



2000

**STANDING COMMITTEE ON
UNIFORM LEGISLATION AND
INTERGOVERNMENTAL AGREEMENTS**

**ORGAN DONATION AND
TRANSPLANTATION**

REPORT No. 25

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**ORGAN DONATION AND
TRANSPLANTATION**

REPORT NO 25

Presented by:

Hon. K.J. Minson, MLA

Laid on the Table of the Legislative Assembly
on Thursday, 23 November 2000

Report of the Standing Committee

Committee Members

Chairman	Hon. K.J. Minson, MLA (Member for Greenough)
Deputy Chairman	Mr F. Riebeling, MLA (Member for Burrup) [Resigned 10 May 2000] Mr W.I. Thomas, MLA (Member for Cockburn) [Appointed 11 May 2000] [Appointed Deputy Chairman 30 August 2000]
Members	Mr E.J. Cunningham, MLA (Member for Girrawheen) Ms M.R. Holmes, MLA (Member for Southern River) Mr W.J. McNee, MLA (Member for Moore)

Committee Staff

Clerk to the Committee	Mr Peter Frantom, BA
Legal/Research Officer	Ms Melina Newnan, BA, LLB
Committees Secretary/Stenographer	Mrs Patricia Roach

Committee Address

Legislative Assembly
Parliament of Western Australia
Harvest Terrace, PERTH WA 6000

Contact: Mr Peter Frantom
Telephone: (08) 9222 7486
Fax: (08) 9222 7804
E-mail: pfrantom@parliament.wa.gov.au

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Terms of Reference

On Wednesday, 4 August 1993, the Legislative Assembly established the Standing Committee on Uniform Legislation and Intergovernmental Agreements.

On Tuesday, 18 March 1997, the Legislative Assembly re-established the Standing Committee on Uniform Legislation and Intergovernmental Agreements with the following terms of reference -

- (1) That a Standing Committee be established for the duration of the 35th Parliament to inquire into, consider and report on matters relating to proposed or current intergovernmental agreements and uniform legislative schemes involving the Commonwealth, States and Territories, or any combination of States and Territories without the participation of the Commonwealth.
- (2) When considering draft agreements and legislation, the Committee shall use its best endeavours to meet any time limits notified to the Committee by the responsible Minister.
- (3) The Committee shall consider and, if the Committee considers a report is required, report on any matter within three months; but if it is unable to report in three months, it shall report its reasons to the Assembly.
- (4) Each member, while otherwise qualified, shall continue in office until discharged, notwithstanding any prorogation of the Parliament.
- (5) No member may be appointed or continue as a member of the Committee if that member is a Presiding Officer or a Minister of the Crown.
- (6) When a vacancy occurs on the Committee during a recess or a period of adjournment in excess of 2 weeks the Speaker may appoint a member to fill the vacancy until an appointment can be made by the Assembly.
- (7) The Committee has power to send for persons and papers, to sit on days over which the House stands adjourned, to move from place to place, to report from time to time, and to confer with any committee of the Legislative Council which is considering similar matters.
- (8) If the Assembly is not sitting, a report may be presented to the Clerk of the Legislative Assembly who shall thereupon take such steps as are necessary and appropriate to publish the report.
- (9) In respect of any matter not provided for in this resolution, the Standing Orders and practices of the Legislative Assembly relating to Select Committees shall apply.

On Wednesday, 29 March 2000 the Legislative Assembly resolved -

That the Standing Committee on Uniform Legislation and Intergovernmental Agreements examine and report on developments in Organ Donation, Transplantation and Xenotransplantation; the adequacy of the *Human Tissue and Transplant Act 1982* and the need for improved uniform legislation and that the Standing Committee finally report to the House on 30 November 2000.

Chairman's Foreword

This is the twenty-fifth and probably the final report of the Standing Committee on Uniform Legislation and Intergovernmental Agreements.

The Terms of Reference of the Standing Committee allow the Committee to inquire into, consider and report to the Legislative Assembly on matters relating to proposed or current intergovernmental agreements and uniform legislative schemes.

This report is unique for the Committee in that it enquires into a subject at a depth that is far more exhaustive than the Committee's Terms of Reference would normally allow.

Initial research into the area of organ donation and transplantation indicated two important things.

First, that the subject was of growing concern, complexity and importance and secondly, that to table a cursory report to the Parliament would be to avoid doing something that desperately needed to be done. Bear in mind that at the time the Committee agreed to look at the subject, DonateWest did not even exist.

As a consequence, the Committee took the unusual step of asking the Legislative Assembly to broaden its Terms of Reference to enable a wider ranging enquiry that could make more meaningful recommendations. The Legislative Assembly unanimously agreed to those alterations and hence the Committee has been able to present to the House a report that is both informative in its content and practical in its findings and recommendations.

Transplantation is the best, and in some cases the only, alternative for patients suffering end-stage organ failure. Scientific, technical and organisation advances in transplantation have made it a common practice.

The success of transplantation has resulted in a continued increase in waiting lists over the past decade, aggravated by the shortage of organs and tissue donors. Living and cadaveric donors form the source for organ and tissue donation. With living donation, it is possible to obtain regenerative tissue such as blood cells or bone marrow, and organs such as a kidney or a segment of the liver, especially for child recipients. As regards cadaveric donors, there are three different kind of donor (1) brain dead donors, who are potential donors of all organs and tissues; (2) those suffering cardiac death with associated respiratory arrest (CRA), that can only be used for tissue donation and (3) non heart beating donors. This last group is composed of those donors suffering irreversible CRA but with a short warm ischemia time that allows donation of organs such as kidney, liver and tissues.

Organ and tissue procurement is a relatively new discipline which is still evolving. It is susceptible to various organisation and philosophical models, and to a greater or lesser degree subject to financial constraints.

I thank my fellow Committee members for their individual and collective contributions to this report. In particular, I would like to thank the Committee's staff for their professional work and responsible attitude. I commend Melina Newnan, the Legal/Research Officer, who has provided the Committee with considerable expertise and is an efficient and dedicated officer. Peter Frantom, the Clerk to the Committee, I commend for his expert procedural advice and efficient administrative skills. Melina and Peter have shown considerable dedication and talent in becoming well versed in an area outside their training and usual areas of study. It must not have been easy to be confronted with a cutting edge technology in the field of biological sciences and

to not only understand the subject matter, but to come to grips with the jargon and technical language which inevitably goes with a specialised subject. I thank and congratulate them both.

The Committee also wishes to thank Pat Roach for her assistance in producing this report.

I commend the report to the House.

HON. K.J. MINSON, MLA
CHAIRMAN

Executive Summary

This is the twenty-fifth report of the Standing Committee on Uniform Legislation and Intergovernmental Agreements. This report considers the developments in organ and tissue donation, transplantation and xenotransplantation. The report also considers the adequacy of the *Human Tissue and Transplantation Act 1982*, and the need for improved uniform legislation. In considering these issues, the Standing Committee had to consider factors that contributed to the low rate of organ donation in Australia, especially Western Australia, as compared to other western countries.

Chapter 1 of the report describes the basis of organ and tissue donation and transplantation. Human tissue is being used for an increasing range of medical purposes, for therapeutic transplants, as the basis of biological products and for research. The procedure of organ transplantation is well established worldwide. For those patients suffering end stage organ failure, transplantation is the best, and in some cases the only option. The major transplantation programs involve hearts, lungs, livers and kidneys. Other transplants which are being performed on a smaller scale include pancreas and bowels. Tissue transplantation has become widespread with corneas being used to save sight; bone, skin and heart valves are also used in treatment of patients.

The report describes how the majority of organs come from cadaveric donors, largely people who have suffered strokes or accidents and are certified dead while still on life support. This raises the issue of death and the certification of death which are outlined in Chapter 2 of the report.

It is also sometimes possible to retrieve organs from patients who have been certified dead in the normal way (non-heart beating donors). Non-heart beating donation is possible when rapid action is taken to ensure the viability of the organs.

Live donation of organs such as kidneys, and very occasionally, lobes of lungs or livers or sections of the bowel, is possible. Most often, the recipient is a close relative of the donor. Organs and tissue may also become available from live donors if they are removed from a patient who has received, for example, a heart/lung and has donated their own heart for transplantation into another patient. This is known as a domino procedure.

Tissue may also become available from cadaveric donors. Tissue, like organs must be tested for the presence of infectious diseases before use. Tissue can be preserved and stored in tissue banks before use.

When a potential donor has been identified in the intensive care unit (ICU), agreement is then obtained from relatives for organ removal. The issue of consent is discussed in Chapter 2. The different systems of consent, including “opting in” and “opting out” models and their operation are outlined. The Standing Committee found that the problem with organ donation was detection at the critical time of organs available for transplantation. The report considers that the key to donor identification and organ procurement is the placement of well trained senior health professionals in the hospitals. These issues are discussed in Chapters 2 and 3.

The reduced number of fatalities from road traffic accidents and strokes together with the increased possibilities for their use has resulted in a shortage of organs. Chapter 3 of the report outlines the approaches adopted in Australia to increase the organ donation rate. The establishment of DonateWest in Western Australia is discussed as well as the adoption in South Australia of the “Spanish model” which has seen South Australia double its organ donation rate.

The supply of cadaveric organs from traditional donors certified dead while on life support has been insufficient to meet the demand. The range of transplants possible is likely to increase with the combined effects of improvements in anti-rejection therapy and microsurgery.

Advances in techniques and the development of new immunosuppressive drugs have made it possible to perform transplants on a large number of organs. However, the shortage of cadaveric organ donors remains the major obstacle limiting the number of patients who could benefit from the treatment. This is a worldwide problem. The report describes how Australia in Chapter 3 and other countries in Chapter 4 are dealing with the problem of organ shortage.

Chapter 6 of the report outlines the development of a national registry which will enable organ donation coordinators to access information on registered donors. This will help them in seeking the consent of family members.

Developments in genetics and DNA technology have also provided changes for scientific support services for transplantation. Tissue typing of organs, particularly kidneys, to ensure good matches, and hence, better outcomes, is undertaken by laboratory services in hospitals.

In Chapter 7 the report considers xenotransplantation. The Standing Committee found that the fastest growing field is cell transplantation. A major breakthrough is expected soon in the use of growth factors to enable mature cells to replicate and produce a large number of cells which can then be implanted. Cell culture techniques may also open the way to perhaps, growing whole new organs.

Advances in biotechnology and genetic modification have the potential to impact on many aspects of everyday life, from health and health care to agriculture and the environment. Xenotransplantation is one of many developments taking place within the field of biotechnology. The science of transplantation is evolving rapidly. Human organs are in short supply and the need to ensure no infection results from transplantation is still a major issue. New technologies, while offering the potential to solve the problem of waiting lists, heightens concerns about infection risks.

There is a range of xenotransplantation and animal to human transplants therapies being developed. However, solid organ xenotransplantation is thought to be some years away as immunological problems still remain.

The Standing Committee found that developments in this area have aroused considerable public interest and raised concerns about public health. Research in this area needs to be carefully regulated.

The Standing Committee concludes in Chapter 8 that the complexity of the process of procurement of organs requires a coordinated systematic approach involving integrated teamwork and oversight of the whole process. The Standing Committee found that the “Spanish model” adopts a total approach which begins with detection of the donor, diagnosis of brain death, maintenance of the donor, organ viability and family consent. Once all these steps have been completed the extraction of organs and tissues is performed. After the family consent is

obtained, the organ sharing system is checked to find the best recipient on the waiting lists. This is done according to previously established distribution criteria. When all the organs are allocated, transplantation is performed.

The Standing Committee found that the shortage of organs and the low donation rate can be overcome if systems are put in place that help identify potential donors and assist in obtaining consent.

The report makes a number of findings and recommendations which the Standing Committee believes focus on the major issues raised in organ donation and transplantation.

Findings

Finding 1

The shortage of organs is not due simply to a lack of potential donors, but rather a failure to turn many potential donors into actual donors.

Finding 2

Of the thousands of West Australians, who die each year, only a small number are actually suitable donors.

Finding 3

Ticking a box on a drivers licence or donor card demonstrates a willingness to donate, but it is insufficient to allow hospitals to proceed with the removal of organs. The permission of relatives is still requested.

Finding 4

Donor Coordinators are most effective if based in hospitals.

Finding 5

Not only is transplantation of incalculable benefit to patients in terms of length and quality of life, but it is a cost-effective treatment.

Finding 6

Western Australia has not adopted the definition of death recommended by the Australian Law Reform Commission.

Finding 7

The countries with the highest donor rate have a “presumed consent” model.

Finding 8

There is currently a more favourable attitude to “opting out” in the community.

Finding 9

Organs of patients who die in regional hospitals in Western Australia are not being utilised effectively for organ donation.

Finding 10

Transport arrangements for organ donation from regional areas is inadequate.

Finding 11

The attitude of intensive care specialists and their concept of conflict of interest directly correlates with the rate of organ donation.

Finding 12

Potential donors are found in Intensive Care Units. These potential donors need to be identified and the family approached concerning organ donation.

Finding 13

The high cost of retrieving organs deters hospitals from keeping potential donors on a life support system before the necessary collecting operations.

Finding 14

There is a correlation between a low rate of adequately staffed ICU beds and a low rate of organ donation.

Finding 15

Medical staff need to develop appropriate communication skills to contribute to the process of consulting with donor families.

Finding 16

The more community awareness there is of organ donation, the more the supply of organs is likely to increase.

Finding 17

Efforts to increase organ donation should be directed to both the Hospitals and the community.

Finding 18

Only 20 percent of currently available organs are being used.

Finding 19

The organ donation rate needs to be improved. There must be a national effort to standardise and streamline the donation process from the initial diagnosis of brain death through to caring for donor families.

Finding 20

Death audits in hospitals can be applied to ensure that resources are used effectively and that the maximum number of organs are retrieved and transplanted.

Finding 21

The driver's licence registration system only provided for the ticking of a box to indicate a wish to be an organ donor. It did not allow potential donors to indicate which organs or tissue they wished to donate.

Finding 22

The outlook for xenotransplantation is so long term that resources are best directed to increasing transplants from human to human.

Finding 23

Xenotransplantation is not a viable option at present.

Finding 24

A number of matters including rejection of the animal graft, the transfer of diseases between species, ethical and social issues and cost implications need to be resolved before clinical xenotransplantation can be introduced to Australia.

Recommendations

Recommendation One:

A provision be included in the Human Tissue and Transplant Act 1982 (Western Australia) to provide the authority for removal of tissue of the deceased in a place other than a hospital for the purposes of transplantation and/or for therapeutic, scientific or medical purposes.

Recommendation Two:

A proactive donor detection program should be instigated to improve donor identification rates.

Recommendation Three:

Western Australia should adopt the uniform definition of death as recommended by the Australian Law Reform Commission.

Recommendation Four:

The Minister for Health should raise at the next meeting of Australian Health Ministers Conference the adoption of a national organ donation and transplantation model based on “presumed consent” and Western Australia should be ready to adopt the model as soon as possible.

Recommendation Five:

DonateWest develop a Code of Practice setting out standards to be followed and the requirement to approach the next of kin of all potential donors.

Recommendation Six:

Organ retrieval teams should be on stand by to retrieve suitable organs from regional Western Australian hospitals.

Recommendation Seven:

Access to high-speed aircraft should be made available for organ donation and retrieval when required from regional Western Australia.

Recommendation Eight:

That private and defence force aircraft should be seconded for use in emergencies for organ donation and retrieval in regional Western Australia.

Recommendation Nine:

The performance of the coordinator model adopted by DonateWest should be reviewed after two years and then if necessary, consideration be given to the appointment of medical coordinators as part of the donor coordinator system in Western Australia.

Recommendation Ten:

That a senior person in each hospital should be responsible to discuss organ donation and contact DonateWest when a potential donor is identified.

Recommendation Eleven:

There should be a review of the number of ICU beds in Western Australian hospitals to ensure a shortage of ICU beds is not a barrier to increasing organ transplantation rates.

Recommendation Twelve:

ICU beds should be adequately staffed to ensure that all potential donors are maintained so that organs can be retrieved from all actual donors.

Recommendation Thirteen:

Western Australian universities should include as part of the medical and paramedical courses a significant module on organ donation, transplantation and identifying potential organ donors and that module should be developed in consultation with DonateWest.

Recommendation Fourteen:

The school syllabus in High Schools should include a module on organ donation and transplantation to assist understanding of the issue and raise awareness and that module should be developed in consultation with DonateWest.

Recommendation Fifteen:

A national death audit procedure be adopted to ensure that potential donors are not overlooked.

Recommendation Sixteen:

Every hospital develop protocols to ensure that every dead or dying patient is suitably assessed for organ donation.

Recommendation Seventeen:

With the introduction of the new national organ donor registry, consideration should be given to providing for “opting out” and also an option of indicating which organs and tissues, donors wish to donate.

Recommendation Eighteen:

National policies be developed to promote research, subject to safety, efficacy, equity and ethical practice in relation to xenotransplantation.

CHAPTER 1. INTRODUCTION

1.1 Background

The Standing Committee on Uniform Legislation and Intergovernmental Agreements was approached by the Hon. Barbara Scott MLC, Member for South Metropolitan Region who asked the Committee to make enquiries regarding legislative barriers to organ donation and transplantation.

The Standing Committee, at its meeting on 15 September 1999, agreed to inquire into and report on existing and proposed uniform legislation concerning organ donation and transplantation.

The Terms of Reference of the Committee require the Committee to inquire into, consider and report on matters relating to proposed or current intergovernmental agreements and uniform legislative schemes involving the Commonwealth, States and Territories or a combination of States and Territories.

On Wednesday, 29 March 2000 the Legislative Assembly resolved -

That the Standing Committee on Uniform Legislation and Intergovernmental Agreements examine and report on developments in Organ Donation, Transplantation and Xenotransplantation; the adequacy of the *Human Tissue and Transplant Act 1982* and the need for improved uniform legislation and that the Standing Committee finally report to the House on 30 November 2000.¹

Current uniform legislation, the *Human Tissue and Transplantation Act 1982* (Western Australia), is based on “model uniform legislation” agreed to by the Ministers for Health in the 1970's.

The intergovernmental agreement was a result of a report by the Australian Law Reform Commission. The report followed a wide-ranging inquiry into the law and practice of organ donation and tissue transplantation throughout Australia. The essential recommendation from the inquiry was that each State and Territory should pass uniform legislation aimed at regulation of the practice of organ donation and tissue transplantation and removing them from the scope of the common law.

1.2 Organ and Tissue Transplantation

Some illnesses cause one or more of a person’s vital organs to stop working, resulting in organ failure. Unless the organ, or at least its function, can be replaced, that person will die. In the case of kidney failure, for example, the work of the kidneys, removing excess water and waste products from the body can be taken over by a technique called renal dialysis. This is life saving but it takes a lot of time and it is often difficult to keep a dialysis patient fully fit. In the case of bowel failure, people can be kept alive by artificial feeding but again it is complicated and interferes considerably with the patient’s normal life. There are, at present, no satisfactory artificial means of replacing the functions of the heart, lungs or liver over long periods.

¹

Motion by Mr Barnett, Leader of the House, Hansard, Wednesday 29 March 2000, p 5679.

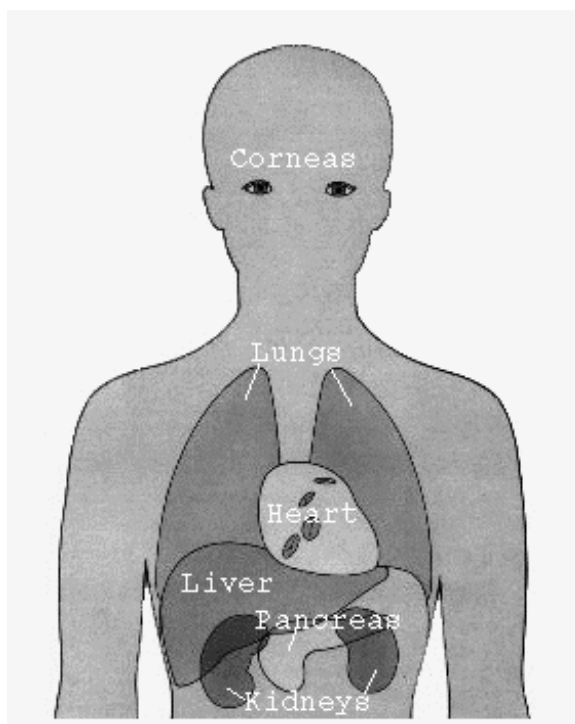
With the increasing success of organ and tissue transplant surgery, transplantation is being considered as the preferred treatment for more and more sick people with end-stage organ failure.

Organ transplant programs for people with kidney, heart, lung and liver failure have been well established for many years and are now very successful. Increasing numbers have survived over 20 years after their transplant and increasing numbers now survive at least five years. More recently transplants of the bowel and pancreas are being performed. Transplantation of tissues like cornea and bone is also well established.² Success rates of transplantation are very high. Recent statistics show that over 80 percent of transplanted kidneys are fully functioning after five years. This compares with just 34 percent of patients on renal dialysis surviving for the same period.³

The great majority of transplant operations use organs from people who have died. However, fit people can donate one of their kidneys, and in rare cases, have donated part of their liver, lung or bowel, without an unacceptable risk to their own health.⁴

Transplant recipients are able to enjoy a healthier life and take part in family and community life again. Over 15,000 Australians have received organ or tissue transplants since 1965.

The diagram below shows the organs and tissues most frequently required.



² Unrelated Live Transplant Regulatory Authority (ULTRA), <http://www.doh.gov.uk/ultra.htm>, p2.

³ Xenotransplantation, http://www.transplantsquare.com/public/...development/xenotrans/general_xeno3.htm, p 1.

⁴ Unrelated Live Transplant Regulatory Authority, *Op Cit*, p2.

1.3 Organs Used in Transplantation

Medical technology makes it possible for organs and tissue to be transplanted. Organs used in transplantation are kidneys, heart, heart-lung, liver, lungs and pancreas. Tissue includes corneas, skin, bone, heart valves and bone marrow.

Tissue can be recovered from both non-heart beating and brain dead cadavers. Some bone is recovered from living donors while bone marrow is only recovered from living donors.

Skin tissue, heart valves and bone must be recovered within 24 hours after death. Corneas must be recovered within 12 hours after death.⁵

However, the Western Australian legislation only makes provision for the removal of “tissue” which includes organs and tissue in a hospital. This is unlike the legislation in other States in Australia which allow the removal of tissue from a deceased person in a place other than a hospital.⁶ In a submission to the Standing Committee, DonateWest requested the Committee consider the issue of bringing the Western Australian legislation in line with the other States as follows -

Authority to remove tissue where body of deceased not in hospital

- place is defined as any place other than hospital;
- the deceased person had, during the person’s lifetime, expressed the wish for, or consented to the removal of tissue after the person’s death of tissue from the person’s body for expressed purpose;
- where the deceased is at a place other than a hospital, the senior next of kin of the person may, in writing, authorise the removal of tissue from the person’s body for the expressed purpose;
- the senior next of kin is satisfied that the deceased person during the person’s lifetime, had not expressed an objection to removal of tissue; and
- another next of kin of the same or higher standing does not object to the removal of tissue from the deceased’s body.⁷

The Standing Committee recommends that -

Recommendation One:

A provision be included in the Human Tissue and Transplant Act 1982 (Western Australia) to provide the authority for removal of tissue of the deceased in a place other than a hospital for the purposes of transplantation and/or for therapeutic, scientific or medical purposes.

⁵ ACCORD, Fact Sheet, wysiwyg://102/http://www.span.com.au/accord/factsheet_tissue.html.

⁶ Section 23 *Transplantation and Anatomy Act 1979* (Queensland), Section 25(2) *Human Tissue Act 1982* (Victoria), Section 24 *Human Tissue Act 1983* (New South Wales), Section 22 *Transplantation and Anatomy Act 1983* (South Australia)

⁷ Submission, DonateWest, 2 November 2000, p 2.

As many as nine people can benefit from the organ and tissue donations of one person. The following table sets out the number of transplants performed in Australia in 1998.

Table 1

Patients Transplanted in 1998.⁸

	QLD	NSW/ACT	VIC/TAS	SA/NT	WA	TOTAL
Organ Donors	40	65	40	38	13	196
DPMP*	12	10	8	23	7	10.5
Kidney	92	156	123	84	47	502
- Cadaveric	67	130	70	64	27	358
- Live	25	26	53	20	20	144
Liver	50	52	28	8	16	154
Heart	10	26	27	-	9	72
Heart/Lung	-	4	-	-	-	4
Lung	13 double	18 double 9 single	18 double 25 single	-	-	83
Pancreas#	-	14	4	-	-	18
Cornea	not provided	450	273	115	115	
Bone	458	119	526	237	283	1623
Total Transplants		848	1024	444	470	

* DPMP - donors per million population

All pancreas transplants are combined with a kidney

1.4 Definitions

The Western Australian *Human Tissue and Transplant Act 1982* uses a blanket definition to include organs and tissue. Section 3 provides -

“tissue” includes an organ or part of the human body or a substance extract from, or from a part of the human body.⁹

There is a separate definition for “blood” in the Act.

“Transplantation” covers the removal from one person of an organ or tissue and the implantation of that organ or tissue into another person.

Many organs and tissues are routinely transplanted from one human to another; such grafts are called “allografts”.

⁸ Australians Donate, figures provided by individual transplant units and the Australia and New Zealand Organ Donations Registry data, http://www.anzdata.org.au/ANZOD/updates/waiting_list.htm.

⁹ Section 3(1) of the *Human Tissue and Transplant Act 1982*, (Western Australia).

1.5 The Shortage of Organs

Because of the success of transplant surgery more organs are needed each year to meet the demand. Unfortunately, the increase in demand has not been matched by a corresponding increase in the number of available organs.

Transplantation is an accepted treatment for many people suffering from organ failure. More patients are referred for transplant surgery and waiting lists are increasing. Yet, there are not enough organs and tissues for transplant.

In recent years, organ procurement from cadaveric donors has increased worldwide. In 1999 mean donation rate was about 15 donors per million population (pmp), 22 in Europe (including Spain) and 22 donors pmp is the USA. Spain leads the world, with a national rate of 33.6 donors pmp. In spite of fact that donation rates have increased, the number of organs are insufficient to meet the increasing demand, considering that the expected number is around 50 donors pmp according to current waiting lists.¹⁰

The Standing Committee was advised that -

Spain is the only country that has decreased the waiting list.¹¹

The following table sets out the number of people on waiting lists for organ transplants in Australia as at January 1999.

Table 2

Organ Waiting List at January 1999.¹²

	QLD	NSW/ACT	VIC/TAS	SA/NT	WA	TOTAL
Kidney	167	720	357	78	137	1459
Liver	14	23	15	1	1	57
Heart	8	52	12	13	2	87
Heart/Lung	1	6	2	1	0	10
Lung	7	25	26	3	3	64
Pancreas	6	12	10	4	2	34
Cornea	Not Provided	approx 400	31	3	87	
Total		1238	453	103	235	

¹⁰ Manyalich M & Other, *The Transplant Procurement Management TPM Project*, p 2.

¹¹ Dr Rafael Matesanz, *Organizacion Nacional de Trasplantes*, Madrid, Spain, meeting with Committee, 4 October 2000.

¹² *Australians Donate, Op Cit.*

The patients on the organ waiting lists are gravely ill and many of those awaiting a heart, heart-lung or liver will die before a transplant becomes available. Generally, around 3,000 Australian children and adults are on waiting lists for a transplant.

The average waiting time varies according to the type of organ. The approximate typical waiting time for each organ is set out in Table 3 below.

Table 3

Organ Waiting Time¹³

Organ	Waiting Time
Kidney	1-3 years
Heart	3-12 months
Heart-Lungs/Lungs	9-12 months
Liver	2-6 months
Pancreas	12-18 months
Cornea	3-24 months
Bone-Marrow	7-8 months

It has been reported that numerous investigations suggest that that the shortage of organs is not simple due to a lack of potential donors but rather a failure to turn many potential donors into actual donors. It has even been suggested that the population of potential organ donors should far exceed the demand for transplantable organs. Surveys show that there is strong public and health care professional support for organ donation¹⁴

Finding 1

The shortage of organs is not due simply to a lack of potential donors, but rather a failure to turn many potential donors into actual donors.

1.6 Donors

In all Australian States, persons of sound mind over 18 years of age may elect to become an organ and/or tissue donor upon their death.¹⁵

Without donors there are no organs and without organs there are no transplants. The best transplant teams, trained at great expense, using the most up-to-date methods and equipment, can only perform transplants if they have an adequate supply of viable organs.¹⁶

¹³ Easten, Renee, "A Question of Consent? The Transplantation and Anatomy Amendment Bill 1998", Queensland Parliamentary Library, *Research Bulletin No 1/99*, Brisbane, February 1999, p 11.

¹⁴ Roels L. & De Meester J., "The relative impact of presumed consent legislation on thoracic organ donation in the Eurotranplant area", *Journal of Transplant Coordination*, Vol 6, No 4, December 1996, p 174.

¹⁵ Sections 8 and 9 of the *Human Tissue and Transplant Act 1982*, (Western Australia).

¹⁶ Paredes D. & Others, "Transplant Procurement Management: A Training Tool to Increase Donation", *Transplant Proceedings*, 31, 1999, p 2610.

The exact donor pool is highly influenced by local factors such as road death rates, intracranial haemorrhage prevalence, population density, number of ICU beds and age structure.

