

AN ANALYSIS OF THE DOCTRINE OF PRESUMED CONSENT AND
THE PRINCIPLES OF REQUIRED RESPONSE AND REQUIRED
REQUEST IN ORGAN PROCUREMENT

by

ETIENNE JEAN FOURIE

submitted in partial fulfilment of the requirements for the degree of

MAGISTER LEGUM

at the Faculty of Law

UNIVERSITY OF PRETORIA

PROMOTER: PROF DR PA CARSTENS

2005

“Unser Leben kann sicherlich durch die
Ärtzte um keinen Tag verlängert werden, wir
leben, so lange es Gott bestimmt hat; aber
es ist ein großer Unterschied, ob wir
jämmerlich wie arme Hunde leben oder wohl
und frisch, und darauf vermag ein kluger
Arzt viel.”

Goethe 1749 - 1832

Preface

The writer's inspiration to conduct an investigation of the doctrine of presumed consent and incentives such as the principles of required response and required request in respect of organ procurement system commenced in 2002 whilst in the employ of the University of Pretoria as an assistant and later as an academic associate at the Department of Public Law. The result of the research indicates that the legal principles relating to transplantation of organs are an exciting and increasing developing area in many foreign jurisdictions. Unfortunately, the research also revealed the lack of South African development both from academic and regulatory perspectives.

The philosophical approach to the undertaking of this dissertation is to contribute to the small percentage of South African literature on transplantation law and to create awareness about this field of study. The topics for discussion are divided into three main research areas namely organ procurement systems, preservation of tissue and allocation procedures. These areas correlate with the completed process of transplantation: procurement of organs, preservation after removal and allocation to a recipient.

The format of the dissertation consists of two parts. Part one deals with organ procurement systems to which the majority of this dissertation has been dedicated. More specifically, this part deals with the procurement of organs of deceased donors and specifically with the problem of increasing the supply of procurable organs for an ever-increasing demand thereof. Part two deals with a *capita selecta* of issues in respect of preservation and allocation of organs. This part extends the discussion from a legal point of view to introduce the reader to certain ethical perspectives surrounding these issues. It must be noted that only a *capita selecta* of ethical theories and criteria was included to emphasize the potential problem areas and policy suggestions.

Against the abovementioned structure of this dissertation, the following should be specifically noted:

- In respect of the procurement process, various organ procurement systems and incentives to support this process have been developed to increase organ procurement. These organ procurement systems can be divided into two distinct forms, namely presumed consent systems and explicit consent systems. Systems that requires explicit consent are well known mainly due it's application in South Africa and the United States of America and are in most part, a fully developed organ procurement system. On the European continent, another form of organ procurement system has in the past few decades been developing which operates in the exact opposite of an explicit consent system. This dissertation analyses the principles of this lesser-known the doctrine of presumed consent in terms of organ procurement as a viable substitution to an explicit consent system.
- Secondly, incentives have been created to assist the functioning of organ procurement systems. In this regard, incentives can be classified as practical activities to encourage the public to participate in a particular activity. In respect of organ procurement systems, these incentives act as "agents" to help the functioning of a procurement system for example prior to completion of a government registration form, an applicant must complete an organ donation questionnaire. This dissertation analyses the principles of required response and required request as possible incentives to assist in increase public awareness to organ donation.
- Finally, problems in the preservation of tissue and allocation procedures pose further problems in respect of fairness and equitable procedures. One of the main reasons is due to the lack of governmental guidance. In South Africa, the promulgation of the National Health Act of 2003 seems to be the first steps to develop and

improve the current legislative frameworks in respect of preservation of tissue and allocation procedures. However, until the final regulatory framework is introduced, this area is still very much in a “twilight zone”.

The writer envisaged providing an informative discussion on foreign law relating to transplantation law. This discussion deals extensively with foreign legal principles as encapsulated in legislation and reflects the objectives of section 39 (1) of the Constitution¹ that the use of public international law and foreign law must / may be utilised as tools of interpretation and guidance mechanisms by our courts. The discussion is structured in such a way that the general principles of each topic is discussed, where after the discussion on the applicable foreign law follows as is applies to that specific topic. Due to the sheer volume of these laws, a *capita selecta* of countries were chosen to provide the reader with the most well known examples of these principles within the global theatre of discussion. In respect of part one, the discussion on organ procurement systems analyses the legal principles of Belgium and Spain as applied. Secondly, it would be appropriate to provide a detailed discussion on the U.S. Federal and State law in respect of incentives to organ procurement system as incentives such as the principle of required response and required request having been developed the United States of America. In part two, the discussion continues in respect of legislative developments in Belgium and the United States with regard to preservation of organs and allocation procedures.. The reason is not only from a perspective of continuing consistency, but also to highlight the quality and stage of development of these laws. Especially, the Belgian legislative framework provides an impressive collection of laws relating to various aspects of medical jurisprudence, including transplantation law.

Research relating to the theoretical perspectives of the doctrine of presumed consent and the principles of required response and required request show, that the South African regulatory framework relating to transplantation law can benefit greatly from foreign experiences. The writer is however, not of the

¹ Act 108 of 1996.

view that these principles should be directly imported into South African law as so-called “africanised” belgian transplantation law.

Finally, attention is drawn to the fact that the practical importance of socio-economic rights has an immense impact on this dissertation. In this regard, the central issue is the patient’s financial ability to pay for the transplant operation. It is a sad fact that if a patient does not have the required financial support to undergo the medical operation, none of the developments in the field of transplantation law would be attributed to that individual. In almost all developing countries and even some developed nations, the realisation of financial aid to transplant recipients, poses the biggest challenge.

It should be pointed out that, if development from a socio-economic perspective were achieved, it would definitely guarantee successful reforms. Unfortunately, in the light of the decision in *Soobramoney v Minister of Health KwaZulu-Natal*² the socio-economical mindset from the South African government has not yet achieved such a point as to realise section 27 of the Constitution³. In other words, this means that the best legislative reforms might be in place, however if the patient is without the necessary financial support to pay for the medical procedures, such reforms seems pointless. In this sense, the findings in the dissertation seem worthless. Hopefully, the future will see the realisation to these problems.

² 1998(1) SA 765(CC)

³ Act 108 of 1996.

INDEX

CHAPTER ONE: INTRODUCTION TO TRANSPLANTATION LAW

1. GENERAL INTRODUCTION	13
2. THE PURPOSE OF THE STUDY	14
3. METHODOLOGY	16
4. THE PROCESS OF TRANSPLANTATION	17
4.1 REMOVAL OF ORGANS.....	18
4.2 PRESERVATION OF ORGANS	19
4.2 ALLOCATION PROCEDURES.....	21
5. TERMINOLOGY	22
5.1 HUMAN ORGAN AND TISSUE.....	22
5.2 THE DOCTRINE OF INFORMED CONSENT	23
5.3 ORGAN PROCUREMENT SYSTEMS	24
5.3.1 <i>A Regime of Routine Salvaging</i>	24
5.3.2 <i>The Doctrine of Presumed Consent</i>	25
5.3.3 <i>The Principle of Required Response</i>	26
5.3.4 <i>The Principle of Required Request</i>	27
5.4 ORGAN ALLOCATION SYSTEMS	28
5.5 DETERMINING THE MOMENT OF DEATH	29
6. THE CONSTITUTION OF SOUTH AFRICA.....	32
7. SOCIO-ECONOMIC PERSPECTIVE ON TRANSPLANTATION LAW.....	34
8. CONCLUSION.....	35

CHAPTER TWO: ORGAN PROCUREMENT SYSTEMS

1. INTRODUCTION	37
2. ORGAN PROCUREMENT SYSTEMS	39
2.1 PROBLEMS ASSOCIATED WITH ORGAN PROCUREMENT	39

2.2 SOLVING ORGAN PROCUREMENT PROBLEMS	42
2.3 ORGAN AND TISSUE DONORS.....	42
3. THE REGIME OF ROUTINE SALVAGING	44
4. THE DOCTRINE OF PRESUMED CONSENT	47
4.1 THE APPLICATION OF TRANSPLANTATION LEGISLATION CONTAINING THE DOCTRINE OF PRESUMED CONSENT.....	49
4.1.1 <i>General Aspects of the Doctrine of Presumed Consent</i>	49
4.1.2 <i>Identifying Presumed Consent</i>	50
4.1.3 <i>Routine Salvaging versus Presumed Consent</i>	51
4.1.4 <i>The Degrees of Presumed Consent</i>	52
4.2 THE ELEMENTS OF PRESUMED CONSENT.....	52
4.2.1 <i>The First Element: The Donor</i>	54
(a) <i>Requirement One: the donor must be deceased</i>	54
(b) <i>Requirement Two: the donor must be clearly identifiable yet anonymous...</i>	55
(c) <i>Requirement Three: the donor must be a South African citizen or permanent resident residing in the Republic more than six months</i>	57
(d) <i>Requirement Four: the donor must have the necessary capacity</i>	58
(i) <i>Minor donors</i>	58
(ii) <i>Mentally ill patients</i>	59
(e) <i>Requirement Five: the donor must not have registered an objection</i>	61
(f) <i>Requirement Six: the donor must nominate a donee for a specified purpose</i>	61
4.2.2 <i>The Second Element: Consent</i>	61
(a) <i>Requirement One: the living donor must consent to organ procurement or in absence of a registered objection; it is presumed that the deceased consented to organ procurement</i>	61
(i) <i>The General Nature of Consent and Informed Consent</i>	63
(1) <i>“Actual” Consent in Medical Jurisprudence</i>	66
(2) <i>“Actual” Consent and The Doctrine of Presumed Consent</i>	68
(3) <i>The Duty of Disclosure and The Role of Information in The Doctrine of Presumed Consent</i>	70
(a) <i>Who Must Inform?</i>	70
(b) <i>How should the Information be Displayed?</i>	71
(c) <i>What is the Nature of Disclosure?</i>	71

(d) <i>What are the Legal Consequences of Providing False Information or Non-Disclosure?</i>	74
4.2.3 <i>The Third Element: Capacity</i>	74
4.2.4 <i>The Fourth Element: The object for transplantation</i>	74
(a) <i>The Restrictive Approach of the Doctrine of Presumed Consent</i>	75
4.2.5 <i>The Fifth Element: The next-of-kin and the right of refusal</i>	76
(a) <i>Who is the Next-of-Kin?</i>	76
(b) <i>What is the Right of Refusal?</i>	77
4.2.6 <i>The Sixth Element: The recipient</i>	77
4.3 FOREIGN LAW	78
4.3.1 <i>Draft Guiding Principles on Human Organ Transplantation</i>	79
4.3.2 <i>Belgium</i>	82
(a) <i>General Provisions</i>	82
(b) <i>Removal of Tissue from Living Persons</i>	83
(c) <i>Legal Duty of the Health Practitioner</i>	84
(d) <i>Procurement from Cadaveric Donors</i>	84
(e) <i>Is Behaviour Indicative of Giving Consent?</i>	86
4.3.3 <i>Spain</i>	87
(a) <i>General Provisions</i>	87
(b) <i>The Deceased Donor</i>	88
(c) <i>Recording an Objections to Organ Procurement</i>	88
(d) <i>No Right of Refusal by the Next-of-Kin of the Deceased</i>	89
4.4 THE ETHICS OF PRESUMED CONSENT	90
5. ORGAN PROCUREMENT INCENTIVES	94
5.1 THE PRINCIPLE OF REQUIRED RESPONSE	94
5.1.1 <i>Defining Required Response</i>	94
5.1.2 <i>Basic Characteristics of Required Response</i>	95
(a) <i>"...required to register a decision"</i>	96
(b) <i>"...at a specific time"</i>	97
(c) <i>"...upon their death"</i>	98
5.1.3 <i>The Role of the Family</i>	98
5.1.4 <i>Required Response versus Presumed Consent</i>	99
5.1.5 <i>Foreign Law</i>	100
5.2. THE PRINCIPLE OF REQUIRED REQUEST	100
6.2.1 <i>Defining Required Request</i>	100
5.2.2 <i>History of Required Request Legislation</i>	100

5.2.3 Foreign Legislation	102
(a) Federal Legislation	103
(i) Uniform Anatomical Gift Act.....	103
(ii) Omnibus Reconciliation Act	105
(a) State Legislation	105
7. CONCLUSION.....	105
CHAPTER THREE: PRESERVATION OF TISSUE AND ALLOCATION PROCEDURES	
1. INTRODUCTION	107
2. PRESERVATION OF HUMAN TISSUE	107
2.1 SOUTH AFRICAN POSITION.....	108
2.1.1 The Human Tissue Act.....	108
(a) Purpose of Donation	108
(b) Preservation of Tissue	110
2.1.2 The National Health Act	110
(a) Purpose of Donation	110
(b) Preservation of Tissue	111
2.1.3 The Health Act	111
2.2 FOREIGN LAW.....	112
2.2.1 United States of America	112
2.2.2 Belgium	114
3. ORGAN ALLOCATION SYSTEMS	114
3.1 PROBLEMS ASSOCIATED WITH ORGAN ALLOCATION	115
3.2 ETHICAL APPROACH TO ORGAN ALLOCATION PROCEDURES	116
3.2.1 Stages of Organ Allocation	117
3.2.2 Medical Criteria	118
3.2.3 Non-Medical Criteria	121
(a) Two Schools of Thought.....	121
(i) The Utilitarian Approach	121
(ii) The Egalitarian Approach.....	123
(iii) Other Ethical Approaches.....	124

(b) <i>Capita Selecta of the Ethically Controversial Criteria effecting Organ Allocation</i>	125
(i) <i>The age of the recipient</i>	125
(ii) <i>The Beneficial and Harmful Effects for Other Persons</i>	127
(iii) <i>Patient Sensitisation</i>	127
(iv) <i>Ability to Pay</i>	128
3.3 LEGISLATIVE FRAMEWORK REGULATING ORGAN ALLOCATION PROCEDURES	
.....	129
3.3.1 <i>South African Law</i>	129
3.3.2 <i>Foreign Law</i>	130
(a) <i>Draft Guiding Principles on Human Organ Transplantation</i>	130
(b) <i>Belgium</i>	130
(i) <i>General Provisions</i>	130
(ii) <i>Provisions relating to Allocation of Organs</i>	131
(b) <i>United States of America</i>	132
(i) <i>Uniform Anatomical Gift Act</i>	132
(ii) <i>National Organ Transplant Act</i>	132
(iii) <i>United Network for Organ Sharing Policies</i>	133
4. CONCLUSION	136
 CHAPTER FOUR: A PROPOSED STATUTORY REGULATION OF ORGAN PROCUREMENT SYSTEMS	
1. INTRODUCTION	138
2.THE HISTORY OF THE LAW OF ORGAN PROCUREMENT IN SOUTH AFRICA (WORKING TOWARDS A LEGISLATIVE FRAMEWORK)	139
3. THE NATIONAL HEALTH AMENDMENT ACT	140
 CHAPTER FIVE: CONCLUSION	
1. INTRODUCTION	144
2. CRITICAL EVALUATION: ORGAN PROCUREMENT SYSTEMS	144
2.1 THE DOCTRINE OF PRESUMED CONSENT	144
2.1.1 <i>Findings</i>	144

(a) <i>Presumed Consent as a Organ Procurement System</i>	145
(b) <i>The Donor</i>	145
(c) <i>The Presences of Consent as a Justification Ground in the Doctrine of Presumed Consent</i>	145
(d) <i>The Degrees of the Doctrine of Presumed Consent</i>	146
2.1.2 <i>Recommendations</i>	147
2.2 THE PRINCIPLE OF REQUIRED RESPONSE AND REQUIRED REQUEST	149
2.2.1 <i>Findings</i>	149
(a) <i>General Principles</i>	149
(b) <i>Distinction</i>	150
(c) <i>Incentives in application</i>	150
2.2.2 <i>Recommendations</i>	150
(a) <i>An Incentive linked to a Procurement System</i>	150
3. CRITICAL EVALUATION: PRESERVATION OF TISSUE AND ALLOCATION PROCEDURES	151
3.1 PRESERVATION OF TISSUE.....	151
3.2 ORGAN ALLOCATION PROCEDURES	151
4. FINAL CONCLUSION	152
BIBLIOGRAPHY	153

CHAPTER ONE

INTRODUCTION TO TRANSPLANTATION LAW

1. General Introduction

Organ donation is, quintessentially a controversial issue. The reason being, it raises many difficult legal and ethical issues relating to the procurement of human organs, transplantation and distribution procedures. Concepts such as these tend to create public deliberation about the quality and the mortality of their own lives and death. People usually shy away when it comes to these issues, which makes their aspiration to consider organ donation remote, even inconceivable.

The principles of transplantation law are a combination of legal principles encapsulated in legislation and case law⁴; bio-ethical proposals and government policies. This integrated combination of ideologies delivers complex issues in a number of areas. In order to establish an effective transplantation best practice policy, interaction and harmonization of the variants of these principles are necessitated.

Research indicate that skin was transplanted to replace noses destroyed by syphilis in Egypt and some Hindu societies over 5000 years ago⁵ transplantation procedures is an invention of the twentieth century.⁶ South Africa, in particular, has a strong history with organ transplantation. In 1967 Dr. Christaan Barnard performed the world's first successful heart

⁴ Specific problems pertaining to the procurement and allocation of organs are not limited to individual countries, but experienced on an international level, which requires the study of the regional transplantation laws. Notably, organ transplant systems are divided into regions applying an explicit consent procurement system a posed to presumed consent countries.

⁵ Price *Legal and Ethical Aspects of Organ Transplantation* (2000) 2.

⁶ Alcorn and Harris *To Solve a Deadly Shortage: Economic Incentives for Human Organ Donation* Issues in Law and Medicine 16 (2001) 213.

transplantation at De Groote Schuur Hospital in Cape Town.⁷ Although, this was not the world's first ever organ transplantation, it paved the way towards the medical advancement of transplantation techniques of human tissue and organs from one human to another. Since 1967 medical technology have increased immensely and in the year 2005, it is possible through complete organ donation from just one donor to save up to 25 people's lives⁸.

2. The Purpose of the Study

In the previous paragraph, it was mentioned that ancient societies experimented with transplantation procedures, but it wasn't until the world's first ever successful heart transplant operation was performed in 1967 that transplantation have been recognised as a medical miracle of the twentieth century. Since then the ever-increasing demand for organs and tissue, prompted governments to introduce different methods of obtaining human organs for transplantation. This led to the introduction of various procurement systems such as routine salvaging, compulsory organ donor registration cards and even financial incentives or benefits to organ donors or a donor's family in the event of organ donation. These procurement systems hold different kinds of ethical, moral and legal implications. The aim of this dissertation is to research the basis, principles, problems and possible solutions of the organ procurement system that incorporates the doctrine of presumed consent and two organ procurement incentives: the principles of required response and required request.⁹ Once organs are procured, the next step in the process is that these organs should be allocated to the correct recipient. In the light of many ethical and legal speculations, these legal and ethical implications of organ allocation procedures are evaluated.

A glance at the history of transplantation provides a good indication that the evolution of transplantation laws is still in its infancy internationally, and there

⁷ Barnard South African Medical Journal (1967) 1271.

⁸ See for further information <http://www.transplantnetcare.co.za/>.

is plenty of opportunity for development. Research conducted for this dissertation show that the problems experienced within this field are not localized to a specific region. Both developed and developing countries share many common problems regarding organ procurement, preservation and allocation procedures. This is the reason behind the need for legislative development at a regional level as so much on an international level, and also that foreign developments pertaining to legislation and policy decisions should be closely monitored.

To keep this dissertation within the reasonable and applicable ground of the South African medical law, it is structured in such a way that reference is made to the current South African legislative position.¹⁰ The South African law is critically analysed and a legal opinion formed which incorporates an evaluation of the exact position with the context of foreign legislative developments. This dissertation have been structured in the following manner:

- Chapter One establishes the introduction to transplantation laws in general and familiarizes the reader with the concepts, which are discussed in this dissertation.
- In Chapter Two, organ procurement systems and procurement incentives are critically evaluated. This chapter analyses the doctrine of presumed consent and the principles of required response and required request. The discussion of the doctrine of presumed consent is based upon the degrees of application of the doctrine, the unique elements and ethical approaches to the doctrine. This analysis is made through a legal comparative study in terms of South African legislation and foreign legislative frameworks.

⁹ The extent and nature of these organ procurement systems have been thoroughly analysed and been introduced in certain continental European countries. Other jurisdictions such as the United States and Brazil have approached these systems on a very cautious basis.

¹⁰ The writer was fortunate to conduct research in a period where new legislation was promulgated through which the national health regulatory framework was radically changed. Throughout this dissertation, reference is however still made to the position prior to the enactment of the National Health Act as it is to provide a complete picture of the current law.

- Chapter Three evaluates the final two stages in the transplantation process; namely preservation of human organs and allocation procedures. With regard to aspects of preservation, the lack in South African legislation to regulate these matters is discussed, with reference to foreign laws. The final part of the chapter assesses the problems areas of allocation of procured organs, and the discussion is based surrounding the discrepancy between the magnitude of ethical approaches and regulation of allocation procedures.
- A proposed draft National Health Amendment Act is presented in Chapter Four, which amends section 62 of the National Health Act 61 of 2003 to include the doctrine of presumed consent as a procurement system for deceased donors.
- Finally, Chapter Five contains concluding remarks on the matters discussed in the preceding chapters and attempts to make recommendations to any future developments within National Health Act relating to organ procurement systems.

3. Methodology

There exist many facets which are applicable towards to the study of the doctrine of presumed consent and the principles of required response and required request for example ethical, moral, philosophical and legal principles. The method used to achieve the purposes of this dissertation is through a process of researching various sources. These include traditional sources such as books, theses and journal articles; however, a large portion of the research material were gathered from the Internet and web based applications for example West Law International. The reason being that the Internet provides an immense source of information, which is easily accessible and, for the most part, up-to-date. In my opinion, it is not only becoming a trend but is an absolute necessity to use these applications and services provided by the Internet more frequently in the gathering of information for the compilation of research reports, dissertations and theses.

Various institutions have also realised the potential of the Internet by making websites and related applications available on the Internet for the easy accessibility to foreign researchers and institutions. This interlinking between institutions creates an immense global network, which is excellent for improving the quality of research done globally.

Due to the nature of the research done for this dissertation, a distinct feature is the reference to foreign laws, regulatory frameworks and policies pertaining to organ procurement systems, incentives and preservation of organs and distribution procedures. The reason for the inclusion of these laws are twofold: firstly, international reforms on transplantation laws set good illustrative models that could be followed in developing local transplantation laws and secondly, guarding against inadequate legislative reforms. A *capita selecta* of countries have been selected, which attempt to provide an informative discussion of these various regulatory frameworks. It should be borne in mind that due to the sheer magnitude of information on procurement systems, preservation methods and distribution procedures at an international level, this dissertation is restricted to provide only certain information relevant to this discussion.

4. The Process of Transplantation

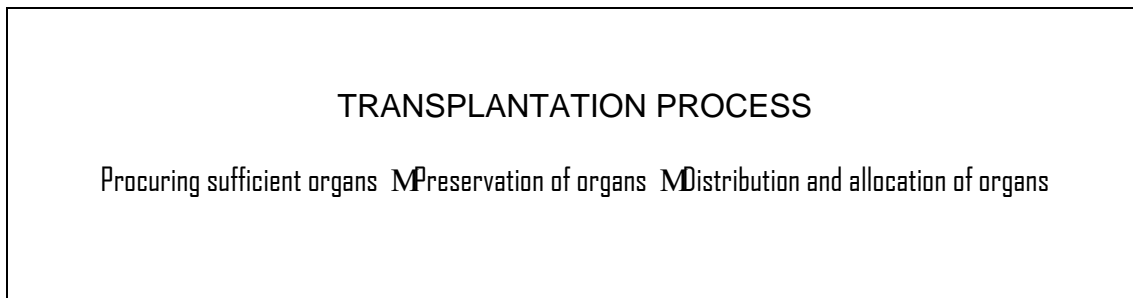
In order to understand the structure of this dissertation in its totality, cognisance must be taken of the process of transplantation. This process establishes the time period between removal of organs, maintaining these organs from harmful diseases and allocation to a recipient or transplant candidate.

Defining the term “transplantation of organs” would be to perform a medical procedure whereby living tissue¹¹ from a human body is removed from that

¹¹ The kinds of organs and tissue, which can be transplanted, are kidneys, livers, hearts, lungs, pancreas and bone marrow. Transplantation methods makes it possible for regenerative tissue and cells such as skin, blood, hair, and oocytes to be transferred from one person to another.

body and transferred to another person. The outcome of the operation is to replace tissue and organs no longer able to fulfil its original function efficiently caused by a disease, injury or another form of abnormality.¹²

A schematic visualization of the regulatory framework containing the principles of transplantation law can be presented as the following:



4.1 Removal of Organs

The opening part of this process, indicate organs and tissue¹³ should be removed from a human body. This requires, in the case of a living donor, that the patient should undergo a non-therapeutically operation for the procurement of organs and tissue. Tissue from cadaveric (deceased) donors is usually removed after it has been established that the patient is deceased. An effective organ procurement system should be established to provide for measures to legitimise established removal procedures, for example was consent obtained from the donor? This process seems relatively uncomplicated. In practice, the entire transplantation process is hampered by the scarcity of procurable organs¹⁴. The demand for human tissue and organs greatly out weighs the supply thereof.¹⁵

¹² Own definition.

¹³ It should be noted that throughout this dissertation the definition of tissue will be used as referred to it the National Health Act 61 of 2003, when reference is made to organs. The definition of tissue includes flesh, bone, a gland, *an organ* (own emphasis), skin, bone marrow or body fluid, but excludes blood or a gamete.

¹⁴ Geysler *Organ Transplantation: New Regulations to Alter Distribution of Organs* Journal of Law, Medicine and Ethics Spring 28 (2000) 95; Keller *The Bed of Life: A Discussion of Organ Donation, Its Legal and Scientific History, and A Recommended "Opt-Out" Solution to Organ Scarcity* Stetson Law Review (2003) 855; Liddy *The New Body Snatchers: Analysing the Effect of Presumed Consent Organ Donation Laws on Privacy, Autonomy and Liberty* Fordham Urban Law Journal 24 (2001) 816; Mehlman *Presumed Consent to Organ Donation: A Reevaluation* Health Matrix 1 (1991) 31.

¹⁵ The key to increase awareness of organ donation lays in the fact that public perception needs to be changed. The only manner to reach this goal is through public education. The argument can be raised that the *onus* should be placed upon the health practitioner and the government to provide sufficient and

In this sense, the medical miracle of extending human life created by advancing medical technology is in actual fact its own victim. Prompted by these circumstances, government policy makers supported by medical ethicists and lawyers, introduced incentives to curtail the problem by increasing the supply of organs through public awareness campaigns, financial rewards and; at times introducing draconian procurement systems.

The basic requirement before transplanting tissue and organs into the recipient is that informed consent must be present. This requirement assumes that there is duty of disclosure upon the health practitioner to inform the recipient patient of the advantages, disadvantages, risks, recovery methods etc.¹⁶ In a hypothetical situation, if a policy for the establishment of presumed consent is introduced in South Africa, the argument can be raised that the duty to provide information becomes the responsibility of the National Department of Health (in collaboration with the Provincial Departments of Health). This dissertation analyses the legitimacy of the following procurement system and procurement incentives, the doctrine of presumed consent and the principles of required response and required request.

4.2 Preservation of Organs

Once the tissue have been legally procured, the second phase of the transplantation process sets in, whereby the tissue needs to be protected against harmful factors such as disease and infection transmission.¹⁷ The effectiveness of these processes is important to guarantee a successful transplantation to the recipient¹⁸. If an organ is damaged post removal, a

correct information relating to organ transplantation to the medical layperson. This duty of disclosure ensures that the patient had a fair opportunity to appreciate the nature, scope, risks and consequences of organ donation in order to enable him to come to a rational decision whether or not to become an organ donor. The duty of disclosure realises the patient to make a decision in the light of constitutionally entrenched right to bodily self-determination and physical integrity.

