indictable offence of child destruction"; and

*Criminal Code Act Compilation Act 1913 (WA)* s 290. The wording of the cited section suggests that, given birth is a process (rather than an immediate event), this offence can occur any time after labour begins and before the birth is completed.

61 D Llewellyn-Jones *Fundamentals of Obstetrics and Gynaecology*, Vol. 1 Obstetrics (3rd ed., 1982) at pp 452-4; HB Valman *The First Year of Life* (1982) at pp 3-4.

62 See citations at note 55 *supra*.

### C THE LEGAL DEFINITION OF DEATH

The concept of death was the preserve of the medical profession in the absence of a common law or statutory definition of death. The traditional criterion was the cessation of circulation and respiration.<sup>63</sup> The advent of transplantation prompted consideration of what constituted an accurate definition of death.<sup>64</sup> Respiration and circulation can be restarted and continued artificially by machinery, but cessation of brain function is not reversible. This fact suggested to the Commission that irreversible cessation of brain function would serve as a more accurate definition of death.<sup>65</sup> The Commission was of the opinion that the recognition of brain death was also warranted by the lack of clarity in the law that could leave members of the medical profession involved in transplantation liable for criminal charges, which was clearly undesirable.<sup>66</sup>

After extensive public consultation,<sup>67</sup> the Commission prepared a draft definition of death intended to be of general application.<sup>68</sup> This definition referred to the criteria of irreversible cessation of all function of the brain or of the circulation.<sup>69</sup> The appropriate diagnostic techniques were not specified, as to incorporate them in the law would produce "verbose legislation".<sup>70</sup> This was a task better left to the Royal Australian Medical Colleges to develop guidelines that would reflect current professional procedures.<sup>71</sup> This definition of death has been promulgated in both Territories and in five of the states.<sup>72</sup>

### D APPLYING THE DEFINITION OF DEATH TO NEWBORNS

The question of when a fetus *ex utero* is dead will not arise very often, as most abortion methods used now result in the death of the fetus *in utero*. However, if a preference for identifiable tissue from intact fetuses for transplantation does emerge, different abortion methods are used or advances in medical technology enable viability of fetuses at earlier stages of development, this question could become critical. To cover such an eventuality, it must be

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63 Australian Law Reform Commission, note 16 *supra* at [123].

64 *Ibid* at [127].

65 *Ibid* at [134].

66 *Ibid* at [133].

67 *Ibid* at [132].

68 *Ibid* at [137].

69 *Ibid* at [136].

70 *Ibid* at [137].

71 *Id.*

72 *Human Tissue Act* 1982 (Vic) s 41; *Transplantation and Anatomy Ordinance* 1978 (ACT) cl 45; *Human Tissue Act* 1983 (NSW) s 33; *Human Tissue Transplant Act* 1979 (NT) s 23; *Transplantation and Anatomy Act* 1979-84 (Qld) s 45(1); *Human Tissue Act* 1985 (Tas) s 27A; in South Australia and Western Australia, there is no definition contained in the transplantation legislation.

clear to the medical profession when tissue from a fetus *ex utero* may be removed.

To determine the death of fetuses *ex utero*, the question is whether the statutory definition of death is applicable and, if not, whether an alternative definition should be devised. Particular difficulty is associated with the use of the brain death criterion in newborns. There are three factors making it difficult to ascertain when a newborn has died: the resilience of their brains to injury, the fact that environmental conditions can produce false results and the inadequacy of data as to which clinical or laboratory test is most accurate.