Improving donor detection requires concentrating efforts on early identification and monitoring of all patients who may eventually be diagnosed as brain dead.

The Standing Committee recommends -

Recommendation Two:

A proactive donor detection program should be instigated to improve donor identification rates.

1.7 Suitability of Organs

Organs must meet certain medical criteria before they are considered suitable for transplantation. For instance, they must be free of diseases or infections.

The clinical history should not reveal any previous diseases, personal habit or medical treatment that could compromise the function of a specific organ, or signify the transmission of a disease to an immunodepressed recipient.¹⁷

To be viable for transplant, organs must be maintained in a satisfactory condition until they can be retrieved and used. Organs deprived of oxygen will degenerate and become unsuitable for transplantation. It is necessary that life support in an intensive care unit (ICU) keep the organs viable within the body and oxygenated until they are retrieved for transplantation.

All internal organs must be retrieved from a “beating heart donor”. The one exception is the kidneys, which can be retrieved within one hour of heart death. Hearts, lungs and livers should be transplanted within 4-5 hours of removal from the donor (although livers have been kept up to 36 hours before transplanting). Kidneys may be kept for up to 48 hours before transplanting. Tissue can be donated after “heart death” and stored in tissue banks for various amounts of time.¹⁸

The Standing Committee found -

Finding 2

Of the thousands of West Australians, who die each year, only a small number are actually suitable donors.

¹⁷ Manyalich M. & Others, “Expanded donor pool”, in Touraine J.L. et al., Eds., *Organ Allocation, 1998*, p. 150.

¹⁸ British Organ Donor Society, Body, <http://www.argonet.co.uk/education/body/Facts.html>.

1.8 Tissue Banks

Organs must be transplanted promptly, however, some tissue can survive much longer and may therefore be kept in tissue banks. Tissues, which may be banked, include corneas, bones, heart valves and skin.¹⁹

1.9 Donor - Recipient Organ Matching

Once organs are retrieved, they are matched; blood group, tissue type and patient sex are important factors in donor-recipient organ matching. Each State and Territory in Australia has its own waiting list. However, priority is given across Australia to certain patients who meet agreed medical criteria.

Dr Millar Forbes advised the Standing Committee that -

There is a national organ matching system for kidney transplantation. The clinical immunology department at Royal Perth Hospital is in charge of that in Western Australia.²⁰

Generally speaking, organs are transplanted into Australian recipients. However, Australians and New Zealanders requiring liver transplants are placed on the one waiting list. Livers from Australian and New Zealand donors are allocated on a “best-match” basis. In the event that there is no suitable Australian or New Zealand patient awaiting liver transplant, the organ may be offered to overseas patients.²¹

1.10 Donor Intention

In Australia, potential donors indicate their wish to become an organ donor in a number of ways. Endorsement on a driver’s licence is the most common form in most jurisdictions. However, in Victoria and Tasmania, a donor register exists and potential donors are registered. Alternatively, potential donors can sign a uniform donor card indicating their consent to be an organ and/or tissue donor on their death. Donor cards are issued by the Australian Kidney Foundation.

Recent public awareness research indicates that 90 percent of the Australian population support organ/tissue donation in principle.²²

Until recently, there was no central register of potential donors, which was nationally accessible. Without such a central register there was a risk that a person’s intentions with respect to organ/tissue donation could be either overlooked or not discovered in time to permit donation to occur, especially when the person died interstate.

¹⁹ National Health and Medical Research Council, *Donating organs after death: ethical issues*, Discussion Paper No 1, AGPS, Canberra, 1997, p 6.

²⁰ Dr Alistair Millar Forbes, Transcript of Evidence, Perth, 14 August 2000, p 10.

²¹ National Health and Medical Research Council, Paper No 1, *Op Cit*, 1997, p 9.

²² ACCORD, Fact Sheet, tissue, *Op Cit*.

The Standing Committee found -

Finding 3

Ticking a box on a drivers licence or donor card demonstrates a willingness to donate, but it is insufficient to allow hospitals to proceed with the removal of organs. The permission of relatives is still requested.

1.11 Ethical Issues

Ethics and ethical principles extend to all spheres of human activity. Most nations have published codes of ethical conduct in health research, often observing the 1964 *Declaration of Helsinki* published by the World Medical Association and a succession of international documents prepared over the past four decades. Australia has followed these trends.²³

Many ethical issues in transplantation result from the need for more organs. The ethical debates focus on the fair allocation of the limited number of organs and on ways to increase the number of organs. There are fundamental ethical issues that affect law making in the area of live and cadaver tissue donation. These issues involve the rights or interests of the community in having a source of organs and tissue for donation for public benefit.

In 1996 the National Health and Medical Research Council (NHMRC) made recommendations for the donation of cadaveric organs and tissue for transplantation. These recommendations covered the legislative and social aspects of organ and tissue donation in addition to the clinical aspects. The Australian and New Zealand Intensive Care Society endorsed the recommendations.

The NHMRC has a code of practice on transplantation of cadaveric organs and tissues, which provides guidelines to health professionals on those issues about which the various State and Territory legislation is silent. The guidelines cover such matters as - how to approach relatives for consent to remove organs, the maintenance of records, consent issues, care of patients where brain death has not been conclusively established, the time at which death is recorded and the maintenance of organs prior to transplantation.²⁴

Guidelines and standards followed in Western Australia regarding obtaining consent are based on the following guidelines and recommendations -

- Australian Transplant Coordinators Association (*National Guidelines for Organ and Tissue Donation 1999*);
- Australian and New Zealand Intensive Care Society (*Recommendations Concerning Brain Death and Organ Donation 1998*); and

²³ National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans*, AusInfo, Canberra, 1999, pp 1-2.

²⁴ Easten, Renee, "A Question of Consent? The Transplantation and Anatomy Amendment Bill 1998", *Op Cit*, 1999, p 24.

- National Health and Medical Research Council (*Recommendations for the Donation of Cadaveric Organs and Tissues for Transplantation 1996*).

Bioethics is the application of ethics to medicine and medical research. Scientific and technological advances in medicine are often well ahead of social, community, ethical and philosophical debate and discussion.

The majority of the world's religions approve and support the practice of organ donation and transplantation.²⁵

The procedures underlying organ allocation in Australia continue to evolve and remain subject to ongoing ethical review.

1.12 Ethics and the Law

Research involving human participation is subject to a variety of legal regulations at Federal, State and Territory levels. Commonwealth laws regulate registration, use of, and certain research on pharmaceutical drugs and medical devices, the protection of privacy and intellectual property. State and Territory laws regulate access to and use of health information held by authorities, consumer protection and professional conduct.

Both legal requirements and ethical guidelines apply. Ethical guidelines have the objective of defining standards of behaviour to which the researchers should adhere.²⁶

1.13 Ethics and Brain Death

The concept of "brain death" has generated considerable debate since it was first described in the 1950's and 60's. There has been widespread discussion in medical, legal and bioethical literature about the precise meaning of "brain death" and debates about its application continue.

The death of a human person is understood to consist of the irreversible loss of the integrated and coordinated life of the person as a single living organism. The National Health and Medical Research Council in their Discussion Paper state -

The concept of "brain death" is not intended to introduce a novel kind of death, but to identify the irreversible loss of the organic unity and integrated activity of a living human person.²⁷

1.14 Live and Cadaveric Donors

Non-heart beating donors are declared dead when their heart stops beating. This is unlike the conventional brain dead donor who is declared dead by special brain death criteria. A potential non-heart beating donor is identified when attempts to resuscitate the patient are unsuccessful or after withdrawal of ventilatory support. A brain dead donor is supported by a ventilator which pumps oxygenated blood throughout the body so that the organs can be used for transplant.

²⁵ Does my religion approve of organ donation? http://www.transweb.org/qa/qa_txp/faq_religion.htm1.

²⁶ National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans, Op Cit*, 1999, p 5.

²⁷ National Health and Medical Research Council, *Certifying death: the brain function criterion*, Discussion Paper No 4, AGPS, Canberra, 1997, p 3.

The principal source of organs for donation are from brain dead donors, only 10-20 percent of kidney transplants are from living donors.²⁸

The *Human Tissue and Transplant Act 1982* (Western Australia) covers organs and tissues that can be donated by living donors as well as organs and tissues that can be donated after death.

In Australia, living donors are most often involved in kidney or bone marrow donation. The *Human Tissue and Transplant Act 1982* (Western Australia) distinguishes between regenerative and non-regenerative tissue.

The Act provides that -

“regenerative tissue” means tissue that, after injury or removal, is replaced in the body of a living person by natural processes of growth or repair.²⁹

Regenerative tissue includes blood, bone marrow, bone and liver segments, which grow back naturally after removal. The main risks to the donor derive from the removal procedure itself.

The Act states that -

“non-regenerative tissue” means tissue other than regenerative tissue.³⁰

Non-regenerative tissue, such as a kidney, once removed, is not naturally restored in the donor. Kidney donation is the most common form of such donation in Australia. Each person has two kidneys and, if one is donated, the remaining one (provided it is healthy) is capable of carrying out the function of cleansing the blood normally.³¹

Experience of organ donation by living donors indicates that the best outcomes are achieved when donors are parents, mature siblings or grandparents of the recipient. The genetic relationship usually leads to a donor being closely matched in tissue type so that risks of rejection are small; this is important for kidney and bone marrow donation.³²

Because there are not enough cadaver donors, transplant programs will transplant a kidney from a living donor to a relative, providing the donor is in good health and the transplant will likely be successful.

Dr Millar Forbes advised the Standing Committee that in Western Australia in 1999 -

Up to 60 percent of kidney recipients receive their kidney from living relatives rather than from a recently deceased person.³³

28 Manyalich M. & Others, “Expanded donor pool”, *Op Cit*, 1998, p. 147.

29 Section 3 of the *Human Tissue and Transplant Act 1982*, (Western Australia).

30 *Ibid.*

31 National Health and Medical Research Council, *Ethical issues in donation of organs or tissues by living donors*, Discussion Paper No 2, AGPS, Canberra, 1997, p 4.

32 *Ibid*, p 10.

33 Dr Alistair Millar Forbes, Transcript of Evidence, Perth, 14 August 2000, p 12.

The average rate of for live kidney donation was 31 percent for Australia. The rate in South Australia was 15 percent.

It has recently been reported that for the first time in Australia, a living relative has donated part of a liver to an adult.

Sir Charles Gairdner Hospital surgeons dissected the right lobe of the donor sister's liver and transplanted it to the recipient sister.³⁴

1.15 Donations from Children

Living donation of regenerative tissue by children is legally permitted, under certain strict conditions, in all Australian States except the Northern Territory. It is not lawful to remove non-regenerative tissue from the body of a living child.³⁵ Only in the Australian Capital Territory, is living donation by children permitted, but only under the most exceptional circumstances.³⁶

Section 13 of the *Human Tissue and Transplant Act 1982* (Western Australia) sets out under what circumstances regenerative tissue can be removed from a child. Child donation is only permissible for transplantation into close relatives of the child.

The Act defines a child as -

“child” means a person who has not attained the age of 18 years.³⁷

1.16 Transplant Coordinators

In many countries transplant coordinators work within the hospital as part of the transplant teams. In other countries, procurement is the task of national or regional organisations working independently outside the hospital. Working within the hospital provides instant access to possible donors, thus facilitating active donor detection. This should occur independently of the transplant teams.

The process of transplantation starts with the identification of all brain dead patients. After evaluating such patients the potential donors are identified. Then the patients must be clinically and legally certified as dead. During this time, the viability of the organs must be maintained. The existence of the donor must be referred to the transplant coordinating office. In countries where the coordinator is located outside the hospital the transplant coordinator must go to the hospital where the donor is and the organisational aspect of the procurement process can begin. The consent of the family is sought in most countries. If consent is obtained, arrangements are made both within and outside the hospital for the retrieval of the organs.

The organs are shared according to the previously approved criteria and the coordinating office provides complete logistic support. Once retrieval is completed the organs or tissues will be transplanted or stored.

³⁴ Ashworth, K., “Gift of Life: Sister in donor first”, *The West Australian*, Thursday, 8 June 2000, pp 1-2.

³⁵ Section 12(2) of the *Human Tissue and Transplant Act 1982*, (Western Australia).

³⁶ National Health and Medical Research Council, Discussion Paper No 2, *Op Cit*, 1997, p 17.

³⁷ Section 3 of the *Human Tissue and Transplant Act 1982* (Western Australia).

Dr Martesanz the Director of *Organizacion Nacional de Trasplantes* in Spain, advised the Standing Committee that -

Coordinators need to be located in the hospital to detect potential donors. They must be a well trained group of enthusiastic people who can transmit enthusiasm to others.³⁸

This was endorsed by Robina Balderson, Chief Executive of the United Kingdom Transplant Services Authority who advised the Standing Committee that -

Coordinators must be based in the hospital.³⁹

This was confirmed by Dr Peter Doyle, Medical Adviser of the United Kingdom Department of Health, who advised the Standing Committee that -

The key element to handling donor procurement was to have a person on the floor of the hospital.⁴⁰

Dr Martesanz advised the Standing Committee that there is a direct relation between the person who is a coordinator and the number of organs donated. He stated -

The coordinator should be a doctor located in the hospital. What is required is a young enthusiastic doctor who will be able to get donor organs.⁴¹

In Spain, in larger hospitals the teams of coordinators are made up of one doctor and two or three nurses.

In Western Australia, the coordination of all organ and tissue donation is carried out by DonateWest's three Donor coordinators.⁴²

Finding 4

Donor Coordinators are most effective if based in hospitals.

1.17 Cost of Transplants

There is a perception that transplantation is a very costly procedure from which relatively few people benefit. In fact, the costs involved vary a great deal depending on the type of transplantation. Some transplants such as heart and liver are specialised and relatively costly. However, kidney transplantation is less costly than maintaining a patient on hospital-based kidney dialysis as well as the non-financial benefits such as improvements to health and lifestyle.

³⁸ Dr Rafael Martesanz, Director, *Organizacion Nacional de Trasplantes*, Madrid, Spain, meeting with Committee, 4 October 2000.

³⁹ Robina Balderson, Chief Executive, United Kingdom Transplant Services Authority, London, United Kingdom, meeting with Committee, 6 October 2000.

⁴⁰ Dr Peter Doyle, Medical Adviser, Department of Health and Unrelated Live Transplant Regulatory Authority, London, United Kingdom, meeting with Committee, 6 October 2000.

⁴¹ Dr Rafael Martesanz, Director, *Organizacion Nacional de Trasplantes*, Madrid, Spain, meeting with Committee, 4 October 2000.

⁴² Submission, DonateWest, 2 November 2000, p 2.

The costs of transplantation procedures were addressed in several studies, in particular in regard to kidney transplantation. A study in France lists the costs.

Table 4

Economic Aspects⁴³

Year	Dialysis	Transplant
1st	FF140,00*	FF170,00
2nd	FF140,00	FF 47,200*
3rd	FF140,00	FF 52,250*

* After transplantation, the cost of drug treatment.

In the United Kingdom, the cost of dialysis is about £18 000 per year

In the long term, transplantation is estimated to produce a saving of 63 percent over total medical expenses for a renal patient when compared to lifelong dialysis treatment.

The cost of other transplant operations varies according to how long the patient is hospitalised. In France, a liver transplant costs on average FF280,000 (£15 000 in the United Kingdom), while heart transplants are of the order of FF192,000 (£10 000-£18 000 in the United Kingdom). Thus, the most important savings is in indirect costs. However, the cost-benefit analysis in these cases has to take into account the fact that without transplantation the patient would have no chance of surviving, that is, the “life-years” gained by these terminal patients and their quality of life.⁴⁴

The Standing Committee found that -

Finding 5

Not only is transplantation of incalculable benefit to patients in terms of length and quality of life, but it is a cost-effective treatment.

1.18 Allocation of Organs

The system of allocation of organs for transplantation in Australia varies with the individual organ. With the allocation of kidneys, candidates for transplantation are drawn exclusively from patients already within a dialysis program. Because of the short time that hearts and lungs can be safely stored between collection and implantation, the initial offer for livers and hearts is made to its State of origin and if it cannot be used there, an offer is made to other States. Patients awaiting a corneal graft are placed on a waiting list and are then treated in the order of entry to it.

⁴³ Organisation for Economic Co-operation and Development, *Xenotransplantation: International Policy Issues*, 1999, p 63.

⁴⁴ *Ibid*, p 63.

1.19 Costs

In Australia and New Zealand, the system of transplantation is such that donated organs and tissues are provided free of charge to other members of the community.⁴⁵ In fact, the sale or purchase of human tissue is prohibited.⁴⁶

1.20 Source of Organs for Transplant

The best source of suitable organs is probably a young healthy patient who dies in hospital from a cause unrelated to the condition of the organ concerned. For example, a person who has been involved in a motor accident or some other sudden death. Such patients have frequently suffered severe head injuries and brain damage.

Such patients may be in a state of unconsciousness and their breathing and circulation maintained only by support of an artificial respirator or ventilator.⁴⁷

However, better health care and new surgical techniques are saving more people who may have been suitable donors in the past. Mandatory helmet laws for motorcyclists, seat belt and infant car seat laws, anti drink-driving campaigns and air bags in cars may also contribute to fewer road fatalities and fewer donors.

The predominant causes of death for Australian organ donors over all are cerebrovascular accident in 47 percent of cases, road trauma in 29 percent and non-road trauma in 12 percent of cases.⁴⁸ This changing profile of donors is reflected in other countries. In Spain, most donors, 75 percent now die of cerebrovascular accidents and only 22 percent of organ donors die in road traffic accidents.⁴⁹

1.21 Factors that Influence Organ Donation

The figures for organ transplants are alarmingly low in Western Australia. It has been reported that there are a number of factors that influence organ donation. Some of the factors that affect organ donation include -

- the unsuitability of organs;
- permission for donating organs; and

⁴⁵ National Health and Medical Research Council, *Ethical issues raised by allocation of transplant resources*, Discussion Paper No 3, AGPS, Canberra, 1997, p 29.

⁴⁶ Sections 29 and 30 of the *Human Tissue and Transplant Act 1982* (Western Australia).

⁴⁷ The Parliament of the Commonwealth of Australia, Law Reform Commission, "Human Tissue Transplants", Report No 7, June 1977, Parliamentary Paper, No 287/1977, Canberra, p 52.

⁴⁸ ACCORD, Fact Sheet, www.span.com.au/accord/factsheet.html, p 2.

⁴⁹ Miranda B. & Others, *The Spanish organisational structure for organ donation. Up to date*, *Organizacion Nacional de Trasplantes*, Madrid, Spain, p 2.

- the high cost of harvesting organs.⁵⁰

Other factors include -

- the culture within the hospitals and staff in the hospitals;
- the availability of facilities to maintain a “heart beating” donor and to perform transplants;
- costs;
- professional attitudes;
- inadequate recognition; and
- public attitudes.

1.22 Issues to be Addressed

The Standing Committee is of the view that Western Australia’s low donations rate is affected by a number of factors including -

- the tyranny of distance;
- lack of a statewide coordinated approach in identifying potential donors and facilitating the donation and procurement process;
- uncertainty amongst family members about individual donation wishes prior to death;
- limited community discussion about the benefits of donation and transplantation;
- confusion about how and where to become a registered donor; and
- reluctance on the part of doctors and family members to proceed with donation even when the wishes of the donor were known to favour donation.

These issues will be discussed further in the report.

50

“When donations offer gift of life”, *The West Australian*, Tuesday, 12 October 1999, p 14.

CHAPTER 2. LEGISLATION

2.1 Introduction

Most countries have enacted transplant law that define the different legal aspects affecting transplantation procedures. Most transplant law include a definition of death, the position with respect to consent for organ donation, general principles with respect to confidentiality and the avoidance of commercialisation.

2.2 Constitution

Within Australia, the Commonwealth Constitution does not confer power on the Federal Parliament to make laws with respect to health care. This power resides with the Australian States. However, the Commonwealth raises the majority of the funds collected by all Australian governments and through the control of medical insurance exerts a large influence upon the practice of medicine within Australia.

2.3 The Introduction of Uniform Legislation

In 1977, the Australian Law Reform Commission (ALRC) reported on a wide-ranging inquiry into the law and practice of organ and tissue donation and transplantation in Australia. The main issues canvassed being, “opting out”, “brain death”, and “live donations”. The inquiry resulted in the ALRC’s report “Human Tissue Transplants” which was tabled in the Federal Parliament in November 1977. The inquiry exposed the inadequacy of the common law in regulating a number of matters in this area. The ALRC recommended that uniform legislation be introduced throughout Australia to provide for the removal of human organs and tissue. The *Human Tissue and Transplant Act 1982* (Western Australia) was enacted in response to a report of the Australian Law Reform Commission. The Commission’s report included a draft bill as a model for uniform legislation throughout Australia that provided for the removal of human organs and tissue and created a statutory definition of brain death. All Australian States have enacted more or less similar legislation.

Legislation around Australia is relatively uniform, although the Western Australian legislation does not include a definition of “death”.

Finding 6

Western Australia has not adopted the definition of death recommended by the Australian Law Reform Commission.

Organ donation and transplantation is a rapidly changing field with a number of issues emerging from not only a public policy perspective but also community expectations, therefore uniformity in legislation and practice is desirable. Along these lines, Dr Jones advised the Standing Committee that -

In a balanced uniform legislation approach, uniformity of management and clinical issues are just as important as increasing organ donation rates around Australia. It is pleasing to see the emergence of a national approach to clinical guidelines, management principles, fair and equitable access to available organ tissue and standardisation of procedures and protocols.⁵¹

Dr Millar Forbes advised the Standing Committee that -

It would be nice to move towards uniformity of legislation throughout the country.⁵²

2.4 Definition of Death

There has been some ambiguity surrounding the definition of death. Death has been defined as -

The cessation of life; the ceasing to exist; defined by physicians as a total stoppage of the circulation of the blood, and a cessation of the animal and vital functions consequent thereupon, such as respiration, pulsation, etc. ...⁵³

This definition has been cited in law.

However, with the development of new resuscitative techniques and the pharmacological and mechanical means to support life for protracted periods, it became necessary to develop new techniques to determine whether or not there was any chance of recovery. Thus, in 1968, the concept of whole brain death was first proposed.⁵⁴ The “Harvard criteria” established in 1968 shaped subsequent attitudes and practice concerning diagnosis of brain death.

The idea of “brain death” as an expression of death emerged in response to the recognition of patients with irreversible brain damage of such an extent that suspension of ventilatory support would result in permanent cessation of respiration and, as a consequence, of cardiac contraction.⁵⁵

In his book on brain death Dr McCullagh states -

The requirement for a new set of criteria to identify death became an inevitable consequence of refinements in medical technology, which permitted the artificial maintenance of respiration and, consequently, of cardiac contraction in patients who had sustained brain damage so severe as to interrupt spontaneous respiration irreversibly.⁵⁶

⁵¹ Dr Dorothy Jones, Transcript of Evidence, Perth, 14 August 2000, p 6.

⁵² Dr Alistair Millar Forbes, Transcript of Evidence, Perth, 14 August 2000, p 6.

⁵³ Blacks Law Dictionary 4th Ed. 1951.

⁵⁴ The Ad Hoc Committee of the Harvard Medical School to Examine the Definition of Brain Death was commissioned to define irreversible coma as a criterion for death, 1968.

⁵⁵ McCullagh P., *Brain Dead, Brain Absent, Brain Donor: Human Subjects or Human Objects?* John Wiley & Son Ltd, West Sussex, England, 1993, p 13.

⁵⁶ *Ibid*, p 8.

The incentive to develop and apply the concept of brain death was given impetus by at least two major medical technological advances. The development of intensive care, with mechanical support systems that can artificially maintain respiration and circulation in patients whose brains have irretrievably ceased functioning, and the advent of organ transplantation for which viable and intact organs are needed. The suitability of organs for transplantation diminishes rapidly once the donor's respiration and circulation stop.⁵⁷

Dr McCullagh also states -

The notion of brain death was not, in the first instance, a contrivance to facilitate the identification of subjects who would be suitable donors of transplantable organs.⁵⁸

There are different mechanisms followed throughout the world for the certification of brain death and in some countries, they require an ancillary test (an electroencephalogram (EEG) or some kind of angiography), although this test is unnecessary.

2.5 Death - National Definition

The 1977 Australian Law Reform Commission (ALRC) inquiry into Human Tissue Transplants made a number of recommendations. One of its main recommendations was that a new definition of "death" based on brain death should be adopted, and that the donation of tissue by both living and dead donors should be regulated by legislation. These recommendations were implemented in all jurisdictions.

This concept of death has been incorporated into legislation in many countries. In 1977, the Australian Law Reform Commission proposed that uniform legislation should define death and recommended that the law should state that a person had died when either -

- irreversible cessation of all function of the brain; or
- irreversible cessation of circulation of blood in the body of the person had occurred.

This recommendation has been incorporated into relevant legislation in most Australian States, except Western Australia.

In Western Australia, there is no statutory definition, but for the purposes of human tissue removal, the Act provides that tissue shall not be removed until two medical practitioners have certified that all brain function has irreversibly ceased.

⁵⁷ Online Forum: Organ Transplant Controversy, January 2, 1998, <http://www.pbs.org/newshour/forum/january98/organ1-5.htm1>.

⁵⁸ McCullagh P. *Op Cit*, 1993, p.8.

The ALRC's report stated -

There are good reasons for the introduction into the law of Australia of a statutory definition of death or a statutory provision, which recognises the concept of determination of death by reference to cessation of brain function. The reasons include the clear demonstration that the law lacks certainty on the proper criteria of death.⁵⁹

Brain death occurs when the brain has died from lack of blood flow and is unable to recover. The brain cells die and cannot regrow or be replaced, the brain stops functioning and will never function again. Organs, such as the heart, kidney and liver, may continue to function for a short time with the help of mechanical ventilation.

To determine brain death, two senior doctors who cannot be involved in transplantation, carry out a number of tests. The tests focus on brain functions and include, most importantly, the ability of the patient to breathe without mechanical assistance. Additional testing such as an X-ray angiography may be required to show that all blood supply to the brain has ceased.

Section 24 of the *Human Tissue and Transplant Act 1982* (Western Australia) uses the criteria that organs can be removed from a person whose respiration and circulation is being maintained by artificial means and if two medical practitioners have declared that irreversible cessation of all functions of the brain has occurred. In practical terms, that means that a number of tests have been done to determine that brain function has ceased. Dr Stokes stated -

One of the questions that I guess the committee would ask when it considered a change in the legislation is the definition of death.⁶⁰

2.6 Uniform Concept of Death

In the United States in 1981, a joint working party, including the American Bar Association, the American Medical Association, the National Conference of Commissioners on Uniform State Laws, and the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioural Research proposed a model statute. The *Uniform Determination of Death Act 1981* was developed for adoption in all jurisdictions of the United States. The Act stated -

An individual, who has sustained either 1) irreversible cessation of circulatory and respiratory functions, or 2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead.⁶¹

Brain death has now come to be seen as synonymous with death itself. Brain death usually results from sudden, severe trauma.

In order to facilitate the adoption of uniform national standards in the determination of brain death, both the American Academy of Neurology and the Australian and New Zealand Intensive Care Society has produced guidelines, which support the whole brain death concept.

⁵⁹ ALRC Report, *Human Tissue Transplants*, No 7, AGPS, Canberra, 1977, p 62.

⁶⁰ Dr Bryant Stokes, Transcript of Evidence, Parliament House, Perth, Tuesday, 7 December 1999, p 11.

⁶¹ Pearson, A. & Others, "The ambiguity of "The Gift of Life": exploring the experiences of donor families and health workers and the public discourse on organ donation", *Interim Report, 1996*, Department of Clinical Nursing, The University of Adelaide, 1996, p 6.

Mrs Briggs advised the Standing Committee that -

Other jurisdictions, quite validly, because of the recommendations of the Australian Law Reform Commission have included a definition of death as either the cessation of functions of the brain or cessation of circulation of the blood.⁶²

2.7 Death - WA Legislation

The suggested definition of “death” was omitted from the Western Australian legislation. In the second reading speech the then Minister for Health, the Hon. Raymond Young stated -

The suggested definition of “death” has been omitted from the Western Australian version at this stage. This has been done because it is felt that much more public debate is needed on this difficult subject before the definition is embodied in the Statute.⁶³

The Standing Committee understands that originally the Western Australian draft legislation did have the definition of “brain death” included. However, it was excluded from the final legislation. The exclusion of the definition creates some difficulty because the legal position is unclear.

The then Minister for Health indicated that legislation for a definition of “death” should follow when the community had a chance to formulate an opinion. The Minister stated that -

It would be precipitant to include a definition of “death” at this stage, although an early amendment could be called for after the transplant legislation has operated for a short time.⁶⁴

Dr Stokes advised the Standing Committee that -

We do not believe the current section has impeded the donation of organs in any way. Probably to be uniform we should follow New South Wales and Victoria, which define brain death as an irreversible cessation of all functions of the brain of the person.⁶⁵

There is no legal authority in Western Australia to clearly establish death by reference to brain function. In the absence of a statutory definition, the decision will remain with the individual doctor and relatives concerned.

The Standing Committee recommends that -

Recommendation Three:

Western Australia should adopt the uniform definition of death as recommended by the Australian Law Reform Commission.