¹⁶ Van Oosten *Medical Law: South Africa – International Encyclopedia of Laws* (1996) par 119 – 124.

¹⁷ Williams *The Regulation of Human Tissue in the United States: A Regulatory and Legislative Analysis* Food and Drug Law Journal 52 (1997) 409; Indech *The International Harmonization of Human Tissue Regulation: Regulatory Control over Human Tissue Use and Tissue Banking in Select Countries and the Current State of International Harmonization Efforts* Food and Drug Law Journal 55 (2000) 343.

¹⁸ Section 7 of the Human Tissue Act 65 of 1983 regulates matters relating to the removal of donated tissue. Section 9 provides for matters concerned with the removal of tissue at post-mortem examinations and obtaining of tissue by institutions and persons. No act never really regulated tissue and organ allocation procedures. The National Health Act 61 of 2003 that repeals the whole of the Human Tissue Act is the first legislation that proposes that specific regulations should be drafted to accommodate allocation procedures. Section 61(2) states that human organ obtained in terms of section 61(1) must be

range of legal issues can arise for example whether the hospital or medical centre, where the tissue was initially removal could incur liability from damages to tissue post removal? In these circumstances, the principles of the law of delict and the law on quantum of damages are employed to provide relief to the plaintiff. In the United States a number of cases have featured where these issues had to be decided. A good example is *Ravenis v Detroit General Hospital*¹⁹ where the court ruled that a hospital should be held liable for medical malpractice, where two patients both lost an eye due to infection whilst being recipients to the same organ donor.

Another important question which, correlates to the post removal stage, focuses upon who acquires ownership over the organs.²⁰ Section 36 of the Human Tissue Act²¹ (“the Human Tissue Act”) provided that any person who acquires any tissue, blood or gamete in terms of this Act or any other law acquires on receipt exclusive rights provided that the tissue is used for the purposes for which it has been donated. Since the newly promulgated National Health Act²² (“the National Health Act”) does not seem to contain a similar provision, the question pertaining to ownership over tissue has once again become a grey area.

In foreign jurisprudence a legal discrepancy between English law and United States Federal law exists. Under English common law, the general rule is that there is no property right in a corpse.²³ This rule is still in existence in the

allocated in accordance with the prescribed procedures. If a person does not adhere to section 61 or who charges a fee for a human organ is guilty of an offence in terms of section 61(5)(a) and upon conviction will be liable to a fine or imprisonment for a period not exceeding five years or both.

A good example of foreign legislation in this regard is Belgium. The Belgian Legislator enacted two acts: the first in the Law on the Removal and Transplantation of Organs of 13 June 1986 and the second the Crown Order pertaining to the Procurement and Allocation of Tissue of Human Origin of 23 December 1997. Both these acts were enacted to provide for a legislative framework for the removal and allocation of organs. They specifically regulate matters such as when, from whom the organs may be removed and the duties of the health care professional when removing the organs.

¹⁹ 234.N.W.2d 411 (1975).

²⁰ Unfortunately, the ownership rights relating to organs are not discussed in this dissertation.

²¹ Act 65 of 1983.

²² Act 61 of 2003.

²³ Price at 123 refers to the earliest report case in England where the court had to consider the issue of property rights pertaining to corpses. In 1614, the court in the *Haynes Case*, deliberated that a corpse itself was incapable of being owned a material object, the decision was wrongly interpreted to mean that no one was capable of owning a corpse. Various prominent legal scholars of that time such as Sir Edward Coke and Blackstone, accepted this view that no property in a corpse existed.

modern English common law²⁴, however two exceptions exist: where there was a right of possession for the purposes of the disposal of the body and where an application or process of skill was made for example embalming.²⁵ United States jurisprudence recognises that the relatives for purposes of burial has a quasi-property right.²⁶ This means that the next-of-kin proprietary rights is not absolute, but subject to the performances of a specific purpose i.e. burial of the body. The reasoning behind this principle has been briefly explained in *Meek v State*²⁷. The Supreme Court of Indiana stated that “property rights are more limited in some objects than in others, but, if there is any right of control over or interests in an inanimate material thing, it would seem to be a property right.” It would seem that ownership rights over bodies is a contentious issue on a global scale with rationalisation of laws unimaginable at this stage.

4.2 Allocation Procedures

The final stage in the completion of the transplantation process is allocating procured organs to a specified recipient. This requires that an individual needs to be chosen from a pre-established waiting list in accordance with prescribed regulations. In the past number of years, the ethical implications and fairness of these regulations have been questioned.²⁸ Many questions have been raised regarding the criteria used in the selection of recipients for example whether the criteria should purely be based upon medical prerogatives, or whether an allocation system should rather be a combination of medical, social, economical and other related matters to eliminate unfairness. Other important issues relating to the recipient self are for example, upon which basis does information have to be supplied to the recipient.

²⁴ *Regina v Sharpe* (1857) 169 Eng Rep 959; *Williams v Williams* as referred to by Price 124; and *Doodeward v Spence* (1908) 6 CLR 406.

²⁵ *Blackbeard Organ Donation for Profit* *Obiter* 52 (2002) 57.

²⁶ *Siver v Rockingham Memorial Hospital* (1999) 48 F Supp 2d 608; *Brotherton v Cleveland* (1991) 923 F 2d 482; *Georgia Lions Eye Bank, Inc v Lavant* (1985) 335 SE 2d 127.

²⁷ (1933) 185 N.E. 899 at 901.

²⁸ *Lamb Organ Transplant and Ethics* (1990) 126; *Pence Classic Cases in Medical Ethics* (2000) 31; *Veath Medical Ethics* (1997) 247.

Although the advantages of organ donation are great, it is a sad fact that most people do not consent to removal of their organs after death. This lack of organ donors and the increasing demand for organs forced governments, academics and lawyers, to introduce different organ procurement system, some which may be highly unethical and illegal.

5. Terminology

Before a complete discussion on the doctrine of presumed consent and the principles of required response and required request can take place, it is necessary to define certain terms relevant to this dissertation. These terms will form the cornerstone to the correct understanding of the law of organ procurement pertaining to the doctrine of presumed consent and the principle of required response and required request.

5.1 Human Organ²⁹ and Tissue

In the Republic of South Africa, the Human Tissue Act of 1983³⁰ governed the removal of tissue, blood or gametes from the bodies of living persons until the middle of 2004. The Human Tissue Act defined “tissue” as “any human tissue, including any flesh, bone, organ, gland, or body fluid, but excluding any blood or gamete and any device or object implanted, before the death of any person, by a medical practitioner or dentist into the body of such person”.³¹

The National Health Act³², that repeals the Human Tissue Act, defines an “organ” as “any part of the human body adapted by its structure to perform particular vital function, including the eye and its accessories but excluding

²⁹ Davis *Tabor's Cyclopedic Medical Dictionary* (1989) at 1368 defines an organ a part of the body having a special function as part of an integrated living system. Organs can be divided into vital and non-vital organs. Vital organs are those which cannot be removed without loss of function necessary to support life for example the heart and lungs and non-vital organs are able to be procured for organ transplantation Banks *Legal and Ethical Safeguards: Protection of Society's Most Vulnerable Participants in a Commercialised Organ Transplantation System* American Journal of Law and Medicine 21 (1995) 53. In the context of organ procurement, it should be remembered that the transplantable object is not restricted to organs alone, but also tissue.

³⁰ Act 65 of 1983.

³¹ Section 1.

³² Act 61 of 2003.

any skin and appendages, flesh, bone, bone marrow, body fluid, blood or gamete”.³³ The National Health Act defines “tissue” as “any human tissue including any flesh, bone, gland, organ, or body fluid, including any implanted medical or other assistive device, but excluding any bone marrow, blood or gamete”.³⁴

5.2 The Doctrine of Informed Consent

In general, the relationship between a health practitioner or hospital and a patient is based upon contract, presupposing *consensus ad idem*³⁵ between the parties.³⁶ Consent, forms the basis of any medical intervention or treatment.³⁷ In the absence of prior consent given by the patient, any treatment would be unlawful and constitute either assault or an *injuria* or both. In any medical treatment, it should be remembered that the patient is usually a layperson. For the patient to be able to give lawful consent to the proposed medical treatment, a duty of disclosure rests upon the health practitioner to provide the necessary and correct information. This provides the patient with the opportunity to make an informed decision whether to undergo or refuse the treatment.³⁸ The basis upon which this doctrine operates is patient autonomy rather than the views of the medical profession.

The purpose and function of the doctrine is firstly to ensure the patient’s right to self-determination, freedom of choice and secondly to encourage rational decision-making by enabling the patient to weigh and balance the benefits and disadvantages of the proposed treatment in order to make an informed choice. The doctrine of informed consent presupposes that the patient not

³³ Section 1.

³⁴ *Ibid.*

³⁵ Exceptions to the general rule do exist such as emergency situations, statutory authority and authorisation by the court.

³⁶ See *Van Wyk v Lewis* 1924 AD 438 at 443, 450 – 451, 455 – 456; *Correia v Berwind* 1986 (4) SA 60 (Z) at 63 - 66; *Administrator Natal v Edouard* 1990 (3) SA 581(A) at 585; *Castell v De Greef* 1994 (4) SA 408 (C) at 420 and 425; *Phillips v De Klerk* 1983 (T) unreported.

³⁷ See Van Oosten *Medical Law: South Africa – International Encyclopedia of Laws* (1996) par 121.

³⁸ In the case where the health practitioner did not provide the necessary information, his/her liability arises from a breach of a duty of care rather than one of negligence.

only consent to the injury and the proposed medical intervention, but also to the risks and consequences of the intervention.³⁹

In *Castell v De Greef*⁴⁰ the presiding judge formulates the test to be applied when determining whether consent was present in any circumstances and whether such consent is informed:

“For consent to operate as a defence, the following requirements must, *inter alia*, be satisfied:

- (a) the consenting party must have had knowledge and been aware of the nature of the harm or risk;
- (b) the consenting party must have appreciated and understood the nature and extent of the harm and risk;
- (c) the consenting party must have consented to the harm and assumed risk;
- (d) the consent must be comprehensive, that it extend to the entire transaction, inclusive of its consequences.”

When evaluating the principles of the justification ground of consent in the scope of the application of the doctrine of presumed consent, the question is whether it can be assumed that presumed consent in organ procurement is just presuming informed consent is present. This argument is based upon the general principles such as knowledge, comprehension and appreciation and the answer to this question varies, depending on circumstances.

5.3 Organ Procurement Systems

5.3.1 A Regime of Routine Salvaging

The concept of routine salvaging was originally proposed in the late 1960s in the United States of America to serve as a possible solution to the problem of

³⁹ *Oldwage v Louwrens* [2004] 1 All SA 532 (C).

⁴⁰ 1994 (4) SA 408 (C) at 425.

the scarcity of human organs for transplantation purposes.⁴¹ This organ procurement system dictates human organs can be procured without explicit consent upon death. Routine salvaging and the doctrine of presumed consent operate in a very similar manner⁴², however the ethical implications of the systems are different.⁴³ Under a regime of routine salvaging, the right to self-determination is disregarded. Even though a potential organ donor objected prior to his / her death to the procurement of his / her organs or tissue for transplantation purposes, upon the death of the person his / her organs will be procured. The application of a policy of routine salvaging is a direct infringement of the right to bodily integrity and security as guaranteed in section 12 in the Constitution of South Africa⁴⁴.

5.3.2 The Doctrine of Presumed Consent⁴⁵

The doctrine of presumed consent, also known as the “opting out” system, is an organ procurement system under which individuals who have not during their lifetime raised an objection to organ donation, will upon death be presumed that they had no objection against the removal of their organs for transplantation purposes and in effect, gave consent to the removal. A failure to indicate refusal would be considered an implicit statement of consent. Countries⁴⁶ with presumed consent legislation distinguish between the hard and soft application of the doctrine.

⁴¹ Dukeminier and Sanders *Organ Transplantation: A Proposal for Routine Salvaging of Cadaver Organs* New England Journal of Medicine 279 (1968) 413.

⁴² This point is supported by a report by the United Network for Organ Sharing (UNOS) Ethics Committee in the United States. The UNOS Ethics Committee evaluated the ethical implications of presumed consent in organ procurement determined that the policy of Routine Salvaging is inconsistent with liberal individualism. See further Dennis et al *An Evaluation of the Ethics of Presumed Consent and a Proposal Based on Required Response: A Report of the Presumed Consent Subcommittee and United Network For Organ Sharing (Unos) Ethics Committee* available at http://www.unos.org/resources/bioethics_whitepapers_presumedconsent.htm.

⁴³ Certain schools of thoughts take the view that the doctrine of presumed consent and the policy of routine salvaging is quid pro quo. See for example Bailey *Should the state have rights to your organs? Dissecting Brazil's Mandatory Organ Donation Law* University of Miami Inter-American Law Review 30 (1999) 707 at 718.

⁴⁴ Act 108 of 1996.

⁴⁵ The doctrine of presumed consent can also be applied within other spheres of the law for example criminal law. See further Snyman *Criminal Law* (2003) 129. In this dissertation, presumed consent is restricted to organ procurement.

⁴⁶ See for example Austria and Denmark. Austria applies perhaps the most stringent form of the hard application of presumed consent, where the situation in Denmark suggests that a softer approach to the doctrine applies. See further Taupitz *Zivilrechtliche Regelungen zur Absicherung der Patienten Automatic am Ende des Lebens* (2000) 135 – 161, 368- 376, 517 – 521, 543 – 563.

The hard application indicates that a presumption is made that individuals who have not raised an objection to organ procurement, granted consent to the removal of the deceased organs and tissue and the next-of-kin does not have a right to interfere in the decision. The role of the family is disregarded. If the hard application of the doctrine of presumed consent is compared to routine salvaging, the functioning of these procurement systems almost seem identical. However, under a regime of routine salvaging organs could be taken *without* the explicit consent of the individual or his / her family.⁴⁷ The underlining difference between routine salvaging and presumed consent, although the outcome is the same, presumed consent grants an individual the chance to “opt out”. Routine salvaging contradicts the idea of patient autonomy and freedom of choice. The soft application of the doctrine functions exactly the same as the hard application with the exception that the family of the deceased is granted an opportunity to object to the retrieval of organs from the deceased who is presumed to have given his consent.

An evaluation of the application of the definition of the doctrine of presumed consent reveals that this definition consists of various distinct elements for example the donor (all competent persons of a certain age are regarded as organ donors) and consent (those donors who wish to object to organ procurement must raise an objection which is an implicit statement of consent). These are discussed in detail in Chapter Two. The main question raised pertaining to the ground of justification present in the doctrine, is what is the nature of consent? An attempt is made towards assessing the true nature of consent in the medical jurisprudence and applying that concept towards establishing the nature of consent in the doctrine of presumed consent as an organ procurement system.

5.3.3 The Principle of Required Response

An organ procurement system linked with the principle of required response, requires all competent adults to consider organ donation and record their

⁴⁷ See further Dukeminier and Sanders.

wishes regarding organ donation. This process happens during a specified time or event, such as application for a driver's licence or voter registration. A person cannot complete the application for a driver's licence, unless that person submitted the required response form to the appropriate authority. This incentive provides for a more forceful approach to informing the public to consider organ procurement, distribution and general issues relating to transplantation.

This system of acquiring consent is seen as the most effective way of obtaining informed consent and preserving patient autonomy.⁴⁸ The principle of required response grants the potential organ donor and his / her family the opportunity to consider the advantages and possibilities of organ donation under a less stressful situation. The biggest ethical advantage of the principle of required response is that it's a more socially accepted method of obtaining consent as in the case of the doctrine of presumed consent.

5.3.4 The Principle of Required Request

Legislation that regulates incentives the principle of required response and required request have been classified into "strong" or "weak" legislation. Paragraph 5.3.3 refers to the strong approach, whereby individuals are forced to consider and record their wishes about organ donation. In the United States, a weak application of the principle of required response emerged in the early 1980's.⁴⁹ Under a required request legislative framework, health care service providers such as hospitals are required to develop policies to ensure that patients and their next-of-kin were asked to consider organ procurement. The difference between required response and required request are twofold:

- the manner in which an answer regarding a person's opinion towards organ donation is received; and
- the time period when such an answer is obtained.

⁴⁸ Mackey and Kjerulf *The Ethics of Organ Donation: Examining Consent Policies and Donor Criteria* University of Toronto Medical Journal 78 (2000) 51 and Dennis et al 3.

⁴⁹ Price 102.

The principles of required response forces a person to register an opinion about organ donation, where required request only requires hospital staff to approach a patient or as in most cases the next-of-kin to enquire whether that person's organs and tissue can be transplanted upon death.

The regulation of this principle has largely been restricted to the United States where it formed part of a national campaign to increase organ procurement.⁵⁰ At the time of introduction, much hope rested upon required request to improve the lack of organ donors, however the success rate of this principle proved to be for the most part to be unsuccessful.

5.4 Organ allocation systems

The first step in the process of organ transplantation is the procurement of organs. To complete the process of transplantation as referred to in paragraph 4, the organs should be successfully allocated to transplant recipients. Thus, in the evaluation of the legal issues pertaining to organ procurement systems, it is essential to refer also to organ allocation systems.

Organ allocation systems can casually be defined as the process to ration the allocation of procured organs to patients waiting for transplantable organs in an efficient and equitable manner.⁵¹ The decision to allocate procured organs to a specified recipient rests primarily upon two models namely the medical criteria and the non-medical criteria. The medical model depicts the selection criteria for a suitable transplant candidate through an enquiry by a health practitioner. The criteria used depends solely on generally accepted medical techniques and procedures; and depicts that the medical judgement upon health practitioners to make value judgements pertaining to the likelihood of success of the medical procedure linked to preservation of life, minimal life expectancy and improving the quality of life.⁵² The suitability of a transplant

⁵⁰ For a detailed discussion on this principle, see further paragraph 7 of Chapter Two.

⁵¹ Own definition.

⁵² Brock *Ethical Issues in Recipient Selection for Organ Transplantation* that forms part of Mathieu (Editor) *Organ Substitution Technology* (2000) 88.

candidate using sole medical criteria inevitably causes his / her chances to be a recipient as either severely restricted or unlimited based on the outcome of the medical opinion of a health practitioner. This situation led to candidates questioning the medical procedures used to determine suitability and fair and equitable practices. The second type of criteria is the selection based upon non-medical criteria. This selection criteria is founded upon ethical principles that endeavour to establish fairer and equitable selection processes. The interaction between these systems is paramount to find a workable solution to the scarcity of organs for transplant.

Currently, no legislation exists regulating the allocation of procured organs. The National Health Act only states in section 61(2) that “[h]uman organs obtained in terms of subsection (1) must be allocated in accordance with the prescribed procedures.” The content of these “prescribed procedures” falls within the prerogative of the Minister of Health to draft regulations under section 68 of the National Health Act to regulate supply and allocation of tissue or human cells by institutions and persons only.

5.5 Determining the Moment of Death

Throughout this dissertation reference is made to living organ donors and cadaveric organ donors. Each type of donor has different legal implications in the law of organ procurement.⁵³ In cadaveric donations, the primary requirement is that the donor should be deceased, before organ procurement could commence.⁵⁴ Determining the precise time of death has been an intensely debated subject. Before medical advancements made it possible to transplant organs and tissue, little controversy existed to certify the death of a patient. Prior to the first heart transplant was performed; the test for death was mainly the absence of heart activity.⁵⁵ This is the so-called traditional test. The pattern of death contained two requirements: firstly the heart of a patient must

⁵³ It is self-evident that live donors do not need to be deceased at the moment of organ procurement and transplantation.

⁵⁴ Section 1(a) Human Tissue Act 65 of 1983 and section 62 of the National Health Act.

⁵⁵ Strauss *Doctor, Patient and the Law* (1991) 147; Barnard 1271; Curran et al *Health Care Law and Ethics* (1998) 709.

stop beating and secondly, the lungs must stop breathing. Once both requirements were met, medical-recognised death set in.

In 1967, Prof Barnard remarked that the traditional test must be performed within a time scale of five minutes to determine “the absence or cardiac activity for five minutes as measured by the electro-cardiograph, the absence of spontaneous respiratory movements and the absence of reflexes”.⁵⁶ With the ever-increasing medical advancement in transplantation technologies, the traditional test became redundant. The reason being that modern health practitioners regard death as a process that extends over a period of time rather than a simple one off event.

In creating a new definition of death, specific factors were identified which is needed to draft a more refined definition. These factors are the following:

- ”(1) modern medicine’s technological ability to sustain life in the absence of spontaneous heartbeat or respiration;
- (2) the advent of successful organ transplantation capabilities which creates a demand for viable organs from recently deceased donors;
- (3) the enormous expenditure of resources potentially wasted if persons in fact dead are being treated medically as though they were alive; and
- (4) the need for a precise time of death so that persons who have died may be treated appropriately”.⁵⁷

Today, it is generally accepted that sustaining human life, activities from the brain, heart and lungs must be present. Any interruption of these activities (organs) would lead to the almost certain death. The brain is the most vulnerable organ. Medical opinion show that when the blood flow to the brain

⁵⁶ Barnard 1271.

⁵⁷ Curran et al 710.

is interrupted, unconsciousness follow within ten seconds and regular respiratory activity cease within a minute leading to irreparable brain death⁵⁸ after five minutes.⁵⁹

Applying this new concept of death to a practical test for proof of death, the question is, should death be determined by the cessation of both the heart and brain activity or is brain death alone sufficient? In *S v Williams*⁶⁰ the court *a quo* found that the moment of death is when the brainstem death sets in. On appeal, the judgement of the court *a quo* was upheld. The Appellate Division however held that “it was *in casu* not necessary to decide whether a medical test of brainstem death or society’s notion of cardio-pulmonal death prevails in law, but that this was not to be seen as an indication that brainstem death is a purely mechanical or physical one which fails to take moral, religious and social views on the matter into consideration.”⁶¹ In a case⁶² involving active voluntary euthanasia, the patient suffered from irreversible brain damage as result of cardiac arrest. The patient remained for a period of four years in a permanent vegetative state. The court ruled on the moment of death, that neocortical death⁶³ was not regarded as the legal moment of death.

In the absence of a statutory definition, the moment of death remained an unresolved issue until the promulgation of the National Health Act in 2004, which resolved the issue. Currently, the National Health Act defines death as “brain death” in section 1.

⁵⁸ Criteria to determine whether brain death has occurred was developed in 1968 by the Ad Hoc Committee of the Harvard Medical School to Examine the Definition of Brain Death, A Definition of Irreversible Coma. These criteria require “(1) unresponsivity and unresponsivity to even the most intensely painful stimuli; (2) no spontaneous movements or spontaneous breathing for at least one hour, (3) no reflexes, as shown by no ocular movements, no blinking, no swallowing, and fixed and dilated pupils. The report further recommended flat electroencephalograms (EEG’s) as a confirmatory test, and that hypothermia and use of central nervous system depressants as causes be eliminated...”.

⁵⁹ Strauss 57.

⁶⁰ 1986 (4) SA 1188 (A).

⁶¹ Van Oosten *Medical Law: South Africa* par 121.

⁶² *Clarke v Hurst* 1992(4) SA 630 (D).

⁶³ All brain functions of the patient are functional, however no cognitive functionalities are present.

6. The Constitution of South Africa

The promulgation of the Constitution of South Africa⁶⁴ (“The Constitution”) greatly impacts issues relating to organ donation, organ transplantation and organ allocation procedures. The Constitution is the supreme law of South Africa⁶⁵ and any law or conduct inconsistent with the provisions contained therein is invalid⁶⁶. Arguably, the most important section pertaining to the law of organ procurement is section 12(2)(b). This section guarantees every person the right to bodily and psychological integrity, which includes the right to security in and control over their body. This right means that no person’s organs may be procured for transplantation purposes without the lawful consent.

According to the authors De Waal, Currie and Erasmus⁶⁷ section 12(2)(b) comprises of two components namely “security in” and “control over”.⁶⁸ The former term refers to the protection of bodily integrity against intrusions by the state and others.⁶⁹ The latter term refers to the protection of what could be called bodily autonomy or self-determination against interference.⁷⁰ The latter term contained in section 12(2)(b) echoes the decision of the case *Castell v De Greef*⁷¹ where the court clearly adopted patient autonomy in favour of medical paternalism and shifted the emphasis from a professional medical standard to a patient autonomy standard of disclosure.⁷² The court’s point of view is that the decision to undergo or refuse a medical intervention lies with the patient not with the health practitioner. The application of section 12(2)(b)

⁶⁴ Act 108 of 1996.

⁶⁵ Section 2.

⁶⁶ Unless, the infringement by the law or conduct can be justified in terms of section 36 (the Limitation clause).

⁶⁷ *The Bill of Rights Handbook* (2000).

⁶⁸ *ibid* 237.

⁶⁹ “Security in” is a component of the right to be left alone in the sense of being left unmolested by others.

⁷⁰ “Control over” is a component of the right to be left alone in the sense of being allowed to live the life the person chooses.

⁷¹ 1994 (4) SA 408 (C).

⁷² For further information about *Castell v De Greef* 1994(4) SA 408 (C) see Van Oosten *Castell v De Greef and the Doctrine of Informed Consent: Medical Paternalism ousted in Favour of Patient Autonomy* (1995) De Jure 164.

in the law of organ donation and transplantation, guarantees that no person's⁷³ organs may be procured without prior lawful consent.

Other relevant sections of the Constitution that impacts on organ procurement and organ allocation are the equality clause⁷⁴, the right to human dignity⁷⁵, the right to life⁷⁶, the privacy clause⁷⁷, the right to health care⁷⁸, the right to access to information⁷⁹, the just administrative action clause⁸⁰ and the limitation clause⁸¹.

Although, there has been no South African litigation with direct reference to the law of organ donation and transplantation or organ allocation, the Constitutional Court provides insight in the case *Soobramoney v Minister of Health*⁸² to the approach in the allocation of limited resources that can be applied to organ allocation. In this case the availability of the resource in question was limited due to finances, the reasoning of the court can be applied to the allocation of other resources such as organs that are limited due to availability.

In the *Soobramoney* case, the appellant was denied renal dialysis by the Addington Hospital ("the hospital") due to a lack of dialysis machines. According to the hospital's policy, it only provides dialysis to patients who are eligible for a kidney transplant.⁸³ The appellant, who was not eligible for a kidney transplantation operation was, in terms of the policy also not eligible for dialysis. An application was brought by the appellant before the High Court for an order directing the hospital to provide him with dialysis. The application

⁷³ The section applies to all persons who find themselves within the Republic.

⁷⁴ Section 9(1), (2) and (3).

⁷⁵ Section 10.

⁷⁶ Section 11.

⁷⁷ Section 14.

⁷⁸ Section 27.

⁷⁹ Section 32.

⁸⁰ Section 33.

⁸¹ Section 36.

⁸² 1998 (1) SA 765 (CC).

⁸³ Paragraph 3.

was subsequently refused and the appellant appeal to the Constitutional Court for relief.

The court's discussion surrounding the allocation policy of dialysis machines of the hospital can be applied to the allocation of organs. Due to the shortage of dialysis machines the hospital drafted guidelines that dictates only certain patients may receive treatment and other patients who do not qualify may not receive treatment.⁸⁴ These guidelines seem to indicate that in the process of the allocation of resources, efficiency is the primary concern. It ensures that resources are utilised in manner that will create the maximum advantages to the maximum number of patients.⁸⁵ The court's decision therefore seems to attach a greater weight to efficiency than it does to equity. Accordingly, where there is a conflict between two values, efficiency will be predominant.

This case illustrates that where resources such as human organs are severely limited, the resources will be utilised in such a manner that will benefit the greater community of patients. This means that a choice should be made between patients and the ratio of discrimination against a single patient is great. In the drafting of an organ allocation policy, fair guidelines should be set up that aims at allocating resources efficiently.