The resilience of newborn brains makes it difficult to determine whether the cessation of brain function is irreversible. One clinical test for brain death used for adults is the electroencephalogram, but it has not been proven an accurate test for newborns. This is because "[e]lectrical activity in the brain is not fully developed in newborns, and brief periods of flattening on the electroencephalogram are normal".<sup>73</sup> Another test for brain death is the absence of cerebral circulation, but it is not certain what duration of absent flow establishes destruction of infant brain tissue.<sup>74</sup> Infants are capable of surviving total circulatory arrest longer than adults.<sup>75</sup> The most commonly used methods in paediatrics for determining intracranial blood flow only measure flow to the cerebral hemispheres, which do not provide evidence of whole-brain death.<sup>76</sup> The accuracy of tests used to indicate blood flow to the entire brain have yet to be demonstrated when applied to infants.<sup>77</sup>

The environmental conditions surrounding a fetus *ex utero* at the time death is determined may produce false positive results. Studies have been conducted which indicate that a fetus *ex utero* has a higher tolerance to hypothermia than adults.<sup>78</sup> To obtain accurate test results for establishing death the exclusion of hypothermia must be confirmed. This is because of the "well-demonstrated capacity of sufficient lowering of body temperature to produce a fully reversible state simulating death ... [which] can entail the absence of clinically detectable blood circulation or brain function".<sup>79</sup>

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73 DL Coulter "Neurologic Uncertainty in Newborn Intensive Care" *New England Journal of Medicine* 1987; 316: 840-843 at p 841. An electroencephalogram (EEG) is a recording of the electric pressure of the skull generated by currents spontaneously emanating from nerve cells in the brain.

74 DA Shewmon "Caution in the Definition and Diagnosis of Infant Brain Death" in JF Monagle and DC Thomasma (eds) *Medical Ethics* (1988) 38-57 at p 50.

75 *Id.*

76 *Ibid* at p 51.

77 *Id.*

78 P McCullagh *The Foetus as Transplant Donor* (1987) at p 111.

79 *Ibid* at p 113.

#### IV. AMENDING THE HUMAN TISSUE ACT 1982

To accommodate fetal tissue transplantation within the ambit of the Act would require several alterations. In brief, these include deletion of the exclusion of fetal tissue, inclusion of the requirement for consent to the use of fetal tissue by one or both parents and modification of the definition of death. These matters will now be dealt with in turn.

##### A THE EXCLUSION OF FETAL TISSUE

The deletion of the exclusion of fetal tissue entails providing a definition of fetal tissue. It would be quite simple to modify the provision of the Act that excludes fetal tissue: the words "foetal tissue" could be deleted from it.<sup>80</sup> The Act should incorporate a definition of the term "fetus". Such a definition could specify that a fetus is the product of human reproduction from the time of conception to birth, but does not include the placenta, fetal membranes or the umbilical cord.<sup>81</sup>

Particular care needs to be taken when drafting the provision allowing parental consent to the use of fetal tissue for transplantation. Although the sections in the Act concerning consent to removal of tissue refer to "a person" giving consent, the suggested approach to parental consent here is that the new section refer to the pregnant woman giving consent. If the putative father's consent is to be sought, then a sub-section could be added to this effect. A pregnant woman should be given the opportunity to change her mind once she has initially given consent, so as to allow her time to reflect upon her decision. Thus, the new section of the Act should be cast in a similar format to that for the donation of living non-regenerative tissue, albeit certain modifications would be required.

Careful consideration should be given to the timing of the request for her consent. The timing of the request for the use of fetal tissue should occur when a woman is able to make an autonomous decision, which requires that she be reasonably informed and that her decision is free from outside influence or pressure. Institutions conducting abortions might have an interest in obtaining fetal tissue if they also provide fetal tissue transplantation. When a woman comes to have an abortion, she may be requested to sign a consent form that includes a provision allowing the institution to make use of the fetal tissue. In this situation, a woman will not necessarily have the opportunity to consider the matter carefully, nor will she necessarily receive any (or any independent) counselling. In addition, she may feel that her consent to fetal tissue use is a prerequisite to her having an abortion. This is objectionable: a woman should

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80 See citations at note 42 *supra*.