⁶² Ingrid Briggs, Legal Officer, Health Department of Western Australia, Transcript of Evidence, Perth, Tuesday, 7 December 1999, p 11.

⁶³ Legislative Assembly, “Human Tissue and Transplant Bill”, *Second Reading*, Wednesday, 27 October 1982, p 4315.

⁶⁴ *Ibid*, pp 4315-6.

⁶⁵ Dr Bryant Stokes, Transcript of Evidence, Perth, Tuesday, 7 December 1999, p 11.

2.8 Western Australian Law

The *Human Tissue and Transplant Act 1982* (Western Australia) provides the legal framework for the donation of human tissue. The Act deals with consent of the person and next of kin as well as donations by adults and children.

There has not been a review of the Act since 1982, although there have been minor amendments.

2.9 Legal Issues

Donation and transplantation practices need to be developed within the appropriate legal framework. Transplant laws should include an adequate definition of brain death, a position with respect to consent for organ donation, the general accepted principles of confidentiality and avoidance of commercialisation, minimum hospital requirements for organ donation and transplantation.

In response to changes in the powers of the Coroner in the *Coroner's Act 1996*⁶⁶, the *Human Tissue and Transplant Act 1982* was subjected to various consequential amendments. The amendments provided for the development of codes of practice, including guidelines and standards to be observed in obtaining consent under the Act. The Codes were intended to allow the development of guidelines to ensure that all those involved in any process under the *Human Tissue and Transplant Act 1982* could be satisfied that appropriate procedures had been followed.

However, due to a minority recommendation on written consent in a Working Party report in June 1997 the matter of Codes of Practice was not proceeded with at that time.

Although the Codes have not been implemented, they were generally based on current practice in Western Australia. It is understood that many of the matters covered by the Codes reflected current practice. The codes followed NHMRC guidelines.

2.10 Consent

The *Human Tissue and Transplant Act 1982* (Western Australia) requires that a designated officer for the hospital authorises the removal of tissue, which includes organs, from a deceased person for transplantation.⁶⁷

Section 22 of the Act provides that a designated officer for the hospital may authorise the removal of tissue from a dead person in circumstances where the designated officer after making inquiries is satisfied that -

- the deceased person during his lifetime expressed the wish for, or consented to, the removal after death of tissue from his body and had not revoked the consent; or
- the deceased person had not expressed an objection to the removal after death of tissue from his body and the senior available next of kin consents to the removal of tissue.⁶⁸

⁶⁶ The current legislation sets out the powers and duties of the State Coroner and regulates the coronial system. It came into force on 7 April 1997 and repealed the *Coroners Act 1920*, Western Australia.

⁶⁷ Section 22 of the *Human Tissue and Transplant Act 1982* (Western Australia).

⁶⁸ Section 22(2)(a) and (b) of the *Human Tissue and Transplant Act 1982* (Western Australia).

Consent encompasses written and oral consent of the donor and the consent of the next of kin where the donor had not explicitly expressed a wish to be a donor.

The “senior available next of kin” is defined as being, in the case of an adult, the first person available in the following hierarchical order of priority - the spouse, a son or daughter over the age of 18 years, a parent, a brother or sister over the age of 18 years.⁶⁹

In practice however, regardless of the individual’s registration as a donor, consent for donation is always sought from the next of kin.

The report of the Legal, Constitutional and Administrative Review Committee of Queensland indicated that in Queensland -

Where the deceased wished to be a donor and (any of the) the next-of-kin object, hospitals will not go ahead with the donation.⁷⁰

The Queensland Committee reported that -

... it is apparently very rare for families to overturn the deceased’s wishes to be an organ donor where the deceased’s intention is clearly known.⁷¹

The next-of-kin of some potential donors are simply not approached whether because the patient is not recognised as a potential donor, or because medical/nursing staff is reluctant to make the approach to the family.

2.11 Written Consent/Oral Consent

In Australia, as in many other countries, once a patient is declared dead, and assuming the circumstances are suitable for organ or tissue donation it is routine for medical staff to discuss organ and tissue donation with the family.

While written consent is preferred there are circumstances, particularly related to tissue donation, where written consent is not possible.

Ticking a box on a driver’s license is not considered informed consent. It has been noted that a donor consent notation on a driver’s licence, even if “binding” consent, would still not eliminate the need for the hospital to consult with the family to firstly check whether the deceased had withdrawn their consent to organ donation; and secondly to obtain information on the social/medical history of the deceased.⁷²

Western Australian and South Australian donors are provided with information about organ donation with licence application and renewal information. In Western Australia, the material urges potential donors to inform their family of their decision to become an organ donor.

⁶⁹ Section 3(1) of the *Human Tissue and Transplant Act 1982* (Western Australia).

⁷⁰ Legislative Assembly of Queensland, Legal, Constitutional and Administrative Review Committee, Review of the Transplantation and Anatomy Amendment Bill 1998, *Report No 16*, July, 1999, p 7.

⁷¹ *Ibid*, p 8.

⁷² *Ibid*, p 20.

2.12 Opting In

In an “opting in” system, organs and tissue are not retrieved on death for transplantation unless the deceased, while alive, have given actual (usually written) consent to being a donor.

All Australian States and Territories have an “opting in” system of organ donation. Under this “opting in” system permission to proceed with organ donation is required after death has been confirmed. It has to be ascertained whether or not the deceased had expressed a wish for, or consented to, the removal of tissue and that such consent had not been withdrawn or revoked. Alternatively, whether the deceased had expressed an objection to organ donation. Finally, whether the senior next-of-kin has no objection to the removal of tissue from the deceased.

Western Australia currently has an “opting in” system whereby individuals are asked while they are alive to register their intention to be a donor. In Western Australia, organ procurement does not proceed without familial consent regardless of registration. This is a convention rather than legal requirement and would likely continue even if there was a move to an “opting out” system.

Dr Millar Forbes advised the Standing Committee that

In Western Australia, we ask the relatives what their wishes are before we proceed with donation. That is not a legal requirement, but we do that. If we were to move to a presumed consent model, that would still be the case.⁷³

Dr Millar Forbes advised the Standing Committee that in Western Australia -

Up to 60 percent of families approached have declined permission.⁷⁴

The “opting in” is the system used by all States and Territories in Australia. It is also the system being promoted as the basis for the Australian Organ Donor Registry and other national initiatives.

2.13 Presumed Consent/Opting Out

“Opting out”, also known as “presumed consent” refers to a system where all organs of a deceased person are available for transplantation purposes, unless the person expressed a contrary wish before their death. Any person who wishes to “opt-out” of organ donation in the event of their death must decide this in advance and register an objection. If no objection is registered, a person is presumed to consent to their organs being donated on death. Such a system makes organ donation routine and eliminates the additional emotional burden which might be placed on the deceased’s family in having to make a decision about organ donation during a time of emotional upheaval.

At least 13 European countries have presumed consent legislation; that is, organs may be removed after death, unless an individual states during their lifetime that it is not their wish. In approximately half these countries, where the “opting out” system is used, an approach is still

⁷³ Dr Alistair Millar Forbes, Transcript of Evidence, Perth, 14 August 2000, p 14.

⁷⁴ Dr Alistair Millar Forbes, Transcript of Evidence, Perth, 14 August 2000, p 3.

made to families to obtain consent. In the remaining countries, organs are taken routinely if there is no prior objection.⁷⁵

In most countries with transplant laws, family consent for organ procurement is required.

Table 5

Consent for Organ Donation⁷⁶

Presumed Consent	Presumed Consent but practically Informed Consent
Austria Finland Portugal Sweden	Belgium France Greece Italy Luxembourg Spain
Informed Consent	No Legislation practically Informed
Denmark Ireland South America United Kingdom USA	Germany Holland

The Standing Committee found -

Finding 7

The countries with the highest donor rate have a “presumed consent” model.

It has been reported that the British Medical Association has voted overwhelmingly to endorse an “opting-out” system of organ donation. The opting-out scheme requires people who do not want to be donors to state specifically that they do not want their organs to be used. The vote by the British Medical Association reverses the 29 year old Association policy of “opting-in” donation, for which written consent is needed before organs can be used.⁷⁷

⁷⁵ RCN Congress, http://www.rcn.org.uk/congress/news/news_press_brief1.html, p 1.

⁷⁶ Organ Procurement, <http://www.transplantsquare.com/health/congress/Barca96/Presskit/organpro.htm>, p 5.

⁷⁷ BMA backs “opt-out” organ donation, <http://www.guardianunlimited.co.uk/racism/Story/0,2763,64213,00.html>, p 1.

The presumed consent schemes solve a number of problems as it forces people to make a decision. It helps relatives and the patients who are literally dying while waiting for a transplant.⁷⁸

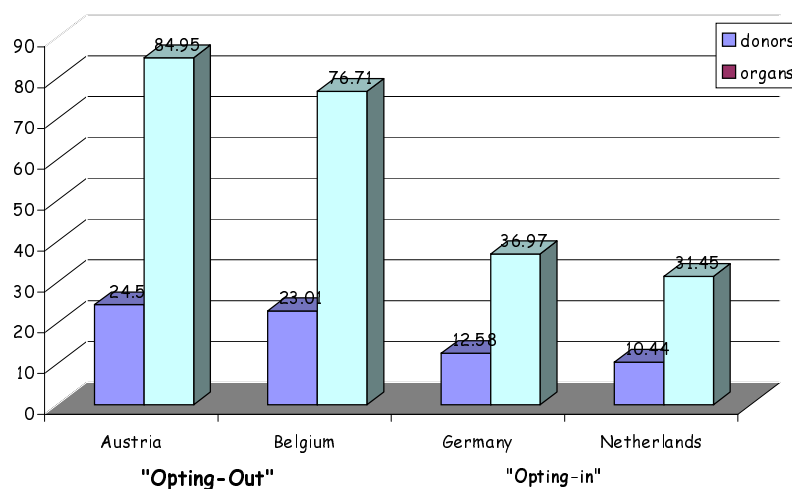
The Australian Law Reform Commission in their 1977 report on Human Tissue Transplants did indicate that there was a strong body of opinion in Australia in favour of “opting out”. Although the Commission did not recommend, “opting out” in their 1977 report they did say that their recommendation was not immutable. Indeed, they felt that as the Australian community and other communities were likely to develop a more favourable attitude to “opting out” the position should be reviewed.

Dr Stokes advised the Standing Committee that -

... the opting-out system is preferable to the opting-in system ... I would prefer everyone to be a potential organ donor unless they say they do not want to be .⁷⁹

Graph No. 1⁸⁰

**Impact of legislative environment: donors & organs p.m.p.
in 1999 (ET)**



The Standing Committee found that -

Finding 8

There is currently a more favourable attitude to “opting out” in the community.

78 BMA backs “opt-out” organ donation,
<http://www.guardianunlimited.co.uk/racism/Story/0,2763,64213,00.htm1>, p 2.

79 Dr Bryant Stokes, Transcript of Evidence, Parliament House, Perth, Tuesday, 7 December 1999, p 15.

80 Donor Action

The Standing Committee after reviewing the evidence in Australia and overseas is of the view that a more flexible model of consent should be considered. The Standing Committee is of the view that a “presumed consent” approach should be introduced. The “presumed consent” model should allow for persons to “opt in” or “opt out” as well as providing for conditions which allow persons to specify which organs they wish or do not wish to donate.

Dr Stokes advised the Standing Committee that -

It was easier to make a negative decision to “opt out” than to decide to “opt in”.⁸¹

The Standing Committee believes that since the evidence suggests that about 90 percent of Australians are in favour of organ donation,⁸² a more flexible model of “presumed consent” should be adopted.

Therefore, Standing Committee recommends -

Recommendation Four:

The Minister for Health should raise at the next meeting of Australian Health Ministers Conference the adoption of a national organ donation and transplantation model based on “presumed consent” and Western Australia should be ready to adopt the model as soon as possible.

The Standing Committee believes that this model can be easily incorporated into the new national register.

Approaching the family represents a key point of the process of organ donation and is the most sensitive. In most countries family consent is sought. Dr Matesanz advised the Standing Committee that -

All countries that have “presumed consent” ask for family consent, except Austria.⁸³

In Spain the family of the potential donor is always approached. It is a pragmatic approach. Dr Matesanz stated -

The opinion of the family is most important. Although the majority of the Spanish population is in favour of organ donation they want to be asked.⁸⁴

⁸¹ Dr Bryant Stokes, Chief Medical Officer, Health Department of Western Australia, Briefing to Committee, 6 November 2000.

⁸² ACCORD, Organ Donation attitudes Research 1995, www.span.com.au/accord/attitudees.htm1.

⁸³ Dr Rafael Matesanz, Director, *Organizacion Nacional de Trasplantes*, Madrid, Spain, meeting with Committee, 4 October 2000.

⁸⁴ *Ibid.*

For these reasons the Standing Committee endorses the practice whereby the consent of the family is always sought for the retrieval of organs.

Dr Miller Forbes advised the Standing Committee that -

Current practice of approaching relatives is the best way. Education and promotion of donation within hospitals is important, and guidelines and code of practice for hospitals will assist and encourage doctors to identify potential donors and seek family consent.⁸⁵

The Standing Committee is of the view that a Code of Practice should be adopted that sets out standards for all hospital personnel to follow in all areas of organ donation. The Code should outline procedures to be followed and the requirement to approach the next of kin of all potential donors.

The Standing Committee recommends that -

Recommendation Five:

DonateWest develop a Code of Practice setting out standards to be followed and the requirement to approach the next of kin of all potential donors.

2.14 Commerce in Human Tissue

Section 29 of the *Human Tissue and Transplant Act 1982* (Western Australia) prohibits trading in tissue. The Act also prohibits advertisements relating the purchase of human tissue.⁸⁶

However, it was reported that a recent Supreme Court decision in Perth could force a legislative review to prevent people selling the bodies of dead relatives or demanding money. The controversial decision declared that -

... the preserved body tissue of a dead man was property.⁸⁷

The decision related to the meaning of a particular term used in the *Rules of Supreme Court 1971* (Western Australia), and is therefore confined in its effect to that narrow issue. It was not about whether or not human tissue can be considered to be “personal property” in the sense that legal rights may be exercised in relation to it. It was rather about the powers of a Court to order DNA tests to be carried out on tissue samples held by a pathology laboratory for the purpose of establishing paternity.⁸⁸

⁸⁵ Submission, Dr Millar Forbes, Medical Director, DonateWest, 8 November 2000.

⁸⁶ Section 30 of the *Human Tissue and Transplant Act 1982* (Western Australia).

⁸⁷ Peace B., “Body sales worry for State”, *The West Australian*, Monday 12 June 2000, p 3.

⁸⁸ Submission by the Department of Health Western Australia, 14 August 2000, p 11.

There have been reports that in some poorer overseas countries people have been pressured to sell the organs of their dying relatives. It has also been reported that -

Murder charges have been brought against three Thai doctors and a former hospital administrator accused of deliberately misdiagnosing patients as brain dead to use their organs for illegal transplants.⁸⁹

It was recently reported that the commercial trade in human body parts was no longer confined to the poorer developing countries. Eastern and Central Europe was becoming a source of cheap human kidneys and other organs for the transplant industry. It has been revealed that a sponsorship company has been organising for Israeli patients to be flown to Estonia for transplant operations. It has been reported that the company charges 160,000 dollars for each operation.⁹⁰

In Australia, human tissue for transplant is habitually obtained by gift, that is, voluntary donation. There is no evidence of any practice anywhere in Australia of the sale by persons of their own tissue, or by persons “lawfully in possession” of dead bodies, of cadaver tissue.⁹¹

At a meeting in Paris, the European Health Ministers decided to establish guidelines in the area of organ donation and transplantation including the non commercialisation of human organs. They held that -

A human organ must not be offered for profit by any organ exchange organisation, organ banking centre or by any other organisation or individual whatsoever.⁹²

The Council of Europe has Protocols to the Convention on Human Rights and Biomedicine, on Transplantation of Organs and Tissue of Human Origin which prohibits financial gain. Under the provision, organs and tissue cannot be bought or sold or give rise to direct financial gain for the person from whom they have been removed or a third party. The Protocol also prohibits organ and tissue trafficking. Any trade in organs and tissues for direct or indirect financial gain is prohibited.⁹³

In fact, transplant laws in most countries impose an absolute prohibition on any form of commerce or organ trafficking.

The Standing Committee agrees that organs transplanted in Western Australia should be obtained from a known and ethical source.

⁸⁹ “Organ scam doctors charged”, *The West Australian*, Thursday 6 April 2000, p 28.

⁹⁰ Ivanov A., “Health: Israeli Link In Estonian ‘Human Kidneys for Sale’ Scam”, <http://www.oneworld.org/ips2/feb98/transplants.html>.

⁹¹ The Parliament of the Commonwealth of Australia, Law Reform Commission, “Human Tissue Transplants”, Report No 7, June, 1977. Parliamentary Paper, No 287/1977, Canberra p 85.

⁹² Council of Europe, Committee of Minister, 3rd Conference of European Health Ministers, Paris, 16-17 November 1987, p 13.

⁹³ Council of Europe, Steering Committee on Bioethics, Draft explanatory report to the additional Protocol to the Convention on Human Rights and Biomedicine, on Transplantation of Organs and Tissues of Human Origin, Strasbourg, 18 September 2000, Articles 20 & 21, pp 21-22.

CHAPTER 3. ORGAN DONATION AND TRANSPLANTATION IN AUSTRALIA

3.1 Background

Australia has the lowest number of donors per million of population in the western world and Western Australia has one of the lowest organ donation rates in Australia. In 1998, there were only 196 donors (10 donors per million of population) in Australia. Thirteen of these donors were from Western Australia (seven donors per million population).

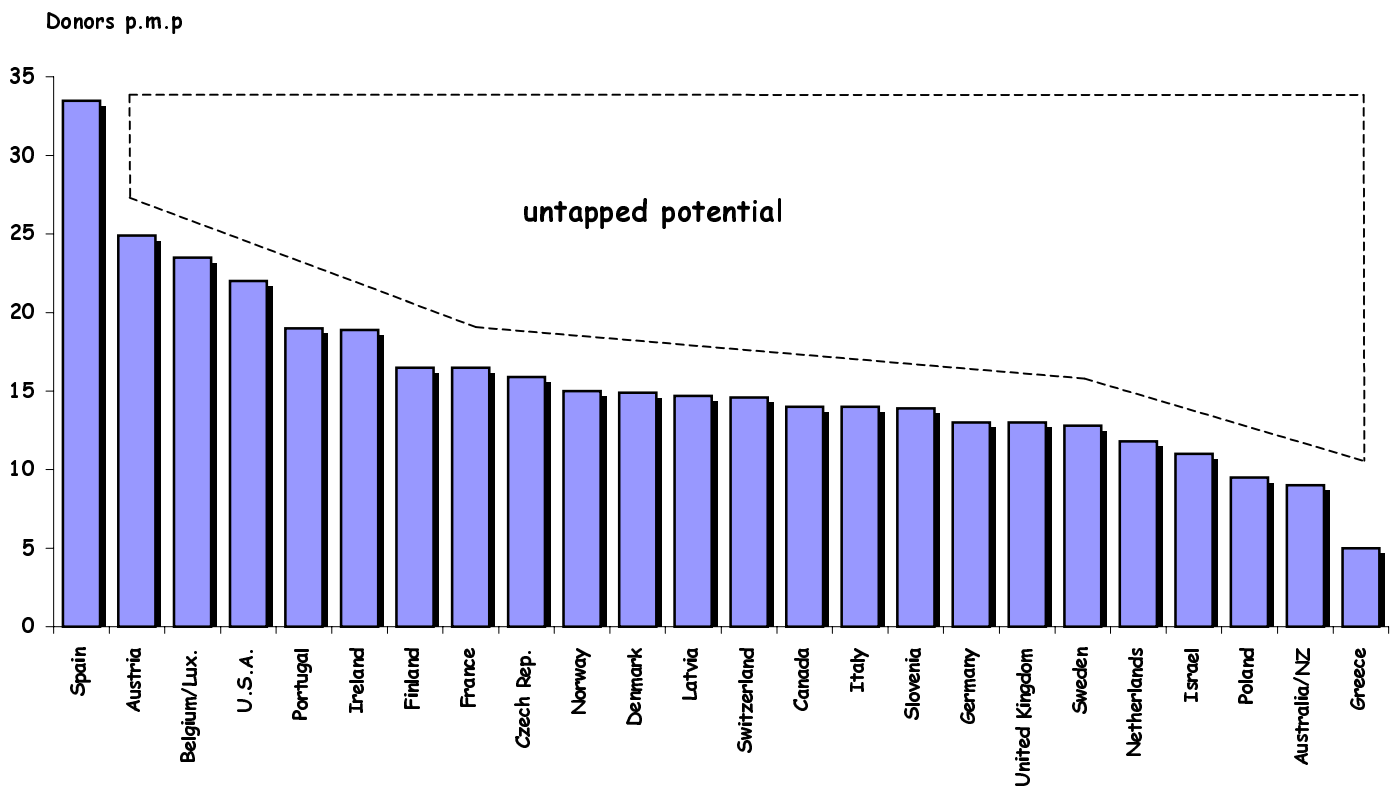
Dr Stokes advised the Standing Committee that -

Western Australia's organ donation rate is very low in comparison with the rest of the world. In my view, it is a matter of education. ... We must consider whether there should be an opting-out or an opting-in situation for organ donation.⁹⁴

Western Australia has an "opting-in" system for donor registration. The graph below compares donor rates in a number of countries.

Graph No. 2⁹⁵

Cadaveric organ donors p.m.p. in 1999



⁹⁴ Dr Bryant Stokes, Transcript of Evidence, Perth, Tuesday, 7 December 1999, p 2.

⁹⁵ Donor Action.

3.2 Western Australia

Thirty-five percent of Western Australian drivers have indicated on their driver's licences that they wish to be organ donors. Theoretically this means 500,000 registered potential donors. However, this number of registered potential donors, must be in a clinical situation to become actual donors. Of those who are clinically in the position to become actual donors only one percent will be suitable donors.

There has been a reduction in the number of individuals who are medically suitable for donation. On average, less than one percent of all deaths meet the criteria for donation. This is significant considering that only two percent of deaths occur in hospitals where facilities exist to maintain donors. In 1996, one percent of all deaths equated to 1093 donors, however actual donors that year totalled 194. There is an increasing need to maximise all opportunities for donation from those who are able to donate.

In the year, 1999 there were eight organ donors and 39 tissue donors in Western Australia. In that time, Western Australia has carried out seven liver, ten kidney and six heart transplants. The Department of Health stated -

Although the WA organ donation rate is still low, it must be noted that the rate has improved since 1999. In 1999 the WA organ donation rate was seven donors per million population compared to the overall national rate of 8.6 donors per million. Up Until 30 June 2000, WA has eight organ donors.⁹⁶

In December 1998, there were approximately 148 Western Australians on the waiting list for kidneys, four for livers, three for hearts and over 130 awaiting corneal transplantation. Patients may have to wait up to three years for a suitable organ or tissue to become available. A successful transplant is a cost-effective and desirable alternative to high costs and ongoing life saving treatments.

Transplants in Western Australia are performed in a number of teaching hospitals. Dr Stokes stated -

Royal Perth and Sir Charles Gairdner Hospitals are the main transplant hospitals. Renal transplantation can be done at Fremantle Hospital, but they are the only hospitals. Princess Margaret Hospital for Children will do children's transplants. [Transplants are performed] ... mainly at the teaching hospitals.⁹⁷

Dr Stokes advised the Standing Committee that when it comes to more complex organs -

... we believe that the only place to do pancreatic transplantation at the moment is in Sydney.⁹⁸

Dr Jones advised the Standing Committee that -

The donors generally come from hospitals with intensive care units. ... we must look at how we will cover regional centres in a State as large as ours.⁹⁹

⁹⁶ Submission by Department of Health, Western Australia, 14 August 2000, p 4.

⁹⁷ Dr Bryant Stokes, Transcript of Evidence, Perth, Tuesday, 7 December 1999, p 4.

⁹⁸ *Ibid*, p 6.

⁹⁹ Dr Dorothy Jones, Transcript of Evidence, Perth, Tuesday, 7 December 1999, p 4.

Dr Stokes advised the Standing Committee that -

... there are patients in Geraldton, Bunbury, Broome and Port Hedland who are dying from untreatable conditions and who may well be suitable donors. It may be appropriate to take an organ donor removal team up there.¹⁰⁰

Dr Stokes advised the Standing Committee that -

... the amount of organ retrieval occurring in the very remote areas would be very small compared with the metropolitan area.¹⁰¹

The Standing Committee found -

Finding 9

Organs of patients who die in regional hospitals in Western Australia are not being utilised effectively for organ donation.

The Standing Committee recommends that -

Recommendation Six:

Organ retrieval teams should be on stand by to retrieve suitable organs from regional Western Australian hospitals.

Dr Stokes added -

If we were to use the rural areas as a source of donor organs, it is almost certain that we would need some form of rapid transportation to take an organ removal team to that person and bring the organs back.¹⁰²

3.3 Donor Registration in Western Australia

In Western Australian organ donation information from the driver licensing database is downloaded to a central donor registry at the QEII medical centre on a daily basis, donor registration status is recorded in the TOPAS computer. The State's donor coordinators can then access this information.

If a patient is admitted to a metropolitan teaching hospital, this information is available on computer or in the in-patient file. With a National Registry, it will be important to retain easy accessibility.

¹⁰⁰ Dr Bryant Stokes, Transcript of Evidence, Perth, Tuesday, 7 December 1999, p 9.

¹⁰¹ *Ibid.*

¹⁰² *Ibid.*

For tissue donation, all deaths in hospital are notified to the donor coordinator. The Department of Health stated -

Encouragement is necessary to ensure doctors and nurses observe this practice.¹⁰³

Persons who die out of hospital may be admitted to the mortuary. If a Coroner's case is a registered donor, that admission may be referred to the donor coordinator. The Department of Health of Western Australia stated -

This is currently under discussion with a view to increasing the number of tissue donors.¹⁰⁴

3.4 Transport

Distance is one factor contributing to Western Australia's low donation rate. Deaths occurring outside the metropolitan teaching hospitals are not currently considered for organ donation. To donate organs an individual must be declared brain dead and maintained on artificial ventilation and respiration until organ procurement can commence. At present organ procurement only takes place in one of the four teaching hospitals.¹⁰⁵ The Department of Health stated -

Distance is also an issue for Western Australia's low donation rate in the rural sector in that individuals arriving at hospital are more likely to be dead or in a very serious condition due to the time taken to reach the hospital even with the provision of air transport (eg. Royal Flying Doctor Service).¹⁰⁶

The Department of Health advised the Standing Committee that -

The effect of distance on Western Australia's low donation rate could be overcome by enabling organ procurement to occur in deaths outside the metropolitan region. This could take the form of transporting surgical teams to regional hospitals or by transporting critically ill or brain dead individuals to Perth. DonateWest will be assessing the benefits of these actions in the future.¹⁰⁷

Another important issue that affects organ donation and transplantation is the need to transport the donor organs to the recipient. Aircraft have been chartered for the purpose of retrieving organs. However, reliance on the commercial jet service is not appropriate because the service is infrequent. Dr Stokes advised the Standing Committee that -

I have the view that we need a high-speed jet in this State, which we can use for these types of issues, and it could also be used for other things.¹⁰⁸

The former Minister for Health, the Hon. Kevin Prince stated that -

Our geographic isolation, time differences and retrieval disadvantages have some bearing on our poor donor rate. Distance and retrieval patterns pose a challenge to gaining access to people killed in the country.¹⁰⁹

103 Submission by Department of Health, Western Australia, 14 August 2000, p 8.

104 *Ibid*, p 8.

105 *Ibid*, p 4.

106 *Ibid*, p 4.

107 *Ibid*, p 4.

108 Dr Bryant Stokes, Transcript of Evidence, Perth, Tuesday, 7 December 1999, p 8.

The then Minister also acknowledged the suggestion to set up a mobile retrieval team but he noted it would be very expensive and he questioned its effectiveness. However, he did state -

... it is a proposition to which I am open. It is certainly something I am more than happy to hear further debate on, not only here but also within the medical fraternity and among people concerned about this issue.¹¹⁰

In a State like Western Australia, transport is one of the issues that must be addressed. Dr Millar Forbes advised the Standing Committee that -

We must examine access to country areas and the involvement of regional hospitals a bit more than we have until now.¹¹¹

The Standing Committee has considered this question of remoteness and transport in Western Australia and is of the view that a more coordinated medical transport system could be implemented. Access to the use of high speed retrieval aircraft should be considered, as well as the use of private and defence force aircraft.

The Standing Committee found -

Finding 10

Transport arrangements for organ donation from regional areas is inadequate.

The Standing Committee recommends that -

Recommendation Seven:

Access to high-speed aircraft should be made available for organ donation and retrieval when required from regional Western Australia.

The Standing Committee also recommends that -

Recommendation Eight:

That private and defence force aircraft should be seconded for use in emergencies for organ donation and retrieval in regional Western Australia.

109 Legislative Assembly of Western Australia, *Human Tissue and Transplant Amendment Bill*, Second Reading, Hon. K. Prince, *Hansard*, 21 August 1997, p 5342.

110 *Ibid*, p 5342.