7. Socio-Economic Perspective on Transplantation Law

The concepts discussed in this dissertation focuses solely on the theoretical standpoint of organ procurement system, tissue preservation and distribution procedures. These findings are important for development of the national health regulatory framework, however the practical implications overshadow possible accomplishments in this regard.

⁸⁴ Paragraph 24.

The most pertinent issue in practice is the economical influence that affects transplant operations and patients' ability to undertake such a decision. Especially in a developing country such as South Africa, this situation is all too vividly clear as available governmental resources to realise socio-economical rights especially those rights contained in section 27 of the Constitution, are at all times constrained by availability of state funds. The abovementioned paragraph illustrates the current stance of the government in allocation state resources for realising of rights entrenched in the Constitution. From the standpoint taken in the *Soobramoney* case, it is certain that any governmental initiative to reform current organ donation legislation without the necessary financial framework in place would be pointless.

8. Conclusion

Organ transplantation law is a recently developed area within the South African law. The legal issues interlink with a broad range of area of the law for example consent, ownership of human tissue, law of delict and the criminal law. Perhaps the most contentious issues are *how* should organs be procured and *how* could more organs be procured to serve the dire need of waiting list patients?

The general legal position in South Africa provides human tissue and organs may only be procured with prior consent by the donor. If the organs are procured without explicit consent, the doctor/health care centre will be liable for assault, breach of contract and an *iniuria*. If more organs wanted to be procured the logical deduction is more people (either live or cadavaric organ donors) should consent to the removal of their organs. A problem is experienced if less people consent to the procurement of their organs.

In the ever-increasing demand for the efficient supply of organs, governments and states have introduced different methods of obtaining human organs for

⁸⁵ Par 30.

transplantation sometimes very contentious and higher unethical⁸⁶. Belgium and Austria promulgated legislation, which made it possible to procure human tissue and organs *without* the consent of the deceased donor. These governments presume consent have been given if the citizen / donor did not raise an objection during his or her life against the procurement of human tissue and organs for transplantation after death. This is the doctrine of presumed consent pertaining to organ procurement.

⁸⁶ For example The People's Republic of China uses the tissue of executed prisoners for transplantation.

CHAPTER TWO

ORGAN PROCUREMENT SYSTEMS

1. Introduction

Until August 2004, the regulation of organ procurement in South Africa fell within the ambit of the Human Tissue Act, which requires that an organ donor must consent to the donation of his or her organs prior to the transplant operation be performed.⁸⁷ No tissue and organs may be procured without the explicit consent from the organ donor. This organ procurement system is identified as an “opting in” system, which requires that the donor must give consent prior to removing tissue for transplant. This system allows patients to exercise their constitutional right to freedom of self-determination through giving consent.⁸⁸ Any organ procurement without explicit consent constitutes an assault and an *iniuria*. During August 2004, the President promulgated the National Health Act, in which Chapter 8 contains provisions relating to control of use of blood, blood products, tissue and gametes in humans. In terms of previous statutory provisions relating to organ procurement, the National Health Act is virtually a *verbatim* copy of the Human Tissue Act of 1983.

The principles of organ procurement systems must be reviewed within a global perspective. On evaluating the principles of organ procurement systems, distinct elements can be identified that impact the manner in which these systems operate, for example consent. In application, these principles differ from jurisdiction and an organ procurement system may be legal and successful in one country may be deemed undesirable or useless in another.

⁸⁷ Section 2(1) read in conjunction with section 18.

⁸⁸ Section 12 of the Constitution.

In the previous chapter, it was mentioned that the discussion of organ procurement systems and incentives are restricted to the doctrine of presumed consent and the principles of required response and required request. This chapter aims to evaluate the organ procurement system and principles through a legal positivistic approach with reference to national legislation as well as foreign legislation and policies. The main focus points are the following:

- The difference between procurement systems requiring explicit consent and those presuming that consent is present is analysed. This discussion focuses on the elements of presumed consent and the individual requirements of each element is analysed.
- The discussion of the principles of required response and required request are centred on the difference between required response as applied in Europe and the American version; required request. The principle of required response and required response is also contrasted to presumed consent.
- Formulation of a legal opinion to form the basis for reforming current organ procurement laws to include presumed consent and / or the principle of required response and required response.⁸⁹

It is reiterated that organ donation is, in essence a very controversial issue. People will usually be reluctant to consider becoming donors based on a variety of factors. This chapter proposes that the doctrine of presumed consent is constitutional in terms of section 12(2)(b) of the Constitution and that presumed consent is actually *presuming* informed consent is present prior to organ procurement.⁹⁰

⁸⁹ Chapter Four is dedicated to the drafting of an amendment national health act, which incorporates the doctrine of presumed consent into South African law.

⁹⁰ *Oldwage v Louwrens* [2004] 1 All SA 532 (C).

2. Organ Procurement Systems

The legal and ethical implications of organ procurement systems differ, for example consent, family participation and so on. Organ procurement systems is generally divided into three categories; those requiring explicit (prior) consent given by the donor, systems where it can in certain instances be presumed that consent is present and systems functioning through routine salvaging or “tissue drafting”.

Each procurement system possesses it's own unique elements which defines the specific system and allows distinction to be drawn between the various systems. The element that features prominently (or should feature) is consent. The manner consent is gathered prior to removing tissue differ dramatically. If consent is evaluated, it can be argued that levels of consent⁹¹ exist. These levels differ between no consent being present to presuming informed consent was granted.⁹²

2.1 Problems associated with Organ Procurement

A clinical glance at the medical procedure of transplantation depicts this process can be divided into three stages: At first, the tissue must be procured from either living or cadaveric donors, stored and protected from harmful diseases and finally allocated to an identified recipient. Although, this process seems relatively simply, the overarching problem sets in at the first phrase, which in turn leads to a number of other problems. The compilation of this dissertation is based upon the problem that the demand of tissue vastly

⁹¹ Blackbeard *Consent to Organ Transplantation* Tydskrif vir die Hedendaagse Romeins Hollandse Reg 66 (2003) 45 at 55. Blackbeard supports the argument of levels or degrees of consent existing, however the author states that a distinction should be made between two levels of consent, express consent and presumed consent. Although Blackbeard is not incorrect with such an interpretation, in this dissertation the question is evaluated whether levels of consent actually exist between general consent, informed consent, presuming consent (which actually signify no consent) and presumed consent (which represent presuming informed consent).

⁹² Identifying whether consent is present in organ procurement systems based upon explicit consent, presumed consent and routine salvaging, the manner in which the latter system functions depicts that no consent from the donor or next-of-kin is required for removing tissue. The former systems are not so extreme and allow the potential donor the right to refuse based upon informed consent or not to consent to procurement.

exceeds the supply.⁹³ The medical miracle created by transplant technology is almost crippled by the reluctance of people to become organ donors and the ill supply of tissue from other resources such as cadavers. In Europe, specific reasons for a low supply in organs have been identified. The reluctance of European Union Nationals to donate organs have been contributed to different diets, cultures, weather conditions, and economic activity.⁹⁴ The European Commission suggests the following general reasons are the *causa causans* for organ shortage:⁹⁵

- Age. Studies show that a greater number of Europeans is that of sixty years of age and over. It is projected that where older person accounted for seventeen and a half percent of the population in the 1980's, this estimation could reach twenty five percent by 2010. This means that the demand in health care services including tissue for transplantation purposes will place at a greater burden on Europe's health departments, which might surpass their ability to supply these services. In terms of organ procurement, this might indicate that where supply for organs are already stretch to the limit, the supply might collapse prompting Europeans to seek other measures to obtain tissue, which might not fall within the ambit of the law.
- Increasing mobility. Due to the easy mobility over Western Europe's borders, migration hampers the ability to locate a citizen to record their wish to become an organ donor, or a citizen who passes away in another country, whose organ might be transplanted in one of that country's citizens.
- Costs. Although new advances in medical transplantation procedures are constantly introduced, the cost associated with performing these

⁹³ Barber *The Tell-Tale Heart: Ethical and Legal Implications of In Situ Organ Preservation in the Non-Heath-Beating Cadaver Donor* Health Matrix 6 (1996) 471; Banks *Legal and Ethical Safeguards: Protection of Society's Most Vulnerable Participants in a Commercialised Organ Transplantation System* American Journal of Law and Medicine (1995) 45; Alcorn and Harris *To Solve a Deadly Shortage: Economic Incentives for Human Organ Donation* Issues in Law and Medicine 16 (2001) 213; Krueger *Life Coming Bravely Out of Death: Organ Donation Legislation Across European Countries* Wisconsin International Law Journal 18 (2000) 321; Anderson and Copeland *Legal Intricacies of Organ Transplantation: Regulations and Liability* Journal of the Missouri Bar 50 (1994) 139.

⁹⁴ The European Commission, Com (93) 559 Final (1993) as referred to by Krueger *supra* at 322.

⁹⁵ This list should not be regarded as a closed list as each country that regulates organ transplantation experience their own individual problems.

procedures hampers increasing organ transplantation. This is a *sine qua non* for the escalating high levels of unemployment and slow economic growth.

- Lack of information, public fear and altruism. Procuring tissue for transplantation purposes involves a degree of permanent physical damages to the human body of the donor. Due to the lack of user friendly information about organ donation, ill-informed Europeans experience mixed feelings about organ donation which, in turn is responsible raising feelings of altruism. Potential donors fear that if they consent to procurement of their organs, their lives could be at risk.⁹⁶

Caplan⁹⁷ adds that other factors, especially in the United States have also contributed to the scarcity of tissue, which includes:

- Demand for transplantation has increased as success rates have been expanded, transplant centres have proliferated, and more people are considered eligible for transplants;
- Successful safety measures, such as speed limits and seat belts, have reduced the number of deaths where organ donation might have been possible; and
- Fear of transmitting HIV and hepatitis are growing.⁹⁸

Authors⁹⁹ agree with the abovementioned list, however some consider that the most important factor is the family's refusal to allow their deceased family member to become a donor. Most surveys show that a high number of

⁹⁶ These fears are due to newspapers articles about tourists whose organs are illegally removed whilst visiting far-eastern countries.

⁹⁷ Arthur Caplan Ph. D, Professor and Director for Bioethics, University of Pennsylvania School of Medicine.

⁹⁸ Caplan, Siminoff, Arnold, Vernig and Seltzer *Public Policy Governing Organ and Tissue Procurement in the United States* Annals of Internal Medicine 123 (1995) 10 at 17; Caplan *Current Ethical Issues in Organ Procurement and Transplantation* Journal of the American Medical Association 272 (1994) 1708 at 1709.

⁹⁹ Price 31, Naylor *The Role of the Family in Cadaveric Organ Procurement* Indiana Law Journal 65 (1989) 167; Mackey and Kjerulf *The Ethics of Organ Donation: Examining Consent Policies and Donor Criteria* University of Toronto Medical Journal 78 (2000) 51; Arnold and Siminoff *Increasing Organ Donation in the African-American Community* Annals of Internal Medicine 130 (1999) 607; Caplan et al 17.

opposition from the potential donor's family exists. Changing perceptions about organ donation in any procurement system would signify an increase in organ donation rates.

2.2 Solving Organ Procurement Problems

The steadily increasing of patient's names on transplant waiting lists, prompted governments to introduce organ procurement systems and incentives to increase supply in organs. The initial concept was based on straightforward economic principles, that in theory, if supply in organ procurement were increased, the demand in organs would depreciate resulting in relieving ever-increasing waiting lists. One of the first organ procurement systems introduced were solely based on medical paternalism and took no regard towards basic fundamental rights such as patient autonomy.¹⁰⁰ The only focus was on meeting the demand of organs, which created other problems such as questions regarding consent prior to removal of organs and ethical implications.¹⁰¹ Other systems initiated which were directed upon retrieving consent from the donor before tissue were procured, were less formidable, but procured less organs than anticipated.¹⁰² Search for the perfect solution of the organ procurement problem is in its infancy.

2.3 Organ and Tissue Donors

Before the different organ procurement systems and principles can be discussed, a distinction must be made between the different types of donors.

¹⁰⁰ According to Blumstein *The Use of Financial Incentives in Medical Care: The Case of Commerce in Transplantable Organs* Health Matrix 3 (1993) 1, the use of incentives was rejected based on grounds of ethics and effectiveness: "[e]thically, the objection stemmed from the ideological commitment in some quarters that unrestricted access to medical care on the basis of medical need was the appropriate normative benchmark. This was a component of the rhetorical espousal of medical care as a right. If one believes that access to medical care should be costless to users, the imposition of financial disincentives is directly in conflict with that principle".

¹⁰¹ The policy of regime salvaging was originally introduced by Dukeminier and Sanders *Organ Transplantation: A Proposal for Routine Salvaging of Cadaver Organs* New England Journal of Medicine 279 (1968) 413. This policy proposed that organs may be procured without explicit consent by either the donor or the next-of-kin of the donor. Routine salvaging will be discussed in detail later in the chapter.

¹⁰² Blumstein at 6 "In terms of effectiveness, financial incentives were questioned because of the prevailing medical view that money did not affect how patients were treated. It was assumed that there was a correct course of treatment, and that was a professionally determined decision. Science not economic incentives drove medical care diagnosis and treatment decisions."

Organ donors can broadly be divided into two categories: living donors and cadaveric donors¹⁰³.

In general, organ donation holds no medical benefit to the donor. Prior consent before the transplant operation is a necessity in living organ donation as well as cadaveric donations. Where a patient decides to donate tissue and organs, that patient must “opt in” to the donation of his / her organs. This means the patient must explicitly consent to the removal of organs. It is regarded that the patient holds; *inter alia* sufficient information about the operation to make a properly informed decision. In other words, the patient provides informed consent. The doctrine of informed consent can only apply to living organ donors. If it were presumed that a patient consented to the removal of his / her human tissue and organs, the removal would constitute a gross violation of that patient’s right to self-determination¹⁰⁴. The patient may be able to institute legal action against the hospital and the health practitioner for damages.

The situation is slightly different in the case of cadaveric organ donors. It should be remembered the greater pool of transplantable tissue and organs come from the deceased. These donors must also provide consent prior to organ procurement. Any removal of organs and tissue without consent will also constitute violating a corpse. The doctrine of presumed consent can only be applied to cadaveric organ donors.

¹⁰³ The pool of deceased organ donors can further be divided into anencephalic donors, non heart-beating donors and non therapeutic ventilation. Mackey and Kjerulf at 51 assert that organ procurement from anaencephalic donors could poses a problem: “Anencephalic infants typically die from cardiopulmonary failure within hours or days of birth, and could represent a pool of potential organ donors for pediatric patients who are otherwise restricted by size...[the] expansion of the donor pool to include this population could lead to the creation of a number of ethical ‘slippery slopes’. For instance, how would the inclusion of anencephalic infants affect the donor status of other infants with conditions incompatible with life who also do not meet the criteria for brain death? It is important that any discussion of anencephalic donation address these sensitive issues and propose appropriate safeguards for the slippery slopes that may result.”

¹⁰⁴ Section 12 of the Constitution Act 108 of 1996.

3. The Regime of Routine Salvaging

Ever since the first transplantation operation in the western world was performed in 1954 at Boston's Peter Bent Brigham Hospital in the United States, organ recipients had to rely upon volunteerism from the public to receive organs and tissue. It became clear that volunteerism was not producing enough organs.

The continued shortage of donor organs prompted the search for an alternative to increasing the supply of organs, academics, government officials and medical ethicists have been proposing policies, theories and incentives to increase organ procurement. These proposals impact primarily the principles of medical ethics and applicable legislation. Any proposal viewed to be *contra* the legal perception of the community would nullify any believes in a sufficiently administered legal system.

The first proposals that were made to increase the supply of human organs and tissue for transplantation purposes were by Drs David Sanders and Jesse Dukeminier in the late 1960's.¹⁰⁵ They proposed legislation should be promulgated to make the removal of usable cadaver organs a routine process. This system makes it possible for human organs to be procured for transplantation purposes without the explicit consent of the donor or the family.¹⁰⁶ Under this extreme approach to organ procurement, any attempt to object or "opt out" by either the donor or next-of-kin is disregarded. The philosophical approach to the acceptance of routine salvaging entails the following two reasons: Firstly, strong public support in favour of organ transplantation and secondly, the subordination of the individual to the state.¹⁰⁷ The latter presupposes that consent is not required due to every citizen's obligation to serve the state-lead national community. After death, all the *belongings* of each citizen should be utilised to increase the greater

¹⁰⁵ Dukeminier and Sanders *Organ Transplantation: A Proposal for Routine Salvaging of Cadaver Organs* New England Journal of Medicine 279 (1968) 413.

¹⁰⁶ *Ibid* 413; Kennedy and Grubb *Medical Law: Text with Materials* (1994) 1165.

¹⁰⁷ Dennis et al 6.

functionality of the community. This includes the living tissue and organs that could be procured for transplant.

The only country that employed routine salvaging in organ procurement was France.¹⁰⁸ The Law of December 22 of 1976 provides that organs may be removed from a deceased person for therapeutic or scientific purposes where the deceased had not, during his / her lifetime, made known his / her objection¹⁰⁹ to such a removal.¹¹⁰ The 1976 Act further stated that cadaver organs could be removed without permission of the family if the person dies in a hospital approved by the Minister of Public Health¹¹¹ and, the *Decret* of the *Conseil d'Etat* did not provide a right of refusal¹¹² to relatives.¹¹³ The success of organ procurement legislation in France is due to strong public support for organ procurement.¹¹⁴ In an interview with health practitioners, Caplan reported that “consent rate of between 90 and 95 percent” are given by the public when consent is sought for organ procurement.

In South Africa, where explicit informed consent is the main requirement in any medical intervention, the constitutional validity of routine salvaging in terms of section 12(2)(b) of the Constitution is highly questionable. Section 12(2)(b) guarantees that every person has the right to bodily and psychological integrity, which includes the right to security in and control over their body. The effect of this right guarantee that there may be no medical intervention without consent on any patient for example unlawful human tissue and organs procurement, unless a limitation ground exist in terms of section 36¹¹⁵. The element of consent in routine salvaging required before procurement may commence is simple: no consent has to be present. In

¹⁰⁸ Kennedy 1165; Dennis et al 6 ; Dukeminier *Supplying Organs for Transplantation* Michigan Law Review 68 (1970) 811 as referred to by Kennedy at 1165.

¹⁰⁹ Any indication of an objection from either the patient or the next-of-kin must be supported by the necessary evidence and entered into a special register.

¹¹⁰ Article 2(i) of Law of December 22 of 1976.

¹¹¹ Dukeminier 811.

¹¹² Caplan at 1709 states that French doctors in practice still prefer to obtain consent from the next-of-kin of the deceased. These health practitioners “find it psychologically intolerable to remove tissue from a body without obtaining the permission of next-of-kin”.

¹¹³ Redmond-Cooper *Transplants Opting Out or In –The Implications* New Law Journal 134 (1984) 648.

¹¹⁴ Kennedy 1164.

practice, if legislation is promulgated similar to the French law of December 1976 providing firstly every citizen's organs and tissue after death will be subject to procurement and secondly, the family has no right to refuse procurement.

No right is absolute and may be legitimately limited if it is a law of general application that is reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom. To determine if a constitutionally protected right may be limited, the Court must apply a proportionality test in light of the five factors¹¹⁶ given in section 36. Even before the promulgation of the Final Constitution, the court in *Castell v De Greef*¹¹⁷ endorsed patient autonomy in favour of medical paternalism. The court made clear that prior to the commencement of any medical intervention, the patient has a fundamental right to decide whether to undergo the operation. The patient's right to bodily integrity and "autonomous moral agency" entitles the patient to refuse medical treatment, even if the patient's mind-set is regarded as grossly unreasonable in terms of medical best practice.

A general policy of routine salvaging was almost introduced with the promulgation of the Human Tissue Act¹¹⁸ in 1983. During the second discussion pertaining to the drafting of section 10¹¹⁹ of the then Human Tissue Bill, the *Volksraad* debated whether to introduce a general policy of routine salvaging. Some members called for the amendment of the draft section 10 to include the body of any deceased person may be routinely salvaged to be

¹¹⁵ The Limitation Clause.

¹¹⁶ The Court takes into account the relevant factors given in Section 36(1)(a) to (e) when considering the reasonableness and justifiability of a limitation. These are (1) the nature of the right; (2) the importance of the purpose of the limitation; (3) the nature and extent of the limitation; (4) the relation between the limitation and its purpose; and (5) less restrictive means to achieve the purpose. Chaskalson P in *S v Makwanyane* 1995 (3) SA 391 mentioned that a general limitation clause "does not translate into a standard limitation test". The application of the test depends upon the circumstances of each case.

¹¹⁷ 1994(4) SA 408(C) at 420 I/J to 421C/D – D/E.

¹¹⁸ Act 65 of 1983.

¹¹⁹ Section 10 is an extraordinary provision that makes it possible to dispose of a body of a destitute person for medical research purposes, without explicit consent from the destitute or the next-of-kin of the deceased destitute.

utilised for any of the purposes endeavoured in the Human Tissue Bill (Act).¹²⁰ This recommendation was refused because the general public would find such a policy “aanstootlik”. The *Volksraad*, in its reasoning suggested the public would never accept any infringement of the right of bodily disposal and the notion of a general policy of routine salvaging was rejected. However, section 10 was promulgated as an extraordinary provision. Van Der Walt¹²¹ remarked the following regarding the rejection of routine salvaging:

“So ‘n inkorting is dus vir die meeste mense onaanvaarbaar: die meeste mense sal (volgens hulle verkose verteenwoordigers in die volksraad) verkies dat daar op die ‘gebruiklike wyse’ oor hulle dooie liggame beskik word in die gevalle waar hulle nie self uitdruklik anders gereël het nie. Die feit dat hierdie keuse aan die kieserspubliek toegeskryf word, en dat dit deur die wetgewer gerespekteer word, beklemtoon die buitengewone behandeling wat die armlastige persoon via artikel 10 te beurt te val. Slegs in die geval van die armslastige persoon, wat ook as ‘n sosiaal verstopene gesien kan word, is die wetgewer bereid om die status quo om te keer, in dié sin dat daar op ‘n klaarblyklik ongewone wyse oor sy liggaam beskik kan word, afgesien van sy onuitgesproke wilsbeskikking in die verband.”

In conclusion, the regime of routine salvaging is based upon a socialistic point of view that the purpose of every citizen should serve the greater community. In organ procurement, this translates into the notion that the state gains the exclusive rights of ownership over the body of the deceased citizen; and the state may procure any part of that body including the tissue and organs for any purpose; and finally consent is irrelevant.

4. The Doctrine of Presumed Consent

The primary reason for reforming current organ procurement legislation is to improve the current level of scarcity of organ donors. Whilst gathering research material for this dissertation, almost every article starts by informing

¹²⁰ *Hansard* 1983 (13) 4 May col 6500 – 6501; 6523 – 6524; 6534; 6559 – 6560.

the reader of the scarcity of available human tissue and organs, the low level of donor willingness and the long transplant waiting lists. The scarcity does not only effect organ procurement, but it also creates competition among recipient candidates who question the equitability of organ allocation procedures and guidelines.¹²² Many proposals to increasing organ procurement have been introduced, however more governments are considering the doctrine of presumed consent as a possible solution.

Stated throughout this dissertation, the basic and most significant requirement before any medical intervention may take place is consent. The *onus* rests upon health practitioners to obtain consent in transplant cases. In practice, this task is usually delegated to the hospital nursing staff who are not necessarily competent to inform patients and their families correctly about all the relevant facts of organ donation and who do not carry the burden of a duty of disclosure as health practitioners do. Based upon the information received most patients (or the next-of-kin of the deceased person) do not consent to organ procurement.¹²³ To avoid the problems associated obtaining informed consent, an increasing number of governments have since the 1980's reformed transplantation laws to organ procurement systems based upon a mandatory procurement policy. The effects of these policies have met mixed results¹²⁴.

¹²¹ *Artikel 10 van die Wet op Menslike Weefsel 65 van 1983 in 'n Juridiese, Etiese en Filosofiese Perspektief* Tydskrif vir die Suid Afrikaanse Reg 2 (1984) 154 at 157.

¹²² New York State Task Force *Life and the Law, Transplantation in New York: The Procurement and Distribution of Organs and Tissues* (1988) as referred to by Banks *Legal and Ethical Safeguards: Protection of Society's Most Vulnerable Participants in a Commercialised Organ Transplantation System* American Journal of Law and Medicine 21 (1995) 53.

¹²³ The question is whether this manner of supplying information conforms to the principles of the doctrine of informed consent? *Prima facie* the question can be answer in the negative. This will be explored in detail later in this chapter.

¹²⁴ The U.S. National Kidney Foundation raised the objection that it was "relatively coercive compared to the more classical freedom of choice that characterizes our way of life". See further Butler *The Law of Human Organ Procurement: A Modest Proposal* Journal of Contemporary Health Law and Policy 1(1985) 195; Cwiek *Presumed Consent as a Solution to the Organ Shortfall Problem* Journal of the American Medical Association 4 (1984) 81. The most raised objection was the concern that presumed consent would deprive individuals of the exercise of the virtue of generosity. Mehlman *Presumed Consent to Organ Donation: A Reevaluation* Health Matrix 1 (1991) 31.

4.1 The Application of Transplantation Legislation containing the Doctrine of Presumed Consent

4.1.1 General Aspects of the Doctrine of Presumed Consent

The doctrine of presumed consent as an organ procurement system is based upon a two-legged approach: legal and ethical. The latter approach establishes a number of guidelines, which are used in moral decision-making processes¹²⁵, whereas the former establishes the regulatory framework in which the process of transplantation should operate. Both play an important role in the implementation to increase organ procurement and society's acceptance of this procurement system.

South Africa provides for an "opting in" system whereby persons who want to become organ donors either during their lifetime or after death, must in writing or an oral statement in the presence of at least two competent witnesses, consent to the procurement of tissue and organs prior to performing the transplant operation. The effect of the doctrine of presumed consent provides for a so-called "opting out" system to organ donation. This procurement system functions exactly opposite to procurement systems requiring explicit consent: a donor is required to "opt in", in other words, must consent prior to procurement of organs, the "opting out" system requires persons who wishes not to become donors after death to make their objection publicly known. Without sufficient evidence of an objection, it is presumed that the deceased granted permission to the removal of human tissue and organs.

The principles of transplantation law are a recent development in the South African law as well as foreign jurisdictions. The regulation of organ procurement and allocation systems can only occur through statute. Most presumed consent statutes originated in legislation passed to facilitate the

¹²⁵ Lamb *Ethical Aspects of Different Types of Living Organ Donation* that forms part of *Living Organ Donation in the Nineties: European Medico-Legal Perspectives* (1995) 43. Lamb states that "[t]ransplantation ethics has been mainly presented in terms of the utilitarian benefit maximising effects of therapy countered with notions of respects for the autonomy and dignity of the donor, family wishes and respect for religious beliefs." Lamb further argues that the general principles of moral decision-making can be divided into the principles of beneficence and non-maleficence; which "involve an obligation to help others and an obligation not to harm others"; the principle of justice, which involves an obligation to deal fairly with competing claims; and the principle of respect for autonomy and self-determination, with the related doctrine of informed consent.

supply of unclaimed corpses to medical schools for anatomical research in the nineteenth century. These statutes authorised the use of unclaimed corpses without consent where no relatives claimed the body of the deceased person back. The change in organ procurement legislation started in 1981 with a variety of presumed consent and the principles of required response and required request statutes.¹²⁶ The application of the degrees of presumed consent depends on geographical position of the country. The trend depicts that most continental European countries have some form of presumed consent where North America governments are slow to adopt reforms to current explicit consent. The position is mixed in South America¹²⁷, while Singapore is the only country in Asia that has a restricted presumed consent statute.¹²⁸ In Africa, only Tunisia favours the doctrine of presumed consent.¹²⁹ All organ procurement laws featuring presumed consent are unique, however common features or elements can be identified.¹³⁰

4.1.2 Identifying Presumed Consent

The doctrine of presumed consent is a statutory created organ procurement system. A simplified version of presumed consent legislation would lead:

*All competent persons of a certain age are regarded as organ donors upon being deceased; unless such individual who wishes to object to organ procurement must raise an objection. Such objection must be registered with the recognised authority and any failure to make such objection known, would be considered as an implicit statement of consent to the procurement of tissue and organs; subject to the limited right of refusal of the next-of-kin.*¹³¹

¹²⁶ Stuart et al *Brain Death Laws and Patterns of Consent to Remove Organs for Transplantation from Cadavers in the United States and 28 other Countries* Transplantation 31(1981) 238 state that thirteen out of twenty-eight countries surveyed outside the United States adopted some form of presumed consent policy.