81 RJ Levine, "Viability of the Human Fetus: Biologic Definitions", *Clinical Research* 1975; 23; 211-216 at 212. The term "human reproduction" could be taken to include reproduction assisted by AI and IVF.

be able to obtain an abortion free from any pressure to co-operate in the provision of fetal tissue. The only way to respect a woman's beliefs about fetal tissue transplantation is to ensure that her consent to the use of fetal tissue is kept as a separate issue from her decision to have an abortion. This suggests that the request for tissue should be made after she has indicated her decision to have an abortion, but before the abortion is conducted - unless the request can be delayed until such time as she has fully recovered from the surgery.<sup>82</sup>

There should be a provision specifying what occupation the person obtaining her consent should have. It would be preferable for that person to have counselling experience. In particular, that person should not be involved in fetal tissue transplantation.

Consideration might be given as to whether the consent (or objection) of the father is to be obtained too. A preliminary point is whether his consent may only be required if it is reasonably practicable for his consent to be obtained.<sup>83</sup> If the decision of both parents is to have equal weight, then provision could be made to the effect that neither parent may consent to the use of fetal tissue for transplantation if he or she knows that the other parent objects to the donation of fetal tissue.<sup>84</sup>

The provision concerning parental consent to the use of fetal tissue should be couched in terms that the tissue removal may only occur when the fetus is dead. For most abortions, tissue removal could occur as soon as the abortion is complete. For those relatively few abortions that result in a living abortus, this provision would require that tissue removal not occur until the abortus is dead. This provision embodies legal recognition of tissue removal from the fetus being regarded as comparable to tissue removal from a deceased person.

In keeping with the prohibition of trade in human tissue in the Act, fetal tissue should only be made available through donation. Consequently, no amendment to the Act should be made allowing a pregnant woman consenting to the use of fetal tissue to receive, or for anyone receiving such tissue to provide, a financial reward.

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82 To avoid tissue deterioration, transplantation usually occurs fairly soon after the supply of tissue is obtained, however, this problem can be overcome if tissue can be cryopreserved: J Brown, et. al., "Cryopreservation of Human Fetal Pancreas" *Diabetes* 1980; 29 (supplement 1): 70-73 at 72.

83 Given that consent usually must be obtained within a short time period (especially if obtained after a woman has decided to have an abortion, but before it is conducted), this could hinder the success of the transplantation if the father is not contactable.

84 This is the situation in those States in the United States that have adopted the 1987 version of the *Uniform Anatomical Gift Act*. By s 1, "Decedent" is defined to include a fetus. Either parent of the decedent may make an anatomical gift of all or part of the decedent may make an anatomical gift of all or part of the decedent's body for an authorised purpose, provided the parent proposing to make an anatomical gift does not know of an objection to making an anatomical gift by the other parent: s 3(a)(3) and s 3(b)(3).



## B THE DEFINITION OF DEATH

The uncertainty surrounding the determination of newborn death suggests that before fetal tissue transplantation becomes widely practised, there should be a consensus of medical opinion as to what are the appropriate criteria and tests for determining death. A number of suggestions have already been made as to what criterion should be used and how it should be applied. The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioural Research encouraged the preparation of guidelines based on accepted medical practices to provide further assistance for doctors and specialists in establishing brain death. In relation to infants, the guidelines specify only that doctors should be "particularly cautious in applying neurologic criteria to determine death in children younger than five years".<sup>85</sup> The Polkinghorne Committee in the United Kingdom<sup>86</sup> found that as "tests to determine brain-stem death cannot be carried out on a whole fetus at the stage of development at which it will have been aborted", death should be established by reference to absence of spontaneous respiration and heartbeat.<sup>87</sup> Likewise, the National Health and Medical Research Council implicitly suggests, in its recommendation as to when dissection of a previable fetus is ethical, that death of the fetus occurs when its heartbeat ceases.<sup>88</sup> However, the Polkinghorne Committee recommended that such testing should only be conducted after the "consideration of possible reversible factors such as the effects of hypothermia in the fetus, and of drugs or metabolic disorders in the mother".<sup>89</sup>