111 Dr Alistair Millar Forbes, Transcript of Evidence, Perth, 14 August 2000, p 7.

3.5 Establishment of DonateWest

Western Australia has had a poor rate of organ donation for a variety of reasons, with the main one being a lack of an organisation or group dedicated to improving the current organ donation rate. Without a body to provide a coordinated approach, identification of organ donors and facilitation of the process has been haphazard and inefficient.¹¹²

To help address some of these issues, the Western Australian Organ and Tissue Donation Agency known as DonateWest was established on 27 September 1999. DonateWest will provide a statewide coordinated approach. The aim of DonateWest is to maximise Western Australia's donation rates and ensure positive outcomes for donor families and recipients.

The State Government has allocated \$1 million to establish DonateWest - the WA Organ and Tissue Agency - that aims to boost donor rates.¹¹³

Dr Jones advised the Standing Committee about the initiatives that led to the creation of DonateWest -

It appeared that we had mechanisms whereby we could do the transplant surgery; that is, the scientific and technological capacity to do the operations - heart, lung and liver transplants. The barrier to doing more of them and getting people off the growing waiting lists was the low donation rate of available organs.¹¹⁴

As a result the South Australian system was examined as well as undertaking research into international best practice, in particular, the "Spanish model". Dr Jones stated -

The key element of the "Spanish model" and the South Australian model involve clinicians and, specifically, intensive care doctors. The critical element in the Spanish model that South Australia introduced was the concept of a medical donor coordinator. Traditionally in Australia, we have non-medical coordinators, and they do a fantastic job. The Spanish model noted a number of factors: Firstly, having a doctor in the coordinator position gave it some authority, some legitimacy, some mainstream official recognition and acceptability; and, secondly, it allowed doctors to deal with other doctors. In general, doctors listen to other doctors before they will listen to other allied health professionals.¹¹⁵

DonateWest will act as a statewide coordinating agency to improve -

- donor identification and the coordinating of donation services;
- provide support to donor families during the decision-making process;
- ensure appropriate referrals to bereavement services; and
- educate the public and medical community.

¹¹² Submission by Department of Health, Western Australia, 14 August 2000, p 4.

¹¹³ Hodge F., "\$1m organ donors boost", *The West Australian*, Tuesday September 28, 1999, p 13.

¹¹⁴ Dr Dorothy Jones, Transcript of Evidence, Perth, Tuesday, 7 December 1999, p 3.

¹¹⁵ Dr Dorothy Jones, Transcript of Evidence, Perth, Tuesday, 7 December 1999, p 3-4.

DonateWest will provide a statewide framework for policy and practice and work collaboratively with all other key stakeholders in organ donation. The Standing Committee was advised that -

DonateWest will also review costs associated with the donation process from education to retrieval to transplantation in order to ensure that there are no ongoing barriers to organ donation within the system.¹¹⁶

DonateWest has appointed three donor coordinators, who have a background in critical care nursing. The donor coordinators will be responsible for facilitation of effective and efficient retrieval of organs and tissue from consenting donors. They will also provide support to families and education of the clinical teams in multiple sites and the wider public. No medical coordinators have been appointed. The Standing Committee was advised that -

DonateWest is currently exploring service agreements with relevant hospitals to promote clinical leadership on donation issues across clinical teams with a view to promoting donation through increased awareness.¹¹⁷

The Standing Committee believes that medical donor coordinators are the key factor in successful organ donor systems in both Spain and South Australia. The Standing Committee recommends that -

Recommendation Nine:

The performance of the coordinator model adopted by DonateWest should be reviewed after two years and then if necessary, consideration be given to the appointment of medical coordinators as part of the donor coordinator system in Western Australia.

3.6 The “South Australian” Model

In May 1994, a Select Committee of the House of Assembly of the South Australian Parliament was established and chaired by the then Minister for Health Dr Michael Armitage to consider organ donation and transplantation in South Australia. The Select Committee reviewed different legislative approaches in place in various countries around the world and looked at a number of ways of overcoming the shortages of organs for donation.

The Select Committee was impressed with the work of Dr Rafael Matesanz and the *Organizacion Nacional de Trasplantes* in Spain and the results achieved in Spain. Dr Armitage states -

The element which most impressed me both as a former medical practitioner and as a politician seeking to address the need for organ donation was the total professionalism with which every detail of the donation process is addressed by Dr Matesanz and his team. I was left in no doubt

¹¹⁶ Submission by Department of Health, Western Australia, 14 August 2000, p 14.

¹¹⁷ *Ibid*, p 15.

as to why the ONT had built up such a spectacular reputation, and was enthusiastic to attempt the implementation of an Australian version of the Spanish model as soon as I returned.¹¹⁸

The Select Committee reported to the South Australian Parliament that the implementation of the “Spanish model” might provide an impetus to increase the Australian donation rate.

The South Australian Organ Donation Agency (SAODA) is based on the “Spanish model”. SAODA was established in July 1996 and was formed with the agreement of the Australian Health Ministers Conference, following review of the “Spanish model” of organ donation. SAODA closely follows the “Spanish model”, employing medical donor coordinators whose role it is to identify potential organ donors within their hospital in liaison with the transplant coordinators who speak with families about their knowledge of the deceased's wishes regarding organ donation.

SAODA is located in shop-front premises in central Adelaide to enhance the visibility of the issue. Donor coordinating teams consisting of sessional medical donor coordinators, who are all senior Intensive Care Consultants and full-time donor coordinators, are based in the major teaching hospitals. The medical donor coordinators identify within the Intensive Care Unit and other areas of the hospital any potential organ donors. They discuss with relatives, in conjunction with the donor coordinators, the option of organ donation. They provide medial assistance to the donor coordinator in the initial stage of the donation process and have clinical management of the donor. They also provide education within the hospital. SAODA reimburses the intensive care unit for the services.

The team approach has proved to be very successful. The Donor Coordinator makes all the donor arrangements including tissue typing, virology testing, liaising with transplant units, operating theatres and ICU.

Education is provided to hospital staff and the community. Donor Coordinators also provide the essential immediate support and follow up care for the relatives of the donor. SAODA believes that -

It is [the task of providing support to the donor family] which is so important to a successful organ donation program.¹¹⁹

SAODA also provides specialised bereavement services to donor families to help them cope with the loss of their loved one.

Along with identifying potential donors, SAODA concentrates on the need to maintain the dignity of donors and provide support for donor families. Since its establishment South Australia and Northern Territory organ donation rates have risen from 17 to 23 donors per million of population in 1998.

118 Armitage, “Comments on the Spanish Model (I)”, in Organ donation for Transplantation: The Spanish Model, Matesanz R. & Miranda, Eds., *Organizacion Nacional de Trasplantes*, Madrid, 1996, p 2.

119 Prof. Dahlenburg & Herbertt K., “Annual Report of the Activities of the South Australian Organ Donation Agency”, South Australian Organ Donation Agency, 1998, p 5.

The very positive results in reflect the success of the modified Spanish model of organ procurement in South Australia. SAODA believes that -

The most important factor in increasing the organ donation rate is the assiduity with which hospital intensive care staff identify potential donors and, with a coordinated and sensitive approach to the relatives of the potential donor, obtain permission for organ donation.¹²⁰

3.7 Queensland

Queensland has twenty-three donor hospitals and two transplant hospitals. It has specialist retrieval staff, which includes specialist technicians, nurses and social workers.

Organ donation programs in Queensland must take into account the impact that the decentralised nature of Queensland has on time frames for successful negotiation and retrieval of donated organs. Time is of the essence in organ retrieval, a potential donor must be kept on a ventilator until retrieval, and consent can be organised.

Queensland's major tertiary hospitals are all located in Queensland's south eastern corner and not within easy reach of the majority of donors and secondary hospitals. The major provincial hospitals are also a considerable distance from Brisbane.¹²¹

In Queensland, the Premier's aircraft is available for the retrieval of organs. Once a patient is declared brain dead by two independent specialists, organ donation is discussed with the family. If consent for organ donation is given the necessary blood tests and matching occurs. The retrieval team is then contacted and retrieval of the organs for transplantation takes place.

Due to road safety legislation, the donor pool from road trauma has reduced from 59% to 29%. The majority of donors are medical donors. Multiple strategies are required to increase the organ donor rate.

Although Queensland has one of the highest rates of positive donor status indicated on drivers' licences in Australia, the value of this is largely negated because the information on the driver's licences is not available to those involved in the organ donation process. A report of the Legal, Constitutional and Administrative Review Committee on the review of the *Transplant and Anatomy Amendment Bill 1998* found that -

Section 14A of the *Traffic Act 1949* (Qld) prevents the release of driver's licence information to 'another person' without the driver's written agreement. Therefore, it operates to deny donor coordinators access to the licence database in order to establish whether a person has consented to being an organ donor on his licence.¹²²

The Amendment Bill under review by the Queensland Committee sought to prevent relatives from stopping organ donation by providing that the hospital need not consult with a potential donor's next-of-kin. The Queensland Committee although supportive of the general objectives

¹²⁰ Prof. Dahlenburg & Herbertt K., "Annual Report of the Activities of the South Australian Organ Donation Agency", South Australian Organ Donation Agency, 1998, p 5.

¹²¹ Legislative Assembly of Queensland, *Op Cit, Report No. 16*, July, 1999, p 16.

¹²² *Ibid*, p 11.

of the bill to increase organ donor rate did not believe that the current practice by hospitals of consulting with the potential donor's family as a matter of course should be changed.

The Committee did call for the provisions regarding the donation of organs and tissue after death to be reviewed in their entirety. The Committee stated -

Given the relative uniformity of these provisions in Australia (and given the desirability of maintaining that uniformity), this is a matter which the Minister might wish to raise at an appropriate Australian Health Ministers' forum.¹²³

Consent of the family for organ donation is always sought. The families usually do not veto the donor's wishes.

The Queensland Committee found it was important that the wishes of the donor are made known to the family. If the family is aware of the wishes of the donor, it is generally carried out.

If the body of the donor is at a place other than a hospital written consent of the donor family is required. However, this is impractical because of the limited life of the organ. The Standing Committee was advised that in such cases that oral consent followed by written consent should be sufficient.

Queensland Health established Queenslanders Donate to provide a comprehensive and coordinated approach to organ donation with the State's hospitals. It seeks to establish a cohesive network of staff involved in organ and tissue donation, retrieval and transplantation.¹²⁴ In particular Queenslanders Donate encourages more active involvement of intensivists in the organ donation process by analysis of the results of death audits, education about organ donation and support from link nurses.¹²⁵ Queenslanders Donate also incorporates a designated social worker to provide follow-up for donor families and offer bereavement support.¹²⁶

Queensland has three to four fulltime transplant coordinators. They identify every possible donor. They approach the family of every patient that has been declared "brain dead". There is a donor family support group and counselling is provided to the donor family. There is a policy against contact between the donor family and the transplant recipient. There is a role for the hospital to consult with the donor family.

3.8 Hospital/Intensive Care Facilities

In Australia, specialists in intensive care units generally care for all critically ill patients, who constitute the majority of potential organ donors. Specialists are the first contact with the donor family. Doctors need the skills to approach the donor family. The counsellors then take the family through the process of organ donation.

¹²³ Recommendation 2 in the Legislative Assembly of Queensland, *Op Cit, Report No 16*, July, 1999, p 25.

¹²⁴ Legislative Assembly of Queensland, *Op Cit, Report No 16*, July, 1999, p 16.

¹²⁵ *Ibid*, p 17.

¹²⁶ *Ibid*, p 28.

The Standing Committee found -

Finding 11

The attitude of intensive care specialists and their concept of conflict of interest directly correlates with the rate of organ donation.

It has been reported that -

The most important aspect of the whole process of organ donation is the active approach of staff within the intensive care units to accept that organ donation is part of their job.¹²⁷

The Standing Committee found that -

Finding 12

Potential donors are found in Intensive Care Units. These potential donors need to be identified and the family approached concerning organ donation.

Dr Millar Forbes advised the Standing Committee that intensive care doctors and emergency department doctors are important in identifying potential donors. He stated -

It is necessary for specialists in teaching hospitals to continue the support for organ and tissue donation ... It is important that they increase awareness throughout hospitals because medical, nursing and allied health groups in hospitals have an incomplete understanding of the issues relating to donation. I believe that specialists, particularly in intensive care, emergency medicine and neurosurgery, can help in the understanding and identification of donors in hospitals.¹²⁸

It has been reported that studies that estimates are that the average hospital misses about one-third of its potential for organ donation mainly because not all donors are identified and many families are not presented with the option of donation.¹²⁹

The studies also conclude that -

Only the introduction of specifically trained staff responsible for organ donation, working in the hospitals at the "grass roots" has proven to be consistently effective.¹³⁰

127 Summary Digest of the Proceedings of the Inaugural National Forum on Organ and Tissue Donation, April 1999, Parliament House, Canberra, p 14.

128 Dr Alistair Millar Forbes, Transcript of Evidence, Perth, 14 August 2000, p 4.

129 Wight C. & Others, "Donor Action: A Quality Assurance Program for Intensive Care Units that Increases Organ donation", *Journal of Intensive Care Medicine*, Vol 15, No 2, March/April 2000, p 104.

130 *Ibid.*

The Standing Committee believes that every hospital should have someone responsible to discuss organ donation when a patient is dying or dead. That person should be allocated the responsibility and should be sufficiently senior and well trained to take on the role in their hospital. The Standing Committee recommends that -

Recommendation Ten:

That a senior person in each hospital should be responsible to discuss organ donation and contact DonateWest when a potential donor is identified.

It is expensive for hospitals to identify and maintain organ donors, as well as run an operating room with several teams of surgical staff. It has also been found that health care staff may be unwilling or unable to approach the next of kin to discuss organ donation and obtain consent.

The Standing Committee found -

Finding 13

The high cost of retrieving organs deters hospitals from keeping potential donors on a life support system before the necessary collecting operations.

A government investigation found that there is a correlation between the shortage of intensive care unit (ICU) beds and the low rate of organ donation in Victoria.¹³¹ To be a donor generally requires the maintenance of a brain dead person on life-support equipment in an intensive care ward. A low rate of ICU beds would hamper any organ retrieval efforts.

Figures from the Australian and New Zealand Intensive Care Association for 1997 appear to confirm the findings of the government investigation. The figures showed that of the States in Australia, Victoria had the second-lowest number of public intensive care beds per head of population, at 4.6 beds per 100,000 people. Victoria also had the second-lowest organ donation rate, at nine donors per million of the population. The State with both the lowest ICU bed rate of 3.9 per 100,000 people and the lowest organ donor rate at four (4) donors per million of the population, was Western Australia.¹³²

The Standing Committee found that this finding appears to be supported by overseas studies. A study in the United Kingdom found that the decline in the number of cadaveric donors could be attributed to the fall in death rates from road traffic accidents and intracranial haemorrhage. It also found that -

An additional contributing factor is the shortage of intensive care beds which precludes the admission of some comatose patients with cerebrovascular accidents who, on the basis of modern

¹³¹ Toy M, "Donor rates fall in bed squeeze", *The Age*, 11 January 1999, p 1.

¹³² *Ibid.*

imaging techniques, have been judged to have a poor prognosis and therefore likely to become organ donors.¹³³

Leo Roels, Chairman of the International Coordinators Society advised the Standing Committee that organ procurement was dependant on resources -

The lack of ICU beds in the United Kingdom was a problem. This was not the case in Belgium.¹³⁴

Dr Maresanz confirmed to the Standing Committee that the United Kingdom had a low rate of ICU beds. He stated -

London had a population of nine million people and had less ICU beds than Madrid with a population of 5 million. The United Kingdom had half the ICU beds than in Spain and in Spain the ICU beds were being used.¹³⁵

Table 6

Demographic Distribution of Public (only) ICU Facilities¹³⁶

Distribution of Public Sector ICU Beds in Australia & New Zealand						
Region	Population 1997	Total beds	Avail Beds	IPPV#	Beds/100,000	IPPV/100,000
ACT	309,800	36	24	15	7.7	4.8
NSW	6,274,400	493	405	282	6.4	4.5
NT	187,100	17	13	10	6.9	5.3
QLD	3,401,200	186	169	138	5.0	4.1
SA	1,479,800	98	88	64	5.9	4.3
TAS	473,500	34	27	19	5.7	4.0
VIC	4,605,100	252	214	176	4.6	3.8
WA	1,798,100	75	71	69	3.9	3.6
AUST	18,532,200	1191	1011	773	5.5	4.2
NZ*	3,618,302	198	155	127	4.3	3.5

IPPV= Intermittent Positive Pressure Ventilator.

* NZ data incomplete, with population figures from March 1996.

¹³³ United Kingdom Guidelines for Living Donor Kidney Transplantation, January, 2000, p 6.

¹³⁴ Leo Roels, Chairman of the International Coordinators Society, Brussels, Belgium, meeting with the Committee, 25 September 2000.

¹³⁵ Dr Rafael Martesanz, Director, *Organizacion Nacional de Trasplantes*, Madrid, Spain, meeting with Committee, 4 October 2000.

¹³⁶ Warnecke & Others, ANZICS Intensive Care Unit Registry Report, Descriptive Analysis of Intensive Care Facilities in Australia & New Zealand, March 1998, p 6.

Robina Balderson, Chief Executive of the United Kingdom Transplant Services Authority advised the Standing Committee that -

In the United Kingdom, intensive care facilities are being reduced, as a result, intensive care specialists are scanning more closely which patients they are prepared to admit, that is, which patient has the best chance of survival.¹³⁷

The following table is a summary of public ICU beds and the availability of advanced ventilator support using in-house resources.

These figures tend to support the reported correlation between low rate of ICU beds and a low rate of organ donation.

The Standing Committee was advised that -

The number of beds in Intensive Care Units in the Perth metropolitan hospitals is adequate. The Australian and New Zealand Intensive Care Society has produced national guidelines regarding optimum numbers of ICU beds. The number of adequately staffed ICU beds, however, is sometimes inadequate. This most frequently results from insufficient skilled nursing staff. Another factor is inadequate general hospital beds to allow transfer of a patient from ICU.¹³⁸

The Standing Committee found that -

Finding 14

There is correlation between a low rate of adequately staffed ICU beds and a low rate of organ donation.

The Standing Committee recommends that -

Recommendation Eleven:

There should be a review of the number of ICU beds in Western Australian hospitals to ensure a shortage of ICU beds is not a barrier to increasing organ transplantation rates.

Recommendation Twelve:

ICU beds should be adequately staffed to ensure that all potential donors are maintained so that organs can be retrieved from all actual donors.

¹³⁷ Robina Balderson, Chief Executive, United Kingdom Transplant Services Authority, London, United Kingdom, meeting with Committee, 6 October 2000.

¹³⁸ Submission, DonateWest, 2 November 2000, p 2.

3.9 Education

Medical intensivists have no training and often little skill in counselling. Intensive care specialists are not all performing at a similar standard with respect to their donor success rate. This demonstrates the need to educate doctors in the art and the skills of talking to donor families, which is the most important area in the whole process of organ donation.

The Standing Committee found that -

Finding 15

Medical staff need to develop appropriate communication skills to contribute to the process of consulting with donor families.

Emergency services staff, and nursing staff in particular, receive no education on organ donation and transplantation, about potential donors or the processes involved.

It is important to structure the education to ensure that there is a culture in the community about organ donation.

The Standing Committee was advised that -

The Australian and New Zealand College of Anaesthetists, Faculty of Intensive Care endorses a course on organ donation as part of their Diploma in the speciality of Intensive Care. The course is known as the Australasian Donor Awareness Program (ADAPT). It aims to provide intensive skills development and increased awareness of the complex issues involved in the donation process. The program has been developed specifically to meet the needs of medical staff.¹³⁹

The Standing Committee was advised that -

Investigating the information provided to medical students relating to organ and tissue donation and transplantation issues is one of the tasks to be incorporated in the Business Plan of DonateWest.¹⁴⁰

The Standing Committee recommends that -

Recommendation Thirteen:

Western Australian universities should include as part of the medical and paramedical courses a significant module on organ donation, transplantation and identifying potential organ donors and that module should be developed in consultation with DonateWest.

¹³⁹ Submission by Department of Health, Western Australia, 14 August 2000, p 17.

¹⁴⁰ *Ibid.*

There is a need for continual community education and promotion about organ and tissue donation and transplantation issues. The most successful education and promotional campaigns have the following elements in common - they are targeted at a specific population group, have a clearly identified aim and use the most appropriate medium for that group.

The Standing Committee is of the view that community education and awareness of the issue of organ donation and transplantation should commence at High School. The Standing Committee believes it would promote a positive attitude to organ donation if understanding the processes of transplantation and donation was part of the health education in the schools.

The High School curriculum provides for different health and social issues to be taught in Health and Physical Education component. This would provide an ideal opportunity to raise awareness of the issue of organ donation and transplantation in High Schools.

The Standing Committee recommends that -

Recommendation Fourteen:

The school syllabus in High Schools should include a module on organ donation and transplantation to assist understanding of the issue and raise awareness and that module should be developed in consultation with DonateWest.

3.10 Community Issues that Influence Organ Donation

Information, whether positive or negative, plays a very important role in the public predisposition towards organ donation. Professional support by communication experts of the messages, both for the contents and the best way to transmit them may assist in promoting organ donation. Controversial issues, such as brain death and organ trafficking rumours, require clear definitions and specific mandatory guidelines.

Recent data from a survey in Spain shows a significant link between the public predisposition to organ donation and the feeling that transplantation is a good health care service. It is thus easy to understand that negative broadcasts about important matters such as brain death, organ trafficking, or the fairness in the access to transplantation can in fact have a negative effect on public predisposition to organ donation.¹⁴¹

Dr Jones advised the Standing Committee that there was considerable interest in organ donation. She stated -

It is an issue that is of interest to the community and it is now of critical interest to people who work in hospitals, as well as potential recipients of organs. With the technological transition in

¹⁴¹

Organ Procurement, <http://www.transplantsquare.com/health/congress/Barca96/Presskit/organpro.htm>, p 8.

medicine, larger number of people are being medically managed who may need a replacement organ for their long-term survival.¹⁴²

The promotion of organ donation must have a community focus and must consider the views of individuals in the community. A community focus also requires a national approach to achieve positive behavioural change and uniformity in the messages. The population in Australia is accepting of transplantation and organ donation.

Most people donate organs so they can help someone else, but some families may need recognition to encourage donation. People may not know about the need for tissues and organs, the success of transplantation, or they may mistrust the medical system.

The Standing Committee found that -

Finding 16

The more community awareness there is of organ donation, the more the supply of organs is likely to increase.

In most countries, the majority of the population is in favour of organ donation. For example in Belgium 85 percent of the population are in favour of organ donation. This solidarity was the basis for the introduction of the “opting out” legislative model in that country, although the family is always consulted.

Surveys have indicated that 90 percent of the Australian population support organ donation. Half the population have discussed donation with their family and 35 percent have discussed it with friends.¹⁴³

In 1999, the Australian Bureau of Statistics conducted a survey of Australian attitudes to organ donation. The Novartis National Survey on Donor Intention surveyed approximately 12,000 households on their current donor status, willingness to donate, reasons for not becoming an organ/tissue donor, and attitude to familial authority to determine donor status. The following table illustrates some results for Western Australia.¹⁴⁴

¹⁴² Dr Dorothy Jones, Transcript of Evidence, Perth, 14 August 2000, p 5.

¹⁴³ ACCORD, Organ donation Attitudes Research 1995, www.span.com.au/accord/attitudes.html.

¹⁴⁴ Submission by Department of Health, Western Australia, 14 August 2000, p 18.

Table 7Western Australian Results from the Norvatis National Survey on Donor Intention¹⁴⁵

Attitude	Percent
Willing to donate, indicated on driver's licence or discussed with family	49.8
Willing to donate, but no steps taken	14.7
Don't know/haven't decided if willing or not	15.8
Not willing to donate	19.7
Total	100

The Standing Committee found that -

Finding 17

Efforts to increase organ donation should be directed to both the community and the Hospitals.

3.11 Differences in Organ Donation Rates Between the States

The 1996 census shows that of 128,000 deaths only 129 were organ donors. In 1998 South Australia had 24 donors per million of population. Spain had 31 donors per million of population.

The Federal Minister for Health and Aged Care advised the Federal Parliament about the disappointingly low and declining rate of organ donation in Australia. Australia had a donation rate of 8.6 donors per million of the population. The Minister stated -

The international benchmark of world best practice is nearly 1,100 donors per year for a country our size. Last year Australia managed only 194 donors against that international benchmark of 1,100.¹⁴⁶

The following table provides a list of donors in Australian States.

¹⁴⁵ *Ibid*, p 18.

¹⁴⁶ Dr Wooldridge, Minister for Health and Aged Care, Commonwealth Parliament, House of Representatives, Hansard, Thursday, 31 August 2000, p17992.

Table 8Comparison of Donor Numbers by State - express as donors per million of population.¹⁴⁷

	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998
SA/NT	21	9	14	14	16	11	12	16	14	15	17	17	23
QLD	17	14	19	13	13	15	22	14	12	11	11	11	12
NSW/ACT	10	10	12	15	13	12	11	12	11	11	11	10	10
VIC/TAS	11	13	13	14	10	10	9	12	7	8	10	9	8
WA	13	11	9	11	7	14	8	11	9	10	7	4	7
Total*	13	11	13	14	12	12	12	12	11	11	11	10	10.5

* Average for all the Australian States and Territories

For the organ donation rate to increase, each patient who dies in intensive care should be considered for donation. Age is not a restriction to donation.¹⁴⁸

Dr Matesanz advised the Standing Committee that -

The potential organ donor rate can be over 60 donors per million population.¹⁴⁹

In 1999 the Basque Country of Spain recorded a donor rate of 50.7 donors pmp.¹⁵⁰

In Western Australia at present organs are not retrieved outside the Perth area. Hospitals outside the four main hospitals are not staffed or equipped for organ retrieval. There is a need to increase the number of transplant surgeons.¹⁵¹

3.12 Organ Donation in Australia

In Australia, roughly two percent of national deaths occur in hospitals. In situations where if circumstances allow, donors can be ventilated after brain death has occurred, so that donation may take place, then if only one percent of the national deaths were medically suitable for donation, it would represent the “potential” number of donors required nationally.

Statistics in 1996 show that there were 128,719 deaths nationally. In that same year there were 194 organ donors (excluding tissue). At one percent of the national death rate, the potential number of donors was 1093. The number of people awaiting organ transplants was 1699 in that year.

¹⁴⁷ Annual Report of the Activities of SAODA, 1998, p 11.

¹⁴⁸ Dr Alistair Miller Forbes, Medical Director DonateWest, meeting with Committee, 6 November 2000.

¹⁴⁹ Dr. Rafael Matesanz, Director, *Organizacion Nacional de Trasplantes*, Madrid, Spain, meeting with Committee, 4 October 2000.

¹⁵⁰ Miranda B. & Others, “The Spanish organisational structure for organ donation. Up to date”, *Organizacion Nacional de Trasplantes*, Madrid, Spain, p 15.

¹⁵¹ Dr Alistair Miller Forbes, Medical Director, DonateWest, meeting with Committee, 6 November 2000.

Finding 18

Only 20 percent of currently available organs are being used.

It is reported that on average two people die every week because of the lack of availability of suitable organs. Bearing in mind that “whole of body” donations can assist up to eight people, it would be possible to wipe out the waiting list in one year if Australia’s potential organ donation rate could be achieved.

3.13 Donation Issues

The different Australian systems affect organ donation. For instance, in Victoria, with the exception of corneas, tissue donation arises from reportable deaths to the State Coroner. Typically tissue donors do not arise from hospital deaths and particularly not from brain dead donors. In other States, namely, Queensland, Western Australia, New South Wales and South Australia, tissue donation is offered as an option with organ donation. Both organ and tissue donation are discussed by the transplant coordinator or the intensive care specialist at the time the issue of organ donation is raised.

It has been reported that -

We need a systematic approach to tissue donation. There needs to be cooperation within the units, there needs to be exchange of information, there needs to be education of professionals - many doctors in hospital settings don’t know a lot about the selection criteria for tissue which is much more rigid than for organs.¹⁵²

The Standing Committee found that -

Finding 19

The organ donation rate needs to be improved. There must be a national effort to standardise and streamline the donation process from the initial diagnosis of brain death through to caring for donor families.

3.14 Death Audits

Death audits in hospitals are conducted to establish how many potential organ donors are missed. Only two percent of deaths occur in hospitals. One percent is suitable for organ donation. However, many of these potential donors are missed.

The Standing Committee was advised that the teaching hospitals in Perth do hold death audit but not the Victorian model. There is no audit in regional hospitals.¹⁵³

In July 1999, the Australian Health Ministers Advisory Council (AHMAC) agreed to the national adoption of the death audit procedure. The application of the death audit procedure affects the accreditation of the hospital.

¹⁵² Summary Digest of the Proceedings of the Inaugural National Forum on Organ and Tissue Donation, April 1999, Parliament House, Canberra, p 18.

¹⁵³ Dr Alistair Miller Forbes, Medical Director, DonateWest, meeting with Committee, 6 November 2000.

The Standing Committee found that -

Finding 20

Death audits in hospitals can be applied to ensure that resources are used effectively and that the maximum number of organs are retrieved and transplanted.

The value of a death audit process is to identify a defect in the system, for example, potential donors dying on the ward or in emergency departments. This information provides the opportunity to direct resources to improve the defect.

The Standing Committee recommends that -

Recommendation Fifteen:

A national death audit procedure be adopted to ensure that potential donors are not overlooked.