¹²⁷ Price 86.

¹²⁸ See further <http://www.thegift.org.sg>

¹²⁹ Price 87.

¹³⁰ Other factors, which are unique to certain presumed consent laws, are for example the hard and soft application of presumed consent and the object of procurement. The latter refers presumed consent legislation that is only applicable to certain organs for example corneas, against unrestricted presumed consent regimes.

¹³¹ Caplan *Organ Procurement: It's Not in the Cards* Hasting Centre Report 14 (1984) 9 (5); Dennis et al 6; Dukeminier *Supplying Organs for Transplantation* 68 (1970) Michigan Law Review 811; Kennedy 1162; Price 83 – 85; Mackey and Kjerulf 50; Taupitz 151 – 153, 546 – 550.

Upon closer reflection of the definition, various distinct elements can be identified. These elements are the following:

- Element One: The Donor (all competent persons of a certain age are regarded as organ donors)
- Element Two: Consent (who wishes to object to organ procurement must raise an objection and implicit statement of consent)
- Element Three: Capacity (all competent persons)
- Element Four: The Next-of-kin (subject to the limited right of refusal of the next-of-kin)
- Element Five: The Recipient

Each element will be evaluated later in the chapter.

4.1.3 Routine Salvaging versus Presumed Consent

Presumed consent should be distinguished from routine salvaging, which permits a government the right to procure every citizen's tissue regardless of the person or his / her next-of-kin's voluntariness to organ donation. The initial outcome of the presumed consent and routine salvaging are the same; every person¹³² of a certain age is upon death regarded as organ donors.

On closer examination, presumed consent permits a person who has an objection, to "opt out" from organ procurement after death, where routine salvaging does not provide for a right of refusal. The philosophical approach tend to be similar, although public support would favour presumed consent rather than routine salvaging, because any policy of routine salvaging would be inconsistent with so-called "liberal individualism".¹³³

¹³² These persons are usually only citizens of that country, however an exception is made to foreigners who has permanent residency in the country concerned for example Belgium. In Belgium, the Law on the Removal and Transplantation of Organs of 13 June 1986 permits in section 10 that organs and tissue may be removed for therapeutic transplantation only from the body of any person recorded in the register of the population or any person recorded for more than six months in the aliens registers, unless it is established that an objection to such removal has been expressed.

¹³³ In my research on the doctrine of presumed consent and routine salvaging, I have come across many authors who misinterpret presumed consent or confused it with routine salvaging. For an example see further Roberts *Presumed Consent for Organ Procurement – Does It Have a Future in the U.S.? (Ethical-Legal Perspectives)* Journal of Neuroscience Nursing 35 (2003) 107(7).

4.1.4 The Degrees of Presumed Consent

If a person decides to object to the procurement of his / her tissue and organs for transplant purposes, that person must during his / her lifetime make the objection known. Various degrees in the application of the doctrine of presumed consent are applied. Presumed consent legislation can be considered as either strong (as known as hard) or weak (also referred to as soft).¹³⁴ A strong application of presumed consent declares that upon death a person who did not register an objection to organ donation, are considered to have consented to the procurement of their tissue and organs for transplant and the organs are procured without any next-of-kin interference. Any right of refusal to the proposed procurement that the next-of-kin might have had is disregarded. A good example of a country that applies a strong presumed consent policy is Austria.¹³⁵

In terms of the soft application of the doctrine of presumed consent, a higher emphasis is placed upon the role of the next-of-kin of the deceased. Although, the *onus* is still placed upon the individual to register his / her objection, the next-of-kin is afforded a right to override the decision of the deceased family member¹³⁶. The primary difference between the hard and soft application is the former require the person (or the next-of-kin) who wants to become a donor to reflect “a positive expression of willingness “ where the latter merely requires that donation is permitted in the “absence if any objection” by the deceased (or the next-of-kin).¹³⁷

4.2 The Elements of Presumed Consent

The fundamental element requires every organ procurement system requires is to procure human tissue or organs from a donor, who is either alive or deceased. The first element analyses the role of the donor in the context of the doctrine of presumed consent.

¹³⁴ Mackey and Kjerulf 52; Price 85 - 86, Blackbeard 55.

¹³⁵ Kopetzki *Landesbericht Österreich* which forms part of Taupitz *Zivilrechtliche Regelungen zur Absicherung der Patientent Automatic am Ende des Lebens* (2000) 1-52.

¹³⁶ In countries using organ procurement systems based upon the doctrine of presumed consent, health practitioners are still hesitant to proceed without asking the family of the deceased, even though consent is presumed.

¹³⁷ Price 85.

The basis of any medical treatment or intervention is consent must be obtained from the patient prior to the intervention for the medical procedure to be lawful. The same counts for organ procurement. Whether the patient consents to the medical procedure verbally or in writing is irrelevant, as long as proof of consent exists. The second element is consent: the donor must consent to the procurement of his / her organs and the donor should have made it publicly known. In this element it is assessed whether consent is an actual requirement in the doctrine of presumed consent and if affirmative, what is the nature is this type of consent?

The third element depicts that the donor should have had the capacity to consent to the procurement operation. This denotes that at the time the donor consented to the donation of organs and tissue, that donor should have appreciated the effects of his / her actions and should have reconciled himself / herself with that actions. The primary question is whether minors and mentally disabled should be excluded from the donor pool? If minors are included, at which age should they be regarded as donors?

Statutes regulating organ procurement refer to the object of removal as human organs and tissue. Certain countries that employ presumed consent legislation restrict procurement only to certain bodily organs for example section 8641 of Title 20 of the Pennsylvania Consolidated Statutes allows the removal of corneas by presuming that a deceased person is a donor, provided that certain conditions are met. Other restrictions on presumed consent procurement legislation regulates that certain persons are automatically excluded due to their belief. In Singapore, which has a large Muslim minority group, members of this faith are prohibited from donating organs and are excluded from the opting out system.¹³⁸ What should the South African position be regarding minority religious groups such as Islamic organ donation

¹³⁸ Part two of the Human Organ Transplant Act 1987, however Muslims can exercise the option of opting in to donate their kidneys.

restrictions? The fourth element for discussion is the object for transplantation i.e. the human tissue relating to the donor thereof.

The soft application of the doctrine of presumed consent grants the next-of-kin of the deceased a right of refusal. The Human Tissue Act regulates the situation where in the absence of consent given by the donor personally, another person such as a spouse or major child may after death permit organ procurement on behalf of that deceased person. The fifth element analyses the identity of the next-of-kin and their role in a “soft” presumed consent regime.

Finally, to complete the organ transplant process, a recipient¹³⁹ must receive the procured tissue or organ. The sixth element assesses fair and equitable organ allocation procedures, which is discussed in Chapter Three.

4.2.1 The First Element: The Donor

(a) Requirement One: the donor must be deceased

The legal position of the donor in any organ procurement system depends primarily upon the manner in which consent can be obtained. In countries where explicit consent systems are applied, it is irrelevant whether the donor is alive or already deceased. In either case, the donor must provide informed consent before any procurement of tissue.¹⁴⁰

Countries that apply a presumed consent organ procurement system must distinguish between living and deceased donor. This system allows the government to remove tissue for all persons *upon death* who did not raise an objection during their lifetime against such removal. In other words, it is presumed that consent have been given, unless proven to the contrary. A living person cannot be subjected to this same provision, as it would infringe

¹⁴⁰ The Human Tissue Act and the National Health Act, as is the case with foreign legislation regulating organ donation, provide for certain persons to provide consent if the “donor” is already deceased. See the discussion of the next-of-kin here under.

upon his / her right to self-determination, freedom of movement, freedom of religion, privacy, equality, human dignity, freedom and security; and especially the right to life. In practice, removing the tissue from a living person would amount to murder and assault with the intention to do grievous bodily harm. Any governmental action initialising the mass removal of tissue from living donors would resemble the genocide committed by the Nazis in World War two.

The doctrine of presumed consent can only be applied when the donor is already deceased. In Chapter One¹⁴¹, it was mentioned that the National Health Act classifies death as brain death in section 1. A health practitioner must prior to the removal of tissue and organs determine whether the donor has died. In the interest of the patient, it must be assessed by a number of health practitioners that whether the donor is deceased. The Human Tissue Act stated that “the death of the person concerned shall be established by at least *two medical practitioners*¹⁴² one of whom shall have been practising as a medical practitioner for at least five years after the date on which he was registered as a medical practitioner, and none of those medical practitioners shall transplant tissue removed from the body of that person into the body of a living person or take part in such a transplantation: Provided that where the tissue concerned is eye tissue, the death of the person from whose body the tissue is removed shall be deemed to have been so established by the issuing of a certificate of death in terms of section 24 of the Births, Marriages and Deaths Registration Act, 1963 (Act 81 of 1963), by a medical practitioner in respect of that person.”¹⁴³ The National Health Act does not provide for a similar provision, however, perhaps this should have been included.

(b) Requirement Two: the donor must be clearly identifiable yet anonymous

Even though a person passes away who did not register an objection, the hospital that performs the transplant operation must still obtain and record the

¹⁴² Own emphasis.

¹⁴³ Section 7.

identity of the deceased. The information should be recorded on the death certificate and sent to a central donor information centre for safekeeping.

The identity of the donor should be held anonymous to the general public including the recipient(s) of the tissue and organs for the protection of the donor and next-of-kin. The procurement of the deceased tissue and organs might have various psychological effects upon the next-of-kin, though no objection to the removal was raised.

The Human Tissue Act granted in section 33 a prohibition against the publication to any other person of any fact whereby the identity of the donor or the body of the deceased person or of any tissue or the donor of tissue removed from the body of a living person, unless consent was given in writing by the deceased person prior to his / her death or after his / her death by the person who consented on behalf of the deceased person or by the district surgeon who donated the tissue. This section contains a similar provision for the recipient. Any unlawful disclosure of identity is a punishable offence in terms of section 34(k) and will be liable on conviction to a fine not exceeding R 2000 to imprisonment for a period not exceeding one year or both.

According to Strauss¹⁴⁴ the inclusion of section 33 was due to the controversial issue whether the donor and the recipient should be protected against publicity. Arguments in favour of protection suggested the possibility of extortion on the part of donors or of the next-of-kin. It was further suggested that this could create public fear and deter potential donors. Others argued that personal freedom of an individual should be protected.

The National Health Act also contains a confidentiality clause. Section 14(1) provides all information concerning a user, including information relating to his/her health status, treatment or stay in a health establishment is confidential. Subsection (2) states subject to section 15, no person may disclose any information contemplated in subsection (1) unless the user

¹⁴⁴ *Doctor, Patient and the Law* (1991) 73.

consents to that disclosure in writing; a court order or any law requires that disclosure or non-disclosure of the information represents a serious threat to public health.

The general policy should be that no information disclosed to save the donor, his/her next-of-kin and the recipient any intrusions later¹⁴⁵. A similar provision is necessitated in drafting of legislation that incorporates the doctrine of presumed consent.

(c) Requirement Three: the donor must be a South African citizen or permanent resident residing in the Republic more than six months

Transplantation legislation requiring either explicit or presumed consent, generally provide that persons who would like to donate their organs and tissue, should provide explicit consent or should not have registered an objection to organ donation during their lifetime. In terms of the doctrine of presumed consent, the analysis of the example provision given above, specify only that all *persons* are to be included in the deceased donor pool. The term *person* according to the Collins Concise Dictionary means, “[a]n individual human being, the body of a human being and a human being...recognised in law as having certain right and obligations”. The latter definition is recognised within South African law.

It is logical that all adult nationals of a specified country would be included. It should be determined whether the organs of foreign nationals who die within the borders of the Republic can be procured. If the answer is affirmative, at which time period of their being present in South Africa, can foreign nationals be subject to organ procurement? The answer to this question lays in the interpretation of section 62(1)(a) which only refers to “a person who is competent to make a will may in the will, in a document signed by him or her and at least two competent witness; or in an oral statement made in the presence of at least two competent witnesses donate his or her body or any specified tissue to be used after his or her death, or give consent to the post

mortem examination of his or her body, for any purpose provided for in this Act.” From the ordinary meaning and the lack of case law stating the negative, it can be deduced that foreigners in South Africa may donate their organs if they comply with section 62.¹⁴⁶

(d) Requirement Four: the donor must have the necessary capacity

Only a person who has the necessary degree of competence would be able to give valid consent to medical treatment including the removal of organs and tissue.¹⁴⁷ For a patient to have the necessary capacity, it is required that the patient must have some form of comprehension of the scope, nature and effects of his / her actions and the patient must not be hindered in the execution of that action by of a mental illness or stupefaction^{148, 149}. In the case of medical treatment, if the patient is a sane and sober adult, the patient will have the capacity to provide legally recognised consent.

Generally, patients who cannot give legally recognised consent due to their lack of capacity are minors and the mentally ill.

(i) Minor donors

The general principles of the medical jurisprudence indicate that minors who have attained the age of fourteen years are legally competent to permit medical treatment of themselves and their children.¹⁵⁰ Minors who have reached the age of eighteen years may consent to undergo medical operations upon themselves and their children.¹⁵¹ In terms of both the Human

¹⁴⁵ Exceptions to the general rule would be allowed if reasonable circumstances are present and should be regulated by the provisions of the Promotion to Access to Information Act 2 of 2000.

¹⁴⁶ Foreigners are in terms of the National Health Act inexplicitly provides in section 61(3) an organ may not be transplanted into a person who is not a South African citizen or a permanent resident of the Republic without the Minister's authorisation in writing.

¹⁴⁷ Strauss *Toestemming tot Benadeling as Verweer in die Strafbreg en die Deliktereg* (1961) at 85 “Hieruit volg alleen wilsvermoende mense kan toestem tot benadeling. Is iemand wilsonvermoend as hy verstandelik voldoende ontwikkel is om die aard en gevolge van sy handeling te besef en hy in die uitoefening van hierdie verstandelike vermoens nie deur geestekwale of beneweling belemmer word nie.”

¹⁴⁸ For example a state of unconsciousness, intoxication, delirium, trance, shock or coma.

¹⁴⁹ Strauss *Toestemming* 86.

¹⁵⁰ Van Oosten *Medical Law: South Africa* (1996) par 116. The implications of *Estherhuizen v Administrator, Transvaal* 1957 (3) SA 710 and *G v Superintendent Groote Schuur Hospital* 1993(2) SA 255 (C) are minors under the age of fourteen need the their parents or guardians consent to undergo medical treatment and operations.

¹⁵¹ *Ibid.*

Tissue Act¹⁵² and the National Health Act¹⁵³ the age requirement to give explicit consent to *post mortem* removal of organs and tissue is fourteen years. In cases where a minor cannot consent to medical treatment, the permission of the parents or guardian is required.¹⁵⁴

In terms of the doctrine of presumed consent, the question is at what age can a minor qualify as a donor? In other words, should a fourteen year old minor be included in the general donor pool where the doctrine of presumed consent is applied? The answer to this question depends whether it is regarded that a minor can make an informed decision about organ transplantation.¹⁵⁵

(ii) Mentally ill patients

The second leg of requirement four, assesses the question whether mentally ill patients can be presumed to have consented to organ procurement? To determine the capacity of a patient is a question of fact: the pendulum between sanity and insanity all depends on the degree of mental illness.¹⁵⁶ The mental capacity of each patient would have to be determined on a case-to-case basis in the light of the circumstances and it might be, therefore difficult to determine whether the patient has the sufficient intellectual capacity to render him / her insane.¹⁵⁷ If the patient's mental state is of such a degree that it, on the preponderance of probabilities negatively influenced his / her decision-making capabilities, the patient will be regarded as incompetent and any action taken by him / her would be declared null and void *ab inintio*.

The Mental Health Act¹⁵⁸ deals in section 60A with consent to medical treatment of patients who, on account of their mental illness, are not capable

¹⁵² Section 2(1).

¹⁵³ Section 62.

¹⁵⁴ Other persons who are also allowed to give their permission for the minor to undergo medical treatment in cases where the parents or guardian have delegated their consent giving powers.

¹⁵⁵ In Belgium, organs and tissue may not be removed from a living donor unless the donor has reached eighteen years of age.

¹⁵⁶ See further *Estate Rehne v Rehne* 1930 OPD 80 at 89.

¹⁵⁷ In *Pienaar v Pienaar's Curator* 1930 OPD 171 at 174 the court stated "The mere fact that such a person has been declared insane or incapable of managing his affairs, and that a curator is appointed to such a person, does not deprive him of the right of administering his own property and entering into contracts and other legal dispositions to the extent to which he may *de facto* be capable, mentally and physically, of doing so. Such mental or physical capacity may vary from day to day, but at all times it remains a question of fact."

of consenting to medical treatment. This section provides that a curator¹⁵⁹ or the patient's spouse, parent, major child, brother or sister may consent to the treatment on behalf of a patient who is incompetent.¹⁶⁰ This order of precedence must be followed unless consent is withheld unreasonably or the intervention is urgent and the person having precedence cannot, with due regard to the urgency of the intervention be found.¹⁶¹ In a case such as this, the person following in precedence may consent. If, however, one of these persons cannot after reasonable inquiry be found and the superintendent is of the opinion "that the life of the patient is being endangered or that his health is being seriously threatened by his condition" and that the relevant intervention is indicated, the superintendent may consent to it.¹⁶²

A patient may be received and treated at an institution on a voluntary basis, or in terms of a reception order issued by a magistrate, or, temporarily and as a matter of urgency, on the authority of the superintendent of the institution concerned. A distinction should be made between voluntary patients and involuntary patients. As a general rule, a voluntary patient who is considered to be competent to enter into a legal agreement such as an agreement to undergo medical treatment, must be also be considered competent to refuse treatment.¹⁶³ Involuntary patients on the other hand, may not be considered competent to refuse or consent to treatment.

Both section 2(1) of the Human Tissue Act and section 62 of the National Health Act confirm that a person who is competent to make a will may also give consent to donate his / her organs and tissue, thus stating if a person had the necessary capacity during his / her lifetime to handle his / her own affairs, that person will be included in the presumed consent donor pool, if the necessary requirements are met. If the person was or experienced stages in his / her life, where it was *prima facie* proven that the person was deemed not

¹⁵⁸ Act 18 of 1973. See further the Mental Health Care Act 17 of 2002.

¹⁵⁹ The court may appoint a curator to the patient's person where it appears that decisions as to the care, custody and welfare or consent to medical treatment may have to be made. The court may appoint a curator to the patient's person either generally or for a specified purpose.

¹⁶⁰ Section 60A(1)(a).

¹⁶¹ Section 60A(1)(b).

¹⁶² Section 60A(2). The medical practitioner may also raise the defence of necessity whence performing medical treatment on a patient incapable of providing consent in an emergency situation.

¹⁶³ Strauss *Toestemming* 3; Allan and Allan 726; Fick and Els *Legal Status of the Mentally Disabled Person in South African Law* Medicine and Law (1995) 601.

to possess the necessary competency required for a normal or average person, this person can hardly be expected to be included in the donor pool.

(e) Requirement Five: the donor must not have registered an objection

This requirement is self-evident.¹⁶⁴ From a practical point of view, it requires that government should establish the necessary infrastructure to process the registration of objections.

(f) Requirement Six: the donor must nominate a donee for a specified purpose

This requirement refers to sections 62(1) (b) and (c) of the National Health Act that requires that for the donation to be legally recognised, the donor must nominate an institution or a person contemplated in section 63. If no donee has been nominated, the donation is null and void.

4.2.2 The Second Element: Consent

(a) Requirement One: the living donor must consent to organ procurement or in absence of a registered objection; it is presumed that the deceased consented to organ procurement

The relationship between the health practitioner and a patient is generally based upon the principles of the law of obligations (the law of contract and the law of delict). This relationship is usually regulated by the private law although it can cross various legal areas for example criminal law.¹⁶⁵ The legal principles of transplantation law provide the relationship between the parties is based rather upon contract rather than delict, although the latter usually comes into play when the liability pertaining to a breach of a duty of care and negligence of the health practitioner is determined.

The basis for any medical intervention is the patient must give informed consent to the proposed intervention. In the absence of legally recognised consent by the patient or a representative acting on behalf of the patient, the

¹⁶⁴ See further the discussion under paragraph 4.2.2.

¹⁶⁵ Van Oosten *Medical Law: South Africa* (1996) par 61.

medical intervention will be unlawful.¹⁶⁶ Generally, it is perceived that the patient who gives consent must know and appreciate the end effect of the action he / she is consenting to. In order for the patient to gain the required knowledge and appreciation, a duty of disclosure rests upon the health practitioner to inform the patient about the general nature, scope, consequences, risks, dangers, complications, benefits and disadvantages of the proposed intervention in simplified terms.¹⁶⁷ The nature of this form of consent is called the doctrine of informed consent. The reason for requiring informed consent is twofold:

- To ensure the patient's right to self-determination and freedom of choice as entrenched in section 12(2)(b) of the Constitution; and
- To encourage rational decision-making by ensuring that the patient consider the advantages and disadvantages of the proposed intervention in order to make an enlightened choice.

The doctrine of informed consent has since the ousting of medical paternalism in favour of patient autonomy in *Castell v De Greef*¹⁶⁸ been accepted and applied to all forms of medical operations. However, on closer analysis of the requirements of informed consent and transplantation law, it seems that a discrepancy exists. The National Health Act, and its predecessor the Human Tissue Act, only requires that the donor prior to organ procurement and allocation should give written or oral consent. No direct reference is made in the relevant sections that the donor should provide *informed* consent. If this is indeed the case, should it be regarded that section 55 and 62 of the National Health Act only requires a "general" form of consent must be given? In other words, can it be argued that, although in the light of patient autonomy and the doctrine of informed consent; consent in terms of section 55 and 62 requires a lower level of consent than informed consent? The consequences of this statement show that various levels of consent can exist for example general consent, informed consent and possibly, presuming informed consent?

¹⁶⁶ Van Oosten *Medical Law: South Africa* par 63.

¹⁶⁷ *Ibid* par 69.

¹⁶⁸ 1994 (4) SA 408 (C).

(i) The General Nature of Consent and Informed Consent

The nature of consent as a ground of justification has been analysed since Roman times.¹⁶⁹ The evaluation of the term “consent” indicates that consent is the combination of a subjective and objective process. The process commences subjectively whereby the person who is required to provide consent for example a patient must possess mental capacity to receive information. The patient is required in his / her mind to receive information and process the information in his / her mind to the extent that the capacity of that individual’s mind allows it.¹⁷⁰ Once processed, the patient must appreciate the information by objectively making his / her intention publicly known.¹⁷¹

If a patient merely acquires and appreciates information, but do not publicly make his / her intention known to the world, that subjective knowledge would not amount to consent, even though that patient has complete understanding and will regarding the topic. It is required that the patient actively makes his / her will known for example by signing a consent form.¹⁷² The conduct of the patient in the light of the circumstances will indicate whether consent has been given.¹⁷³ Consent can be given either expressly (for example by words), or tacitly (for example by conduct). Mere submission is not regarded as consent.¹⁷⁴ Whichever manner consent is given is irrelevant, what is paramount is the conduct of the person. Strauss and Strydom remark “*Hoe ernstiger die aard van die geneeskundige ingryping is, hoe meer beslis behoort die geneeskundige egter ter wille van sy eie beskerming seker te maak dat die pasiënt se uitdruklike toestemming verkry word. Woorde in*

¹⁶⁹ Strauss *Toestemming* 2.

¹⁷⁰ Strauss and Strydom *Suid-Afrikaanse Geneeskundige Reg* (1967) at 187 “*Toestemming, in dieselfde verband gebesig, is ‘n wilsdaad waaruit dié geestesinstelling van begeerte tot, goedkeuring of versoening met, die besondere toedrag van sake te kenne gegee word; dus die manifestasie van die wilsinhoud*”.

¹⁷¹ Strauss *Toestemming* 32.

¹⁷² *Esterhuizen v Administrator, Transvaal* 1957 (3) SA 710 at 720.

¹⁷³ Strauss *Toestemming* at 33 “*Hoewel die voorstanders van die wilsrigtingsteorie reg is vir sover die prysgawe van ‘n belang ‘rein innerlich’ geskied, kan die reg tog nie kennis neem van ‘n geestesinstelling wat sigself nie na buite kenbaar maak nie. Daarom het ek toestemming ...as die uitwendige manifestasie van die wil van die benadeelde.*”; Strauss and Strydom 187; Van der Merwe and Olivier *Die Onregmatige Daad in die Suid-Afrikaanse Reg* (1976) 90.

¹⁷⁴ *R v Taylor* 1927 CPD 16; *R v Swiggelaar* 1950 1 PH H 61 (A) at 110 – 111 “The authorities are clear upon the point that though consent of a woman may be gathered from her conduct, apart from her words, it is fallacious to take the absence of resistance as *per se* proof of consent. Submission by itself is no grant of consent, and if a man so intimidates a woman as to induce her to abandon resistance and submit to intercourse to which she is unwilling, he commits the crime of rape. All the circumstances must be taken into account to determine whether passivity is proof of implied consent or whether it is merely the abandonment of outward resistance which the woman, while persisting in her objection to intercourse, is afraid to display or realises is useless.”

*sigself is nie altyd 'n ware refleskie van die gedagte-inhoud van die spreker nie. Nie selfde nie, wek die mens 'n skyn na buite waaragter hy sy ware gevoelens verberg. Waar die pasiënt deur sy gedrag – woorde of andersoortige gedrag – die skyn van gewilligheid of insiklikheid tot, of versoening met, die geneeskundige operasie te kenne gee, maar inderdaad agter die skyn 'n reservatio mentalis (menslike geestelike voorbehoud) verberg, moet die skynbare toestemming as ware toestemming geld. Prakties kom dit neer dat 'n pasiënt wat volgensse alle redelike afleidings sy insiklikheid tot die operasie laat blyk het, nie later kan omdraai en sê: 'Ek was nie 'eintlik' gewillig om die operasie te ondergaan nie.'*¹⁷⁵ Thus, if this concept is applied to transplantation law and specifically organ procurement, the question, which can be posed: can it be presumed that a donor consented to the removal of organs and tissue, merely by his or her conduct and in the light of the surrounding circumstances? The answer to this question will be assessed later in this chapter, but *prima facie* the answer seems to be affirmative.

The South African law recognises consent as a ground of justification that excludes the unlawfulness or wrongfulness element of a crime¹⁷⁶ or delict¹⁷⁷. This means that a defendant or accused is not liable where the injured person has consented to injury or the risk of the injury. Consent is based upon the maxim *volenti non fit injuria* (*volenti*) which indicates a willing person is not wrong or he who consents cannot be injured.¹⁷⁸ Two forms of *volenti* exists namely consent to injury and consent to the risk of injury.¹⁷⁹ Consent to injury means that the person who gives consent, gives consent relating to a specific harm, where consent to the risk of injury, the person consent to the risk of harm caused by the defendant' conduct.

It is generally accepted that for consent to qualify as a ground of justification the following is required:

¹⁷⁵ 188.

¹⁷⁶ Snyman 117; Milton and Burchell *Principles of Criminal Law* (1997) 33; Van Oosten *The Doctrine of Informed Consent in Medical Law* (1991) 15.