Some recent studies of newborn death provide guidance for ascertaining death. A study of 18 preterm and term infants of less than one month of age all diagnosed as brain dead led the authors of the study to conclude that brain death in the newborn is detectable. In particular, "the combination of neurologic assessment, an EEG showing electrocerebral silence, and isotope estimation of cerebral blood flow followed by 24 hours of observation seems valid in deciding that irreversible cessation of brain function has occurred in the preterm

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85 The President's Commission for the Study of Ethical Problems in Medicine and Behavioural Research *Defining Death, A Report on the Medical, Legal and Ethical Issues in the Determination of Death* (1981) at p 166.

86 The committee chaired by the Rev Dr John Polkinghorne presented its report in 1989 entitled *Review of the Guidance on the Research Use of Fetuses and Fetal Material* (HMSO, Cm 762, July 1989), which was a review of the guidelines formerly presented by the Peel Committee published in its report *The Use of Fetuses and Fetal Material for Research* (HMSO, 1972).

87 *Ibid* at [3.7].

88 National Health and Medical Research Council, note 43 *supra* at [3.1].

89 The Polkinghorne Committee, note 86 *supra* at [3.7].

and term infant".<sup>90</sup> Another study has suggested that if a fetus exhibits a markedly fixed fetal heart rate without decelerations, then a diagnosis of brain death should be considered after exclusion of such factors as anencephaly (absence of the cerebral hemispheres) or consumption of drugs by the mother.<sup>91</sup>

It seems appropriate for a consultative body to ascertain from the medical profession what, if any, consensus of opinion there is in Australia as to the applicability of the definition of death to fetuses *ex utero*. Consideration would also need to be given to what clinical and laboratory tests should be applied, and the appropriate environmental conditions when the tests are preformed. The advantage of having a consultative body draft guidelines rather than rely on the legislature is that the guidelines could be more readily changed to accommodate advances in medical knowledge and techniques. The legislature should confine itself to establishing the "general standards to which society will give legal significance", not to develop or specify medical criteria for diagnosis.<sup>92</sup> Furthermore, the drafting of provisions referring to technical matters may lead to problems of interpretation not only for those to whom the legislation is directed, but also the legal profession.<sup>93</sup> The National Health and Medical Research Council, at the behest of the Commonwealth Government, could be charged with the task of producing an Australian code of practice for the determination of death in newborns.<sup>94</sup>

## V. CONCLUSION

Medical developments are often responsible for precipitating a revision of existing legal principles or the search for new ones. If fetal tissue transplantation is to become a medical therapy accepted by both by the medical profession and society, then consideration should be given to the revision of the *Human Tissue Act* 1982 (and its counterparts in other jurisdictions) as outlined in this paper. One means of regulating fetal tissue transplantation is to treat fetal tissue as comparable to tissue from a deceased adult or child. This will provide a uniform approach to the regulation of the supply of tissue for transplantation, regardless of the type of tissue being used. Any amendments

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90 S Ashwal and S Schneider "Brain Death in the Newborn" *Pediatrics* 1989; 84: 429-437 at 436. A similar conclusion is specified by DL Coulter, note 73 *supra* at 841.

91 JG Nijhuis, N Kruyt and JAM Van Wijck, "Fetal Brain Death. Two Case Reports" *British Journal of Obstetrics and Gynaecology* 1988; 95: 197-200 at p 199.

92 The President's Commission, note 85 *supra* at p 50.

93 *Id.*

94 The National Health and Medical Research Council has issued *An Australian Code of Practice for Transplantation of Cadaveric Organs and Tissues* (1990), which contains advisory guidelines as to the determination of brain death based on current practice. This Code does not refer to fetal tissue: *ibid* at p 7.

made to the human tissue transplantation legislation should focus on ensuring that parental consent is sought before fetal tissue is used for transplantation, and that the tissue is only removed when the aborted fetus is dead.