CHAPTER 4. ORGAN DONATION AND TRANSPLANTATION - OVERSEAS

4.1 National and International Initiatives

A significant factor, which accounts for a higher donor rate in many developed countries, is the doctor patient ratio. Australia has a very low ratio of doctors per head of population compared to many developed countries.

Performance in organ donation and transplantation covers many aspects of medicine, community attitudes and government policy. The following table outlines countries with a higher donation rate than Australia.

Table 9

Donation rates in 1999¹⁵⁴

Country	dpmp
Australia	10.3
Italy	13.7
Scandinavia	14
United Kingdom	13
USA	21.4
Spain	33.6
France	16.2
Portugal	19.1

Around the world a number of different techniques have been used to try and improve the number of organ donors, including legislative changes such as presumed consent, required request and mandated choice, and elective ventilation. Financial incentives have been proposed but are generally seen as ethically unacceptable. Financial incentives have been specifically outlawed by the World Health Organisation.

Processes of organ donation and transplantation are similar in most countries. Differences exist in the USA, Austria, Netherlands and Hong Kong, including management of donors by a private external medical group, change to presumed consent legislation, and circulatory perfusion of deceased patients.¹⁵⁵

By far the most successful initiative that has been used around the world has been the “Spanish model”. An essential element of this model is that all potential organ donors are identified and followed up. Their aim is never to miss a donor or a potential donor.

¹⁵⁴ Submission Department of Health, Western Australia, 15 August 2000, p 22.

¹⁵⁵ *Ibid*, p 23.

International cooperation in transplantation is important. The exchange of information assists in the development of effective transplant services. Other factors include the difficulties of tissue matching, as well as the urgency of a clinical condition, which may require access to a large or very large population if the transplant is to be successful.

4.2 Europe

In Europe until recently, most countries have used presumed consent. Doctors presume that people consent to donate their organs unless they have specifically objected before their death (the “opting out” system). However, in practice, doctors usually talk with the family of the deceased about organ donation.

In the “opting out” system anyone who does not want to donate their organs after death can record their objections. For example, Belgium has a national registry and France uses a hospital registry. Countries that use presumed consent such as, Austria, Belgium, France and Spain always have significantly more organ donors.

The major organ procurement organisations in Western Europe are Eurotransplant, covering the Netherlands, Belgium, Luxembourg, Germany and Austria; the UK Transplant Service; *l’Etablissement Francais des Greffes* for France; *Organizacion Nacional de Trasplantes* for Spain; Hellenic Transplantation Council for Greece; *Hungaro Transplant* for Hungary; *Lusiotransplant* for Portugal; and *Scandiatransplant*, which covers Norway, Denmark, Sweden and Finland.

Eurotransplant International Foundation is a non-profit organisation whose main aim is to encourage organ transplantation. Eurotransplant was founded in 1967 as a central registration of all patients waiting for a donor organ. The aim was to find a good match between the donor’s and the recipient’s tissue groups. The Eurotransplant International Foundation is responsible for the mediation and coordination of organ donation procedures in Austria, Belgium, Germany, Luxembourg, the Netherlands and now also Slovenia. Participants include all transplant hospitals, tissue-typing laboratories and hospitals where organ donations take place. The Eurotransplant region numbers over 120 million inhabitants.¹⁵⁶

The Standing Committee was advised that large organisation such as Eurotransplant are set up specifically to create a larger donor pool. However, this can create problems for the allocation of organs. This is because -

The varying donor rates in member countries means that organ donation flow from high donor rate countries to low donor rate countries.¹⁵⁷

An Ad Hoc Committee of the Council of Europe in 1975 prepared a report on organ donation and transplantation. The Council of Europe adopted a Resolution on the harmonisation of legislation of Member States relating to the removal, grafting and transplantation of human substances in May 1978.¹⁵⁸ The European Ministers of Health in 1987 issued guidelines for work in the field

¹⁵⁶ Eurotransplant key role, <http://www.eurotransplant.nl/Eurotransplant/rechts.html>.

¹⁵⁷ Leo Roels, Chairman, International Transplant Coordinators Society, Brussels, Belgium, meeting with Committee, 25 September 2000.

¹⁵⁸ Resolution (78) 29.

of organ transplantation.¹⁵⁹ The member countries of the Council of Europe and the other countries of the European Community are signatories to the Convention for the Protection of Human Rights and Dignity of the Human Being. That is the Convention on Human Rights and Biomedicine.¹⁶⁰ The Committee of Ministers entrusted the Steering Committee on Bioethics (CDBI) with the preparation of a Protocol on organ transplants. The Protocol provides agreement for facilitating the transplantation of organs and tissues in the interest of patients in Europe. The agreement protects individual rights and freedoms and prevents the commercialisation of parts of the human body involved in organ and tissue procurement, exchange and allocation.

The Protocol applies to the transplantation of organs and tissues of human origin carried out for therapeutic purposes.¹⁶¹ The Protocol applies solely to the transplantation of human organs and tissue and not to organs or tissues, whether genetically modified or not, removed from animals.¹⁶²

The following table outlines the number of organ transplants in selected European countries.

Table 10

Organ donation and transplantation activities in 1995, in selected European countries.¹⁶³

	E.T. ³	France	Greece	Hungary	Italy	Spain	Portugal
Population in millions	113.4	58.8	10	10.3	56.7	38.4	10
Dead donors	1620	889	56	148	576	1037	200
Per million Inhabitants	14.3	15.1	5.6	14.4	10.1	27	20
% Multi-organ donors	63%	73%	60.7%	20%	84.7%	83.4%	45%
Kidney transplants from dead donors	3064	1578	42	278	1042	1765	368
Per million inhabitants	27	26.8	4.2	27	18.3	46	36.8
Kidney transplants from live donors	211	66	85	3	107	35	2
Per million inhabitants	1.9	1.1	8.5	0.3	1.9	0.9	0.2
Liver transplants ¹	969	646	7	10	404	698	70
Per million inhabitants	8.5	10.9	0.7	1	7.1	18.1	7.0
Heart transplants	732	408	10	3	390	278	5
Per million inhabitants ²	6.8	7.3	1	0.3	6.9	7.2	0.5

1. Live donors have been included.

2. Heart-lung transplants per million inhabitants have been included.

3. E.T.: Eurotransplants: Germany, Austria, Belgium, Luxembourg and the Netherlands.

¹⁵⁹ Council of Europe, 3rd Conference of European Health Ministers, Paris, 16-17 November 1987.

¹⁶⁰ Council of Europe, Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, 1997.

¹⁶¹ Steering Committee on Bioethics (CDBI), Draft Protocol on Transplantation of Organs and Tissues of Human Origin, Strasbourg, 3 February 1999, <http://www.bmggesundheits.de/organ/eng1.htm>.

¹⁶² Council of Europe, Steering Committee on Bioethics (CDBI), Draft additional Protocol to the Convention on Human Rights and Biomedicine on Transplantation of Organs and Tissues of Human Origin, Strasbourg, September 2000.

¹⁶³ Organ donation - Informed or presumed consent? - Appendix B, http://www.etiskraad.dk/publikationer/orgdon_eng/kap08.htm, p 1.

The Council of Europe whose aim is to achieve greater unity between its members by the adoption of common action in the health field made a number of recommendations to Member States. In relation to the transplantation of livers donated by live related donors, it resolved that fully informed consent is required from both the donor and the recipient. It also resolved that transplantation from live donors should be considered only when there is a shortage of cadaver organs.

The Council of Europe also made recommendations concerning the banking of human tissue, emphasising that the functions should be carried out by non-profit-making institutions under national health administrations.¹⁶⁴

As early as 1978 the Council of Europe had agreed upon a series of recommendations to harmonise the legislation of its member states regarding organ donation and transplantation based on “presumed consent”. However, the legal situation in Europe, today, is far from harmonised. The overwhelming positive attitude of the general public toward organ donation has been one of the strongest arguments for a majority of European countries to incorporate “presumed consent” principle into their legislation, as recommended by the Council of Europe.

4.3 Belgium

In Austria and Belgium organ and tissue procurement legislation is based on the “presumed consent” principle. In the Austrian definition of “presumed consent”, the donor’s relatives are not allowed to interfere with the donation process, whereas the Belgian version of “presumed consent” law allows relatives to object to donation in the absence of an explicit and registered consent or objection by the deceased during life.

Of the four Eurotransplant countries Austria and Belgium have an “opting out” system of organ donation and Germany and the Netherlands have an “opting in” system. Austria and Belgium have a very high organ donation rate following Spain while Germany and the Netherlands have a very low donation rate.

Table 11¹⁶⁵

Donation Rates - Opting In/Opting Out

	Country	Donors per mil.
Opting out	Austria	25
	Belgium	24
Opting In	Germany	12
	Holland	11

Following the recommendations of the Council of Europe, the Belgian *Law on Organ Procurement and Transplantation 1986* is based on the “presumed consent” principle. The law regulates the procurement of organs as well as harvesting and transplanting of tissue. The law

¹⁶⁴ International Protection of the ONT, <http://www.msc.es/ont/ing/pinternational/iproyection.htm>.

¹⁶⁵ Leo Roels, Chairman, International Transplant Coordinators Society, Brussels, Belgium, meeting with Committee, 25 September 2000.

provides that procurement and transplantation of organs and tissues can only be performed by physicians in authorised hospitals and the law bans any profit motive in organ or tissue procurement. Organs or tissues can be removed from every citizen or foreigner living for more than six months in the country, unless it is clear that an objection against removal has been expressed. A central registry records the objection. Consultation of the database is mandatory before physicians can proceed with any organ or tissue removal.

It has been reported that -

Ten years after the implementation of the Belgian transplant law, organ donation levels have been proven to be among the highest in the world.¹⁶⁶

Belgian law is a “weakened presumed consent law. Although the physician is under no obligation to burden the relative with the decision about organ donation, relatives are consulted and informed about the intention to remove organs from the deceased. If they explicitly object, their opinion is fully respected.

The Belgium transplant framework allows smaller non-university hospitals to cooperate fully with larger transplant centres. Local teams are involved in the process of donor referral and procurement. Each hospital has one or more physicians, usually a nephrologist or an anaesthetists, who act as local coordinators for potential donors. Local surgeons perform kidney procurement and assist visiting heart or liver surgeon. It has been stated that -

Adequate legislation, based on the “presumed consent” principle, certainly should be considered the cornerstone of an efficient donor recruitment system.¹⁶⁷

Professor Van Hecke advised the Standing Committee that -

Hospitals are reimbursed for the cost of procurement per organ that is transplanted. The surgeon is paid for the medical procedure.¹⁶⁸

4.4 The Netherlands

The Netherlands introduced a new law on organ donation and transplantation with a new registration system in 1998.

The promotion of the new law has been criticised. The information sent to the public was incomplete and people were unclear about the concept of “brain death” and the issue of consent. There was confusion about the registration system and as a result, of the population of 12.2 million who received letters for registration, only 40 percent were returned and of those returned 55 percent agreed to organ donation.

¹⁶⁶ Roels L. & Others, “A Profile of People objecting to Organ donation in a Country With a Presumed Consent Law: Data From the Belgian National Registry”, *Transplantation Proceedings*, 29, 1997, p 1473.

¹⁶⁷ Roel L., “Donor Recruitment in Belgium”, in *Systems of Donor Recruitment*, de Charro & Others, Eds., Kluwer, 1992, pp 5.

¹⁶⁸ Prof Van Heck, Cardio Transplant Physician, University Hospital, Leuven, Brussels, Belgium, meeting with Committee, 25 September 2000.

The Netherlands has an “opting in” system of organ donation.

The Netherlands is divided into seven regions. All the regions are connected to a University Hospital. Each hospital has two coordinators who work for the region. The coordinators are part of the University Hospital and part of the transplant program. Transplantation retrieval teams go to the regional hospitals to retrieve organs. Cars, helicopters and planes are used for the purpose of transporting organs. Military airfields are made available when required.

The Netherlands is part of Eurotransplant. All organs retrieved in the Netherlands are firstly offered within the country, if there is no suitable recipient within the country, the organs are offered to Eurotransplant.

The Standing Committee was advised that -

Every hospital is bound to discuss organ donation when a patient is dying or dead.¹⁶⁹

The Standing Committee recommends that -

Recommendation Sixteen:

Every hospital develop protocols to ensure that every dead or dying patient is suitably assessed for organ donation.

The donor hospital receives a payment based on the type of procedure and doctors are paid a fee for the medical procedure.

The Standing Committee was advised that the problems in the Netherlands in regard to organ donation and transplantation relate to -

The extreme shortage of medical personnel in the hospitals.¹⁷⁰

4.5 The “Spanish Model”

Spain is a European Community country with a population of 39 million people living in 17 autonomous regions. The “Spanish model” of organ donation has become the international best practice.¹⁷¹ The *Organizacion Nacional de Trasplantes* (ONT) was created in 1989 and relies on medically trained staff to be involved in the identification of donors within hospitals.

Transplantation law in Spain is similar to corresponding law in other western countries. For example, death is defined as the total and irreversible cessation of brain or cardio-respiratory functions and must be certified by three doctors in the case of brain death. Organs and tissue may be retrieved only after obtaining the consent from the donor or the donor’s family. No compensation can be paid for either donation or for granted organs.

¹⁶⁹ Jose Popma, Transplant Coordinator, Academic Medical Centre, Amsterdam, Netherlands, meeting with Committee, 27 September 2000.

¹⁷⁰ *Ibid.*

¹⁷¹ The South Australian system is based on the “Spanish model”.

Spain has a nationwide transplantation coordination system. There is the headquarters in Madrid, a regional coordinator in each of the 17 regions and a coordinator at every hospital. Responsibility and accountability is decentralised to provincial and local levels, with national coordination and a regional coordinating network. The hospital coordinators play a central role. They are trained to talk to the families of potential donors and explain the benefits of donation to them.

Central to the model are transplant coordinators who are medical doctors located in the hospitals with the intensive care units. The most impressive part of the Spanish model is the way in which donors are detected and the data available on the potential donor pool. Transplant coordinators receive a daily computer print out of all admissions. Once a potential donor is identified, the transplant coordinator visits the hospital unit to check the clinical status of the patient. Death audits are also conducted regularly to ensure that donors are not missed

Dr Matesanz advised the Standing Committee that -

Donor coordinators should be doctors and should be located in the hospital. It is not possible to detect a potential donor if the coordinator is not in the hospital.¹⁷²

There is a national system of coordination of donor and transplant activities. At the moment once an intra-hospital coordination team from any centre of the national health system detects the existence of a potential donor, they communicate it to the central office of the ONT. Early advice, if possible immediately after the diagnosis of brain death, after carrying out the first flat EEG, ensures sufficient time to organise the infrastructures of offers and transport. The process begins with a search for a recipient within prescribed criteria, which includes clinical and geographic criteria. If there is no adequate recipient in the country, the organ is offered to other countries and European transplant organisations.

Once the most adequate recipient is located, the offer is made to the transplant team through the hospital coordinator. When the offer is accepted the generating hospital is informed and steps are taken to organise the necessary transport.

Transport depends on the distance. For short distances, that is, less than 200 kilometres the transfer of teams is carried out with sanitary cars or helicopters. If deemed necessary, the collaboration of security forces is requested to open the way or the assistance of the army to enable the use of military air transport and landing bases. On occasion the helicopters are military ones and on other occasions, they are civilian. If long distances are involved, aircraft of private companies are used and occasionally the intervention of the Air Force is required.¹⁷³

The ONT deals with organ sharing and management of waiting lists, arranges for transplant teams or organ transport, maintains the official statistics on organ donation and transplantation activity, and keep interest groups informed. The ONT is concerned with training programs and research in the field of organ donation and transplantation.¹⁷⁴

¹⁷² Dr Rafael Matesanz, Director, *Organizacion Nacional de Trasplantes*, Madrid, Spain, meeting with Committee, 4 October 2000.

¹⁷³ ONT, http://www.msc.es/ont/ing/Que_esI.htm, p 7.

¹⁷⁴ Miranda B. & Others, "The Spanish organizational structure for organ donation. Up to date",

All coordinators at national and regional level, are employed full-time. The hospital coordinators, however, are employed on a part-time basis in the sense that they have their work at the hospital and work on organ transplantation only when a potential donor becomes evident.¹⁷⁵

Spain has consistently increased its organ donation rate. In the first eight years of operation, Spanish donation rates increased from 14.3 in 1989 to 33.6 donors per million of population in 1999. The average age of donors has increased year after year and more than 30 percent of current donors are older than 60 years of age. Most donors, 75 percent now die of cerebrovascular accident, and only 21 percent die in car accident.¹⁷⁶ In Spain the rate of family refusal of donation is 21.5 percent, a decreased from 30 percent in the early 1990s.

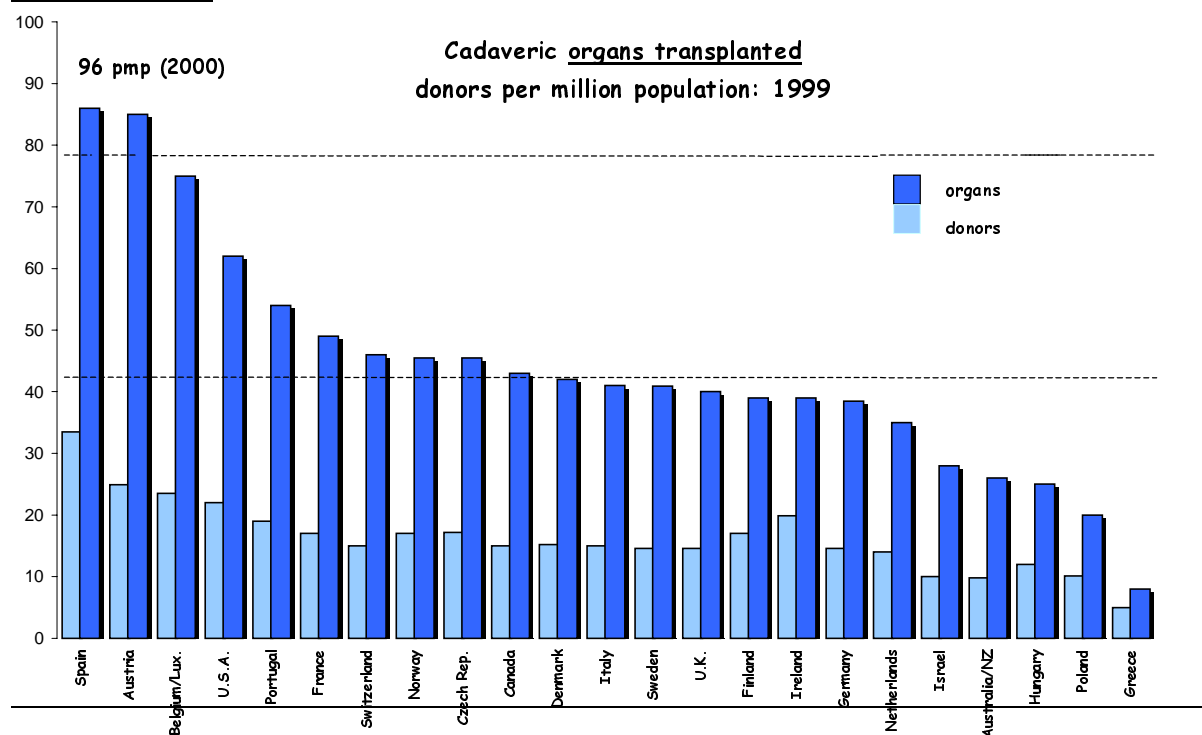
The Standing Committee was advised that -

The health professional is the key to the Spanish model.¹⁷⁷

It has been reported that these changes are the result of efforts to overcome various obstacles, such as untrained or under-trained staff, unidentified donors, and reluctance to approach grieving families. With the professionalisation of organ donation, coordinators are identifying more potential donors in all types of hospitals.

The number of organ transplants in Spain has risen year by year since 1989. In 1996 Spain had the highest number of, amongst others, kidney transplants - 43.8 per million inhabitants.

Graph No. 3¹⁷⁸



Organizacion Nacional de Trasplantes, Madrid, Spain, p 2.

175 Organ donation - Informed or presumed consent? - Appendix C,
http://www.etiskraad.dk/publikationer/orgdon_eng/kap09.htm.

176 Miranda B. & Others, *The Spanish organisational structure for organ donation. Up to date, Op Cit*, p 2.

177 Dr Rafael Matesanz, Director, *Organizacion Nacional de Trasplantes*, Madrid, Spain, meeting with Committee, 4 October 2000.

178 Donor Action

The National Transplant Organisation has increased organ donor rates by measuring donor rates in individual hospitals, thus enabling hospitals with low rates to be identified and targeted for specific measures.¹⁷⁹

The increase of donation of organs maintained in Spain has coincided with the stabilisation or the collapse of rates of donation in most other countries of the world.

The ONT maintains a professional outlook to the obtaining of organs. It promotes the development of courses of continued training for professionals of the hospitals most directly involved in the process of organ donation and transplantation.¹⁸⁰ The ONT conduct international training courses and assists other countries to implement an organ procurement system.

The ONT has become the international best practice for their professional approach to organ donation. The Council of Europe has recommended that its member countries adopt the guidelines of the Spanish model.

In 1995, the South Australian Minister for Health visited Spain and the ONT and recommended the adoption of the Spanish model in South Australia. Since the introduction of the modified Spanish model, the organ procurement rate in South Australia is double the rate of the rest of Australia.

4.6 France

France is a country of approximately 60 million inhabitants with a long term practice and role in innovation in organ transplantation. Transplantation in France was characterised by a major and constant growth, which brought up the rate of organ donation to above 18 donors per million inhabitants in 1990.

France had an “opting out” system. A law established that presumed consent was the principle adopted and several teams for transplantation were authorised by the Ministry of Health.

However, in practice, the family of the donor are still asked and about 30% of relatives refuse donation.

A private body called France Transplant, an association of doctors, was in charge of various regulatory activities.

A crisis occurred in 1991 and lasted until 1994, this saw a reduction in the number of organ donors from 18 to approximately 15. The crisis had nothing to do with transplantation but the contamination of blood with HIV. This health security problem had a major impact on the organ donation rate as it created doubt about the risk of transmission of the disease. The other factor that affected the rate of organ donation was the very high rate of non-resident patients. In some centres, the rate was very high - up to 80 percent in two centres in France.

In 1994, the French Government introduced new laws and regulations, which provided a more precise and complete regulatory framework. Presumed consent was still adopted but a non-donor registry was created that could be interrogated from each hospital. The Standing Committee was advised that -

¹⁷⁹ Holt A.W. & Others, “Organ donor index: a benchmark for comparing hospital organ donor rates”, *MJA*, Vol 170, 17 May 1999, p 479.

¹⁸⁰ Continued Training, ONT, <http://www.msc.es/ont/ing/formacion/formai.htm>, p 1.

The national register is checked by a coordinator to determine whether an individual has opted out. 40,000 persons have registered to opt out.¹⁸¹

A national state specialised agency, the *Establissement Francais des Greffes* was created to replace the association France Transplant with wider powers and responsibilities in procurement and transplantation.

In the hospitals, implementation commenced on the Spanish hospital system of organisation for organ procurement.¹⁸²

However, the Standing Committee was advised that Spain has put a lot of human resources into organ procurement in the hospitals. Dr Luiciolli stated by comparison -

France had a shortage of intensivists/doctors in general due to medical school quotas.¹⁸³

The Standing Committee was advised by Dr Luiciolli that -

Organ allocation is based on regions. France is divided into seven regions. Organs are used within the region but if it cannot be used within the region, then the organ is offered nationally.

If there was no national recipient then it is offered internationally - to Spain or Eurotransplant.¹⁸⁴

The number of patients waiting for an organ in December 1999 has increased from 5353 in 1998 to 5818 in 1999.

The following table outlines the number of patients registered on the waiting list by organ on 31 December each year.

Table 12

Waiting lists¹⁸⁵

	1995	1996	1997	1998	1999
Heart	282	259	247	270	336
Heart-lungs	79	79	70	70	67
Lungs	106	100	112	107	116
Liver	304	238	239	259	344
Kidney	4068	4115	4428	4497	4827
Pancreas	89	107	126	141	118
Intestine	0	11	10	9	10
Total	4928	4909	5232	5353	5818

Organ transplantation activity has slightly decreased as compared to 1998.

¹⁸¹ Dr Esmeralda Luiciolli, *Establissement francais des Greffes*, Paris, France, meeting with Committee 22 September 2000.

¹⁸² Professor Didier Houssin, Director General, *Establissement francais des Greffes*, "Improvement on Organ and Tissue Donation in France: Lessons from a Crisis", Address to the National Forum on Organ & Tissue Donation, 12-13 April 1999, Canberra.

¹⁸³ Dr Esmeralda Luiciolli, *Establissement francais des Greffes*, Paris, France, meeting with Committee, 22 September 2000.

¹⁸⁴ *Ibid.*

¹⁸⁵ *Establissement francais des Greffes*, International Letter, April 2000.

The following table outlines the number of organs transplanted by year.

Table 13

Organ Transplantation Activity¹⁸⁶

	1995	1996	1997	1998	1999
Heart	408	397	366	370	321
Heart-lungs	22	27	25	26	28
Lungs	81	69	65	88	71
Liver	646(10)	626(11)	620(19)	693(28)	699(33)
Kidney	1644(66)	1638(57)	1690(70)	1883(73)	1842(77)
Pancreas	55	48	63	47	50
Intestine	1	2	10	9	7
Total	2857(76)	2807(68)	2839(89)	3116(101)	3018(110)

() of which living donor

The following table outlines the number of organ transplants in selected countries.

Table 14

Organ donation and transplantation activities in 1995, in selected countries.¹⁸⁷

	Poland	Sc.T ³	Switzer- Land	England/ Ireland	USA	Canada	Australia
Population in millions	38	23	7	61.1	255	29.5	17.9
Dead donors	190	339	91	967	5360	425	184
Per million inhabitants	5.0	14.7	13	15.8	21	14.4	10.3
% Multi-organ donors	52%	53%	73.6%	79%	82%	79%	81%
Kidney transplants from dead donors	348	604	158	1797	8597	692	347
Per million inhabitants	9.1	26.3	22.6	29.4	33.7	23.4	19.4
Kidney transplants from live donors	6	187	41	152	3213	229	79
Per million inhabitants	0.16	8.1	5.8	2.5	12.6	7.7	4.4
Liver transplants ¹	2	173	47	687	3295	328	118
Per million inhabitants		7.5	6.7	11.3	15.4	11.1	6.6
Heart transplants	82	106	43	338	2362	191	95
Per million inhabitants ²	2.3	4.9	6.1	6.5	9.5	6.7	6

¹ Live donors have been included

² Heart-lung transplants per million inhabitants have been included

³ Sc.T.: Scandiatransplant: Denmark, Finland, Norway and Sweden

186 *Ibid.*

187 Organ donation - Informed or presumed consent? - Appendix B,
http://www.etiskraad.dk/publikationer/orgdon_eng/kap08.htm, p 2.

4.7 Scandinavia

About 30 years ago the countries of Scandinavia namely, Finland, Sweden, Norway, Denmark and Iceland agreed to collaborate in organ transplantation. Scandiatransplant is an organ exchange organisation, which started in 1969. Scandiatransplant covers the five Nordic countries with a population of 23.4 million inhabitants. The organisation includes 11 transplantation centres and eight immunology laboratories.¹⁸⁸

The purpose of Scandiatransplant is to -

- effect the exchange of organs and tissue for transplantation;
- operate a database and communicate information;
- contribute to promote the provision of human organs and tissue for transplantation; and
- support scientific activities.¹⁸⁹

Since the initiation of Scandiatransplant in 1969, there has been one common Nordic waiting list for all patients waiting for transplantation with organs from cadaveric donors.

In 1996 the total number of cadaver donors within the Scandiatransplant organisation was 341, corresponding to 14.6 donors per million population.¹⁹⁰

The Scandiatransplant organ donation rate is similar to that in other Western European organ exchange organisations such as Eurotransplant, UK Transplant Support Service Authority, and *Establissement Francais des Greffes*. However, the rate is considerably lower than Spain and Portugal.

Whenever a harvested Nordic organ cannot be used within the Scandiatransplant area, it is offered to other organ exchange organisations, mostly Eurotransplant and United Kingdom Transplant. Likewise, these organisations offer surplus organs to Scandiatransplant.¹⁹¹

4.8 United Kingdom

The *Human Tissue Act 1961* and the *Human Tissue Act 1962* govern the removal of organs from people after death in the United Kingdom. The *Human Tissue Act 1961* describes the circumstances in which organs may be removed. A designated person may authorise the removal of organs, once enquiries have been made to ensure that the deceased had expressed an objection to organ donation and their next of kin has an objection to the organs of the deceased being donated.

The *Human Organ Transplants Act 1989* prohibits commercial dealing in human organs. It also restricts the transplant of organs between person who are not genetically related.

188 Madsen, M. & Others, "Scandiatransplant: Organ Transplantation in the Nordic Countries 1996", *Elsevier Science Inc*, 1997, p 3084.

189 *Ibid.*

190 Madsen, M. & Others, "Scandiatransplant: Organ Transplantation in the Nordic Countries 1996", *Elsevier Science Inc*, 1997, p 3085.

191 *Ibid*, p 3087.