¹⁷⁷ Boberg *Delict* 44; Neethling, Potgieter and Visser 90.

¹⁷⁸ *Digesta* 47 10 1 5; De Groot 3 35 8; Voet 47 10 4; Strauss *Toestemming* 57.

¹⁷⁹ Van der Merwe and Olivier 89; Neethling; Potgieter and Visser 90.

- Consent should not be *contra bonos mores*;
- The consenting party should have the necessary capacity to give consent;
- Consent must be given free and voluntary;
- The consenting party must have consented to the harm or assuming the risk;
- Consent must be clear and unequivocal;
- The consenting action must precede the conduct in question;
- The conduct to which consent was given must exceed the limits of the justification ground;
- The consenting party must have had knowledge and been aware of the nature and extent of the harm or risk; and
- The consenting party must have appreciated and understood the nature and extent of the harm or risk.

The latter two requirements focus on the doctrine of informed consent. For a patient to comply with the doctrine of informed consent, a duty of disclosure rests on the health practitioner to supply general and further requested information to ensure that the patient makes an informed decision about the intervention. *Van Oosten* suggests “[t]he informed consent requisite...finds its application almost exclusively in those situations where the knowledge and appreciation requirements of effective consent will not be fulfilled unless the consenting parties is furnished with appropriate information. That will particularly be the case in professional transactions where the consenting party is a layman and the party acting upon consent an expert and the relationship between them, in this sense, one of inequality. Applied to the doctor-patient situation, information furnished by the doctor as an expert to the patient as a layman serves the purpose of providing the patient with sufficient knowledge and appreciation of the harm or risks to enable him to reach a decision on whether to grant or withhold consent to medical intervention.”¹⁸⁰ The legal effect of the defence of consent in medical jurisprudence is indicative of the fact that, in the absence of understanding,

¹⁸⁰ Van Oosten *The Doctrine of Informed Consent in Medical Law* (1991) 25.

knowledge and appreciation of the risks and dangers related to the treatment, real consent cannot be present.

(1) “Actual” Consent in Medical Jurisprudence

Analysis of case law¹⁸¹ pertaining to consent as a defence in the medical law show *inter alia* that a patient has a right to refuse treatment and to disclosure of the nature and consequences of the proposed treatment. The health practitioner has a duty of disclosure to provide the patient with a general idea of the serious or dangerous risks of the proposed treatment and to procure consent from the patient. Based upon the information provided by the health practitioner, the patient is enabled to make an enlightened decision. Without the presence of information, knowledge and understanding of these dangerous risks of the treatment prior to the patient giving consent, it is accepted that actual consent is not present.

The consent given by the patient is faulty and void, because the patient did not possess the necessary information or understanding or both, to comply with the requirements of informed consent. In a practical situation, if a patient submits himself / herself to a medical treatment, it can be accepted that informed consent is present.¹⁸² Thus, the lowest level of consent that can be given in the area of medical law is informed consent.¹⁸³ “Mere” consent, which can also be defined, as “mere” submission is not equal to informed consent.

Both the Human Tissue Act and the National Health Act only refer to the expression “consent” which must be provided by the donor. Section 2(1) of the Human Tissue Act provided “[a]ny person who is competent to make a will may in his will, or in a document signed by him and at least two competent witnesses, or in an oral statement made in the presence of at least two

¹⁸¹ *Ibid* 33 – 53.

¹⁸² Strauss *Toestemming* at 33 –34 “*In die Suid-Afrikaanse regspraak het die Engelse beslissings weerklank gevind. Ook by ons word tussen onderwerping en toestemming onderskei. Toestemming is meer as blote kennis en begrip en is iets aktiëts. Dit moet na buite lyk. Hoewel regter Watermeyer in Stoffberg v Elliot, “express consent” by geneeskundige operasies vereis, word algemeen aanvaar dat toestemming of uitdruklik (“express”) of stilswyend (“implied”) kan wees.*”

¹⁸³ This requirement causes havoc in practice. It is alleged that certain health practitioners do not obtain informed consent from the patients, but rather asks the nursing staff who might not be in a properly

competent witnesses (a) donate his body or any specific tissue thereof to be used after his death for any of the purposes referred to in section 4 (1); or (b) give his consent to a post-mortem examination of his body for any of those purposes, and such a person may in such a will or document or statement nominate an institution or person referred to in section 3 (1) as donee.”

Section 18 states that “[n]o tissue, blood or gamete shall be removed or withdrawn from the body of a living person for a purpose referred to in section 19 (a) except in accordance with the prescribed conditions; and (b) unless written consent thereto has been granted (i) where such a person is a major, by that person; (ii) where such a person is a minor, by the parents or guardians of that person: Provided that- (aa) in the case of the removal of tissue which is replaceable by natural processes, or the withdrawal of blood, from the body of a person who is a competent witness, the consent of that person to the removal of that tissue or blood shall be sufficient, whether it be granted in writing or orally;(bb) tissue removed in the interest of his health from the body of a living person with his consent or with the consent of any other person who may in law give consent on his behalf, may be used for any of the purposes referred to in section 19”.

In similar fashion, the National Health Act provides in section 55 that “[a] person may not remove tissue, blood, a blood product or gametes from the body of another living person for the purpose referred to in section 56 unless it is done (a) with the written consent of the person from whom the tissue, blood, blood product or gametes are removed granted in the prescribed manner; and (b) in accordance with prescribed conditions”. Section 62(1)(a) stipulates [a] person who is competent to make a will may (i) in the will; (ii) in a document signed by him or her and at least two competent witnesses; or (iii) in an oral statement made in the presence of at least two competent witnesses, donate his or her body or any specified tissue thereof to be used after his or her death, or give consent to the post mortem examination of his or her body, for any purpose provided for in this Act”.

qualified position to procure informed consent. In cases like these, it cannot be said that the patient gave informed consent.

The Legislator only makes reference to “consent” and “will”. If the general status of consent as perceived in the medical law is applied to the interpretation of both the Human Tissue Act and the National Health Act, then both terms refer to informed consent. It is deduced that a donor, either living or cadaveric gave *informed* consent to the procurement and allocation of his / her organs and tissue and not just merely submitted himself / herself to the operation.¹⁸⁴

(2) “Actual” Consent and The Doctrine of Presumed Consent

This dissertation poses, among others, one fundamental question? What is the legal composition of the element of “consent” in the doctrine of presumed consent? In other words, does the meaning of consent in the doctrine have the same meaning of informed consent in the South African context? In this context, this dissertation is to analyse whether presumed consent, is just another form of informed consent i.e. presuming informed consent. Before this statement can be analysed, the true character of the doctrine should be determined. It has been argued that the true character of the doctrine of presumed consent is essentially “compulsory recycling”¹⁸⁵. Price refers to the opinions of authors that classify the doctrine as a “fiction”¹⁸⁶, “the denial of a need to seek consent”¹⁸⁷ and even “theft”¹⁸⁸. The essence of their arguments is formulated in Richardson’s comment: “[t]his is one of the many misnomers with which the language of transplantation is peppered. Here, lip service is paid to the *need* for consent, but in practice its existence is irrelevant, because it is *assumed* to exist.”¹⁸⁹ To their comprehension, the doctrine is symptomatic of no consent. This classification does not reflect the true nature of the doctrine, but actually reflect the misconception that people have

¹⁸⁴ The National Health Act further stipulates that no health services may be provided to a user thereof without the user’s informed consent in terms of section 8. Section 8(1) does allow exceptions to the general rule. Section 8(2) provides that a health care provider must take all reasonable steps to obtain the user’s informed consent. The National Health Act defines “informed consent” in section 8(3) as “consent for the provision of a specified health service given by a person with legal capacity to do so and who has been informed as contemplated in section 6”.

¹⁸⁵ Price 84.

¹⁸⁶ Erin and Harris *Presumed Consent or Contracting Out* Journal of Medical Ethics 25 (1999) 365.

¹⁸⁷ Richardson *Fearful Symmetry* in Youngner, Fox and O’Connell *Organ Transplantation: Meanings and Realities* (1996) 66 at 78.

¹⁸⁸ Kevorkian *A Controlled Auction Market is a Practical Solution to the Shortage of Transplantable Organs* Medicine and Law 11 (1992) 47 at 48.

¹⁸⁹ Price 87.

regarding the doctrine of presumed consent. The most common misperception is classifying presumed consent as routine salvaging.¹⁹⁰

The doctrine is in many ways different than routine salvaging, however, the most influential is the right of “opting out”. In terms of the doctrine of presumed consent, procurement of organ and tissue will start *only* after it can be proven that *no* objection pertaining to organ procurement has been registered. Routine salvaging regimes do not allow the donor the opportunity to object to procurement for example in countries such as the People’s Republic of China and certain Arab Republics, which remove organs and tissue from executed prisoners. The right to “opt out” of the potential donor pool is paramount to determine whether actual consent was present when the person decided not to become a donor after death.

The right of “opting out” created by the doctrine show *prima facie* that the donor has the opportunity during his / her lifetime to object to post mortem removal of organs and tissue. It is clear that the right of opting out either is or should indicate that the donor has made a voluntary and informed decision to refuse becoming a donor. To determine whether this is indeed the situation, the decision must be analysed in the light of the surrounding circumstances. Here, the question ultimately reflects upon the person’s informedness based upon the circumstances of the particular case. Just as the doctrine of informed consent requires that a health practitioner has a duty to inform the patient about *inter alia* the risks, advantages and diagnoses before the patient undergoes the proposed treatment, in the same capacity, does the doctrine of presumed consent requires that information regarding organ transplantation should be provided to the general public. Without sufficient information to allow the person to make an informed decision (which will result in registering an objection) it cannot be said that consent is present.¹⁹¹ The nature, scope

¹⁹⁰ Erin and Harris *supra* remark that “[w]ithout the actual consent of the individual, there is no consent.”

¹⁹¹ Presumed consent legislation further affects only adults who have the capacity to make decision on their own behalf. This further requirement is indicative that the doctrine of presumed consent is different than routine salvaging.

and the accessibility to the information¹⁹² will determine whether the element of consent, is informed consent in the doctrine of presumed consent.

(3) The Duty of Disclosure and The Role of Information in The Doctrine of Presumed Consent

The scope of the duty to disclose information regarding all relevant matter to transplantation stays exactly the same as the duty of disclosure in informed consent. The information disclosed to the public should provide a general idea in broad terms about organ transplantation that must provide *inter alia* the scope, nature, risk, advantages and disadvantages.¹⁹³ The most important factor is easy accessibility to the information for example Internet and television.¹⁹⁴ To comply with the requirement of disclosure the establishment of a user friendly website which provides general information would prove to be invaluable.

(a) Who Must Inform?

The general rule is that the health practitioner who is consulted and tasked to perform the treatment, is required to inform the patient.¹⁹⁵ If a website is created to provide information about organ and tissue transplantation, the duty would rest upon a single health practitioner or a group of practitioners commissioned to write content to be placed upon the web site. It is important that the health practitioner may not delegate the duty to disclose information to a person who is not registered as a health practitioner.¹⁹⁶ In my opinion the role of procuring organs should be the task of both private institutions and

¹⁹² Kane *Information is The Key to Patient Empowerment* Annals of Health Law 11 (2002) 25.

¹⁹³ Van Oosten *Medical Law: South Africa* (1996) par 69.

¹⁹⁴ In the United States, the notion of using the Internet in medical practice leads to the concept of telemedicine. Telemedicine is defined as "the use of remote transmissions of video, audio, and text data to provide information to individuals involved in a patient's care (for example, specialists and consultants)"; See further Molzen and Sokol *The Changing Standard of Care in Medicine: E-Health, Medical Errors, and Technology Add New Obstacles* Journal of Legal Medicine 23 (2002) 449.

Accordingly, telemedicine allows health practitioners to use available technology to cure patients who might not be in easy reach or cannot get access of health care facilities.

¹⁹⁵ *Lymbery v Jefferies* 1925 AD 236; *Rompel v Botha* 1953 (T) unreported; *Esterhuizen v Administrator Transvaal* 1957 (3) SA 710 (T); *Richter v Estate Hammann* 1976 (3) SA 226 (C); *Castell v De Greef* 1994(4) SA 408(C).

¹⁹⁶ Van Oosten *The Doctrine of Informed Consent in Medical Law* (1991) 348. If a person enters a website that contains medical information pertaining to a specific illness or treatment, it is as if that person visit a medical practitioner in real life. It is important that the information should be drafted by a health practitioner and the content correct, precise and frequently updated. The same standard of care has to be applied as with a real life consultation.

government. In this sense, the duty to disclosure of information about organ transplantation rests with health practitioners employed by this joint venture, rather than private health practitioners.

(b) How should the Information be Displayed?

No specific manner exists through which information should be conveyed to the patient. Usually, a health practitioner will discuss the matter during consultation and verbally convey the information to the patient. Information can also be given in written form for example in a brochure or web browser. The information displayed in this manner, will usually take the form of general information that serves to introduce the medical matter to the public. The information must be written in such a manner, which should stay in touch with the patient's capacity to comprehend and digest the information. If the patient requires specific information on a general topic or information that was not specifically discussed, the patient could direct the question to a specialist.¹⁹⁷

(c) What is the Nature of Disclosure?

If sufficient information is provided which serves to inform the general public about organ and tissue transplantation, the question is what is the nature of the disclosure? To determine the true nature of disclosure, it is necessary to conduct research into German medical jurisprudence rather than the South African concept. German authors¹⁹⁸ have extensively studied the doctrine of informed consent in the past few decades. Particular interest is shown towards the duty of disclosure (*Die ärztliche Aufklärungspflicht*) that rests upon the health practitioner.

German jurists place much value to the duty of disclosure and the patient's right to self-determination (*Selbstbestimmungsrecht des Patienten*), that it is even entrenched in Article 1 and 2 of the German Constitution.¹⁹⁹ The

¹⁹⁷ A number of ways exist through which the patient could get in contact with the specialist without actually visiting a consultation room for example the patient could very easily send an email message to the list of specialist provided on the relevant web page.

¹⁹⁸ Bockelmann *Strafrecht des Arztes* (1968); Deutsch *Artzrecht und Arzneimittelrecht* (1983); Giesen *Artz Haftungs recht* (1990); Kern und Laufs *Die Ärztliche Aufklärungspflicht* (1983) and Kohlhaas *Medizin und Recht* (1997).

¹⁹⁹ Andreas *Neue Tendenzen in the Rechtsprechung zur Aufklärungspflicht* (1987) 175; Deutsch *Artzrecht*; Giesen. It should be noted that the duty of disclosure existed some time before the promulgated of the German Constitution. However, the principles of Article 1 and 2 reflect to meaning of the duty of disclosure.

purpose of the *aufklärungspflicht* is almost exactly the same as in South African medical law; i.e to provide the patient an opportunity to make a well informed decision whether to undergo the proposed treatment.

In German medical jurisprudence, the duty of disclosure is divided into *Selbstbestimmungsaufklärung*, *Therapeutische aufklärung* and *Basisaufklärung*.²⁰⁰ The *Selbstbestimmungsaufklärung* is used for the purpose of procuring consent from a patient and to guarantee that that patient exercises his / her right to self-determination.²⁰¹

The *selbstbestimmungsaufklärung* is divided into *diagnoseaufklärung*; *verlaufsaufklärung* and *risikoaufklärung*. *Diagnoseaufklärung* proposes that the health practitioner is obliged to disclose to the patient, that the patient is ill, the disease and the most probable prospects and fears.²⁰² *Verlaufsaufklärung* poses that the health practitioner should disclose the progress of the illness, the nature, scope, advantages and disadvantages of the proposed treatment and possibility of alternative treatments and if no treatment is administered.²⁰³ Finally, *risikoaufklärung* directs that all the risks attached to the treatment should be disclosed.²⁰⁴

The second kind of the duty of disclosure is *therapeutische aufklärung*. This kind of disclosure stands in total contrast with the *selbstbestimmungsaufklärung*, because it does not ensure that the patient's right of self determination is secured, but ensure that his / her health is protected.²⁰⁵ Kuhnert²⁰⁶ remarks "[d]ie Therapeutische Aufklärung steht ... in einem kontradikotsichen Verhältnis zu der Selbstbestimmungsaufklärung. Während diese das Recht des Patienten respektiert, über sein weiteres Schikal selbst zu bestimmen, ist es Ziel der therapeutischen Aufklärung, den

²⁰⁰ Deutsch *Arztrecht* 42; Kern and Laufs 53; Van Oosten *The Doctrine of Informed Consent in Medical Law* (1991) 295.

²⁰¹ Deutsch *Arztrecht* 37; Kern and Laufs 53; Van Oosten *The Doctrine of Informed Consent in Medical Law* (1991)296.

²⁰² Deutsch *Arztrecht* 43; Kern and Laufs 54; Van Oosten *The Doctrine of Informed Consent in Medical Law* (1991)296 – 297.

²⁰³ Deutsch *Arztrecht* 43; Kern and Laufs 58; Van Oosten *The Doctrine of Informed Consent in Medical Law* (1991)297.

²⁰⁴ Van Oosten *The Doctrine of Informed Consent in Medical Law* 298.

²⁰⁵ Deutsch *Arztrecht* 44; Van Oosten *The Doctrine of Informed Consent in Medical Law* 299.

²⁰⁶ *Die Vertragliche Aufklärungspflicht des Arztes – Insbesondere bei der Anwendung und Verschreibung von Arzneimitteln* (1982) 12 – 13.

Patienten aufzurufen, von seinem Selbstbestimmungsrecht Gebrauch zu machen und sich zu entschließen, eine Heilungchance wahrzunehmen.”

The third kind of *Aufklärungspflicht* that could prove to be of particular importance to the doctrine of presumed consent, is *basisaufklärung* also known as *stufenaufklärung*.²⁰⁷ The disclosure of information in terms of *basisaufklärung* commences in stages, from general information to the specific. The reason why this kind of disclosure is best suited to the doctrine of presumed consent²⁰⁸ is the manner in which information should be displayed. In other words, as discussed *supra* the nature of consent in the doctrine of presumed consent could only qualify as informed consent, if sufficient information is provided. The best manner to provide the information is in a written form through computer-based applications, such as the Internet and CR-ROM.²⁰⁹ In this context, information are displayed in terms of principles of *basisaufklärung*: information are divulged in two phases. To start with the patient has access to general information, usually in written form about the ailment, treatment and recovery process. This is followed, if required by a verbal disclosure of specific information. This is the case if the patient consults with a health practitioner to ask specific questions.

In my opinion, this form of disclosure of information is the best manner to supply information to a large group of people on a specific topic or interconnected topic such as organ and tissue transplantation, which allow the patients or potential donor to get in contact with a specialist.

²⁰⁷ Deutsch *Artzrecht* 43; Kern and Laufs 46; Van Oosten *The Doctrine of Informed Consent in Medical Law* (1991)300.

²⁰⁸ Van Oosten *The Doctrine of Informed Consent in Medical Law* (1991) states at 300 that “no specific form of disclosure and consent is required. Oral disclosure and consent will usually suffice, although written disclosure and consent will, of course, facilitate their proof. In fact, it is generally acknowledged that a discussion and dialogue between doctor and patient are of paramount importance. Written disclosure and consent may, at best, form a basis for and supplement or support oral disclosure and consent. In this connection, it has further been accepted that although the nature and manner in which disclosure takes place are matter in the discretion of the medical profession, they must correspond with the patient’s capacity to understand and assimilate the information, as well as with his wish to be informed fully, or partially or not at all”.

²⁰⁹ Singapore provides an excellent example of a web-based information centre on organ transplantation available at <http://www.moh.gov.sg/corp/systems/organ/intro.do>

(d) What are the Legal Consequences of Providing False Information or Non-Disclosure?

The legal consequences for providing false information or non-disclosure are applied *mero meto* to the doctrine of informed consent.²¹⁰

4.2.3 The Third Element: Capacity

See the discussion under paragraph 4.2.1, requirement four: the donor must have the necessary capacity.

4.2.4 The Fourth Element: The object for transplantation

This element focuses on the practical side of transplantation operations: what can be transplanted? A brief overview of transplantation history suggest that Soviet surgeons performed the first kidney transplant in 1936 using a cadaveric donor but lacked success. The world's first successful live kidney transplant was accomplished in Boston, in 1956. This operation formed the basis of new medical technology; and in 1967, Dr Christaan Barnard achieved the unthinkable, the first ever successful heart transplant operation at the De Groote Schuur Hospital, in Cape Town, South Africa.²¹¹ Medical technology has since 1967 made it possible to transplant various human organs and tissue.

The object for transplantation is statutory regulated in terms of the National Health Act that states that in the case of living donors, only tissue, blood (including a blood product) and gametes may be removed for transplantation purposes, if the removal complies with the statutory requirements.²¹² Cadaveric donors may donate their entire body or any specified tissue for transplantation purposes.²¹³ The National Health Act defines tissue as "human tissue, and includes flesh, bone, a gland, an organ²¹⁴, skin, bone marrow or

²¹⁰ See further Van Oosten *Medical Law: South Africa* par 95, 98 and 99.

²¹¹ Jefferies *The Body as Commodity: The Use of Markets to Cure the Organ Deficit* Indiana Journal of Global Studies 5 (1998) 621 at 623; and Barnard 1271.

²¹² Section 55.

²¹³ Section 62.

²¹⁴ An organ is defined as "any part of the human body adapted by its structure to perform any particular vital function, including the eye and its accessories, but does not include skin and appendages, flesh,

body fluid, but excludes blood or a gamete”.²¹⁵ The effect of this definition is various parts of tissue and all types of “vital” organs may be procured and used for legitimate purposes. The explicit consent regime used in South Africa does not place a restriction on the type of transplantable organ that may be transplanted.

(a) The Restrictive Approach of the Doctrine of Presumed Consent

The restriction on the type of organ, which may be procured, can be found in organ transplantation legislation that applies the doctrine of presumed consent. These statutory provisions stipulate that the “opting out” system is only applied to certain types of organs such as kidneys. Explicit consent is used for procurement and transplantation of all other organs. The most notable example of a restrictive presumed consent regime can be found in the Human Organ Transplant Act of 1987 of Singapore. This Act presumes that an individual donated his / her kidneys after death unless they have during their lifetime raised an objection. If a person wants to make an anatomical gift in respects of the following organs:

- Tissues;
- Lungs;
- Kidneys;
- Heart;
- Corneas;
- Bones and Ligaments;
- Skin; and
- Pancreas;

that person must make the donation in writing or verbally, in the presences of two or more witnesses, any time prior to his / her death, i.e. the donor must provide explicit consent.²¹⁶

bone, bone marrow, body fluid, blood or a gamete;” Examples of organs are heart, lung, pancreas, stomach, and kidneys.

²¹⁵ Section 1.

²¹⁶ The requirements of this explicit consent regime are regulated by the Medical (Therapy, Education and Research) Act of 1972. The Human Organ Transplant Act of 1987 is only applicable to procuring kidneys for transplantation purpose in terms of the doctrine of presumed consent.

A decision to apply a restrictive approach depends ultimately on the objectives of a government programme or similar private initiated programme that incorporates the doctrine of presumed consent.

4.2.5 The Fifth Element: The next-of-kin and the right of refusal

The role of the next-of-kin plays a pivotal role in determining the degree of application used in the doctrine. As mentioned *supra* the doctrine of presumed consent employs two degrees of application, namely the hard application that waives any right of refusal the next-of-kin might have been entitled to.²¹⁷ The basis of the soft application of the doctrine provides for a right of refusal that the next-of-kin is entitled to. Although, the weak application does not require that the next-of-kin should be approached to ask permission before the deceased family member's organs are procured, however the next-of-kin does have a right to stop the process of procurement.²¹⁸

(a) Who is the Next-of-Kin?

The term "next-of-kin" which is, in essence, a synonym for the term "family", can be given a wider definition and a narrow definition.²¹⁹ The wider definition establishes that the family are all persons related through some form of blood-relation or marriage. The narrow definition states that a family consists of a man (husband), woman (the husband's wife) and their children. Neither the National Health Act nor the Human Tissue Act provides a definition of the term "next-of-kin" or "family". The only reference to the next-of-kin can be found in section 62(2) and section 2(2)(a) respectively. Both of these sections, which have been drafted in similar fashion, states "in the absence of a donation under subsection (1) (a) or of a contrary direction given by a person

²¹⁷ A good example is the Austrian Federal Law of 1 June 1982 does not grant any right of refusal and further places no duty of the health practitioner to inform relatives of the death of the patient or approach the next-of-kin about the possibilities of organ transplantation.

²¹⁸ Mackey and Kjerulf states at 52 "... retrieval of organs would be considered a routine procedure from which one may opt-out, families would be asked if they objected to the removal of organs rather than requesting explicit consent to do so. This approach is often considered more psychological manageable, as the family would be spared the emotional stress of considering a procedure that is unfamiliar to them. Families are also less likely to object to a routine procedure and more likely to be anticipating a discussion about retrieval, this minimizing the "bad timing" effect that is often related to our current system of request."

²¹⁹ Potgieter and Visser *Introduction to Family Law* (1998) 1, Barnard, Cronje and Olivier *Die Suid-Afrikaanse Persone –en Familiereg* (1994) 133.

whilst alive, the spouse, partner²²⁰, major child, parent, guardian, major brother or major sister of that person, in the specific order mentioned, may, after that person's death, donate the body or any specific tissue of that person to an institution or a person...".²²¹ It is clear that the National Health Act, as much as the Human Tissue Act, classifies the next-of-kin under the wider definition.

(b) What is the Right of Refusal?

The definition of this right is almost self-explanatory. The next-of-kin has the right to stop the process of procurement of one of their family's organs, regardless of the reason for hesitation. To my understanding, the extent of this right depends on the organ procurement system used, which means that the more limited this right, the harder application of the doctrine of presumed consent is applied.

4.2.6 The Sixth Element: The recipient

The final stage in the transplantation process reflects upon the legal and ethical implications of organ allocation procedures. In the past number of years, various questions pertaining to the effectiveness and equitability of organ allocation procedures have surfaced. Even though, organ procurement systems and incentives have managed to increase procurement rates, the real key to creating and maintaining successful procurement rates in general, lays with effective and equitable allocation procedures. Chapter Three is dedicated towards evaluating principles of preservation of organs and tissue and equitable allocation procedures.

²²⁰ The term "partner" did not exist in section 2(2)(a) of the Human Tissue Act which was just transferred to the new National Health Act as section 62. Currently, no interpretation have been given to the term "partner", however it is possible that persons in homosexual partnership and heterosexual partners living together outside wedlock can give permission that their deceased partner's organs and tissue may be used for donation purposes. For remarks on the current U.S. perspective see Chen *Can Same-Sex Partners Consent to Organ Donation?* American Journal Of Law and Medicine 29 (2003) 31(14)

²²¹ Section 2(2)(a) of the Human Tissue Act states "In the absence of a donation under subsection (1) by a person and of a contrary direction given by that person (a) his spouse, major child, parent, guardian, major brother or major sister may after his death donate his body or any specific tissue thereof to an institution or person referred to in section 3(1), to be used for any of the purposes referred to in section 4(1);".

4.3 Foreign Law

An organ procurement system that incorporates the doctrine of presumed consent and incentives such as the principles of required response and required request are legal concepts unknown to the South African legal system. The principles of these procurement systems, having been developed in last 40 years, is still within its early stages of reaching formal legal recognition on a global scale. Although similarities between the general principles of presumed consent legislation as applied by different countries can be identified, each country has its own unique version. This dissertation refers a great deal to various foreign legal principles; however, certain specific countries have been identified as models, which will be discussed in depth.

The global position pertaining to organ procurement legislation can be divided into three areas:

- Organ procurement legislation based upon explicit consent. Countries, which predominantly feature as requiring explicit consent prior to removing tissue, are the United States of States²²² and South Africa.
- Presumed consent legislation. Mainly continental European countries incorporate the doctrine of presumed consent in organ procurement legislation. The most formidable countries are Austria, Belgium, France, Luxembourg, Poland, Portugal, The Slovak Republic and Spain. Non-European countries that have similar legislation are Peru and Singapore.²²³
- Routine Salvaging. Currently, the only country known to practise routine salvaging is the People's Republic of China (PRC). The PRC is well known to procure organs from executed prisoners. Whether the "donors" permitted to the removal of their tissue is highly questionable. Post-communist countries have also been suspected of allowing routine salvaging. In many of these countries, it is presumed that it is a

²²² Certain states within the United States have promulgated required request and presumed consent. Most notably, the State of Pennsylvania introduced a partial presumed consent law permitting cornea donation in terms of Sections 2101 to 2110 of Title 20 of the Pennsylvania Consolidated Statutes.

²²³ The only country on the African continent with presumed consent legislation is Tunisia.

citizen's body automatically becomes the property of the government after death. The philosophical approach provides that it is each citizen's duty to serve the state, even after death.

Under a discussion of the doctrine of presumed consent, the countries that can be classified as classic models are Austria²²⁴, Belgium and Spain. Belgium has since introducing the doctrine of presumed consent legislation experienced exceptional success in increasing organ transplantation rates and has been viewed as an advertisement for presumed consent. To keep this chapter within reasonable scope, the discussion pertaining to the soft application of presumed consent is restricted to the presumed consent legislation in Belgium and the hard application to Spain.

To begin the discussion on foreign law, it is necessary to consider guidelines from certain international organisations such as the World Health Organisation (WHO). Although these guidelines are not binding principles, it is necessary to include these guidelines under a discussion on foreign legal principles as to provide for the international mindset in respect of transplantation laws.

4.3.1 Draft Guiding Principles on Human Organ Transplantation

The World Health Organization (WHO)²²⁵ adopted in May 1987, under resolution WHA40.13, draft guiding principles on human organ transplantation.²²⁶ These draft guidelines were drafted "to study, in

²²⁴ Austria promulgated the Federal Law of 1 June 1982 that regulates organ transplantation related matters. In terms of this Act, the doctrine of presumed consent was introduced to procure organs and tissue from cadaveric donors. The Act states that "[d]ie Entnahme von Organen und Geweben ist ex lege zulässig, sofern der Spender nicht zu Lebzeiten ausdrücklich widersprochen hat und dieser Widerspruch den Ärzten auch vorliegt". This section explicitly establishes that if a person does raise an objection during his / her lifetime, it will be presumed that person consented to the post mortem removal of organs and tissue. Procurement from living donors is not statutory regulated, however the norm is that explicit consent must be provided. See further Kopetzki *Landesbericht Österreich* which forms part of Taupitz *Zivilrechtliche Regelungen zur Absicherung der Patientent Automatic am Ende des Lebens* (2000) 21. Kopetzki states that "[d]ie Organentnahme am Lebenden ist gesetzlich nicht ausdrücklich geregelt. Das Erfordernis umfassender Aufklärung und höchpersönlicher Einwilligung ist aufgrund straf- und zivilrechtlicher Grundsätze unbestritten."

²²⁵ <http://www.who.int/en>

²²⁶ http://www.who.int/ethics/topics/transplantation_guiding_principles/en/print.html

collaboration with other organizations concerned the possibility of developing appropriate guiding principles for human organ transplants".²²⁷ The methodology of the draft guidelines were initiated by the Director General of the WHO through a process of consultation which involved various organizations and experts from various related fields. The outcome were the establishment of an informal group at the WHO headquarters and the arranging of an informal consultation on organ transplantation which consisted of medical ethics, international experts in organ transplantation, health policy and law, and representatives of intergovernmental and NGOs. After a rigorous stage of consultation, the working group set forth a report to a consultation group which was convened in Geneva, Switzerland on the 3rd and 4th of October 1990. This meeting resulted in the final draft of the guidelines on organ transplantation that was subsequently adopted.²²⁸

The Guidelines establishes nine guiding principles, which has the purpose to establish a comprehensive system for the removal of organs from deceased and living donors for transplantation, to provide guidelines for the allocation of procured organs and related matters.²²⁹

Guiding principle 1

Organs may be removed from the bodies of deceased persons for the purpose of transplantation if:(a) any consents required by law are obtained; and (b)there is no reason to believe that the deceased person objected to such removal, in the absence of any formal consent given during the person's lifetime.

Guiding principle 2

Physicians determining that the death of a potential donor has occurred should not be directly involved in organ removal from the donor and subsequent transplantation procedures, or be responsible for the care of potential recipients of such organs.

²²⁷ *Ibid.*

²²⁸ *Ibid.*

²²⁹ http://www.who.int/ethics/topics/transplantation_guiding_principles/en/index1.html.

Guiding principle 3

Organs for transplantation should be removed preferably from the bodies of deceased persons. However, adult living persons may donate organs, but in general such donors should be genetically related to the recipients. Exceptions may be made in the case of transplantation of bone marrow and other acceptable regenerative tissues. An organ may be removed from the body of an adult living donor for the purpose of transplantation if the donor gives free consent. The donor should be free of any undue influence and pressure and sufficiently informed to be able to understand and weigh the risks, benefits and consequences of consent.

Guiding principle 4

No organ should be removed from the body of a living minor for the purpose of transplantation. Exceptions may be made under national law in the case of regenerative tissues.

Guiding principle 5

The human body and its parts cannot be the subject of commercial transactions. Accordingly, giving or receiving payment (including any other compensation or reward) for organs should be prohibited.

Guiding principle 6

Advertising the need for or availability of organs, with a view to offering or seeking payment, should be prohibited.

Guiding principle 7

It should be prohibited for physicians and other health professionals to engage in organ transplantation procedures if they have reason to believe that the organs concerned have been the subject of commercial transactions.

Guiding principle 8

It should be prohibited for any person or facility involved in organ transplantation procedures to receive any payment that exceeds a justifiable fee for the services rendered.

Guiding principle 9

In the light of the principles of distributive justice and equity, donated organs should be made available to patients on the basis of medical need and not on the basis of financial or other considerations.

4.3.2 Belgium

The basis for regulating organ procurement and transplantation in Belgium has been entrenched in the provisions of the Law on the Removal and Transplantation of Organs, Law of 13 June 1986 as amended by the Law of 17 February 1987²³⁰. The adoption of the Law of 13 June 1986 was an attempt by the Belgian Parliament to reform organ transplantation laws to increase organ procurement. The Law of 1986 introduces the doctrine of presumed consent in Belgian law when tissue procurement occurs from cadaveric donors. The Law creates an “opting out” system whereby a person who wishes not to become an organ donor must register an objection indicating such a wish.

(a) General Provisions

The Law of 1986 was promulgated to apply to the removal of organs and tissues for therapeutic purposes.²³¹ The removal and transplantation may in terms of section 3 only be carried out by a health practitioner in a registered hospital and a prohibition is placed against organs and tissue procured for profit.²³² After procurement, section 4(1) provides that neither the donor nor close relatives of the donor will have a right in relation to the recipient.

²³⁰ *Wet Betreffende het Wegnemen en Transplanteren van Organen (Stbl. 14-2-1987 Erratum Stbl. 26-2-1987; gewzd wet 17-2-1987).*

²³¹ Section 1 states “Deze wet is van toepassing op de wegneming van organen of weefsels van het lichaam van een persoon, « donor » genoemd, met het oog op het voor therapeutische doeleinden transplanteren van die organen of weefsels op het lichaam van een ander persoon, « receptor » genoemd.” The scope of the removal is limited to therapeutic purposes. Any removal for any other purposes does not fall within the scope of the Law of 1986. The reason behind excluding removal of organs and tissue for diagnostic or research purposes is political. According to Nys *Medical Law in Belgium* (1997) at 118 - 119 “The distinction between therapy and experiment has given rise to overwhelming literature, especially with regard to the lawfulness of non-therapeutic medical experiments. Research and therapy often go hand in hand. Medical scientists and physicians are inclined to qualify nearly every medical experiment as a therapy, at least as a potential therapy. In this way, the scope of the Belgian Law might be silent extended and the difference with the scope of resolution (78) 29 on the harmonization of the legislation of Member States relating to removal, grafting and transplantation of human substances, adopted by the Committee of Ministers of the Council of Europe on 11 May 1978 (that applies to removal for therapeutic, diagnostic and research purposes) might become negligible. However, from a legal point of view the extension of the scope of the law without a legislative change cannot be accepted. A lot of M.P’s especially those belonging to the Christian Democratic Party, hesitates to approve the opting-out donor system for removal of cadaveric organs. For these, the limitation of the scope of the law to removal for therapeutic purposes only, was a *conditio sine qua non* for voting the law. Thus, the limitation of the scope of the law to therapeutic purposes is not just a matter of wording that might be subjected to interpretation. Very knowingly, the majority of M.P’s has restricted the scope of the law and more in particular the opting-out donor system to removal for therapeutic transplantation purposes. A broader scope of the law would presumably not have been approved in 1986.”

²³² Section 4.

(b) Removal of Tissue from Living Persons

The Belgium transplantation law creates a dual organ procurement system i.e. the doctrine of presumed consent with regard to cadaveric donors and explicit consent prior to procurement from living donors. In terms of section 8, prior consent to removal is required and the living donor has to consent freely and knowingly²³³. For consent to be legally recognised, section 1 of the Crown Order of 30 October 1986 which regulates the method of expressing consent to the removal of tissue from living persons, the written consent form must contain the following information:

- The name and age of the donor;
- The name and age of the persons consenting to the removal; if appropriate;
- The capacity in which such persons act;
- The signature of the witness;
- The date of the signature; and
- The name and address of the hospital to which the consent is to be communicated.

Finally, a written consent form must be handed to the health practitioner and has to be recorded in the medical file of the donor.²³⁴ Section 8(1) empowers the donor to revoke the consent at any time. The same procedure must be followed as with registering consent. The process of revocation is only after registering the revocation of the medical file of the patient complete.²³⁵

The Law of 1986 unequivocally control the age of donor by stating that organs and tissue may only be removed from a person who reached eighteen years of age.²³⁶ Two exceptions to the general rule are allowed by section 6(1) and

²³³ The term "knowingly" suggests that informed consent must be present. The information that should be supplied by the health practitioner is referred to below.

²³⁴ Section 2 of the Crown Order read with section 8(3) of the Law of 1986.

²³⁵ Section 3 and 4 of the Crown Order.

²³⁶ Section 5.

7. If the removal of organs and tissue from a living person may seriously affect the donor, or if such organs and tissue are non regenerable, it is not sufficient that the donor has reached eighteen years of age. Section 6(1) states that procurement will only be allowed if the recipient's life is in danger and if the transplantation of organs and tissue from a cadaveric donor could not produce an equally satisfactory result.²³⁷

Section 7 allows an exception only in the following instance: if procurement from a living person does not have serious effects on the donor or if the substances removed are regenerable and if the removal is intended for transplantation to a brother or sister of the donor, organs and tissue may be removed from the minor donor.

(c) Legal Duty of the Health Practitioner

The Law of 1986 confers various duties upon the health practitioner who is required to procure tissue from a living donor. The health practitioner is required to provide clear and complete information to the donor and any persons whose consent is required, on the physical, mental, family and social effects of the removal. The health practitioner is further required to assess whether the conditions for procurement have been fulfilled, by satisfying himself / herself that the donor has taken his decision in the knowledge of the facts and that there is no doubt as the patient's "altruistic motives".²³⁸

(d) Procurement from Cadaveric Donors

Chapter 3 of the Law of 1986 regulates the removal of tissue from deceased donors. Section 10(1) introduces the doctrine of presumed consent whereby organs and tissue may be procured from the body of any person recorded in

²³⁷ "Wanneer de wegneming bij levenden ernstige gevolgen kan hebben voor de donor of wanneer zij betrekking heeft op organen of weefsels die niet regenereren, kan ze alleen worden verricht als de receptor in levensgevaar verkeert en de transplantatie van organen of weefsels van een overledene geen even bevredigend resultaat kan opleveren."

²³⁸ Section 9 states. "De geneesheer die zich voorneemt een wegneming van een orgaan of weefsel te verrichten, moet zich ervan vergewissen dat de voorwaarden van de artikelen 5 tot 8 zijn vervuld. Hij moet de donor en in voorkomend geval de personen van wie de toestemming vereist is, duidelijk en volledig inlichten over de lichamelijke, psychische, familiale en sociale gevolgen van de wegneming. Hij moet vaststellen dat de donor zijn beslissing oordeelkundig en met een niet te betwijfelen altruïstisch doel heeft genomen."

the Register of the Population or any person recorded for more than six months in the Aliens Register for therapeutic purposes, unless it is established that an objection to such removal has been expressed. The age of the donor from whom the tissue may be removed is restricted to persons who are above the age of eighteen years of age. Any person who does not comply with the provisions of section 10 is required to provide explicit consent.

Section 10 requires that any person who does not wish to become an organ donor must raise an objection. The objection to the removal of tissue may be expressed by any person who is eighteen years of age and capable of making known his / her wishes. Where a person is eighteen years of age but incapable of making his / her wishes known, the objection may be expressed during his / her lifetime by the next-of-kin or by any legal representative.²³⁹

As in the case with registering consent, the Crown Order provides for specific rules pertaining to the objection raised. Section 2 stipulates that the objection must be dated and signed on the approved form, which is to be processed by the Data Processing and Information Centre of the Ministry of Public Health, through the National Register of Natural Persons. Once such an objection has been processed, the main transplantation centres are given access to information. A health practitioner is prohibited from procuring tissue once such an objection has been registered.²⁴⁰

The possibility exists that an objection may be raised in another way than the section 2 objection.²⁴¹ The validity of the objection is subject to it being unambiguous. The ways in which an objection can be expressed is by direct communication by the objecting donor to the health practitioner and post mortem objection by the next-of-kin of the already deceased donor. In the latter situation, the next-of-kin must take place in the form of direct

²³⁹ Section 10(2).

²⁴⁰ Section 10(4)(1).

²⁴¹ Section 10 (4)(2) provides that the donor may express an objection "in another manner that has been communicated to the health practitioner".

communication between the next-of-kin and the relevant health practitioner. The objection may, however may not override the expressed wishes²⁴² of the donor.

In Belgium, a soft application of the doctrine of presumed consent is applied. The reason is indicative of the right of refusal by the next-of-kin post mortem. Nys²⁴³ states that legal uncertainties exist pertaining to the right of refusal provided by the Legislator. Nys raises the question “whether the physician who wants to remove organs has an obligation to inform the relatives of his intention and has to ask whether or not they object. The law itself does not contain these obligations.”²⁴⁴

In 1987 on advice provided by the *National Council of the Order of Physicians*, health practitioners is obliged to inform the close relatives about their intention to remove organs. Although the health practitioner is not required to ask for explicit consent, if they neglect, health practitioners face the possibility of disciplinary steps taken against them. The legal dilemma created by this advice is health practitioners explicitly ask the next-of-kin to give their consent to the removal of organs and tissue, in fear that they would be subjected to the disciplinary hearing; thus undermining the essence of the doctrine of presumed consent.

(e) Is Behaviour Indicative of Giving Consent?

The general rule in medical law as applied over the globe is that consent of the patient is required before any medical intervention. No patient may be subjected to treatment of whichever kind without consent. In certain instances, the behaviour of a patient can direct that, after receiving sufficient information about the treatment, the patient is willing to undergo the treatment, without directly stating the obvious. In this case, the question is whether it can be presumed that the patient gave consent? Apply this question to organ

²⁴² Section 10(4)(3) states “*uitdrukkelijke wilsbeschikking van de donor.*”

²⁴³ 123

procurement; the question follows: should the absence of any objection or remark about organ donation be indicative that consent to organ procurement was given?

The Belgian *Cour de Cassation*, in evaluating the doctrine of presumed consent and the silent behaviour of behalf of the patient, ruled in the affirmative to the question. The court in a decision of October 4, 1973 accepted that behaviour is indicative of permitting a proposed medical intervention²⁴⁵ and thus, accepted the validity of the doctrine of presumed consent. According to Nys²⁴⁶ mere passivity on the part of the patient should not be seen as the court applied the doctrine of presumed consent. The presumed consent of a patient is only valid insofar as the patient's declaration of will is sufficiently clear and certain. The factors to determine whether presumed consent is present depend on the nature of the medical intervention, consequences and the attitude of the patient. In this sense, it can be argued that the doctrine of presumed consent is nothing further than presuming informed consent is present. The same test that should be applied to test whether a patient provided informed consent can also be applied to the doctrine of presumed consent; i.e. was sufficient information²⁴⁷ regarding the proposed intervention given to the patient? This question really reflects upon the duty of disclosure that rests upon the health practitioner and if that duty has been fulfilled?

4.3.3 Spain

(a) General Provisions

Spain enacted the Law No 30 of 27 October 1979 to serve as the key piece of legislation that regulates removal and transplantation of organs and tissue from about living and cadaveric donors. The Law of 1979 has since its promulgation been amended numerous times by various Royal Decrees,

²⁴⁴ *Ibid*

²⁴⁵ A health practitioner may consider a patient to have consented in a certain procedure if that patient has received sufficient information and did not refuse it.

²⁴⁶ Nys *Country Report Belgium* which forms part of Taupitz *Zivilrechtliche Regelungen zur Absicherung der Patientent Automatic am Ende des Lebens* (2000)137.

²⁴⁷ For example advantages, disadvantages, prognoses and diagnoses.

Ministerial Orders, Resolutions and Circulars. The objectives of the Law of 1979 envisage addressing important local and European issues by:²⁴⁸

- Facilitating the obtaining of viable / usable organs for subsequent transplant operations performed on persons in dire need for suitable organs;
- Adequately protection of rights and interest of the individuals concerned; and
- Provide a legal framework for health practitioners within which they may perform medical operations unhindered and that are in accordance with user friendly guidelines.

(b) The Deceased Donor

Section 5 of the Law of 1979, in conjunction with section 10 of the Royal Decree of 1980 regulates the position pertaining to removing organs and tissue from deceased donors. In terms of section 5, it is legally assumed that any person who dies is an organ donor, unless that person during his / her lifetime explicitly stated that he / she does not wish to become a donor. Organs or other anatomical parts may only be removed from a deceased person, if the organs are to be used for therapeutic or scientific purposes.²⁴⁹ Furthermore, the organs or other anatomical parts may only be removed if the person did not expressly prohibited the removal.

(c) Recording an Objections to Organ Procurement

The Royal Decree of 1980 established specific procedures for recording objections and a register of volunteers have been established in authorised hospitals.²⁵⁰ If an objection were recorded in another manner than those

²⁴⁸ Romeo-Casabona and Emaldi-Cirion *Country Report Spain* which forms part of Taupitz *Zivilrechtliche Regelungen zur Absicherung der Patientent Automatic an Ende des Lebens*(2000) 544.

²⁴⁹ Section 5.2.

²⁵⁰ Section 8 and 9.

established in the Royal Decree, those objections would also be legally binding.²⁵¹

(d) No Right of Refusal by the Next-of-Kin of the Deceased

Spain applies a hard application of the doctrine of presumed consent.²⁵² The Law of 1979 does not require the next-of-kin of the deceased person to give consent to procuring of organs and tissue, unless the donor is either a minor or mentally ill person. The philosophical logic behind this approach, is “[i]t is a question of respecting the wishes of the deceased – although at the same time it is recognised that the family are most likely to know or be able to indicate the wishes of the deceased if they were made known during his lifetime. But this does not mean that they have property rights over the cadaver, because no such right exists. Furthermore, from the humanitarian point of view it would seem ill-advised to subject the family to a further emotional burden after being informed of the sudden tragic death of a loved one – husband, son or daughter etc.”²⁵³

The Spanish Legislator realised that confronting the next-of-kin of a person who passed fairly recently away, increases the already emotional state of the next-of-kin and creates altruistic feelings towards organ procurement. Due to this situation, the Royal Decree of 1980 only indicates that the next-of-kin should be informed about organ procurement, unless circumstances exist which prevent this.²⁵⁴

²⁵¹ For example written declarations, membership of religious groups who are clearly oppose to donations and information from the next-of-kin that the deceased was opposed to organ donation

²⁵² Romeo-Casabona and Emaldi-Cirion *Country Report Spain* which forms part of Taupitz *Zivilrechtliche Regelungen zur Absicherung der Patientent Automatic am Ende des Lebens* (2000) 548.

²⁵³ *Ibid.*

²⁵⁴ Romeo-Casabona and Emaldi-Cirion remark at 548 that although the Law of 1979 nor the Royal Decree of 1980 do not required health practitioners to approach the next-of-kin to get permission for organ procurement “...it is customary for physicians (or transplant coordinators) to seek the agreement of the family of the deceased, which is a sensible precaution as long as it is done tactfully.”

4.4 The Ethics of Presumed Consent

The ethical approach of the doctrine of presumed consent is based upon strong public support for organ donation. The *raison d'être* is firstly the percentage of organ donation supporting citizens exceeds the possible objectors by a great margin²⁵⁵ and secondly, a custom of neglecting to leave sufficient evidence of permission have been developed over a number of years by most potential and actual donors. Based upon this custom, governments around the globe only have to record the small percentage of people with altruistic feelings. France is a good example of these two theoretical approaches. Study show 90 to 95 percent of French citizens support organ donation, which resulted in the amendment of organ donation legislation to change to a system of presumed consent organ procurement.²⁵⁶

If a person considers the eventual result of the application of presumed consent in organ procurement and what it would mean to the community, the implications would probably result in a difference of opinion. On the one hand, advocates of presumed consent would argue that the application of presumed consent in organ procurement does procure more organs for transplantation purposes. Critics of presumed consent argue that the individual's right to self-determination precedes the interests of the community. Public policy is determined in the light of constitutional democracy in South Africa. This means, the development of organ procurement and allocation laws are subject to the Constitution as the supreme law of the country²⁵⁷ and any laws conflicting with the principles set out in section one will be declared unconstitutional.²⁵⁸ Legislation containing the doctrine of presumed consent have been introduced in various jurisdictions with mixed results. The main opposition to presumed consent was due to incorrect public awareness about the functioning of presumed consent for example Brazil.

²⁵⁵ Caplan *Organ Procurement: It's Not in the Cards* Hasting Centre Report 14 (1984) 9 (5)

²⁵⁶ *Ibid*

²⁵⁷ Section 2.

²⁵⁸ Brazil introduced the doctrine of presumed consent in 1997. After widespread criticism and "popular imagination", the Government of Brazil repealed the act in 1998, after only one year in operation. Various reasons affected the operation of the presumed consent law, however, the main reason was part of the population believed their organs would be removed even before they were clinically dead and many of it's citizens rushed to register themselves as non-donors to avoid this risk. Csillag *Brazil abolishes "Presumed Consent" in Organ Donation* *The Lancet* 352 (1998) 1367(1).

In the United Kingdom, the British Government²⁵⁹ rejected proposals by the British Medical Association (BMA) to change the policy of rejection of presumed consent laws.²⁶⁰ On continental Europe, the French Legislator promulgated Law of December 1976, which introduced a regime of routine salvaging.²⁶¹ Research show that between 90 and 95 percent of French nationals would consent to the removal of tissue and organs for organ donation purposes.²⁶²

The South African public perception has grave concerns about organ procurement, which might not always be based upon true facts. The possibility of reforming organ procurement legislation in South Africa to include a policy of either presumed consent or mandated choice would depend on government should institute a public awareness and education program on the advantages and myths of organ program and allocation.

A report of the *Presumed Consent Subcommittee and United Network for Organ Sharing Ethics Committee*²⁶³ assessed the ethics pertaining to the various organ procurement systems. Their study shows that “advocates and opponents of presumed consent are not distinguished by their divergent assessments of the risk that some persons who object to donation will become donors under the presumed consent regime. Rather, the origin of divergence lies in the ethical assessment of tolerable risk. Advocates of presumed consent find permissible cases of false positives. Such cases are excusable due to the following:

- Individual objectors ultimately have the responsibility to register their objections; and

²⁵⁹ Critics argued that presumed consent creates a tyrannical system where “humanity itself ... become[s] no more than the sum of its body parts” Liddy *The “New Body Snatchers”: Analysing the Effect of Presumed Consent Organ Donation Laws on Privacy, Autonomy, and Liberty* Fordham Urban Law Journal (2001) 816.

²⁶⁰ Cassell *Health and Wellbeing: Options for Organ Donors* The Daily Telegraph (London) July 16 1999.

²⁶¹ The *Conseil d’Etat* later, in March 1978 amendment the Law of 1976 to a strong presumed consent organ procurement system. The reason was primarily due to health professionals asking permission for organ procurement, even though it is not required.

²⁶² Caplan *Organ Procurement: It’s Not in the Cards* 14 Hastings Center Report (1984) 9 (5).

²⁶³ Dennis et al 4.

- False positives, which arise due to mechanical breakdowns, must be weighed against the greater good of increasing the supply of organs.

Opponents, in contrast, perceive a statist, non-individualistic intent behind presumed consent. That is, opponents perceive that advocates of presumed consent can predict -- before the policy is implemented -- that presumed consent would remove organs from persons who objected to donation. Respect for individual conscience, for policy opponents, is a core value that should supersede the social utilitarianism underlying presumed consent.”²⁶⁴

The report lists the following ethical advantages²⁶⁵ (supported by the advocates in favour of the doctrine of presumed consent) and the disadvantages²⁶⁶ (supported by the opponents of the doctrine of presumed consent). Advocates argue the following points:

- “Efficiency is good. Increasing the supply of organs -- that is, supply-side efficiency -- is a worthwhile goal. It is sufficiently important to collect more organs that other goals and values, within limits, may be compromised;
- Asking for consent can be cruel. Presumed consent would obviate the need to ask the donor's family for consent at a time of family's painful grieving;
- Individual conscience can be respected. Presumed consent respects the principle of individual choice by giving objectors to organ donation an opportunity to empower their anti-donation preference; and
- Individuals owe society the effort to register their objection. Individuals who object to organ donation should be burdened with the task of registering their preference to the public authorities because organ donation is, presumptively, socially desirable. The burden of

²⁶⁴ *Ibid.*

²⁶⁵ Dennis et al 3.

²⁶⁶ Dennis et al 4.

communicating objection should be placed on objectors to organ donation.”

Opponents of presumed consent base their position on the following presuppositions:

- “There will be false positives, that is, persons who were 'presumed' to consent but who, in fact, objected to donation. Under a policy of "presumed consent," some individuals who do object to organ donation in principle will not register their preference with public authorities because of one of many factors. For instance, individuals on the margins of society might not learn of their option to register their refusal. Furthermore, individuals have differential access to the mechanism for registering refusal, as in the case of itinerant persons who may not receive a postcard informing them of the opting-out alternative
- Problems in registering and transmitting objection status. The mechanism for registering and transmitting objection status is likely to be inadequate. Only a nationwide database of objectors is ethically justified because individuals may suffer irreversible cessation of brain function outside their state of residence. There is uncertainty whether mailed-in objection notices will be entered on the database and whether the information will be distributed to organ procurement organizations in a timely fashion.
- Individual autonomy speaks to a core value. Asking individuals to publicly express their objection to donation does not respect the individual's right not to choose. Individuals do not have a social duty to express an objection.
- Deciding whether to consent is not a dichotomous choice. Individuals should have the right to delegate the decision to family members.

Presumed consent would authorize collection of organs of a non-objector who had trusted his family to make the decision.”²⁶⁷

To evaluate the ethics of presumed consent, it not merely a simple decision to determine that the advocates are correct and the opponents are wrong or *vice versa*. The issues surrounding the law and ethics of these organ procurement systems are very complex. Both sides of the ethical argument have valid points.

5. Organ Procurement Incentives

Incentives were created to assist the functioning of organ procurement systems. In this regard, these incentives focus on practical activities that should be preformed by the public to realise the “static” requirements of organ procurement systems. This dissertation analyses the following incentives: the principle of required response and the principle of required request.