The United Kingdom has an “opting-in” system of organ donation. Organs are removed only if the deceased patient has consented while living or the next of kin consented after death. Although a signed donor card is a legal document, organs are not removed unless the next of kin consents to the donation. However, there is increasing concern that this system is failing to meet the demand for organs suitable for transplantation. At its annual conference in June 1999, the British Medical Association passed a resolution to lobby the Government to introduce a system of presumed consent.¹⁹²

The Institute of Biology in the United Kingdom have stated -

... the availability of human organs could be improved, for instance by having an “opt out “(as opposed to the current “opt in”) organ donation system.¹⁹³

Dr Forsythe, Consultant Surgeon with the Scottish Liver Transplant Unit advised the Standing Committee that -

Experienced medical doctors ask the first question regarding organ donation. Intensivists then pass on the responsibility of organ donation to the donor coordinators at the time of the second test to determine whether the patient is brain dead.¹⁹⁴

It has been reported that there has been a decrease of two percent in the number of United Kingdom organ donors from 761 in 1998 to 748 in 1999. This figure is the lowest since 1988. This has resulted in a two percent decrease in the number of kidney and 0.2 percent decrease in the total number of transplants for 1999. Whilst the kidney transplant waiting list increased by two percent, the total waiting list increased by one percent to 6436 patients needing an organ transplant.¹⁹⁵

Dr Doyle advised the Standing Committee that -

The key element to handling donor procurement is to have a person on the floor of the hospital.¹⁹⁶

The National Organ Donor Register is a computerised database of potential organ donors. It is accessible to transplant coordinators at the United Kingdom Transplant Support Service Authority (UKTSSA). The UKTSSA is a 24 hour support service to all transplant units in the United Kingdom and the Republic of Ireland for matching and allocation of organs for transplantation. It maintains a database of patients waiting for an organ transplant. It also manages the Department of Health strictly confidential National Organ Donor Register.¹⁹⁷

192 RCN Congress, http://www.rcn.org.uk/congress/news/news_press_brief1.html, pp 1-2.

193 Institute of Biology, “Response to the Advisory Group on the Ethics of Xenotransplantation, made to the Department of health, April 1996.

194 Dr John Forsythe, Consultant Surgeon, Scottish Liver Transplant Unit, Edinburgh, UK, Meeting with the Committee, 19 September 2000.

195 National Organ donor Register, <http://www.argonet.co.uk/body/DoH.html>, p 2.

196 Dr Peter Doyle, Medical Adviser, ULTRA, London, United Kingdom, meeting with Committee, 6 October 2000.

197 National Organ donor Register, <http://www.argonet.co.uk/body/DoH.html>, p 2.

The United Kingdom is divided into 8 regions and retrieval zones of approximately the same population. Any organs retrieved in a zone must be offered to hospitals within the region. If the organs cannot be used within the region it is then offered through the UKTSSA to other regions.

The Standing Committee was advised by Andrea Hussain, Transplant Manager of the Papworth Hospital that -

Mostly nurses approach the families about donation. ... the weakest link is the attitude of medical staff.¹⁹⁸

The Standing Committee was also advised that -

The attitude of the medical management was not to keep a dying patient on ICU, but to use the bed for other patients.¹⁹⁹

The following tables provide information of the number of the on the waiting list for transplant and the number of transplants performed in the United Kingdom in 1997, 1998 and 1999.²⁰⁰

Table 15

Waiting List on 31 December 1997 and number of transplants performed in 1997.²⁰¹

	Patient Waiting	Transplant	Live Donor
Kidney	5539	1503	174
Kidney/Pancreas	61	20	-
Pancreas	4	11	-
Heart	305	247	19
Heart/Lung	139	44	-
Lung/s	227	101	1
Liver	184	666	4
Cornea	-	2297	4

Table 16

Waiting List on 31 December 1998 and number of transplants performed in 1998.²⁰²

	Patient Waiting	Transplant	Live Donor
Kidney	5631	1349	240
Kidney/Pancreas	49	26	-
Pancreas	7	1	-
Heart	232	238	28
Heart/Lung	97	52	-
Lung/s	184	84	8
Liver	201	665	2
Cornea	-	2217	0

¹⁹⁸ Andrea Hussain, Transplant Manager, Papworth Hospital NHS Trust, Cambridge, UK, meeting with Committee, 20 September 2000.

¹⁹⁹ *Ibid.*

²⁰⁰ Professional Transplant Services, <http://www.argonet.co.uk/body/DoH.html>, p 2.

²⁰¹ *Ibid.*

²⁰² *Ibid.*

Table 17Waiting List on 31 December 1999 and number of transplants performed in 1999.²⁰³

	Patient Waiting	Transplant	Live Donor
Kidney	5731	1325	235
Kidney/Pancreas	46	38	-
Pancreas	3	4	-
Heart	212	208	23
Heart/Lung	106	50	-
Lung/s	182	108	2
Liver	156	677	12
Cornea		2258	0

The “transplant” figures concern people receiving transplants from dead donors. “Live donor” figures concern people who have had a transplant from a living relative or emotionally close friend. Most people have two kidneys and can live with one; hearts are donated by patients who have had a heart/lung transplant and their own heart is healthy - a domino transplant.

In the new development of live “liver” and “lung” donors, a small section (a lobe) only is removed from the liver and lung.²⁰⁴

In the United Kingdom, live organ donation is governed under the *Human Organ Transplants Act 1989* which allows anyone suitable to donate all or part of a vital organ, for example, kidney, part of the liver, to a close blood relative. If the person is not a close blood relative, live donation is still possible with the prior approval of the Unrelated Live Transplant Regulatory Authority (ULTRA).

The Standing Committee was advised by Caroline Whitworth, Consultant Physician, of the Scottish Liver Transplant Unit that -

... there was and acute shortage of donors in the United Kingdom. ... There was debate about adopting an “opting out” system, however, what was required was a more integrated coordinator network. The system needed to better identify potential donors, provide evaluation, selection and maintenance of potential donor. Attitudes towards donation and the rate of ICU beds required improvement.²⁰⁵

4.9 United States of America

In the United States, the *Uniform Anatomical Gift Act* was drafted, approved and recommended for enactment in all the States by the National Conference of Commissioners on Uniform State Laws in 1968. The Act was adopted in all States in 1970. The Act provides that an individual of sound mind and 18 years of age or more may give all or any part of his body. The gift may be for the purpose of medical or dental education, research, advancement of medical or dental

²⁰³ *Ibid.*

²⁰⁴ Professional Transplant Services, <http://www.argonet.co.uk/body/DoH.html>, p 2-3.

²⁰⁵ Dr Caroline Whitworth, Consultant Physician, Scottish Liver Transplant Unit, Edinburgh, UK, meeting with Committee 19 September 2000.

science, therapy or transplantation. Under the provisions, it is intended that the right of the individual to dispose of his own body should be paramount. The Act provides that a gift may be made by will or by document other than a will. The Act also provides for a gift by a surviving relative in the absence of a gift by the deceased provided the relative has no actual notice of contrary indication by the deceased. Specified, in order of priority, are the classes of persons able to make such a gift.

Laws regarding organ donation, as opposed to organ distribution, which is where organs go once procured, are determined by the State and not by the national government. The laws vary from State to State creating some confusion. There are two types of organ laws. Firstly, "required request" is where everyone is required to be asked whether they want to donate. If there is no response, it is assumed they do not want to donate. Secondly, required refusal, where it is assumed that everyone wants to donate unless they refuse. Therefore, no response is a tacit approval for donation.²⁰⁶

Anyone over the age of 18 years can become a donor by completing a donor card in the presence of two witnesses.

Organs are distributed according to federal guidelines, based on medical criteria. Financial or social status is not considered in the distribution of organs. It is illegal to buy or sell organs in the United States.

An estimated 10,000 to 15,000 deaths in the USA each year could result in organ donation. However, there are only about 5,500 cadaveric donors per year. Some 20,000 Americans received organ transplants in 1996, but more than 55,000 people remained on the national organ transplant waiting list. It is reported that about 10 people die each day while awaiting an organ transplant.²⁰⁷

There is a national organisation responsible for organ distribution and for oversight of transplantation in general. The United Network for Organ Sharing (UNOS) has been chartered by Congress and is an independent organisation that reports to Congress. Every transplant hospital, organ procurement organisation and histocompatibility laboratory in the United States is a member of UNOS.

UNOS among other things, maintains the national transplant waiting list; coordinates matching and distribution of donated organs as well as developing standards that transplant surgeons and physicians must meet to be members of UNOS.

The Department of Health and Human Services in the United States has imposed several requirements on hospitals designed to increase organ donation. The hospital must implement written protocols that incorporate an agreement with an Organ Procurement Organisation (OPO) under which the hospital must notify the OPO of a person whose death is imminent or has died in the hospital. The hospital must have an agreement with at least one tissue bank and eye bank to cooperate in the retrieval, processing, preservation, storage and distribution of tissues and eyes. In collaboration with the OPO, the hospital must ensure that the family of each potential donor

²⁰⁶ Online Forum: Organ Transplant Controversy, January 2, 1998,
<http://www.pbs.org/newshour/forum/january98/organ1.html>.

²⁰⁷ Clinton Administration Launches National Organ and Tissue Donation Initiative, Press Release,
<http://www.hhs.gov/news/press/1997pres/971215a.html>.

is informed of the option to donate. The hospital works cooperatively with the OPO, tissue bank and eye bank in educating staff on donation issues.²⁰⁸

Regulation introduced in 1998 requires hospitals to notify OPOs of all deaths and imminent death so potential donors can be identified and families approached about donation.

It is reported that in the United States there are 69 organ procurement organisations providing services to 278 transplant centres.²⁰⁹

Protocols to recover organs from non-heart-beating donors have been introduced in at least 20 regions in the United States. This protocol gives families the option of organ donation when a family member is declared cardiac dead, but not brain dead. The protocol for non-heart-beating donors involves patients who are on the brink of death and whose condition is irreversible. Changes in the law recognise the patients' right to avoid extreme measures to extend their lives and to be organ donors.²¹⁰

With the recognition of the cessation of the brain's function as death, doctors were able to recover more useable organs for transplant because the organs could continue to receive oxygen-rich blood, via ventilator support, preserving them longer.

The non-heart-beating donor is a person whose death is defined by "irreversible cessation of circulatory and respiratory functions" as opposed to "irreversible cessation of all functions of the entire brain, including the brainstem".²¹¹

It was recently reported that attempts by the Department of Health and Human Services to introduce regulations to lessen the geographic disparities in the allocation of organs for transplantation was blocked by legislation approved by the House Commerce Committee. The legislation authorises programs under the *National Organ Transplant Act 1984* and strips the department of authority to oversee the activities of the contractor that runs the organ procurement and transplant network, the UNOS. The legislation states -

The responsibility for developing, establishing and maintaining medical criteria and standards for organ procurement and transplantation belongs in the private sector and is a function of the Network.²¹²

However, some Democrats and the Clinton Administration raised concerns and held that -

... the organisation wants to thwart efforts to make the allocation process more fair in order to protect the economic interests of transplant centres that could lose patients if organs are given to the sickest, rather than the nearest, patients.²¹³

208 Law and Medicine: Bioethics, <http://www.smu.edu/~tmayo/cop.htm>, p 9.

209 About Transplantation, http://www.sangstat.com/transplantation/trans_back-future.htm1, p1.

210 Maryland Hospitals Consider Additional Organ Donation Policy, <http://www.mdtransplant.org/nhbd.htm>, p 1.

211 *Ibid.*

212 Reuters Health Information, "Committee approves bill overturning organ transplant rules", October 14, 1998, <http://heartinfor.org/reutersnews/t101410f.htm>.

213 *Ibid.*

It has recently been reported that -

the House of Representatives has voted to block a move by President Bill Clinton to make available hearts, livers and kidneys to those who are in most need of them.²¹⁴

The US laws would give the transplant network total control over the rules governing how to distribute more than 20,000 organs donated each year. Under the network's system, patients who live in the same area as donors have first chance at organs. It is reported that -

Mr Clinton had proposed amendments to eliminate geographic barriers, saying someone's chance at life should not be dictated by where they live.²¹⁵

It has been reported that the United States Congress was considering laws to encourage organ donation. The proposed laws called for financial aid for living donors who give away a kidney or part of a liver and offered grants for States to encourage donation. It was reported that -

only half of the US families asked agreed to donate organs and many families are never asked.²¹⁶

4.10 Canada

The Canadian *Uniform Human Tissues Gift Act 1971* provides for the consent of any person who has attained the age of majority to use their body or any parts thereof after death for therapeutic purposes, medical education or scientific research. The *Uniform Human Tissues Gift Act 1971* is a model Act recommended by the Conference of Commissioners on Uniformity of Legislation in Canada. Under the Canadian provisions, it is intended that the right of the individual to dispose of his own body should be paramount. The *Uniform Human Tissues Gift Act 1971* provides that a person may consent to the use of his body by a signed statement or, if in his last illness, orally in the presence of two witnesses.²¹⁷

In Canada, all provinces and territories have their own organ donation legislation, which is similar among the provinces. Legislation covers both living and cadaver donations. The legislation defines what is meant by consent, including who can give consent for organ removal. For donations after death, death must be determined by at least two physicians using accepted medical guidelines. The buying or selling of organs is prohibited.

Constitutionally, the provincial governments have wide powers to regulate local health matters and particularly the delivery of health care services; specifically, they have the authority to make laws concerning the establishment, maintenance and management of hospitals. This gives them the primary role in health care activities and legal concerns relating to organ and tissue donations and transplantation.

The federal government's role in relation to organ and tissue donation and transplantation has been minimal. Generally, this is related to the division of constitutional powers. The federal government gains its authority in health matters through general powers, namely those pertaining to criminal law, spending, and peace, order and good government.

214 "Organ scam doctors charged", *The West Australian*, Thursday 6 April 2000, p 28.

215 *Ibid.*

216 "Organ scam doctors charged," *The West Australian*, Thursday 6 April 2000, p 28.

217 Section 4(1) of the *Uniform Human Tissue Gift Act 1971*.

Health Canada's primary activity on organs and tissue donation has been in the area of safety standards. The primary legislation is the *Food and Drugs Act 1981* (and its Regulations).

According to the *Public Hospitals Act*, amended in 1990, all hospitals in Ontario must have some procedure to help staff identify potential donors and to make potential donors families aware of the possibility of organ donation (Regulation 518/88).²¹⁸

Canada has multiple local and provincial organisations, facilities, professionals and governments involved in organ and tissue donation and transplantation. Organ Procurement Organisations (OPO's) have grown out of local initiatives and are frequently supported by provincial governments. A total of 28 hospitals perform organ transplants.

Some hospitals are paid a fee to help cover the costs of organ retrieval and to encourage their efforts in identifying donors. There is recognition of the donor family with either a medal or plaque commemorating the donation or by helping to pay funeral expenses to help increase the number of organ donors.

In Canada, the number of organ donors remains fairly constant each year at about 14 donors per million population. Although transplantation techniques have improved, the supply of organs has not kept pace. Access to organs that become available is often blocked by an uncoordinated donation system. Canada does not have a law requiring hospitals to inform an organ-recovery organisation of the death of a potential donor. There has been a call for the national government to create a coordinated donation system.²¹⁹

Initiatives endorsed by the federal, provincial and territory Ministers of Health have resulted in greater cooperation and coordination in recent times.

Table 18

Number of Organs Transplanted in Canada in 1998²²⁰

Organ	Number
Kidney (Cadaveric)	665
Kidney (living)	336
Heart	154
Heart/Lung	7
Lungs	75
Liver	342
Pancreas	9
Pancreas/kidney	33
Bowel	2

²¹⁸ "The shortage of organs: reasons and solutions", London Health Sciences Centre, <http://www.lhsc.on.ca/transplant/orgshort.htm>, p 1.

²¹⁹ Hurst L., "Advocates making desperate push to fix Canada's organ-donor system", <http://www.life-101.org/canada.htm>.

²²⁰ Report Number 05, <http://www.parl.gc.ca/InfoComDoc/36/1/HEAL/Studies/Reports/healrp05/12-ch-e.htm>, p 2.

The Canadian government announced in 1997 the establishment of a national donor registry. The national donor registry can be easily facilitated through the national health care system. It has been reported that -

One advantage in Canada is that they have a national health care system where every resident is registered in the system with an identification number. This will aid in developing the donor registry.²²¹

221

Online Forum Organ Transplant Controversy January 2 1998
<http://www.pbs.org/newshour/forum/January98/organ1.html>.

CHAPTER 5. DONOR ORGANISATIONS

5.1 National Organisations

There are a number of national organisations that promote transplantation. The Transplantation Society of Australia and New Zealand (TSANZ); the Australasian Transplant Coordinators Association; the Australian Kidney Foundation and the Australian Coordinating Committee for Organ Registries and Donation (ACCORD). ACCORD is a national body responsible for the development, coordination and implementation of national strategies aimed at improving the process of cadaveric organ donations. The secretariat of ACCORD is funded by both Federal and State governments through the Australian Health Ministers' Advisory Council (AHMAC).

The Australian Health Ministers Conference (AHMC) agreed to a national approach to organ donation, reflecting the belief that the most benefit will occur if there is national coordination of donation, retrieval and allocation and transplantation.

In October 1989, the AHMAC established ACCORD to develop and implement strategies to overcome the low organ donation rate in Australia. Australians Donate (AD) replaced ACCORD as the national organisation in 1998.

5.2 Australians Donate

Australians Donate the new national organisation is based in Adelaide. Its aims are to maximise organ and tissue donation for transplantation and to enhance community confidence in organ donation and transplantation.

Australians Donate, has a number of responsibilities including lifting donor rates nationally, improving the coordination and networking of existing donor registries and databases nationally and implementing public and professional education programs to raise awareness understanding of organ/tissue donation issues. To this end, Australians Donate has endorsed a national direction, which aims to -

- provide public, professional and school education programs;
- sympathetically manage donor families' issues and problems;
- build donor databases and provide improved data access for coordinators;
- improve data flow between those participating in the network;
- provide incentives at a hospital level to identify and manage potential donors; and
- actively encourage positive media coverage of organ and tissue donation.²²²

Australians Donate is endeavouring to provide standardised organ donation information throughout Australia. Australians Donate has stressed that nationally standard information is important, given Australians are mobile and organs can be provided interstate.

222

Legislative Assembly of Queensland, *Op Cit, Report No 16*, July, 1999, p 15 citing the Brennan report.

5.3 Developments in the States

South Australia has developed an agency for the purpose of coordinating the procurement of organs for transplantation. The debate on the structure of the agency focused on the type of model used internationally that has been most successful in increasing organ donation rates. The model introduced in South Australia is known as the Spanish model because it has been developed in Spain. The model includes specially trained medical donor coordinators who are situated in each hospital and are responsible to the central office of organ donation. The South Australian unit is a model for other States in Australia. It will assist in the development of this particular approach to organ donation throughout Australia. This model has the potential to rapidly increase the rate of organ procurement and hence assist in cost-containment especially in the area of the heavy cost of kidney dialysis.

5.4 Developments in Western Australia

The Western Australian Government announced on 28 September 1999 the creation of the Western Australia Organ and Tissue Donation Agency, or DonateWest which would lift organ donation rates and cut waiting times.²²³

5.5 Support Organisations

South Australia has established a donor support group called GIFT. GIFT (Give in faith and trust) is a counselling service which was established to assist donor families. The mission of GIFT is to promote the concept of organ and tissue donation in the community, to support those who donate and encourage their growth and development.

GIFT is a support group for donor families and/or friends who have suffered the loss of a relative who has become an organ or tissue donor.

SAODA makes available multi-lingual bereavement counsellors at no cost to relatives.

5.6 Donor Family Support

There is a role for counsellors for both donors and recipients. Development of a national standard of process and care will provide a valuable resource of donor families as advocates on the promotion of the value of organ donation.

There is a lack of consistency across all areas of the process dealing with sudden death.

5.7 International Organisations

There are a number of international organisations concerned with organ donation and support for organ donors and recipients. A few examples, are described below.

5.8 Donor Family Care and Support

The British Organ Donor Society (BODY) is a voluntary organisation whose members come

²²³

Hodge F., "\$1m organ donors boost", *The West Australian*, Tuesday, 28 September, 1999, p 13.

from families brought together by organ transplantation. The aim of the Society is to -

- promote the carrying of multi-organ donor cards; and
- offer help and support to donor and recipient families.

As well as supporting one another many BODY members promote organ donation and transplantation.

5.9 Donor Action

In March 1998 the Donor Action foundation was established as a non-profit entity. Donor Action is an international program developed by the Partnership of Organ Donation, USA, Eurotransplant Foundation, the Netherlands, and the *Organizacion Nacional de Trasplantes*, Spain. Its objective is to increase the rate of organ donors, placing special emphasis on correcting insufficient detection problems.²²⁴

Donor Action is an international initiative that helps intensive care units (ICUs) improve donation. Existing best practices from around the world have been incorporated into its quality assurance program.

Donation practices are reviewed and weaknesses identified. Corrective measures have been developed in the form of five core program modules which correspond to critical steps in the donation process.

The program is designed to help hospitals develop improved donation practices that are tailored to meet the identified needs of the ICU. Donor Action aims to streamline the roles and responsibilities of professional staff involved in the donation process and focus responsibility on dedicated and trained individuals.²²⁵

5.10 Transplant Recipients International Organisation

The Transplant Recipients International Organisation (TRIO) is an independent, non-profit, international organisation, working to improve the quality of life of transplant candidates, recipients, donors and their families.²²⁶

²²⁴ Alonso M. & Others, "Donor Action in Spain: A Program to Increase Organ Donation", *Transplantation Proceedings*, 31, 1999, pp 1084-1085.

²²⁵ Wight C. & Others, "Donor Action: A Quality Assurance Program for Intensive Care Units that Increases Organ Donation", *Journal of Intensive Care Medicine*, Vol 15, No 2, March/April 2000, pp 104-114.

²²⁶ Transplant Recipients International Organisation, Inc., http://www.trioweb.org/about/factsheet_c.html.

CHAPTER 6. NATIONAL REGISTRY

6.1 National Data Base

The Australian Health Ministers' Advisory Council (AHMAC) had recommended a national database using the Medicare cards. Such a national database would provide -

- centralised uniform procedures;
- national organ donor matching system; and
- coordination of a national system.

Bruce Lindsay, National Director of Australians Donate stated -

There would be value in a national donor registry.²²⁷

Support for the development of a nationally based accessible information system which identifies persons willing to be organ donors on their drivers licence was reached at the Australian Health Ministers Conference held on 4 August 1999. At that meeting the Health Ministers also agreed to request Transport Ministers to support the central recording of information on organ donor status on the National Electronic Vehicle Information System (NEVDIS) database as well as to request that Australians Donate work with individual Transport Ministers and the Australian Transport Council to achieve a national donor database which was accessible on a 24 hour basis.²²⁸

Australians Donate pursued the proposal of a national computer database of registered donors, which could be accessed from any hospital in the country.

Australians Donate examined a number of avenues for the establishment of a national database. These included using the NEVDIS, which would place all driver and vehicle data onto one centralised database and also the Federal Health Insurance Commission's (HIC) database. Australians Donate preferred the option of attaching donor status to the Health Insurance Commission's records, which they considered would provide the best possible chance for a truly national database.²²⁹

In June 2000 the Federal Minister for Health announced the establishment of a national donor register attached to Medicare. Dr Wooldridge advised the Federal Parliament that the National Australian Organ Donor Register -

²²⁷ Bruce Lindsay, National Director, Australians Donate, briefing to Standing Committee, Adelaide, 4 November 1999.

²²⁸ Response to Parliament by Ministers of the Legislative Assembly of Queensland to the Legal, Constitutional and Administrative Review Committee, Review of the Transplantation and Anatomy Amendment Bill 1998, *Report No 16*, July, 1999.

²²⁹ Legislative Assembly of Queensland, *Op Cit, Report No 16*, July, 1999, p 37.

... will enable organ donation coordinators to securely access the information and help them in seeking the consent of family members.²³⁰

Dr Millar Forbes advised the Standing Committee that -

... the national register is now very close, and we all need to work as quickly as possible to make that happen and to cooperate with the Commonwealth Department of Health and the Health Insurance Commission. At the moment, we are having discussions with the licensing division of the Department of Transport, with the computer experts, and with those involved in the clinical care system in the hospitals.²³¹

It was reported that the Federal Government hopes to boost organ donation with a national donor register. The Health Minister, Michael Wooldridge stated -

Australia had a dangerously low level of organ donation.²³²

The Standing Committee was advised that -

A national registry of organ donor status is a good initiative, as is registering intent through Medicare.²³³

The Standing Committee was advised that representatives from Western Australia attended a series of consultations held by the Department of Health and Aged Care to discuss the initial plan and implementation of the Australian Organ Donor Registry (AODR). Western Australia has made available details of the local registration system to the Commonwealth Department of Health and Aged care and also to the HIC.²³⁴

Dr Millar Forbes advised the Standing Committee that -

I believe the national registry will be helpful. ... having a national registry will be an improvement. It is a matter of getting the cooperation as soon as possible from the State and Commonwealth Governments to put the new procedures in place so that registration will be linked to Medicare numbers.²³⁵

6.2 Australian Organ Donor Registry

The HIC who administers Medicare had investigated ways to package health data including the development of a national organ donor register.

A donor register is widely valued as a means of allowing potential donors to committing their intentions to a database that is accessible upon their death. It is believed donor families are likely to allow donation if the wishes of the donor are known.

230 Dr Wooldridge, Minister for Health and Aged Care, Commonwealth Parliament, House of Representatives, Hansard, Thursday, 31 August 2000, p 17992.

231 Dr Alistair Millar Forbes, Transcript of Evidence, Perth, 14 August 2000, p 13.

232 Perkins, J., "Register aims for organs", *The West Australian*, Monday, 12 June 2000.

233 Submission by Department of Health, Western Australia, 14 August 2000, p 18.

234 *Ibid*, p 19.

235 Dr Alistair Millar Forbes, Transcript of Evidence, Perth, 14 August 2000, p 4.

The function a national register is to list in an accessible format the wishes of all Australians with respect to donation. It is believed that this would result in a dramatic increase in donations, as it would remove any doubts about the potential donor's wishes.²³⁶

The Queensland Legal, Constitutional and Administrative Review Committee favoured the establishment of a national register of organ donors. The Health Ministers Advisory Council has supported a national register.

The Standing Committee was advised that -

There is value in centralised uniform procedures particularly for States with organ donor registry systems less developed than that of Western Australia. Centralised uniform procedures (for registration) will also reassure the community that their consideration as organ donors will be the same regardless of location.²³⁷

6.3 Existing Donor Registries

Prior to the initiative to introduce a national registry, a number of donor registries existed in Australia.

The most comprehensive was the positive donor status information held on drivers licence data in most Australian States, except Victoria, Northern Territory and the Australian Capital Territory.

Although more than 3½ million Australians registered their wish to donate organs, the registry was flawed with respect to access, which in some jurisdictions was denied by Crown Law on the basis of opinions relating to privacy and confidentiality of government-held information on individuals. The Victorian Organ Donor Registry had fewer than three percent of the Victorian population registered as donors. The major shortcoming of the registry was its stand-alone nature.

The MedicAlert Foundation routinely asked clients to register their donor status. Nationwide there were around 14,000 intending donors listed on this registry. However, the information was not available to donor coordinators.

In Western Australia the primary source for people to register their wish to be an organ donor was on their driver's licence. Dr Jones advised the Standing Committee that -

One of the things we do well in Western Australia is register people who would like to be identified as organ donors on their licence. That register is kept at Sir Charles Gairdner Hospital and is attached to the patient master index files. When patients are admitted, it can be seen immediately whether they have registered their desire to be an organ donor.²³⁸

The Standing Committee was made aware by a potential organ donor that the drivers licence system in Western Australia only allowed for the ticking of a box to indicate a person wishes to

²³⁶ "Australian Organ Donor Registry", *Business Proposal*, Health Insurance Commission, ACT, October 1999.

²³⁷ Submission by Department of Health, Western Australia, 14 August 2000, p 18.

²³⁸ Dr Dorothy Jones, Transcript of Evidence, Perth, 7 December 1999, p 13.

become an organ donor. This system did not allow a potential donor to indicate which organs or tissue they wished to donate. This created a problem for potential donors who wished to be donors but had an objection to donating particular organs or tissue.

The Standing Committee found that -

Finding 21

The driver's licence registration system only provided for the ticking of a box to indicate a wish to be an organ donor. It did not allow potential donors to indicate which organs or tissue they wished to donate.

The Standing Committee considered this issue and was of the opinion that not providing the opportunity for potential donors to indicate their wishes could be a factor which contributes to people electing not to donate. For this reason, the Standing Committee believes that such an option should be made available to all potential donors with the introduction of the new national donor registry.

The Standing Committee recommends that -

Recommendation Seventeen:

With the introduction of the new national organ donor registry, consideration should be given to providing for "opting out" and also an option of indicating which organs and tissues, donors wish to donate.

6.4 Aim of a National Donor Registry

A national donor register would significantly advance the management and promotion of organ donation. The national database of intending organ donors in Australia would assist in improving the profile of organ donation by making people more aware of the benefits of organ and tissue donation, and increase the number of individual donors in Australia.²³⁹

The Standing Committee was advised that -

A national register would reduce the familial refusal rate by raising the profile of organ and tissue donation in the community, and by increasing the proportion of individuals whose intent is known.²⁴⁰

A national donor-recipient matching system is currently in place, known as the National Organ Matching System (NOMS). NOMS comprises information relating to patients awaiting kidney transplants as well as some organ donor information.²⁴¹

²³⁹ Health Insurance Commission, "Australian Organ Donor Registry", Business Proposal, October 1999.