5.1 The Principle of Required Response

One of the main characteristics of a legitimate and publicly accepted organ procurement system, is the donor’s degree of active participation in his / her decision to either “opt-in” or “opt-out” of the organ donor pool. Procurement systems which do not provide an opportunity to give legally recognised consent by the person who is regarded as a donor, is not only illegal in terms of most legal systems based upon the principles of fundamental rights, but will also receive a great deal of public disapproval. This incentive that is deemed to receive more public support is the principle of required response, also referred to a mandated choice.²⁶⁸

5.1.1 Defining Required Response

The principle of Required Response is a statutory created procurement incentive, which requires that all adult citizens be obliged to express their

²⁶⁷ *Ibid.*

personal preferences²⁶⁹ in respect of organ transplantation. Objections will be recorded pertaining to their willingness or objection to donation.²⁷⁰

These recorded decisions are subsequently registered in an organ donation register, upon which the donor would be issued with a registered donor card²⁷¹, which indicates that the person consented to organ donation after death.

5.1.2 Basic Characteristics of Required Response

The principle of required response has been created as an incentive to increase organ procurement through an established organ procurement system requiring explicit consent, by compensating altruistic feelings experienced by an individual and his / her next-of-kin, into the creation of active association and positive feelings about organ transplantation by the individual and his / her next-of-kin.²⁷² The main characteristic whereupon this principle is based, is twofold:

- Patient autonomy through an individual's freedom of choice to either "opt in" or decline organ transplantation which is preserved;²⁷³ and
- Promotion of active association between potential donor and family members.²⁷⁴

²⁶⁸ Price 155; Dennis et al 6; Spital *In the Balance, Mandated Choice for Organ Donation: Time to Give it a Try* Annals of Internal Medicine 125 (1996) 66 at 69; Mackey and Kjerulf 52

²⁶⁹ According to Dennis et al, the individual would have the option to delegate the donation decision to his or her next-of-kin or designated surrogate.

²⁷⁰ Dennis et al 6.

²⁷¹ The decision to "opt" in can also be recorded on an official document such as a driver's licence or identification book. Johnson *A Study of the United States' Organ Donor Programs* Report prepared for the United States State Departments of Motor Vehicles (May 1993).

²⁷² Cohen *Increasing the Supply of Transplant Organs: The Virtues of a Futures Market* George Washington Law Review 58 (1989) 1 at 1-51; Matas, Arras, Muyskens, Tellis, and Veith . *A Proposal for Cadaver Organ Procurement: Routine Removal with Right of Informed Refusal* Journal of Health Politics, Policy and Law 10 (1985) 231 at 231-245. Katz *Increasing the Supply of Human Organs for Transplantation: A Proposal for a System of Mandated Choice* Beverly Hills Bar journal, Summer (1985) 152.

²⁷³ Stipal suggests at 70 that "...because all adults would be forced to consider this issue, mandated choice might be the most effective method for increasing public awareness of the great value of organ donation, and this might further stimulate participation ... Finally, mandated choice would preserve altruism and voluntarism, which are the philosophical foundations of our current system for obtaining consent. Indeed, mandated choice would promote autonomy because, more than any other system, it would ensure that a person's wishes would be honored, whatever they may be."

²⁷⁴ An American Medical Association report on strategies for organ procurement states that "Clear knowledge of the decedent's preferences may make it easier for families who might be opposed to accept the decision to donate. One recent survey indicated that 93% of respondents would honor the

This incentive functions through the belief that if a compulsory registering system linked to an aggressive informative public awareness campaign is introduced, it would eventually increase donor rates. This system would not only help initiate discussions and decision-making between family members, but also help health practitioners who are in most cases reluctant to approach family members to procure organs and tissue.

The principle of required response envisages to “force” a person to decide upon becoming a donor and to encourage family participation in this matter prior to that person’s death, the donor’s right to patient autonomy and freedom of choice are respected as well as the family “right of approval”.

(a) “...required to register a decision”

Studies show that the primary reason for people not wanting to become organ donors, even though they might support the concept of organ donation, is a prevalent reluctance to consider their own mortality and “the prospect of bodily mutilation that organ harvesting entail”.²⁷⁵ Most authors refer thereto that further detrimental factors hampering organ procurement, such as the inappropriate time period in which family members are approached to consent to the removal of organs and tissue of their deceased family member and the stress accompanying that decision-making process.²⁷⁶

To alleviate this problem, Robert Veatch²⁷⁷ proposed a system whereby every adult citizen should at a specific time such as elections, filling of tax returns or applying for a driver’s licence, register a form stating their willingness or reluctance to organ donation. The application of such person will not be processed, unless the required response registration form accompanies the application. This “forceful” method allows that person a chance to learn about organ transplantation, does not infringe his / her rights to self-determination

expressed wishes of their family member regarding organ donation if those wishes were known”
American Medical Association (AMA) *Strategies for Cadaveric Organ Procurement* 810.

²⁷⁵ *Ibid* 178.

²⁷⁶ Dennis et al 6; Stipal 68 - 70; AMA *Strategies for Cadaveric Organ Procurement* 810; Price 155

²⁷⁷ Veatch *Death Dying and the Biological Revolution* (1976) referred to by Dennis et al.

and to make an informed decision; and decrease the regularity of family refusals by involving the family in the decision making process.

Price raises the question if it wouldn't be too intrusive and coercive to legally force individuals to make a decision, especially in countries with organ procurement systems based upon explicit consent?²⁷⁸ Advocates of required response answer this question in the negative, because they point out that required response in actual fact allows that the choices of individuals are respected.²⁷⁹ Dennis further states "...based on previous survey research, is that the primary reason more people do not sign their donor cards is because no authority had asked them."²⁸⁰

Thus, the principle of required response respects and promote decision-making on individual level, whilst easing the stress levels associated with normal organ donation decision-making processes.

(b) "...at a specific time"

Required response can only function at the occurrence of a specified event or time.²⁸¹ The nature and re-occurrence of the selected time is of utmost importance to establish the correct functioning of required response. The time or event should be chosen, to include the greatest number of adult citizens and to ensure frequent re-occurrence. Most authors refer to the time when the required response form should be filled in, when adult citizens apply for national identification documents, driver's licences²⁸², or submit tax return forms.²⁸³

²⁷⁸ Price 155.

²⁷⁹ Stipal 70; Katz 152; AMA *Strategies for Cadaveric Organ Procurement* 809. Surveys taken in the United States show 65% out of a total 1000 adults interviewed would support mandated choice.

²⁸⁰ Dennis et al 7

²⁸¹ Stipal 70; Dennis et al 6; Price 155

²⁸² Research done in the United States indicate in 15 states which the States Departments of Motor Vehicles (DMVs) which requires DMV employees to ask applicants for drivers licences whether they would like to become organ donors, most states have experienced problems with donor registries. Dennis *ibid* states "Donor registries have not yet been organized on a scale and accessibility necessary to be useful to organ procurement organizations. Four states (Florida, Ohio, Illinois, and Oregon) have gone furthest in registering donors however; it is unclear whether the collected information assists procurement organizations in the identification of donors. While many states have recognized the need for a more active approach to informing individuals of the importance of expressing their preference toward organ donation, few have begun to collect this preference information systematically. To implement the policy of required response, the federal government would coordinate the activities of

(c) “...upon their death”

It is re-affirmed that the principle of required response is only an incentive used with an existing procurement system such as explicit consent. Once a person registered to become an organ donor after death, the registration form will be *prima facie* proof of consent and furthermore, guaranteeing the presence of informed consent.²⁸⁴ Interestingly, required response can also be used as a transitional instrument in reforming organ transplantation regimes from explicit consent to procurement system based upon the doctrine of presumed consent.²⁸⁵ The information campaign used in required response would lay the basis for establishing information used to inform the public about presumed consent.

5.1.3 The Role of the Family

Probably the most notable philosophical directive of required response, is promoting a more direct role that the family should play in organ transplantation, especially increasing organ procurement.²⁸⁶ This philosophical approach tries to create awareness, trust and decision making among family members, which would stimulate a positive reaction in the community as a whole to organ transplantation. Stipal states “[a]lthough mandated choice would give ultimate control regarding organ donation to the individual, this does not mean that the family is unimportant. Family discussions about this sensitive issue have always been of great value, and they always will be. Such discussions may provide useful insights that can help people explore

DMVs. Coordination is necessary to standardize the form that is used to collect preferences and for computerized recording of preferences and identifying information. Motor vehicle departments would "require responses" from driving-age adults at the time of license acquisition and renewal. In "mandating response," states would be required to distribute the Required Response Form (to be given a less officious name) to individual applicants and collect the signed forms as a condition for individuals to receive a driver's license or renewal. Although the states would administer the form and collect signatures, the information itself would be centralized in a National Donor Registry. On a weekly basis, states would collect signed forms and ship them to the relevant organization for processing. The NDR would be accessible by all OPOs on a real-time basis so that OPOs can be told of the individual's preference towards donation regardless of the individual's place of residence (i.e., in or out of state)."

²⁸³ Mackey and Kjerulf 52

²⁸⁴ The nature of informed consent can be identified as "*selbstbestimmungsaufklärung*". This form of informed consent is used for the purpose of procuring consent from a patient and to guarantee that that patient exercises his / her right to self-determination.

²⁸⁵ See further Dennis et al who also support this notion.

²⁸⁶ Dennis et al 7; Stipal 170; American Medical Association Report *Mandated Choice and Presumed Consent for Cadaveric Organ Donation* Journal of the American Medical Association 272(10) (1994) 809 at 809 – 812; Price 155.

their own feelings as they try to decide whether or not to donate. These exchanges also serve to inform family members of each other's wishes. This knowledge may avoid the distress that might otherwise occur if organs were taken from recently deceased persons who had previously agreed to donate but had not notified their families of their wishes. Furthermore, although most people in the United States seem to believe that adults should decide about organ donation for themselves, a significant minority believe that their families are better suited for this task.”

Earlier in this chapter, reference was made to the degrees of the doctrine of presumed consent. Any right of refusal, which is granted to the family members of the donor, is important to determine whether a hard application or soft application of the principle is used.²⁸⁷

5.1.4 Required Response versus Presumed Consent

The main distinction between required response and presumed consent is reflected upon the fact that required response is not regarded as an organ procurement system, but rather an incentive to increase procurement of organs and tissue using an organ procurement system based upon explicit consent. The doctrine of presumed consent has been established, as an organ procurement system in it's own right.²⁸⁸

Explicit consent systems uses required response to establish whether the nature of a particular person mind set about organ donation. Thus, the difference between required response and presumed consent is actually just the differences between explicit consent and presumed consent, which is applicable to this paragraph.

²⁸⁷ The principles relating to the hard and soft application of the doctrine of presumed consent is equally applicable in this paragraph.

²⁸⁸ The principle of required response should be used in conjunction with the doctrine of presumed consent to inform the public about organ donation issues and the form can also be used to register objections against the “opting in” system.

5.1.5 Foreign Law

Required response legislation have been primarily regulated on State level in the United States of America, with twenty states applying required response. The following states, Florida, Ohio, Illinois and Oregon apply a rigorous regime of required response. At Federal Law, a required response system has been proposed in the Cadaveric Organ Donor Act, whereby applicants for either a driver's licence, alien registration card, or social security card would be required to indicate whether they would like to become donors and if all organs may be procured, or just stipulated organs.²⁸⁹

5.2. The Principle of Required Request

This incentive is probably one of the oldest. It was originally created in the United States of America to promote organ donation rates by respecting civil liberty rights. The theoretical background looked promising, however the practical implementation proved otherwise.

6.2.1 Defining Required Request

A policy of required request²⁹⁰ places the burden upon hospital staff to consult with either patients or patients' next-of-kin and request that the patient or his / her next-of-kin should consider organ donation, should the patient be near to death or already deceased.²⁹¹ This request only entails a patient or next-of-kin of the patient to consider organ donation and in no manner "forces" the relevant party to provide an answer.

5.2.2 History of Required Request Legislation

The lack in the supply of organs and tissue and in an effort to increase hospital referral rates, led to the institution required request legislation.²⁹²

²⁸⁹ Cadaveric Organ Donor Act as referred to by Kurtz and Saks *The Transplant Paradox: Overwhelming Public Support for Organ Donation versus Under-Supply of Organs: The Iowa Organ Procurement Study* Journal of Corporation Law 21 (1996) 767.

²⁹⁰ Required request is also known as routine enquiry

²⁹¹ Price 102 – 103; Government Accountability Office (GAO) Special Publication On Organ Donation available at <http://www.gao.gov/special/pub/organ/chapter4.pdf> ; Kolber *A Matter of Priority: Transplanting Organs Preferentially to Registered Donors* Rutgers Law Review 55 (2003) 671 at 685; Galen *Organ transplantation at the Millennium: Regulatory Framework, Allocation Prerogatives, and Political Interests* Southern California Interdisciplinary Law Journal 9 (1999) 335; Caplan *Organ Procurement and Transplantation: Ethical and Practical Issues* Centre for Bioethics, University of Pennsylvania Newsletter 2 (1995) available at http://www.upenn.edu/ldi/issuebrief2_5.html

²⁹² See further GAO Special Publication on Organ Donation.

Required request is probably one of the oldest incentives that were introduced to increase organ procurement. The philosophical approach to promulgating required request legislation was that supply of organs were weak due to hospital staff and health practitioners who do not approach patients and families of possible donors, to inform them about the possibility of organ donation.²⁹³ The fundamental belief was, without the possibility of infringing civil liberty rights of patients, if patients and their families were informed about organ donation and option of donating an organ, this would increase the supply of organs and tissue.

The first required request legislation was promulgated in the US state of Oregon in 1985.²⁹⁴ This act, which was repealed in 1995, required hospital personnel to request donation from the next-of-kin of deceased patients and the request had to be certified in the medical records and on death certificates of the deceased donor, as proof that the request was made.²⁹⁵ By the late 1980's twenty six states and the District of Columbia had enacted similar required request legislation. At this stage, implementing of the regulation of required request only fell within the ambit of State Legislators. This situation instituted the Federal Legislator to include required request provisions in the Uniform Anatomical Gift Act of 1987.²⁹⁶

After 1990, two types of required request laws had been developed. The first type focused upon ascertaining the wishes of the person about how they wish their cadaver should be treated after their death and the second type establishes policies that target the next-of-kin of the deceased person.²⁹⁷ The first type focuses solely on the personal feelings of the patient and this type can be classified as a hard application of required request.²⁹⁸ The latter type reflects the weak version of this incentive whereby it is simply required that

²⁹³ Kolber 685.

²⁹⁴ Price 103; Kolber 685

²⁹⁵ *Ibid*

²⁹⁶ Section 5 provides for routine inquiry and required request to be incorporated at U.S. Federal level.

²⁹⁷ Price 30, 102 – 105. The second type of required response can also be called the classical North American type.

²⁹⁸ Authors such as Caplan and Virnig support this statement.

hospital should implement policies to make sure that the next-of-kin are approached.

The outcomes of required request legislation proved to be disappointing. In most case, non-compliance with statutory provisions caused that a lesser amount of organs were procured than originally estimated.²⁹⁹ Other factors, which decreased the success rate, are reluctance on the part of health practitioners to approach grieving family members³⁰⁰ and feelings of altruism on the part of grieving family members.

The expected impact that required request legislation would have had to alleviate the demand of organ donor proved largely to be unsubstantiated³⁰¹ and the principle of required request, as an organ procurement incentive totally failed to achieve it's objectives.³⁰²

5.2.3 Foreign Legislation

The principle of required request originates from the United States of America where required request has mainly been regulated at State level. At Federal level, the most important legislative provision to incorporate required request is the Uniform Anatomical Gift Act of 1968 (as amended in 1987) and the Omnibus Reconciliation Act of 1986.

²⁹⁹ Price 103; Kolber 685; Robertson et al *Concentrated Professional Education to Implement Routine Referral Legislation Increases Organ Donation* Transplantation Proceedings 30 (1998) 214 as referred by Price at 104; GAO Special Report on Organ Donation states "Required request legislation, on both the state and national levels, did not appear to contribute to a substantial increase in donation. In continuing the effort to increase donation, several states, led by Pennsylvania, have passed "routine notification" legislation to address the problem of failure to determine which patients are potential donors (Ehrle et al., 1999). This legislation requires that all deaths or deaths that are imminent within a hospital be referred to the Medicare certified OPO. In other areas of the United States, hospitals and OPOS have voluntarily adopted a policy of routine notification. Reports from an OPO in Pennsylvania indicated substantial increases in organ as well as tissue and eye donations in the 3 years since implementation of routine notification". Siminoff et al *Factors Influencing Families' Consent for Donation of Solid Organs for Transplantation* Journal of the American Medical Association 286 (2001) 71 at 72 states that research show that 13.5% in the United States and 25% in Canada of families were never asked if they considered organ donation.

³⁰⁰ See further Sullivan *The Uniform Anatomical Gift Act, in Organ and Tissue Donation: Ethical, Legal and Policy Issues* (1996).

³⁰¹ Price 104.

³⁰² Sullivan at 24 comments that due to the failure of required request legislation, U.S lawmakers introduced new required request policies, but these "were criticised as imposing too great a burden on physicians and families. Moreover, they too failed to increase donations."

(a) Federal Legislation

(i) Uniform Anatomical Gift Act

The Uniform Anatomical Gift Act was promulgated in 1968 and has been adopted in all fifty states including the District of Columbia. One of the main objectives of the UAGA is noted in the prefatory note of the Act: "... if utilization of bodies and parts of bodies is to be effectuated, a number of competing interests in a dead body must be harmonized, and several troublesome legal questions must be answered. Both the common law and the present statutory picture is one of confusion, diversity, and inadequacy...The Uniform Anatomical Gift Act herewith presented by the National Conference of Commissioners on Uniform State Laws carefully weighs the numerous conflicting interests and legal problems. Wherever adopted it will encourage the making of anatomical gifts, thus facilitating therapy involving such procedures...It will provide a useful and uniform legal environment throughout the country for this new frontier of modern medicine."

Section 5 of the UAGA incorporates the institution of required request at Federal level. Section 5 provides:

“(a) On or before admission to a hospital, or as soon as possible thereafter, a person designated by the hospital shall ask each patient who is at least 18 years of age: "Are you an organ or tissue donor?" If the answer is affirmative the person shall request a copy of the document of gift. If the answer is negative or there is no answer and the attending physician consents, the person designated shall discuss with the patient the option to make or refuse to make an anatomical gift. The answer to the question, an available copy of any document of gift or refusal to make an anatomical gift, and any other relevant information, must be placed in the patient's medical record.

(b) If, at or near the time of death of a patient, there is no medical record that the patient has made or refused to make an anatomical gift, the hospital [administrator] or a representative designated by the [administrator] shall discuss the option to make or refuse to make an anatomical gift and request the making of an anatomical gift pursuant to Section 3(a). The request must be made with reasonable discretion and sensitivity to the circumstances of the

family. A request is not required if the gift is not suitable, based upon accepted medical standards, for a purpose specified in Section 6. An entry must be made in the medical record of the patient, stating the name and affiliation of the individual making the request, and of the name, response, and relationship to the patient of the person to whom the request was made. The [Commissioner of Health] shall [establish guidelines] [adopt regulations] to implement this subsection.

(c) The following persons shall make a reasonable search for a document of gift or other information identifying the bearer as a donor or as an individual who has refused to make an anatomical gift:

(1) a law enforcement officer, fireman, paramedic, or other emergency rescuer finding an individual who the searcher believes is dead or near death; and

(2) a hospital, upon the admission of an individual at or near the time of death, if there is not immediately available any other source of that information.

(d) If a document of gift or evidence of refusal to make an anatomical gift is located by the search required by subsection (c)(1), and the individual or body to whom it relates is taken to a hospital, the hospital must be notified of the contents and the document or other evidence must be sent to the hospital.

(e) If, at or near the time of death of a patient, a hospital knows that an anatomical gift has been made pursuant to Section 3(a) or a release and removal of a part has been permitted pursuant to Section 4, or that a patient or an individual identified as in transit to the hospital is a donor, the hospital shall notify the donee if one is named and known to the hospital; if not, it shall notify an appropriate procurement organization. The hospital shall cooperate in the implementation of the anatomical gift or release and removal of a part.

(f) A person who fails to discharge the duties imposed by this section is not subject to criminal or civil liability but is subject to appropriate administrative sanctions.”

(ii) Omnibus Reconciliation Act

This Act was enacted on the recommendation of a Task Force established by the U.S. Government to investigate the required request. The objectives of the Act require *inter alia* all hospitals participating in MediCare or Medicaid to institute required request policies. One of the directives of the Act at Federal level requires hospital to be affiliated with a federal mandated Organ Procurement Organisation (OPO) and to coordinate the procurement and transplantation process at local levels.

(a) State Legislation

Required Request was first introduced at U.S. state level in the mid 1980's as an incentive to increase organ donation. In 1985, three U.S. states promulgated the Required Request Law. The first state was Oregon, where after New York State and Pennsylvania followed suit in the same year. By 1990 most remaining state implemented required response.

7. Conclusion

The primary purpose of this chapter is critically scrutinizing the doctrine of presumed consent in light of current South African law. The most important part of this chapter assesses the true nature of consent in presumed consent. The question is whether it can be stated that real consent is present in presumed consent? If the answer is yes, is consent, in actual fact informed consent? These are just some of the most important questions raised in this chapter. The true nature of the doctrine of presumed consent as an organ procurement system, depends mainly upon the supply and easy accessibility of information. Just as in the case with the doctrine of informed consent, the duty of disclosure that rests with the health practitioner is equally of importance in the application of presumed consent.

For a person to be able to give informed consent, or to be presumed that the (now deceased) person gave consent through his / her omission to register an objection, there must be *prima facie* evidence that the person had sufficient information about the medical procedure supplied by the health practitioner, understood the information and made the decision based upon that information. If it is proved that there was a breach in the duty to disclosure information by the health practitioner, it cannot be said that the patient gave informed consent, or it cannot be presumed that (informed) consent is present.

Apart from the legal principles of the doctrine of presumed consent, this chapter introduced the reader to some of the most important ethical perspectives surrounding the doctrine of presumed consent. Although, the ethical approach to organ procurement systems are not binding principles as legal requirements given by legislation, they are of importance to the development of policy, which will later be used to develop the law.

Finally, the dissertation introduces the reader to two of the most well-known organ procurement incentives. Incentives play a very important role in the practical execution of organ procurement systems, and without proper functioning incentives, organ procurement systems will never function properly.

CHAPTER THREE

PRESERVATION OF TISSUE AND ALLOCATION PROCEDURES

1. Introduction

In Chapter One, it was mentioned that the substance of transplantation law contains, by nature very controversial issues. However, none is more so controversial than distribution of human organs and tissue. Ever since medical technological advancement made saving lives possible through transplantation procedures, patients sought after the opportunity that their lives might be saved. The harsh reality depicts that there are numerous obstacles standing in the way of successful transplants for many transplant candidates. This unfortunate situation is the foremost cause for candidates to question the fairness and equitability of procurement and allocation procedures. The media has also contributed towards speculations of corrupt organ distribution practices.

In this chapter, issues pertaining to preservation of human tissue is analysed in view of a deficient regulatory framework. Secondly, an overview is provided of the main ethical approaches to organ allocation procedures. The primary focus in the part of the chapter evaluates a selection of ethically controversial criteria that effects organ allocation. Finally, a comparative discussion evaluates the provisions of the legislative framework regulating organ allocation in South Africa, Belgium and the United States.

2. Preservation of Human Tissue

The second phase in the transplantation process establishes a framework for the protection of human tissue once it has been removed from the donor and prior to transplantation in the body of the recipient. It is crucial that there should be an efficient interchange between the health practitioner who

performs the operation and the hospital or institution where the recipient is located, to ensure fast and reliable transplantation best practice. This means that a regulatory framework should be drafted to indicate the best manner in which such processes should function.

The main purpose of safeguarding human tissue focuses firstly on ensuring that tissue should be used for the correct purpose and secondly, protection from infectious diseases. The approach ensures that this regulatory framework ensures public confidence in the national health system, transplantation technology and organ transplantation.

2.1 South African Position

South African regulatory framework does not provide a comprehensive system for preserving tissue. Within these limited measures present donated tissue may only be used for a specific purpose. These guidelines are statutory entrenched in terms of the National Health Act. However, it is important to analyse repealed legislation to get an understanding of the evolution of these provisions.

2.1.1 The Human Tissue Act

(a) Purpose of Donation

The Human Tissue Act establishes that removed tissue may only be used for certain purposes. The Human Tissue Act, such as in the case of the National Health Act was drafted to make a distinction between tissue procured from living donors and cadavers. The Human Tissue Act commences in section 4 by stating that a human body or specific tissue may after removal only be used for the following purposes:

- if the tissue was donated to a hospital, educational institution, a dentist or a medical practitioner or an authorised institution³⁰³, the tissue may only be used for medical or dental training and research; and the advancement of medicine, dentistry or therapy which

³⁰³ Section 3(1)(a) to (e)

includes the use of the tissue in any living person³⁰⁴ for the production of a therapeutic, diagnostic or prophylactic substance³⁰⁵;

- if tissue was procured to be used for therapeutic purposes, that procured tissue may only be used for such purposes³⁰⁶; and
- if the tissue was donated to a hospital, a university or technikon; or an authorised institution (the donee), that donee may supply the tissue to any other authorised institution or medical practitioner or dentist³⁰⁷

The purpose for which the donated tissue are to be used, need not be expressly stated, however a donation will have no effect if it was made for any other purpose that stipulated in section 4(1).

Section 19 continues by declaring tissue, blood and gamete procured from living persons will only be used for medical or dental purposes³⁰⁸. A statutory limitation is placed upon any tissue, blood or gamete procured from a person who is mentally ill³⁰⁹, a minor and which is not replaceable by natural processes, a person who has been declared a habitual criminal³¹⁰ and the usage of a placenta, foetal tissue and umbilical cord³¹¹. Section 23 grants the authority to control of removal and use of tissue and blood to medical practitioners, dentists and a person acting under their supervision to remove, use and transplant any tissue for the body of a living person.

³⁰⁴ A prohibition is placed in terms of section 16 against the removal of a gonad and transplantation into a living person, if it was to be used for procreation.

³⁰⁵ Section 4(1)(a).

³⁰⁶ Section 3(1)(a) read with section 4(1)(b).

³⁰⁷ The authorised institution, medical practitioner or dentist must possess the authority to receive and use tissue.

³⁰⁸ The use of tissue is limited to the transplantation in the body of another living person or the production of a therapeutic, diagnostic or prophylactic substance, in the case of blood, the administering to another living person or the production of a blood product and the use of gamete is limited to artificial fertilization.

³⁰⁹ As defined under the Mental Health Act 18 of 1973.

³¹⁰ Section 286 of the Criminal Procedure Act 51 of 1977.

(b) Preservation of Tissue

The entire Human Tissue Act contains only one section relevant to the preservation of tissue. Section 13 regulates the preservation of bodies for a certain period before use. The person who is in charge of an institution, to which a body has been handed over, must preserve that body for a period of at least fourteen days before it may be used.³¹²

2.1.2 The National Health Act

(a) Purpose of Donation

The legislative drafters used little imagination during the drafting process of the National Health Bill B 32 of 2003. The final version of the National Health Bill (which was promulgated as the National Health Act 61 of 2003) echoes the provisions of the Human Tissue Act pertaining to the purposes and use of tissue from both living persons and cadavers. Section 56 regulates the use of tissue, blood, blood products or gametes removed or withdrawn from living persons. A person is restricted to the medical and dental use of tissue, gametes, blood or blood products removed or withdrawn from a living person.³¹³ Section 56(2)(a) prohibits the removal and withdrawal of tissue, gametes, blood or blood products from mentally ill patients³¹⁴, tissue which is not replaceable by natural processes from a minor, a gamete from a minor and placenta, embryonic or foetal tissue, stem cells and umbilical cord (excluding umbilical cord progenitor cells).³¹⁵

In the case of a donation made from a deceased person, section 64 limits the purposes for which the donation is used. A donation that complies with the requirements of section 62 may only be made for the following purposes: training of students in health sciences; health research; advancement of

³¹¹ The general principle prohibiting the usage of a placenta, foetal tissue and umbilical cord may be suspended if the Minister of Health grants his or her consent that these tissues may be used and the consent given by the donor complies with the statutory requirements.