²⁴⁰ Submission by Department of Health, Western Australia, 14 August 2000, p 19.

²⁴¹ *Ibid.*

6.5 Scope of a National Donor Registry

On 9 June 2000 the Federal Minister for Health and Aged Care announced Commonwealth funding for the development of a national database of intending organ donors in Australia. This register will be known as the Australian Organ Donor Registry (AODR). The Health Insurance Commission (HIC) will develop and maintain the AODR, in collaboration with the Department of Health and Aged Care and Australians Donate.

The AODR will contain data about each person's intention toward donation and a small amount of demographic data for identification purposes. Each person will be identified on the AODR through their Medicare number, and people will be able to register on the AODR through Medicare offices or through their Medicare renewal form. HIC are also considering sending registration forms with the Medicare reimbursement cheques. The AODR will be ready to accept registrations by 1 November 2000. The data of the Australian Organ Donor Registry (AODR) will contain details of the consenting individual that will be matched to records contained on the Medicare enrolment database. The AODR will be separate from the Medicare database.²⁴²

The AODR will initially be populated from all available sources; including information from existing donor registers. The provision of information from consenting individuals will result in a comprehensive intending donor database available for use by authorised health professionals.

There is scope for the AODR to be expanded to capture information that will assist health professionals in contacting and determining candidates for living donation, for example blood or bone marrow.²⁴³

6.6 National Donor Registry Model

All Australians will be eligible to register their intention to be a potential organ donor. Registration will be voluntary. The consent of the individual's family will also be obtained before the removal of donor organs.

Registration forms will be available from a variety of sources including Medicare offices, organisations/agencies, hospitals, general practitioners, pharmacies, motor vehicle registries, post offices, telephone 1800 inquiry number and the Internet. Medicare cardholders will be invited to register their donor status as part of the ongoing Medicare card replacement program.²⁴⁴ It has been reported -

While we are hearing a lot of support for a national process, each of the States is individually committing large resources and going in their own directions, at a time when we are trying to set up the national body and make it an effective organisation.²⁴⁵

²⁴² Submission by Department of Health, Western Australia, 14 August 2000, p 19.

²⁴³ Health Insurance Commission, "Australian Organ Donor Registry", Business Proposal, October 1999.

²⁴⁴ *Ibid.*

²⁴⁵ Summary Digest of the Proceedings of the Inaugural National Forum on Organ and Tissue Donation, April 1999, Parliament House, Canberra, p 12.

6.7 Conclusions

The Standing Committee is of the view that a national organ donor registry is vital in terms of improving organ donation. It would be a cost effective method of maintaining an accessible registry to replace the current multiple uncoordinated and inaccessible registers that exist in the various States and Territories.

The Standing Committee is of the view that if Western Australia or any other State adopts a “presumed consent” model, then the national register can easily be modified to provide for “opting out”.

CHAPTER 7. ORGAN TRANSPLANTS FROM ANIMALS

7.1 Introduction

Transplantation has gained general acceptance as a practice for treating patients with a variety of medical conditions. The human donation of transplantable organs and tissues, however, has not kept pace with demand. The world shortage of human organ and tissue donation is exacerbated by insufficient national capacity to provide chronic and expensive treatments such as dialysis.

Therefore, additional and alternative sources are being sought. One possibility currently under investigation is the use of animals as a source of cells, tissues and organs. As an alternative to human organ and tissue donation, xenotransplantation may become a practical treatment, if reasonable standards of safety and efficacy can be assured. In the long term, xenotransplantation may become an economical alternative to human organ or tissue transplantation.

Xenotransplantation is the transplantation of live non-human animal cells, tissues and organs in human patients. It is currently a vital area of clinical research, which may one day become part of medical practice. Xenotransplantation has the potential to contribute to the alleviation of the global shortage of human tissues and organs for allotransplantation.

Xenotransplantation can take a number of forms, including -

- transplantation of solid animal organs such as hearts, kidneys, livers;
- cell therapies, such as the transplantation of pig neural cells and pig pancreatic islet cells;
- use as part of a medical device, such as an extra-corporeal liver device utilising viable animal cells; or
- the use of viable animal cells in gene therapies such as the use of murine cells.²⁴⁶

The entry of xenotransplantation into the modern clinical arena is being approached in a cautious manner. There is preliminary evidence that porcine cellular grafts may endure in human recipients.

7.2 Definitions

Xenotransplantation is the use of live non-human animal cells, tissues and organs in human patients. These cells can be implanted or enclosed in a device that is used outside the body (“*ex vivo* perfusion”).

“Zoonoses” are defined as diseases of animals that can be transmitted to humans under natural conditions (eg. toxoplasmosis, salmonella infections).

A xenogeneic infection is a transmissible disease introduced from animals into humans through

²⁴⁶

Department of Health, United Kingdom Xenotransplantation Interim Regulatory Authority (UKXIRA), <http://www.doh.gov.uk/ukxira.htm>, pp 2-3.

xenotransplantation.²⁴⁷

A “xenotransplant” is a transplant between species. Transplanted organs are called “grafts”; hence, a “xenograft” is an organ transplanted from one species to another.

A transplant between genetically different members of the same species is called an “allograft”

A transplant between members of the same species that are genetically identical (inbred animals or identical twins) is called an “isograft”.

A transplant from one person to himself or herself (for example moving bone from the hip to the back to fix a broken vertebra) is called an autograft.²⁴⁸

7.3 Xenotransplants

Many scientists believe that xenotransplantation may be the only solution to the increasing shortage of human transplant organs. More than 50,000 people are currently waiting for a transplant in Europe,²⁴⁹ and 4,000 in Australia awaiting transplants,²⁵⁰ but there are not enough available organs

While this may seem a simple solution to a complex problem, there are many practical, social and medical hurdles to overcome. The donor organ must be compatible in size and it must also function in the same way. It must also be accepted by the human body and work properly once it has been transplanted.

The animal chosen for this purpose is the pig. Its organs closely match those of humans in function and size, in both infancy and adulthood. The pig produces large litters, so that large numbers of life-saving organs can be provided quickly if necessary, reducing the need for people to spend so long waiting for a transplant.²⁵¹

Dr Stokes stated that for some time heart valves from pigs have successfully been used in heart surgery -

Pig heart valves have a very low immunological response, because they are mainly made up of elastin tissue and fibreglass and there is very little in the way of antibody response to them.²⁵²

Pigs are being raised in sterile environments and genetically altered with human DNA so that the chance of rejection is greatly reduced. These transgenic pigs are being bred so that their organs, such as hearts and lungs can be used in transplantation in humans.

²⁴⁷ FDA Backgrounder, Fact Sheet on Xenotransplantation, <http://www.xenotransplant.ineu.org/xenotrans/news/19960920.htm1>, p 4.

²⁴⁸ Xenotransplants, http://www.transweb.org/qa/qa_txp/faq_xeno.htm1, p 1.

²⁴⁹ Reaney, Patricia, “Study casts doubt on pigs for organ transplants” Broadcasted on BICNews, 16 October 1997, <http://www.iol.ie/~afifi/BICNews/Health/health16.htm>.

²⁵⁰ O’Neill, G., “Operation pig”, *The Bulletin*, 6 June 2000, p 30.

²⁵¹ Xenotransplantation, http://www.transplantsquare.com/public/...development/xenotrans/general_xeno5.htm, p 1.

²⁵² Dr Bryant Stokes, Transcript of Evidence, Perth, 7 December 1999, p 19.

It has been reported that -

Pig organs have been transplanted to humans several times in the last few years.²⁵³

It has been recently reported that cloned piglets had been born in Virginia in the United States of America. The report stated that -

The clones raised hopes that pigs could be genetically engineered so that their organs or cells would be more readily accepted by the human body, making them more easily transplantable.²⁵⁴

It was claimed to be a significant breakthrough because pigs are thought to be the most genetically suitable animal for organ transplant to humans. It was also reported that the company involved stated -

... transplantation of genetically altered pig organs could be tested on humans in four years and that analysts believed the market for them could be worth \$9.78 billion.²⁵⁵

The Standing Committee was advised by Dr Michel Bouvier d'Yvoire that -

Where we are with xenotransplantation is "research" and it will be research for quite a while - animal research, clinical research for a number of years.²⁵⁶

Dr Harry Griffin of the Roslin Institute advised the Standing Committee that -

There are good technical reason to delay decisions about xenotransplantation. There are more technical advances to be made before we would realistically test genetically modified pig organs.²⁵⁷

7.4 Transplant Organ Rejection

The main problem scientists have to overcome is that an animal organ would normally be rejected by the human body. Humans have a natural defence system called the immune system which fights any "foreign" invasion in the body, such as infection or an organ transplanted from either a human or animal donor. Whilst the organ is "taking" to its new host, immunosuppression drugs are used to reduce the possibility of rejection.

The major problem, as with allografts, is rejection. Humans have "natural antibodies" that circulate in the blood and cause immediate failure when organs from some species are transplanted. A system of proteins in the body called "complement" are activated whenever, for example, pig organs are transplanted, leading to severe systemic toxicity. Genetic engineers are attempting to solve the problem by genetically modifying pigs so that they have some

253 Williams, Rebecca D., "Organ Transplants from Animals: Examining the Possibilities", http://www.fda.gov/fdac/features/596_xeno.html, p 2.

254 "Transplant hope in cloned pigs", *The West Australian*, Wednesday, 15 March 2000, p 11.

255 *Ibid.*

256 Dr Michel Bouvier d'Yvoire, *Ettablissement francais de Greffes*, Paris, France, meeting with the Committee, 22 September 2000.

257 Dr Harry Griffin, Assistant Director, Roslin Institute, meeting with the Committee, Edinburgh, Scotland, Monday 18 September 2000.

complement regulatory proteins in their cells.²⁵⁸ It is believed that this will “trick” the body’s immune system into thinking that the new organ is in fact human.

Research is now aimed at suppressing and averting the immune responses through genetically modifying the donating animals. Scientists believe that humanising the animal will increase the organ’s chance of acceptance by the human patient’s immune system.²⁵⁹

It has recently been reported that the Melbourne’s Austin Research Institute -

... have demonstrated a way of defusing the shock-of-the new response that causes the human immune system to reject an alien organ within minutes of it being installed.²⁶⁰

However, the director of the Institute, Ian McKenzie warned that there were obstacles and that the new technique may still be five to 10 years away from use in humans.²⁶¹

7.5 Disease Transmission

The development and implementation of such technology requires careful management and consideration. Xenotransplantation could have adverse consequences such as the cross-species transmission of animal infectious diseases to human xenograft recipients, their contacts and wider human population. Of concern with xenotransplantation is the transmission of diseases. These diseases, which are called zoonoses, would expand zoonoses (infections transmitted from animals to humans under natural conditions) to include infections not currently recognised as transmitted via animals or those in which xenotransplantation alters pathogenicity. Xenotransplantation in humans might engender human infection with animal pathogens not previously known or recognised. Special procedures are required to screen source animals and lifelong surveillance of patients who undergo xenotransplantation is essential.

Dr Stokes advised the Standing Committee that -

People are very concerned about the zoonoses, which are these viruses that are in animal species that can then be transmitted to human beings.²⁶²

Viruses from the pigs can mutate and the human will then host a mutated virus, which can spread to other humans who will not have immunity.

Dr Stokes advised the Standing Committee that the World Health Organisation (WHO) -

... has a whole series of committees looking at xenotransplantation under its communicable disease group.²⁶³

The first steps towards global cooperation on xenotransplantation surveillance was suggested in 1997, through the development of internationally agreed guidance on reporting norms, and the use of compatible information technology. This and subsequent international consultative

²⁵⁸ Xenotransplants, http://www.transweb.org/qa/qa_txp/faq_xeno.html, p 1.

²⁵⁹ “Xenotransplants, HTTP://www.transweb.org/qa/qa_txp/faq_xeno.html.

²⁶⁰ O’Neill, G., “Operation pig”, *The Bulletin*, 6 June 2000, p 30.

²⁶¹ O’Neill, G., “Operation pig”, *The Bulletin*, 6 June 2000, p 30.

²⁶² Dr Bryant Stokes, Transcript of Evidence, Perth, 7 December 1999, p 20.

²⁶³ Dr Bryant Stokes, Transcript of Evidence, Perth, 7 December 1999, p 20.

meetings and forums were followed by a joint WHO and the Organisation for Economic Cooperation and Development (OECD) in October 2000 consultative meeting to address national and international policy on xenotransplantation and effective international xenogeneic infection/disease surveillance.²⁶⁴

A number of patients around the world who have been treated with living pig tissues in the last ten years are being studied by medical scientists to discover whether or not there has been any transmission of viruses from the pigs to the patients.²⁶⁵

The Standing Committee was advised that a retrospective review of patients published in 1999 indicated that recipients of porcine tissue up to 12 years earlier did not show any overt evidence of infection with porcine viruses -

One study examined 160 patients who had been exposed to living pig tissue up to 12 years earlier. Patients did not seem to have been infected with any porcine viruses, although two patients showed antibody responses to the virus. These responses may have been present prior to the tissue exposure. Although promising, experts are not agreed on the significance of this study.²⁶⁶

Preventing infections in source animals is the key to preventing their subsequent transmission into xenotransplant recipients.

It has recently been reported that researchers working at the Roslin Institute near Edinburgh, Scotland will stop experiments into genetically modifying pigs because of concerns that diseases could be passed to humans through the use of transplanted organs.²⁶⁷

The Standing Committee found that -

Finding 22

The outlook for xenotransplantation is so long term that resources are best directed to increasing transplants from human to human.

7.6 Retro Viruses

Dr Michel Bouvier d'Yvoire advised the Standing Committee that there is the natural desire to use the organs of cordant species, species that are genetically similar to humans, for transplants. However, the risk of viruses being transferred from infected organs to the human recipient are extremely high due to the genetic similarity between the species.²⁶⁸

²⁶⁴ Joint WHO/OECD Consultation on Xenotransplantation Surveillance, OECD Paris, 4-6 October 2000.

²⁶⁵ Reaney, P., "Company Plans to Use Pig Livers on Critical Human Patients", <http://www.sightings.com/health/pigliver.htm>.

²⁶⁶ Submission by Health Department, Western Australia, 14 August 2000, p 25.

²⁶⁷ "Virus fears halt pig researchers", *The Times*, Monday 14 August 2000.

²⁶⁸ Dr Michel Bouvier d'Yvoire, *Establissement francais des Greffes*, Paris, France, meeting with Committee, 22 September 2000.

Primate organs have been ruled out in the possibilities for xenotransplants mainly because of viruses that can infect humans. Certain viruses from primates namely Ebola, Marburg virus and possibly AIDS have been identified.

Discordant species like the pig have similar physiology to humans, however, they are genetically more removed. This reduces the risk of virus assimilation by the host.

Consequently, pigs became the species whose organs could be used in transplantation. Researchers believe that there was a lower risk in retrovirus infections from pigs to people. Viruses that can mutate and cross the species barrier are considered to be the most deadly and difficult to work with. Researchers have been able to eliminate most non-inherited viruses from human transplants bred in pigs.²⁶⁹

Scientists have cast doubts about the feasibility of using pig organs for human transplants after finding two types of viruses that could infect human cells. It was reported that -

Further support for these fears comes from the discovery of two different classes of porcine endogenous (PERVs),²⁷⁰ capable of infecting human cells.²⁷¹

The Standing Committee was advised that -

In 1997, researchers at the Institute of Cancer Research in London showed that porcine endogenous retrovirus (pig viruses) crossed the species barrier and infected human cells *in vitro*. These retroviruses are of particular concern as they are incorporated into the pig DNA. Since that time porcine retroviruses have been the focus of much research and regulatory concern.²⁷²

7.7 Gene Technology

Gene therapy can be defined as a therapeutic technique in which a functioning gene is inserted into the somatic cells of a patient to correct an inborn error or to provide the cell with a new function. Current methods for gene therapy make use of directly harvested cells, cultured cell lines, genetically modified cell lines, viral vectors and non-viral approaches such as liposomes or naked DNA.²⁷³

Gene therapy in xenotransplantation may be used to transfect genes into the transplant animal organ before implantation or into the recipient's bone marrow cells to induce tolerance.²⁷⁴

Genetic engineering is the next step in overcoming organ rejection. It has been reported that -

Researchers have begun experimenting with ways to insert human genes into animal organs, so that the organ will produce proteins the body will recognise as human.²⁷⁵

²⁶⁹ Xenotransplants, <http://icdweb.cc.purdue.edu/~snydere/xenotransplants.html>, p 1.

²⁷⁰ PERVs means Porcine Endogenous Retro Viruses.

²⁷¹ Reaney, Patricia, "Study casts doubt on pigs for organ transplants", Broadcasted on BICNews, 16 October 1997, <http://www.iol.ie/~afifi/BICNews/Health/health16.htm>.

²⁷² Submission by Health Department, Western Australia, 14 August 2000, p 25.

²⁷³ Organisation for Economic Co-operation and Development, *Xenotransplantation: International Policy Issues*, 1999, p 58.

²⁷⁴ *Ibid.*

²⁷⁵ Williams, Rebecca D., "Organ Transplants from Animals: Examining the Possibilities",

Gene therapies and their role in xenotransplantations are still in the early stages.

Developments in gene technology have the potential to revolutionise procedures in transplantation. It has recently been reported that Australian researchers have achieved a breakthrough in the growth of human nerve cells. It has been reported that -

Monash University researchers are the first in the world to grow the cells from embryonic stem cells.²⁷⁶

Embryonic stem cells are derived from an embryo up to five days old. They have the ability to become any adult cell in the body, such as nerve, blood or heart cells. Professor Trounson stated that -

There was a promising outlook for transplantation in humans.²⁷⁷

It has also been reported that scientists in the United Kingdom are involved in developing new stem cell therapies. Researchers will apply chimeraplasty²⁷⁸ and nuclear transfer technology²⁷⁹ to demonstrate the ability to produce animals carrying modified genes and create transgenic animals whose organs will be suitable for human transplants.²⁸⁰

Professor Van Hecke advised the Standing Committee that -

Xenotransplantation of whole organs was not for the near future. However, cells could be used sooner, but legal and ethical principles had to be clarified first.²⁸¹

There is also research into the procedure of transplantation of pig foetal neural cells into the brains of Parkinson disease patients. In France there have been trials transplanting human foetal cells into the brain of patients with Huntington disease.²⁸²

The Standing Committee was advised that -

Xenotransplantation can cover a number of different things including the transplantation of cells for instance neural cells into the brain of Parkinson or Huntington disease patients it includes also xenoperfusion.²⁸³

http://www.fda.gov/fdac/features/596_xeno.html, p 4.

276 “Cultured cells are hope in nerve diseases fight”, *The West Australian*, Wednesday, 5 April 2000, p 41.

277 “Cultured cells are hope in nerve diseases fight”, *The West Australian*, Wednesday, 5 April 2000, p 41.

278 Chimeraplasty technology seeks to modify genes.

279 Nuclear transfer technology has given the world the first animal cloned from an adult cell.

280 Kimeragen and Roslin Bio-Med unite to develop methods for precise genetic modification procedures of livestock, <http://www.xenotransplant.ineu.org/xenotrans/news/19981020.html>, p 1.

281 Professor Van Hecke, Cardio Transplant Physician, University Hospital, Leuven, Brussels, Belgium, meeting with Committee, 25 September 2000.

282 Dr Michel Bouvier d’Yvoire, *Ettablissement francais de Greffes*, Paris, France, meeting with Committee, 22 September 2000.

283 Dr Michel Bouvier d’Yvoire, *Ettablissement francais de Greffes*, Paris, France, meeting with Committee, 22 September 2000.

Xenoperfusion has been used in situations where a patient has acute liver failure and a suitable liver is not available. The patient will die because the liver is a vital organ. The Standing Committee was advised that there is a mechanical device that is useful to help the patients -

The development of bio-artificial livers can assist patients during the period they are waiting for a human liver to become available. The artificial liver consists of inserting living cells (these can be human or animal cells) in a technical device and running the patient's blood through the device. The blood comes into contact with animal liver cells, is detoxified and is then put back into the patient. In this process there is close contact between the patient and the animal cells.²⁸⁴

Clinical trials have been conducted by several teams but there is debate about the efficacy of the results.

7.8 Disease Risk and Prevention Issues

Since the potential advantages and risks cross national boundaries, xenotransplantation is a public health issue, which must be dealt with at both the national and international level. If national approaches to xenotransplantation research and use are to be viable, they will require complementary international activities and initiatives.

Ethical, social and religious values and perceptions have a major influence on the ultimate acceptance or rejection of xenotransplantation as an implemental biomedical technology. The potential for secondary transmission of infections makes the risk of zoonoses a global issue. The World Health Organisation (WHO) has produced a detailed guidance document on the prevention and management of zoonoses.

It has been reported that European parliamentarians have called for a moratorium on xenotransplantation until the new technology, which uses animal parts for human transplants, is evaluated and guidelines established and agreed to. Fears of a threat to public health prompted the Council of Europe's Parliamentary Assembly to call for a worldwide ban.

The Parliamentary Assembly stated -

The risks involved in allowing xenotransplantation in clinics is currently too high to be acceptable. Much more research is needed before we will have satisfactorily answered all the unanswered questions.²⁸⁵

The serious risk of disease transfer had to be weighed against the potential benefits.

The question is how to proceed with trials without creating a new disease. The Standing Committee was advised that clinical trials need to be regulated. Regulation needs to be world wide -

Expert committees need to be set up. The committees need to be balanced to include people who are pro xenotransplantation, immunologists and specialists in bio-safety.²⁸⁶

National and international registries of xenotransplant source animals, animal colonies and

284 *Ibid.*

285 European parliamentarians today call for a moratorium on xenotransplantation, <http://www.xenotransplant.ineu.org/xenotrans/news/19990129.htm>.

286 Dr Michel Bouvier d'Yvoire, *Establishment francais de Greffes*, Paris, France, meeting with Committee, 22 September 2000.

recipients should be kept. Such registries will allow epidemiological monitoring of xenograft recipient populations for evidence of xenozoonotic events.

From a public health perspective, attention must be given not only to xenograft recipients but also to their contacts.

The Standing Committee concludes therefore, that -

Finding 23

Xenotransplantation is not a viable option at present.

7.9 Ethical and Social Considerations

Several ethical issues are raised by research on xenotransplantation and its potential use. They can be categorised as those concerning -

- its impact on allotransplant donation and availability;
- personal and societal perceptions of the appropriateness and acceptability of technology and its attendant risks;
- issues of informed consent, protection of human rights and community interest including access to information; and
- animal species selection, animal welfare and use, and the genetic engineering of animals, including cloning.

Some ethicists give precedence to human needs so they focus on the outcome that best serves the interest of patients and, if successful, xenotransplants could save thousands of human lives.²⁸⁷

Xenotransplantation may raise specific issues such as the appropriateness of the use of animals as sources of cells, tissues or organs for transplantation into humans, the implications of genetic engineering for animals and humans, and the potential psychological issues which may arise from the presence of animal cells, tissues, or organs in a recipient. Cultural norms, attitudes, and belief systems shape the perceptions of societies and individuals. A major influence on people's attitudes towards xenotransplantation will be their perception of the scientific validity and medical justification for the procedure. Regulatory mechanisms for ensuring accountability, protection of public interest, and the minimisation of risk are also required.

Basic principles of biomedical ethics such as beneficence, non-maleficence, autonomy and justice are also applicable to xenotransplantation. They should be applied to both the recipient and the community. In general, the informed consent of a patient is considered a prerequisite for any medical intervention.

The regulatory balance between recipient and community interests will vary between nations and societies, and will reflect legal, ethical and cultural norms. Laws may have to be modified or enacted to establish a regulatory infrastructure for this new technology. International cooperation

287

Ethical Issues, London Health Sciences Centre, <http://www.lhsc.on.ca/transplant/ethics.htm>, p3.

will be necessary to promote the compatibility of the national regulatory frameworks applicable to xenotransplantation and its related infectious disease management activities.

Pigs have been considered as xenotransplant source animals because of their comparable organ size and general anatomic similarities to humans. Xenotransplant source animals, regardless of species should be treated in a manner consistent with animal welfare principles and not be subjected to undue pain or distress.²⁸⁸

7.10 Europe

The Council of Europe, through its Steering Committee on Health and Bioethics and by the Working Group on Organ Transplantation, is reviewing xenotransplantation as it relates to issues of human rights and bioethics.

The Council is conscious that xenotransplantation, that is, the use of living organs, tissues and/or cells from animals, whether genetically modified or not, for transplantation into humans, may become a practicable therapeutic intervention in the very near future. The Council of Europe's Committee of Ministers to Member States on Xenotransplantation adopted Recommendation No R(97)15.²⁸⁹ The Council recommended that Member States should establish a mechanism for registration and regulation of aspects of xenotransplantation with a view to minimising the risk of transmission of known or unknown diseases and infection to the human or animal population.

The Council of Europe's Parliamentary Assembly called on 29 January 1999 for a worldwide ban on xenotransplantation until the technology is evaluated and guidelines are established and agreed.

7.11 United Kingdom

The United Kingdom Government established the Advisory Group on the Ethics of Xenotransplantation in March 1996. Their report, *Animal Tissue into Humans*²⁹⁰ concluded that xenotransplantation was acceptable provided certain criteria was met and there was a national committee to oversee developments. The Government established the United Kingdom Xenotransplantation Interim Regulatory Authority (UKXIRA) to regulate the development and implementation of xenotransplantation. Any proposal to undertake a trial or procedure involving xenotransplantation in the United Kingdom must be first submitted to the UKXIRA for consideration (with the exception of xenotransplantation procedures involving gene therapy which should be directed to the Gene Therapy Advisory Committee).²⁹¹

An independent body, the Nuffield Council on Bioethics published a report in March 1996, *Animal to Human Transplants: The Ethics of Xenotransplantation* and recommended that the

288 The Council for International Organisations of Medical Sciences (CIOMS), in *Principles for Biomedical Research Involving Animals* (1985) outline some principles that may be used to govern the use of animals for xenotransplantation.

289 Adopted by the Committee of Minister on 30 September 1997 at the 602nd meeting of the Ministers' Deputies.

290 Published in January 1997.

291 Department of Health, United Kingdom Xenotransplantation Interim Regulatory Authority (UKXIRA), <http://www.doh.gov.uk/ukxira.htm>, p 2.

clinical application of xenotransplantation should not proceed until preclinical safety and efficacy issues were fully addressed.²⁹²

7.12 United States

The Department of Health and Human Services, through its Public Health Service agencies (National Institutes of Health, Centres for Disease Control and Prevention, the Health Resources and Services Administration, and the Food and Drug Administration), (FDA) has formed a national level Committee on Xenotransplantation. The goal of the Committee is to outline safety requirements for the procurement, screening, and use of xenografts. Also under development is a pilot National Xenotransplantation Registry Database (NXRD). The model will be a national data collection system or network for the detection, identification, monitoring and evaluation of zoonotic risk.

In the United States limited clinical trials in xenotransplantation are in progress under FDA regulation.

7.13 Canada

Xenotransplantation is not prohibited in Canada. However, as it is considered “therapeutic”, Health Canada has the authority to regulate xenotransplantation as a new technology. Companies or hospitals wanting to undertake clinical studies involving xenografts must obtain the approval of the Therapeutic Products Program of Health Canada before they may proceed.²⁹³

Pre-clinical xenotransplantation research is occurring in Canada. A Standards Based Risk Management (SBRM) regulatory framework is being developed for organ and tissue transplantation including xenotransplantation. The legislative basis for regulation of xenotransplantation is the Canadian *Food and Drugs Act 1981*.

7.14 The Netherlands

A Committee on Xenotransplantation of the Health Council reported in January 1998 and concluded that xenotransplantation could be an alternative transplantation of human organs, tissues or cells. It also reported that clinical experiments should not be performed until rejection problems are of approximately the same order as with human organs and the risk of pathogen transfer can be managed.

7.15 Spain

In May 1997 the Permanent Committee on Transplantation of the Interterritorial Council of the Spanish National Health System approved a proposal to form a Subcommittee on

²⁹² Annex 1, Summary of recommendation, *Xenotransplantation: International Policy Issues*, Organisation for Economic Cooperation and Development 1999.

²⁹³ Xenotransplantation, London Health Sciences Centre, <http://www.lhsc.on.ca/transplant/xenograf.htm>, p 2.

Xenotransplantation. The Subcommittee released a background document on xenotransplantation and Spanish Guidelines of Xenotransplantation in June 1998.

The Guidelines require that before human trials can begin, preclinical studies must demonstrate six-month survival and function of cells, tissues and organ and absence, during the same time period of transmission of infectious agents. In case such transmission is detected, the guidelines require that there be no signs of infections for 12 months.

The Spanish Health Department has set up a multi-disciplinary Commission, the Xenotransplantation Commission, in which experts from different field related to the topic will be officially responsible for informing and reporting about xenotransplantation research in Spain.²⁹⁴

7.16 France

In 1995, the *Establissement Francais des Greffes*, the French national transplantation agency formed an expert committee on xenotransplantation for reviewing and analysing developments in xenotransplantation technology. The Committee has developed guidelines on various aspects of safety. Health safety law in this area is also being developed.

In January 1998, the French Parliament adopted a draft law on new Health and Safety Regulation, which include a statement on xenotransplantation. This law stipulates that research on xenotransplantation will be regulated by existing biomedical research legislation and that applications for clinical trials need approval of both the *Agence Francaise de Securite Sanitaire des Produits de Sante* and the Ministry of Health. Clinical trials will only be considered after the establishment of a national mechanism for long-term epidemiological surveillance.

7.17 Conclusions

A number of countries are or have developed guidelines, policies and regulation on xenotransplantation.

The use of transgenic, cloned, or otherwise genetically engineered animals as sources of cells, tissues or organs may be considered acceptable as long as the dignity and identity of humans are respected, human health is protected, and animal welfare is adequately taken into account.

International cooperation and coordination is needed to help promote safety, efficacy and equitable access to the technology. As well as to protect human dignity and individual rights together with community interests.

Attitude surveys in Australia, the United States and Switzerland suggest that xenotransplantation is acceptable to only 50-75 percent of those surveyed.²⁹⁵

294 *Xenotransplantation: Recommendations for the regulation of xenotransplantation activities in Spain*, Extracted from the Report of the Xenotransplantation Commission of the National Commission, Madrid, 1999.

295 Organisation for Economic Co-operation and Development, *Xenotransplantation: International Policy Issues*, 1999, p 70.

The Standing Committee found that -

Finding 24

A number of matters including rejection of the animal graft, the transfer of diseases between species, ethical and social issues and cost implications need to be resolved before clinical xenotransplantation can be introduced to Australia.

The Standing Committee recommends that -

Recommendation Eighteen:

National policies should be developed to promote research, subject to safety, efficacy, equity and ethical practice in relation to xenotransplantation.

CHAPTER 8. CONCLUSIONS

8.1 Introduction

New surgical procedures, and the success of immunosuppressive therapies have increased the demand for organ donation. As a result, waiting lists of people who face organ failure have also increased. The shortage of organs and tissue continues to be the main concern in transplantation. Approaches to deal with the organ shortage problem are discussed in this Report. In brief, it requires a number of strategies including the training of health professionals in organ procurement and the development of a cooperative network, as well as the establishment of a professional organ procurement system and strategies to increase donor awareness in the medical community as well as in society.

At the beginning of this Report, the Standing Committee raised a number of issues relating to organ donation in Western Australia that had to be addressed. These issues were discussed in earlier chapters of the Report. However, those matters are summarised in this concluding chapter.

8.2 Tyranny of Distance

Western Australia more than any other State in Australia must contend with special circumstances which prevail in the State, most notably low population densities and remoteness of some areas which affect not only the provision of health services but the ability to retrieve organs from potential donors in more remote areas of the State.

Western Australia's isolation makes it difficult to import organs, which have a limited life outside the body. For this reason, local availability of organs and a more integrated transport system is essential.

The Standing Committee noted that other countries and regions have an established integrated transport system, which includes the use of aircraft and medical transplant teams to ensure that organs from potential donors can be retrieved even from remote areas. Most notably the integrated national system in Spain. Spain has a transport system established to cater for short distances as well as long distances using a variety of transport methods including vehicles, helicopters, military air transport as well as the Air Force.

Queensland has dealt with the issue of distance with the Premier's aircraft being available for the retrieval of organs.

The Standing Committee concluded that a more coordinated medical transport system was required for Western Australia.

8.3 Statewide Coordinated Approach

The Standing Committee is of the view that a more coordinated approach in identifying potential donors and facilitating the donation process is essential.

The Standing Committee acknowledges that the establishment of DonateWest will provide the

State with a more coordinated approach and would benefit the whole donation process.

Although DonateWest is still in its infancy and in the process of developing procedures, it has appointed three donor coordinators.

It is hoped that the initiatives will be developed to ensure that its stated benefits will be realised and its potential progressed.

The Standing Committee is of the view that a systematic approach to organ donation is essential. Cooperation, exchange of information and education of professionals is required. The results in South Australia are proof that the Spanish model, which is the international best practice, can be adapted successfully in Australia.

8.4 Family Awareness of Donation Wish

Surveys show that over 90 percent of Australians favour organ donation, with many indicating their willingness on driver's licences. However, that information is often not available to doctors at crucial moments and the final decision is up to the family.

Western Australia has 500,000 registered donors but for a variety of reasons, few would have organs in useable condition after their death.

Although a potential donor may have indicated their wish to become a donor on their drivers licence, family members may not be aware of the donors wishes or may object to organ donation despite the donor's intention because of the emotional stress on the family with the unanticipated death of a loved one. In Western Australia, the refusal rate by family was about 60 percent.²⁹⁶

Although the potential donor may have registered their desire to be an organ donor, it is in fact, the family who must in practice, give consent and thus it is they who must know what the wishes of the deceased were.

Approaching the family represents a key point of the process of organ donation and is the most sensitive. The families of the potential donors must be approached by well trained professional health carers who know how to communicate with the family appropriately about the process of donation.

8.5 Community Awareness of Organ Donation

The Standing Committee believes that there should be more community discussion about the benefits of organ donation and transplantation.

The Standing Committee is of the view that the profile of the benefits of organ donation should be raised by a coordinated approach through DonateWest.

The benefits of organ donation and transplantation should be part of educational programs and most certainly medical courses but also part of ongoing community education.

8.6 Registered Donor

The lack of a national approach to becoming a registered organ donor had created confusion in

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Submission by Department of Health, Western Australia, 14 august, 2000, p 19.

the community. The different organ registry systems, which operated in each State and Territory, as well as within a State or Territory, did not convey a clear message about how to become an organ donor. While in many Australian States the indication on a drivers licence was broadly used, access to the data was limited.

In Western Australia, the data on driver's licences concerning organ donation was available and could be accessed in the hospital. However, not everyone who is a potential donor has a current drivers licence and information was not available interstate visitors to Western Australia.

The Standing Committee acknowledges the Federal Government's initiative which established a national donor registration system. An initiative, supported by Health Ministers of the States and Territories. A national register of organ donors will enable doctors to identify potential donors, especially those who have moved interstate. The Standing Committee endorses this initiative.

8.7 Reluctance to Proceed with Donation

It has been found that unless there is general community knowledge and understanding of organ donation and transplantation there is a reluctance on the part of doctors and family members to proceed with organ donation and transplantation.

There are two critical factors that need to be addressed, firstly, the willingness of the population to donate organs and secondly, the cooperation of the medical doctors and nurses in identifying potential donors and approaching all the families.

Dealing sensitively with the families of critically injured patients appears to be one of the major obstacles.

The Standing Committee found that national surveys indicate that the majority of the Australian population is in favour of organ donation. The problem with organ donation is detection of donors. Detection occurs in the hospitals where the potential donors are to be found. The key to organ procurement then is to have a person on the floor of the hospital.

The Standing Committee also found that well trained health carers are the key to sensitively dealing with the families of potential donors.

8.8 Organ Donation in Australia

Australia's organ donation record is now among the worst in the western world. Donor numbers have fallen to a record low, with only around 160 last year. Over 2000 people in Australia are on a waiting list for organ donation. Organ donations have dropped 25 percent in just a few years.

Western Australian patients have to wait up to seven years for a kidney transplant despite improvements in the rate of organ donation. There are 120 people waiting for kidney transplants, 90 for corneal transplant and between four and 10 needing liver or heart transplants.

The Standing Committee believes that an overall approach needs to be adopted to improve the organ donation rate in Western Australia. An integrated approach to organ donation includes not only public education and awareness of the need and importance of organ donation and

transplantation but includes all issues and processes through to adequate and appropriate resources and procedures in hospitals.

8.9 The “Spanish Model” in Australia

Australian authorities have been looking towards Spain, a country that has the highest donor rates in the world. In the last 10 years, Spain has more than doubled the number of organ donors and the number of solid organ transplantation is more than three times what it was.

Doctor Blanca Miranda of the Spanish Transplant Organisation, in Australia recently at the second National Forum on Organ and Tissue Donation, stated -

... while Spain had benefited from a concerted campaign to retrain hospital staff, Australia needed to carefully analyse the problems here.²⁹⁷

The Standing Committee was advised that a possibility exists to transfer the “Spanish model” to Australia. This was dependent upon several key factors -

- coordinators should be highly trained doctors;
- coordinators must be based inside a hospital;
- detection of possible donors is imperative;
- change coordinators that are not effective. Statistics indicate immediately whether coordinators are failing to identify potential donors; and
- sufficient intensive care beds to enable donors to be ventilated to allow organ retrieval.²⁹⁸

The Standing Committee was advised by Dr Peter Doyle of the United Kingdom Department of Health that in Italy -

The organ donation rate rose from 12 donors per million population to 30 donors per million population in Tuscany, after the introduction of the “Spanish model”.²⁹⁹

Important features of the Spanish model are that it has a central agency in Madrid (*Organizacion Nacional Trasplantes*) which coordinates organ and tissue donation and transplantation throughout the country. There is a public hospital network and there is cooperation between 17 autonomous regions who have well trained transplant coordinators in all regions who are appointed locally. Organ donation is part of normal medical work, and is allocated a special budget.

Spain is the world leader in encouraging organ donation. South Australia had adopted the Spanish model and has donation rates more than twice those of Western Australia and rising.

²⁹⁷ “Organ donations at record low”, 7.30 Report, Transcript, 20 July 2000. p 2.

²⁹⁸ Dr Rafael Matesanz, Director, Organizacion Nacional de Trasplantes, Madrid, Spain, meeting with Committee, 4 October 2000.

²⁹⁹ Dr Peter Doyle, Medical Adviser, United Kingdom Department of Health, London, United Kingdom, meeting with Committee, 6 October 2000.

8.10 Hospital Intensive Care Units

Many potential donors who are declared brain dead are not being placed on life support in time.

Professor Geoffrey Dahlenburg stated -

A lot of donors don't get to intensive care units because of the lack of beds in hospitals, so it's a domino effect - if you don't have the beds, you don't have the patients, you don't have the donors.³⁰⁰

The Standing committee is of the view that the focus should be on intensive care units in hospitals, to make sure they are aware of all the possibilities for organ transplants.

8.11 Xenotransplantation

Xenotransplantation refers to the transplant of living cells, tissues and organs between unrelated species, and animal to human transplants. It can take a number of forms, including -

- the transplantation of solid animal organs (such as hearts, kidneys, livers);
- the transplantation of cells and tissues (such a pig neural cells and pig pancreatic islet cells);
- use as part of a medical device;
- use in gene therapies.

Animal tissue is already being utilised for various therapeutic reasons, such as replacement heart valves from pigs. However, these therapeutic products have been chemically treated and are not functional, living tissue. This distinguishes them from the viable organs and cells used in xenotransplantation. Whole organ xenografts have been largely unsuccessful so far.

Xenotransplantation is not a recognised medical practice in Australia or in other industrialised countries. However, research is progressing in the xenotransplantation field from molecular and genetic manipulation to inter-animal transplants, and in some countries such as the United States of America, to limited and controlled clinical trials.³⁰¹

There are four main issues associated with xenotransplantation at this present time. These are as follows -

- rejection of the animal graft;
- creation of new diseases or transfer of diseases between species;
- ethical and social dilemmas; and
- cost implications.

³⁰⁰ "Organ donations at record low", 7.30 Report, Transcript, 20 July 2000. p 3.

³⁰¹ Submission by Health Department, Western Australia, 14 August 2000, p 24.

These four issues will need to be resolved before xenotransplantation can be introduced into Australia. It is unlikely that this will occur within the next 10 years.³⁰²

There is concern that many people believe there is no longer a need to donate organs, following reports that organs can be cloned or taken from pigs.

Professor Geoffrey Dahlenburg stated -

Years ago, everyone said, "Oh, it will be in five years time", and five years ago, everyone said "Oh, in five years time," and I think now, it might be another five years time. ... It's going to be a long time before we can actually get to that stage.³⁰³

The Standing Committee is of the view that xenotransplantation raises complex ethical issues. While it is seen to some to provide a potential solution to the shortage of human organs and tissues available for transplantation, it also raises concerns of safety to the individual and to the wider community.

The Standing Committee has concluded that techniques such as xenotransplantation, which involves genetically modifying animals to make their organs suitable for humans, or growing organs from single human cells, is many years away and there are also fears the research could spread viruses and needs to be monitored and regulated.

8.12 Conclusions

Organ donation has the potential to be of significant social and financial benefit to the health system. The transplant of a single kidney can result in a saving of up to \$50,000 per year in renal dialysis. It is estimated that a single donor has the potential to save \$1 million over ten years through replacing demand for renal dialysis and intensive care. Similar cost savings are acknowledged with respect to other organ and tissue transplants. The British Transplantation Society in 1998 stated -

Renal transplantation is the most cost-effective form of treatment for patients in end stage renal failure.³⁰⁴

The Standing Committee after examining all the evidence and measures used in Australia and overseas has come to the conclusion that an integrated system of organ donation and transplantation is the most appropriate.

The Standing Committee is of the view that organ procurement needs to be supported on a 24 hour basis throughout the year. It is essential that sufficient personnel are available to allow for a full 24 hour cover by donor coordinators. It is important that awareness of the need for organ donation within intensive care units in the hospitals be developed and sustained by educational programs. As part of an integrated system the donor coordinator network should include the education of nursing and medical staff in hospitals most likely to be involved with identifying potential donors, whether they be in intensive care units, in operating theatres and/or in Accident

302 *Ibid.*

303 "Organ donations at record low", 7.30 Report, Transcript, 20 July 2000. p 3

304 "Towards standards for organ and tissue transplantation in the United Kingdom", British Transplantation Society, November 1998, p 15.

and Emergency departments. A teaching service should also be provided to medical students and nurses in training.

The Standing Committee is of the view that a sufficient number of well-trained coordinators should be employed to ensure that all duties are carried out efficiently. It is important that systems are put in place to ensure that organ retrieval services are not jeopardised by lack of funding. It follows that transplant units need to be adequately staffed both medically and surgically, with appropriate training programs for junior staff.

As Spain's experience shows, the development of efficient infrastructure can significantly improve the rate of organ procurement.

The Standing Committee agrees with the view of Dr Peter Doyle, Medical Adviser of the United Kingdom Department of Health that -

The experience of Spain must be taken seriously.³⁰⁵

Family consent and the identification of potential donors remain the most serious obstacles to improvement in the organ donation rate. In this regard, special attention should be paid to the education of the population at large and of medical and support staff.

³⁰⁵

Dr Peter Doyle, Medical Adviser, United Kingdom Department of Health, London, United Kingdom, meeting with Committee, 6 November 2000.

Appendix One

Glossary

Throughout this report the following terminology has been used -

“Standing Committee” means	the Standing Committee on Uniform Legislation and Intergovernmental Agreements established by the Legislative Assembly of the Western Australian Parliament on 4 August 1993 and re-established on 18 March 1997.
“non-heart beating donor” means	a patient who is declared dead when their heart stops beating.
“heart beating donor” means	a patient who is declared brain dead and is supported by artificial ventilation which allows oxygenated blood to be pumped throughout the body to keep the organs viable for transplantation.
“live donor” means	the donation of an organ or tissue by a living person.
“brain dead donor” means	a patient who is certified dead by two medical practitioners when all brain function has irreversibly ceased.
“cadaveric donor” means	a patient who is dead either by irreversible cessation of all function of the brain, or irreversible cessation of circulation of blood in the body.

Abbreviations

“ACCORD”	Australian Co-ordinating Committee for Organ Registries and Donations.
“AD”	Australians Donate.
“AHMAC”	Australian Health Ministers Advisory Council.
“AHMC”	Australian Health Ministers Conference.
“AG”	Attorney General.
“ALRC”	Australian Law Reform Commission.
“AODR”	Australian Organ Donor Registry.
“CBDI”	Steering Committee on Bioethics.
“COAG”	Council of Australian Governments.
“DNA”	Deoxyribonucleic Acid.
“DonateWest”	The Western Australian Organ and Tissue Donation Agency.
“DPMP”	Donors Per Million Population.

“EEG”	Electroencephalogram.
“E.T.”	Eurotransplant: Germany, Austria, Belgium, Luxembourg and the Netherlands.
“FDA”	Food and Drug Administration.
“GIFT”	Give in Faith and Trust (Donor support group).
“HIC”	Health Insurance Commission.
“HIV”	Human Immunodeficiency Virus.
“ICU”	Intensive Care Units.
“IPPV”	Intermittent Positive Pressure Ventilator.
“NEVDIS”	National Electronic Vehicle Information System.
“NXRD”	National Xenotransplantation Registry Database.
“NHMRC”	National Health and Medical Research Council.
“NOMS”	National Organ Matching Systems.
“OECD”	Organisation for Economic Cooperation and Development.
“ONT”	<i>Organizacion Nacional de Trasplantes.</i>
“OPO”	Organ Procurement Organisation.
“PERVS”	Porcine Endogenous Retro-Viruses.
“SAODA”	South Australian Organ Donation Agency.
“SBRM”	Standards Based Risk Management.
“SCAG”	Standing Committee of Attorneys-General.
“Sc.T.”	Scandiatransplant: Denmark, Finland, Norway and Sweden.
“TRIO”	Transplant Recipients International Organisation.
“TSANZ”	The Transplantation Society of Australia and New Zealand.
“UKTSSA”	United Kingdom Transplant Support Service Authority.
“UKXIRA”	United Kingdom Xenotransplantation Interim Regulatory Authority.
“UNOS”	United Network for Organ Sharing.
“WHO”	World Health Organisation.

Appendix Two

List of Overseas Meetings Held by the Standing Committee

Date	Contact	Organisation	Place
18/9/2000	Dr Harry Griffin, Assistant Director	Roslin Institute	Edinburgh, UK
19/9/2000	Sister Gillian Greenhill	Scottish Liver Transplant Unit	Edinburgh, UK
19/9/2000	Dr John Forsythe, Consultant Surgeon	Scottish Liver Transplant Unit	Edinburgh, UK
19/9/2000	Jackie Bradie, Procurement/Renal Transplant Coordinator	Scottish Liver Transplant Unit	Edinburgh, UK
19/9/2000	Lesley Logan, Clinical Manager	Scottish Liver Transplant Unit	Edinburgh, UK
19/9/2000	Judith Bennet, Recipient/Liver Transplant Coordinator	Scottish Liver Transplant Unit	Edinburgh, UK
19/9/2000	Caroline Whitworth, Consultant Physician	Scottish Liver Transplant Unit	Edinburgh, UK
19/9/2000	Antony Pollock, Consultant Anaesthetist	Scottish Liver Transplant Unit	Edinburgh, UK
19/9/2000	Murat Akyol, Consultant Surgeon	Scottish Liver Transplant Unit	Edinburgh, UK
19/9/2000	Sue Wright, Organ Donation Link Nurse	Scottish Liver Transplant Unit	Edinburgh, UK
19/9/2000	Liz Waite, Organ Donation Link Nurse	Scottish Liver Transplant Unit	Edinburgh, UK
19/9/2000	Scott Haine, Finance	Scottish Liver Transplant Unit	Edinburgh, UK
19/9/2000	Pam Niven, Operations Manager	Scottish Liver Transplant Unit	Edinburgh, UK
19/9/2000	Jenny Kennedy, Theatre Sister	Scottish Liver Transplant Unit	Edinburgh, UK
19/9/2000	Graeme Johnston, Operating Department Assistant	Scottish Liver Transplant Unit	Edinburgh, UK
19/9/2000	Ken Simpson, Consultant Physician	Scottish Liver Transplant Unit	Edinburgh, UK
19/9/2000	Kirsty Martin, Database Manager	Scottish Liver Transplant Unit	Edinburgh, UK

Date	Contact	Organisation	Place
20/9/2000	Andrea Hussain, Transplant Manager	Papworth Hospital NHS Trust	Cambridge, UK
20/9/2000	John Wallwork, Director, Transplant Unit	Papworth Hospital NHS Trust	Cambridge, UK
20/9/2000	Barbara Clark, Transplant Secretary	Papworth Hospital NHS Trust	Cambridge, UK
20/9/2000	Stephen Bridge, Chief Executive Officer	Papworth Hospital NHS Trust	Cambridge, UK
20/9/2000	John Evans	British Organ Donor Society (BODY)	Cambridge, UK
20/9/2000	Margaret Evans	British Organ Donor Society (BODY)	Cambridge, UK
22/9/2000	Dr Esmeralda Luicioli	Etablissement Francais des Greffes	Paris, France
22/9/2000	Dr Michel Bouvier d'Yvoire	Etablissement Francais des Greffes	Paris, France
22/9/2000	Elettra Ronchi, Coordinator , Biotechnology and Health	Directorate for Science, Technology and Industry, OECD	Paris, France
22/9/2000	Anne Carblanc, Legal Expert	Directorate for Science, Technology and Industry, OECD	Paris, France
22/9/2000	Taizo Nakatomi, Principal Administrator	Information, Computer & Communications Policy Division, Directorate for Science, Technology and Industry, OECD	Paris, France
22/9/2000	Dr Alain Mallet, Unit Director	INSERM	Paris, France
22/9/2000	Dr Goldmard	INSERM	Paris, France
25/9/2000	Leo Roels, Chairman	International Transplant Coordinators Society	Brussels, Belgium
25/9/2000	Francine Roggen	International Transplant Coordinators Society	Brussels, Belgium
25/9/2000	Prof Scholtsmans, Member	Comite Consultatif National Belge de Bioethique et de la Societe Belge de Transplantation	Brussels, Belgium
25/9/2000	Prof Van Hecke, Cardio Transplant Physician	University Hospital, Leuven	Brussels, Belgium
27/9/2000	Jose Popma, Transplant Coordinator	Academical Medical Centre	Amsterdam, Netherlands
27/9/2000	Patricia Batavier, Transplant Coordinator	Academical Medical Centre	Amsterdam, Netherlands
27/9/2000	Fred Ultee, Transplant Coordinator	Academical Medical Centre	Amsterdam, Netherlands
29/9/2000	Representatives	Council of Europe	Strasbourg, France

Date	Contact	Organisation	Place
29/9/2000	Mr Carlos de Sola, Secretary, Steering Committee on Bioethics	Council of Europe	Strasbourg, France
29/9/2000	Peteris Zilgalvis, Steering Committee on Bioethics	Council of Europe	Strasbourg, France
29/9/2000	Halvor Lervik, Secretary, Committee on Science & Technology	Council of Europe	Strasbourg, France
2/10/2000	Dr Marti Manyalich, Transplant Procurement Manager	Transplant Services Foundation, Hospital Clinic, Coordinacio de Trasplantaments	Barcelona, Spain
2/10/2000	Ms Montse Soley, Transplant Coordinator	Transplant Services Foundation, Hospital Clinic, Coordinacio de Trasplantaments	Barcelona, Spain
2/10/2000	Dr David Paredes, Promotion & Education	Hospital Clinic, Coordinacio de Trasplantaments	Barcelona, Spain
2/10/2000	Dr Rafael Gotsens, Managing Director	Transplant Services Foundation Hospital Clinic, Coordinacio de Trasplantaments	Barcelona, Spain
2/10/2000	Mrs Maria Lopez	Transplant Services Foundation	Barcelona, Spain
2/10/2000	Dr Jordi Vilardelli Bergada, Director	Organizacio Catalana de Trasplantament (OCATT)	Barcelona, Spain
2/10/2000	Montserrat Anguera Serisier	Organizacio Catalana de Trasplantament (OCATT)	Barcelona, Spain
2/10/2000	M Jesus Felix Facerias	Organizacio Catalana de Trasplantament (OCATT)	Barcelona, Spain
4/10/2000	Dr Blanca Miranda, Medical Director	Organizacion National de Trasplantes (ONT)	Madrid, Spain
4/10/2000	Dr Rafael Matesanz, Director	Organizacion National de Trasplantes (ONT)	Madrid, Spain
4/10/2000	Dr Jose Cannon, Medical Director	Organizacion National de Trasplantes (ONT)	Madrid, Spain
4/10/2000	Dr Eduardo Zincke	Organizacion National de Trasplantes (ONT)	Madrid, Spain
4/10/2000	Mr Manuel Serrano	Organizacion National de Trasplantes (ONT)	Madrid, Spain
6/10/2000	Kate Darwin, Transplant Team Leader	Department of Health & Unrelated Live Transplant Regulatory Authority (ULTRA)	London, UK
6/10/2000	Martin Houghton, Xenotransplants	ULTRA	London, UK

Date	Contact	Organisation	Place
6/10/2000	Dr Peter Doyle, Medical Adviser	ULTRA	London, UK
6/10/2000	Mrs Robina Balderson, Chief Executive	United Kingdom Transplant Authority UKTSSA	London, UK
6/10/2000	Katharyn Burdon, Administration	UKTSSA	London, UK
6/10/2000	Phil Hatton, Director	Transplant Support Network	London, UK

Appendix Three

List of Interstate Meetings Held by the Standing Committee

Date	Name	Organisation	Place
2/11/1999	Gary Fenlon, MLA, Chair	Legal, Constitutional & Administrative Review Committee	Brisbane, Qld.
2/11/1999	Denver Beanland, MLA, Member	Legal, Constitutional & Administrative Review Committee	Brisbane, Qld.
2/11/1999	Kerryn Newton, Research Director	Legal, Constitutional & Administrative Review Committee	Brisbane, Qld.
2/11/1999	Katrina Horsely, Principal Policy Officer	Queensland Health	Brisbane, Qld.
2/11/1999	Peter Brockett, Legal Officer	Queensland Health	Brisbane, Qld.
2/11/1999	Tina Cooper, Manager	Queensland Health	Brisbane, Qld.
3/11/1999	Dr Peter McCullagh	John Curtin School of Medical Research	Canberra, ACT.
3/11/1999	Sue Ingram, Assistant Secretary, Health Investment & Advisory Branch	National Health & Medical Research Council	Canberra, ACT.
3/11/1999	Cathy Clutton, Director, Council Support & Health Ethics Section	National Health & Medical Research Council	Canberra, ACT.
4/11/1999	Bruce Lindsay, National Director	Australians Donate	Adelaide, SA.
4/11/1999	Ross Forbes, Project Officer	Australians Donate	Adelaide, SA.
4/11/1999	Kim Van Schaik, Administrative Officer	Australians Donate	Adelaide, SA.
4/11/1999	Dr Peter Bardy, Director, Research & Development	Australian Red Cross Blood Service	Adelaide, SA.
4/11/1999	Prof Geoffrey Dahlenburg, Director	South Australian Organ Donation Agency	Adelaide, SA.
4/11/1999	Glenys Hodgeman, Transplant Coordinator	South Australian Organ Donation Agency	Adelaide, SA.

Appendix Four

List of Briefings

Date	Name	Organisation
7/10/1999	Erica Bremner-Kneipp, Manager, Purchasing Unit	Health Department of Western Australia
7/10/1999	Ingrid Briggs, Legal Officer	Health Department of Western Australia
27/10/1999	Hon. Barbara Scott, MLC	Member of the Legislative Council
6/11/2000	Dr Dorothy Jones, Director	Health Department of Western Australia
6/11/2000	Dr Bryant Stokes, Chief Medical Officer	Health Department of Western Australia
6/11/2000	Dr Alistair Millar Forbes, Medical Director	DonateWest
6/11/2000	Amanda Leigh, Manager	DonateWest
6/11/2000	Jean-Marie Cusack, Donor Coordinator	DonateWest
6/11/2000	Suzanne Foot, Donor Coordinator	DonateWest
6/11/2000	Melissa Smith, Donor Coordinator	DonateWest

Appendix Five

List of Submissions

	Date	Organisation
1	14/8/2000	Health Department of Western Australia
2	21/8/2000	Health Department of Western Australia
3	24/10/2000	DonateWest
4	3/11/2000	DonateWest
5	8/11/2000	DonateWest

Appendix Six**List of Witnesses**

Date	Name	Position	Organisation
7/12/1999	Dr Bryant Stokes	Chief Medical Officer	Health Department of Western Australia
7/12/1999	Dr Dorothy Jones	Director, Clinical Purchasing and Casemix Unit	Health Department of Western Australia
7/12/1999	Ingrid Briggs	Legal Officer	Health Department of Western Australia
7/12/1999	Erica Bremner Kneipp	Manager, Purchasing Unit	Health Department of Western Australia
14/8/2000	Dr Dorothy Jones	Medical Director	Health Department of Western Australia
14/8/2000	Dr Alistair M Forbes	Medical Director	DonateWest
14/8/2000	Amanda Leigh	Manager	DonateWest
14/8/2000	Tanya Gawthorne	Purchasing Officer	Health Department of Western Australia
14/8/2000	Ingrid Briggs	Legal Officer	Health Department of Western Australia

Appendix Seven

Legislation in Australia

Legislation	State
<i>Coroner's Act 1996</i>	Western Australia
<i>Human Tissue Act 1982</i>	Victoria
<i>Human Tissue Act 1983</i>	New South Wales
<i>Human Tissue Act 1985</i>	Tasmania
<i>Human Tissue and Transplant Act 1982</i>	Western Australia
<i>Human Tissue Transplant Act 1978</i>	Northern Territory
<i>Transplantation and Anatomy Act 1978</i>	Australian Capital Territory
<i>Transplantation and Anatomy Act 1979</i>	Queensland
<i>Transplantation and Anatomy Act 1983</i>	South Australia

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