³¹² The authorised person may remove and preserve any tissue of the body separately.

³¹³ The Minister of Health may authorise the removal or withdrawal of tissue, blood, a blood product or gametes contemplated in section 56(2)(a) and reserves the right to impose any condition which may be necessary in respect of such removal or withdrawal.

³¹⁴ Section 56(2)(a)(i) refers to the mentally ill patients as defined in the Mental Health Care Act 17 of 2002.

health science; therapeutic purposes and the production of a therapeutic, diagnostic or prophylactic substance.³¹⁶

(b) Preservation of Tissue

The National Health Act does not have a particular section that deals with preservation the bodies and tissue as is the case with the Human Tissue Act. Section 68 grants the Minister of Health authority to draft regulations pertaining to tissue, cells, organs, blood, blood products and gametes. This section includes regulations may be drafted on the preservation, use and disposal of bodies, including unclaimed bodies.

Until the date of promulgation of the Regulations of the National Health Act pertaining to the preservation of bodies and tissue are drafted, the extent of the current framework is unclear.

2.1.3 The Health Act³¹⁷

The preservation of tissue through protection against the spread of infectious diseases such as HIV/AIDS plays a central feature in the preservation of tissue. Even though an excellent organ procurement and allocation system might have been established, if healthy tissue cannot be allocate to recipients, all efforts would be deemed pointless.

The Health Act 63 of 1977 (“the Health Act”) was promulgated to provide *inter alia* for measures for the promotion of the health of the South African public. Although this act does not regulate organ donation, two sections impacts related aspects in this chapter. Section 46 establishes a post-mortem examination should be preformed on a human body, if it is suspected that the person died of a communicable disease³¹⁸.

³¹⁵ Section 56(2)(a)(ii) to (iv).

³¹⁶ Section 64(1)(a) to (e).

³¹⁷ The whole of the Health Act 63 of 1977 has been repealed by section 93 of the National Health Act.

³¹⁸ “Whenever any person is suspected of having died of a communicable disease or other medical condition and further information pertaining to the facts of such disease or condition is required in order to determine what steps, if any, may be necessary with a view to preventing the spread of such disease

Removal and burial of dead body is regulated by section 48. When a body is found who has died or is suspected to have died of a communicable disease in a habitable room or where food is kept and prepared, the body is kept for more than twenty four hours elsewhere than in a mortuary or a body is kept in any dwelling where it is likely to cause a nuisance or endanger public health, any magistrate, justice of the peace or medical officer of health may subject to various statutes³¹⁹ direct that the body be removed³¹⁹ to a mortuary, if readily available and buried within a specified time or if no mortuary is available or if the body is of a person certified by a medical practitioner to have died of a communicable disease, that the body be buried immediately or within a specified time.

2.2 Foreign Law

2.2.1 United States of America

The United States provides for one of the most extensive regulatory frameworks on preservation of human tissue. Since the introduction of organ transplantation procedures in the 1950's, the organ procurement, transplantation and banking of tissue produced an industry with an annual turnover of \$100,000,000 however, the preservation of procured tissue went mostly unregulated until the middle of the 1990's.³²⁰ Interests in protecting tissue from the transmission of disease, however commenced almost a decade earlier when ever-increasing medical breakthroughs in transplantation procedures made it clear that tissue can be procured, stored for a period in time and only later, be allocated to a specified recipient. Growing concern by the American public fuelled speculation over the quality and safety of imported

or the recurrence of such condition, and such information cannot be obtained except by means of a postmortem examination of the body of the deceased person, the Director-General or a magistrate for the district in which such body is, may order that a post-mortem examination of such body be made by a medical practitioner and that such body, if buried, shall be disinterred for the purposes of such examination."

³¹⁹ Anatomy Act 20 of 1959, Inquests Act 58 of 1959, Births, Marriages and Deaths Registration Act 81 of 1963, the Anatomical Donations and Post-Mortem Examinations Act 24 of 1970 and Occupation Disease in Mines and Works Act 78 of 1973.

³²⁰ *Human Tissue Intended for Transplantation*, 58 Federal Regulation 65,514 (December 14 1993).

tissue from foreign countries, which prompted the development of a federal regulatory scheme.³²¹

Currently, the Food and Drug Administration (FDA) is responsible for regulating human cellular and tissue-based products.³²² Section 361 of the Public Health Service Act of 1994³²³, establishes a regulatory framework in terms of which the FDA is authorised to regulate human cellular and tissue-based products. This section further provides that the Secretary of the Department of Health and Human Services³²⁴ must draft regulations pertaining to the prevention of transmission or spread of communicable diseases at state level and from foreign countries into the United States.³²⁵

This framework consists of an Interim Rule and a Final Rule. The FDA under the authority of the Public Health Service Act issued an Interim Rule which was applicable to all “banked human tissue and to establishments or persons engaged in the recovery, processing, storage, or distribution of banked human tissue”.³²⁶ The Interim Rule required that all donors be tested for hepatitis B, hepatitis C, HIV/AIDS and that the medical history, “behavioural risk factors, and clinical evidence of disease” should also be assessed.³²⁷ All tested were recorded setting out the results and interpretations of tests information with regard to the donor’s identity, medical history and the destruction of human tissue.³²⁸

In 1998, the Final Rule was issued to amend various aspects regulated by the Interim Rule.³²⁹ The most important development was the introduction of regulations applicable to human tissue obtained and processed from foreign countries.³³⁰ The Final Rule specified that all human tissue imported from foreign sources with the purpose of transplantation into U.S. recipients must

³²¹ Williams *The Regulation of Human Tissue in the United States: A Regulatory and Legislative Analysis* Food and Drug Law Journal 52 (1997) 409.

³²² Official website of the FDA is <http://www.fda.gov>.

³²³ 42 U.S.C Section 264 (1994).

³²⁴ This is the U.S. Minister of Health.

³²⁵ 21 C.F.R. pts 16, 1270; 62 Federal Regulations at 40, 430-31.

³²⁶ 21 C.F.R. Section 1270 (a).

³²⁷ *Ibid* Section 1270.3(b).

³²⁸ Wells *Overview of FDA Regulation of Human Cellular and Tissue-Based Products* Food and Drug Law Journal 52 (1997) 401 at 404.

³²⁹ 21 C.F.R. pts 16, 1270, 62 Federal Regulations at 40,429.

be held in quarantine until cleared by the FDA.³³¹ The Final Rule also requires development of procedures for infectious disease testing, retrieval, review and assessment of medical records; and infectious disease contamination prevention during processing.³³² The FDA drafted an instruction manual to be used in conjunction with the Final Rule entitled “Guidance for Screening and Testing of Donors of Human Tissue Intended for Transplantation”. This manual establishes the FDA’s policy towards the manner in which donors and tissue should be tested.

2.2.2 Belgium

Preservation of human tissue, testing for infectious diseases and regulating tissue banks in Belgium is regulated by one of the most extensive frameworks to be found in the European Union. The Royal Decision of 15 April 1988³³³ regulates human tissue banking from storage of human tissue since procurement of organs until transplantation in the recipient. The Royal Decision requires that clinical, biological, microbiological and immunological donor and donor tissue testing is performed and also stipulates that detailed records should be kept which it used to track the origin, processing and handling of human tissue.³³⁴

3. Organ Allocation Systems

One of the most instrumental reasons for conducting research into the legal implications of organ transplantation is to find a solution to this crucial question: which measures should be introduced to alleviate the ever-increasing demand for transplantable human organs and tissue? This question sparked an immense debate between a number of ethicists, government representatives and jurists, which produced various possible solutions; some of which might be hard to justify under even the most crucial

³³⁰ 21 C.F.R. pts 16, 1270; 62 Federal Regulations at 40, 439-40.

³³¹ *Ibid.*

³³² Wells 405.

³³³ *Koninklijk besluit betreffende de weelselbanken en het wegnemen, bewaren, bereiden, invoeren, vervoeren, distribueren en afleveren van weefsels.* (Besluit 29/04/1988).

principles of basic human rights. The pendulum to determine public acceptance of these solutions range between illegal, unethical to legal but impractical. The purpose of this dissertation is to analyse the legal aspects of some of these solutions.

If one extrapolates the organ transplantation process, three distinct stages can be identified:

- Stage One: Organs and tissue must be removed from a donor;
- Stage Two: The procured organs and tissue must be preserved and maintained; and
- Stage Three: A recipient must be identified to which the organs and tissue are allocated for transplant.

Analysis of each one of these stages show that to facilitate a fully functional and effective transplantation best practice, these stages should be functioning as a single process, rather than three individual processes; for example an established organ procurement system can supply a sufficient number of organs and tissue to waiting list patients, but if these organs cannot be safeguarded sufficiently or ineffective allocation procedures influences that the correct patient obtains the correct organs, the complete process goes into disarray. Thus, it is important that as much time and effort goes into each one of these stages to establish interaction and harmonization in order to ensure transplantation best practice.³³⁵

3.1 Problems associated with Organ Allocation

Once an organ has been removed from a donor, the stage begins to find a suitable recipient that would comply with the unique characteristics of the

³³⁴ See further Markenstein *An Analysis of the State of the Debate on Further Use of Human Tissue in Various European Countries* European Journal of Health Law 2 (1995) 125.

³³⁵ This notion is supported by the Report of the United States Task Force on Organ Transplantation, *Organ Transplantation: Issues and Recommendations*, U.S. Department of Health and Human Services, Washington D.C., 1986 at 86 states "...public support for organ transplantation depends on public confidence that organs are distributed equitably to those who need them".

procured organ. The selection criteria are based upon a number of medical and non-medical procedures, both setting different requirements to determine suitability of organ and tissue recipients. Due to unsubstantiated rumours and media speculation, questions regarding the fairness and equitable of these procedures have been steadily increasing. This chapter evaluates the requirements of organ allocation procedures, especially non-medical criteria and determines whether these requirements hampers fair and equitable distribution of organs.

The second problem that is of particular importance to developing countries such as South Africa; is the macro allocation problem which depends primarily on the public health care system and the availability of resources to fund provision of health care. The type of health care systems (that is an extension of socio-economic rights and policies) used by the country determines if public funds will be reserved to cater for specified medical procedures such as organ transplantation. The main question to the usage of public funds is, whether an obligation rests upon the government to provide transplantation services to the public free of charge or partially free? In other words, is anyone entitled in terms of section 27 of the Constitution to a claim to have access to these specialised health care services? In the light of the *Soobramoney*³³⁶ case, the reality of the *status quo* of the public health system in South Africa, suggests the answer is negative.

3.2 Ethical Approach to Organ Allocation Procedures

The theories of bio-medical ethicists have in the past number of years been the source of power behind the development of allocation procedures. The main reason behind the debates has been to find a solution to guarantee fair and equitable allocation procedures. Many theories have since been introduced which supports the principles of fair and equitable distribution of organs. This dissertation reflects only upon a *capita selecta* of these theories.

³³⁶ 1998 (1) SA 765 (CC).

3.2.1 Stages of Organ Allocation

It is abundantly clear that resources pertaining to the number of transplantable organs and tissue are severely limited. Deciding exactly which patient should be the recipient of an organ proves to be an immensely difficult task as it involves diverse groups of decision-makers.³³⁷ The process of selection can be divided into four distinct stages:³³⁸

- Stage one: which organs are available for allocation;
- Stage two: who is eligible to receive a transplant if an organ is available;
- Stage three: a patient must have been accepted as a transplant candidate; and
- Stage four: the transplant candidate's claim for a particular organ needs to be weighed against the claim of other transplant candidates.

For a successful completion of the transplantation process, the transplant candidate needs to pass through each one of these stages complying with an assortment of medical and non-medical criteria. It is inevitable that only one transplant candidate from a large number of candidates will be chosen and it is obviously unfortunate that the remaining number of waiting list patients would have to wait their turn. Due to this unfortunate situation and constant speculations of favouritism from the media and other sources, for example a certain person of a high social status receiving a transplant after only a short wait, prompted public suggestions on unfair and inequitable allocation practices.

The primary models, which are used to determine the criteria for fair and equitable organ allocation rests upon the medical criteria and the non-medical criteria.

³³⁷ Price 443.

³³⁸ *Ibid.*

3.2.2 Medical Criteria

This first primary model provides for guidelines based upon a medical enquiry to select a suitable transplant candidate. The criteria used to choose a suitable candidate depends solely on medical techniques and procedures. This approach depends on the medical judgement of a health practitioner to make a value judgement pertaining to the likelihood of success of the medical procedure linked to preserving the life of the candidate (minimal life expectancy) and improving the quality of life.³³⁹ The rationale of this approach can be found in the policy guidelines on allocation of limited medical resources of the American Medical Association: “[a] physician has a duty to do all that he or she can for the benefit of the individual patient. Policies for allocating limited resources have the potential to limit the ability of physicians to fulfil this obligation to patients. Physicians have a responsibility to participate and to contribute their professional expertise in order to safeguard the interests of patients in decisions made at the societal level regarding the allocation or rationing of health resources.”³⁴⁰ The guidelines stress further that decisions should always respect the individuality of patients and the health practitioner treating the patient should never make the allocation decision by himself / herself.

The medical criteria involve a two-stage selection. Firstly, a waiting list should be formulated to determine the size of the donor pool³⁴¹ and secondly, a recipient needs to be chosen from the list. This selection is based upon the critical examination of the transplant candidate based predominantly upon various medical examinations and tests.

In order to facilitate that the correct candidate is chosen, various factors such as organ size, blood type, tissue typing, patient compliance and so on are

³³⁹ Brock *Ethical Issues in Recipient Selection for Organ Transplantation*, which forms part of Mathieu (Editor) *Organ Substitution Technology* (2000) 88.

³⁴⁰ Available from the American Medical Association website at <http://www.ama-assn.org/ama/pub/category/8295.html>.

³⁴¹ Brock 87; Writers such as Caplan argue that donor pool should be restricted to only individuals who are suffering from end-stage organ failure. Caplan (1992) as referred by Almeida *Market Failure in Health Care: The Effect of Altruism on the Supply of Blood and Human Organs in South Africa* (Masters Dissertation 2001 University of the Witwatersrand) available at <http://www.geocities.com/humanoffal/>.

used in the selection process.³⁴² In the United States, allocation procedures have been established depending on the type of organ. These policies regulate organ distribution through a process of individual assessment depending on the organ.³⁴³

These policies established by the United Network for Organ Sharing³⁴⁴ (UNOS) is based upon a selection of medical criteria to restrict the number of transplant candidates and to identify the most suitable candidate more securely. Although these policies have been developed as guidelines to be followed in the allocation process, UNOS iterates that the final decision to allocate an organ to a specified recipient remains the prerogative of the transplant surgeon or the health practitioner responsible for the patient.³⁴⁵ The *raison d'être* behind this decision is that allocation procedures should allow health practitioners “to exercise their medical judgement regarding the suitability of the organ being offered for a specific patient, to be faithful to their personal and programmatic philosophy about such controversial matters as the importance of cold ischemia time and anatomic anomalies; and to give their best assessment of the prospective recipient's medical condition at the moment.”³⁴⁶

This appears to indicate that the primary selection derivative must be an individual medical assessment that considers doing the most good with the organ (the best medical outcomes test³⁴⁷). In order to establish accurately what the nature and scope of the best medical outcomes test is; varies depending on the transplant candidates, assessment occurs on a case-to-case basis and selection is based upon medical opinion.³⁴⁸

³⁴² These factors do not form part of a closed list.

³⁴³ <http://www.unos.org/policiesandbylaws/policies.asp?resources=true>.

³⁴⁴ A private, non-profit organization charged with administering the U.S. national organ transplantation network.

³⁴⁵ *Ibid.*

³⁴⁶ *Ibid.*

³⁴⁷ My emphasis.

³⁴⁸ It should be noted that in order to keep this dissertation within a legal perspective, the precise medical criteria are not discussed.

Thus, it would be difficult to establish precise guidelines within a legal context to regulate the best medical outcomes test success rates. This situation is problematic as there is a constant possibility that transplant candidates would feel cheated and in torment that they haven't been selected. This situation will in turn lead to questions regarding fairness and equitability of this test. Due to the nature of this kind of selection process, the possibility of an ethical conflict arising is enormous. According to Brock, the best medical outcomes test will give rise to an ethical conflict when fairness and equitability is evaluated. Brock states "[h]ow these values should be traded off, particularly when the good in question is needed for life itself, is controversial among not only moral philosophers but also the general public. As a result, there is a strong temptation to seek to avoid or absure the ethical or value judgements in selection of recipients...Even in discussions of the issue of recipient selection that are sensitive to the ethical nature of the problem...it is common to find appeals to processes that are said to employ only objective medical criteria to establish a pool or waiting list of eligible recipients and to select recipient from such waiting lists. It is important to emphasize that there are *no* value-neutral selection criteria that could permit bypassing the need to make ethical judgements in the recipient selection process."³⁴⁹

To conclude: selecting a transplant candidate using sole medical criteria presupposes that each candidate's situation will be determined on a case-to-case basis and their chances could either be severely restricted or promising based on the outcome of the medical opinion of a health practitioner. The main problem of the sole medical criteria is the inevitability that certain decision will cause unsuccessful transplant candidates to question the fairness of these procedures. This prompts the immensely controversial question of what would be considered to be fair and equitable allocation of organs?

³⁴⁹ Brock 87 – 88.

3.2.3 Non-Medical Criteria

Fair and equitable organ allocation practices as been widely discussed with many solutions given to solve problems surrounding organ allocation.³⁵⁰

Although the topic of fair and equitable allocation is directly dependent on organ procurement laws, it seems that the main thrust of these allocation solutions are policies developed by ethicists rather than lawyers (which on it's own creates problems for example whether these ethicists properly understand the functioning of the Constitution as jurists would do?).

A variety of ethical theories have been applied to organ allocation, to try to establish an organ allocation system, which proposes to be fair and equitable, yet totally functional to allocate scarce resources. In order to achieve this immense task, various ethical theories and principles have been developed to embark upon deriving at the prefect organ allocation system.³⁵¹

(a) Two Schools of Thought

Although various different ethical theories on allocation procedures have been developed, two overarching ethical approaches have been developed: one school of thought believes distribution of scarce resources such as human organs should be allocated in terms of the principle of social utility (utilitarian approach) where the other school suggest the egalitarian approach should be followed.³⁵²

(i) The Utilitarian Approach

The utilitarian approach requires explicit assessment of the qualifications of candidates with the purpose of achieving the best consequences of activities.³⁵³ The primary focus of this approach is to attempt to create the

³⁵⁰ Brock 93;Curran et al *Health Care Law and Ethics* (1998) 767; Lamb *Organ Transplants and Ethics* (1990) 129;Price 459; Veatch *Medical Ethics* (1997) 259.

³⁵¹ To my observation of this topic, it is my impression that these policies should be developed by a multi-discipline (diverse) group of professionals consisting of jurists, ethicists, health practitioners and other professionals who have an interest in the development of these policies and a government funded health care system that would be able to provided these transplantation services (or part thereof) to the general public.

³⁵² Veatch 259.

³⁵³ Veatch 259; Cookson *Principles of Justice in Health Care Rationing* Journal of Medical Ethics 26 (2000) 326.

greatest happiness³⁵⁴ within society, which in terms of an organ allocation procedure translates into organs, being allocated to promote the greatest advantage to the largest number of people.³⁵⁵

The utilitarian approach can be divided into act and rule utilitarianism, where the former refers to “rightness with respect to particular acts – an act is right if and only if it maximizes net utility” and the latter refers to “rightness with respect to rules of action and make the rightness of particular acts depend on the rules under which those acts fall”.³⁵⁶ According to Buchanan the distinction between act and rule utilitarianism is important when establishing a theory of justice “...because rule utilitarianism must include an account of when institutions are just. Thus, institutional rules may maximize utility even though the rules do not direct individuals as individuals or as occupants of institutional positions to maximize utility in a case-by-case fashion. For example, it may be that a judicial system that maximizes utility will do so by including rules that prohibit judges from deciding a case according to their estimates of what would maximize utility in that particular case. Some utilitarians hold that principles of justice are the most basic moral principle because the utility of adherence to them is especially great. According to this view, utilitarian principles of justice are those utilitarian moral principles that are of such importance that they may be enforced, if necessary. Some utilitarians also hold that among the utilitarian principles of justice are principles specifying individual rights, in which that latter are thought of as enforceable claims that take precedence over appeals to what would maximize utility in the particular case.”³⁵⁷ In laymen’s terms this can be interpreted that to maximizing the benefit to society and ensuring that wrong candidates are not chosen, utilitarians will consider the social impact of allocating a scarce resource, expected medical benefits and medical and non-medical consequences to all living within society.³⁵⁸

³⁵⁴ Philosophers state that the essence of the term “utility” gives reference to “pleasure, satisfaction, happiness or as the realization of preferences, as the latter are revealed through individuals’ choices. See further Veatch 339.

³⁵⁵ Humber et al *Biomedical Ethics and the Law* (1979) 2 – 3.

³⁵⁶ Veatch 339.

³⁵⁷ Veatch 339.

³⁵⁸ Veatch 312.

Although this theory applies the principle *for the good of society*, also seems to support fair and equitable organ allocation, the main problem facing utilitarians is determining the effect of forecasting outcomes, such as estimating and quantification of costs and benefits of actions and consequences.³⁵⁹ Further problems experienced is that it is impossible to have an absolute fair and equitable allocation based upon utilitarian theory.³⁶⁰

(ii) The Egalitarian Approach

The utilitarian theory centres their approach to efficiency where the egalitarian theory focuses their approach to equity, dignity, fairness and especially justice. The egalitarians emphasize equal access to the goods in life that every rational person values.³⁶¹ A particular emphasize is placed upon those persons in society who are the least well off. If this theory is related to organ allocation procedures, it means that everyone having equal need for the scarce resource is to have equal access to it.³⁶² Beauchamp refers to Daniels's theory which emphasises that the importance of this theory should be placed upon the allocation of needs and when a decision to allocate a scarce resource is made, that decision should incorporate fair opportunity: "Daniels's thesis is that social institution affecting health care distribution should be arranged, as far as possible, to allow each person to achieve a fair share of the normal range of opportunities present in that society. The normal range of opportunity reflects the range of life plans that a person could reasonably hope to pursue, given his or her talents and skills. This theory, like Rawls's recognizes a positive societal obligation to eliminate or reduce

³⁵⁹ Davies *Textbook on Medical Law* (1996) 7.

³⁶⁰ Veatch at 340 states "It has been argued that utilitarianism is not capable of providing a secure foundation for a universal right to health care – a right to at least some minimal core of health-care service for everyone. Certain classes of individuals might be excluded from virtually all health-care services. The class of newcomers with Down syndrome (formerly classed Mongolism), for example, might well be excluded from the 'decent minimum' of health care (and other goods and services), which others should receive as a matter of derivative right on utilitarian grounds. These retarded individuals, who often also suffer from serious physical disabilities, tend to require a rather large outlay of social resources over the course of their lives. Relative to the costs of caring for them, the contribution these individuals make to social utility may not be large, at least so far we are limited to a concept of contribution that permits quantification. If this is the case, utilitarianism will permit – indeed will require – that these individuals be excluded from the right to health care."

³⁶¹ Beauchamp and Childress *Principles of Biomedical Ethics* (2001) 230; Veatch 266.

³⁶² Veatch 349; Menzel as referred to by Veatch, states that "all resources are to be distributed so as to approximate, as nearly as possible, a condition in which everyone's net welfare over a lifetime is equal".

barriers that prevent fair equality of opportunity, an obligation that extends to programs to correct or compensate for various disadvantages.”³⁶³

The equalitarian approach focuses primarily on the length of time transplant candidates have to wait on the waiting list and the possible usage of a national organ lottery system. Although these methods seem to promote fairness and equitability, critics point out this theory is flawed by reason that “it would be irrational for anyone – including the worst-off – to insist on equality if allowing certain inequalities would improve everyone’s situation”³⁶⁴ and secondly, whilst the egalitarian theory proclaims that everyone will have access to scarce resources, if those resources are not available to everyone else of similar need, allocation procedures can never be absolutely fair and equitable, because those “so long as there are inequalities in income and differences...some people will be prohibited”³⁶⁵ from receiving an organ due to their financial status. Thus, although this approach promotes equality, it lacks in various other areas such as regarding the patient’s financial standing in society.

(iii) Other Ethical Approaches

Apart from utilitarianism and the egalitarian approach, other theories have been developed such as the entitlement theory, which promotes that human organs may be bought and sold, if it would promote the procurement and allocation thereof.³⁶⁶ This theory is morally apprehensive, because it literally encourages buying life and just enhances the divide between rich and poor to obtain organs within a fair and equitable manner.³⁶⁷

The theory developed by Liberal Individualists establishes a rights-based theoretical approach. According to this theory the rights of all participants, for

³⁶³ Beauchamp 234.

³⁶⁴ Veatch 350.

³⁶⁵ *Ibid.*

³⁶⁶ See further Merrill *The Control of Living Body Materials* Annals of Internal Medicine 75 (1971) 631.

³⁶⁷ Veatch *The Patient-Physician Relation: The Patient as Partner (Part 2)* in *Smith Medical Ethics Series* (1991) 217.

example donor and recipient are assessed to determine unequal treatment, intolerance and so forth.³⁶⁸

Finally, the Rawlsian Maximin Principle, introduced by Rawls in “A Theory of Justice” in 1971 proposes that every person is the bearer of equal rights to “the most extensive total system of equal liberties compatible with a similar system of liberty for all”.³⁶⁹ This principle presupposes that resources should be committed to the least well off in society, even if this decision might not be the most plausible.³⁷⁰

It is certainly clear from the principles of each one of these ethical approaches that they assist in creating various frameworks on organ allocation through which organs and tissue can be allocation in the most fair and equitable manner possible. However, as opinions regarding these approaches differ, it is impossible to determine which one of these theories is absolutely suited to providing the most favoured policy. In my opinion, a combination of these ethical theories should be applied to devise an allocation policy that would be suited to most people (which is also clearly questionable).

(b) *Capita Selecta* of the Ethically Controversial Criteria effecting Organ Allocation

In the above-mentioned paragraphs, reference was made to the various ethical theories that propose a philosophical approach to organ allocation and developing of policies, which undertake to promote fairness and equitability. Although, the fundamental principles of these theories differ, several ethically controversial selection factors exist affecting fairness and equitability.

(i) The Age of the Recipient

Probably one of the most predominantly featuring non-medical criteria is evaluating the age of a transplant candidate to determine whether it would do the most good to allocate the scarce resource to a person falling within a

³⁶⁸ See further Beauchamp 355.

³⁶⁹ Hiller *Medical Ethics and the Law, Implications for Public Policy* (1981) 23.

³⁷⁰ Veatch *Transplantation Ethics* (2000) 264.

certain age group. The reason why age features so predominantly as a factor can be classified as "...in cases in which the increased age of the patient correlates negatively with life expectancy with the transplant."³⁷¹ The age of a candidate directly affects whether it would be doing the most good with the resource if there were little expected length of patient survival.³⁷² This factor raises many ethical dilemmas, the first being the most obvious: a transplant is needed for the candidate to live and without it the candidate will most certainly die. In the light of this dilemma, some authors such as Brock argues that "[a]lthough this is true enough it does not imply that more good is not done when a life-prolonging transplant is provided for a patient who will likely live five years with it instead of for a patient who will likely live only one year with it."³⁷³

Other related questions are whether children and the elderly should receive preference? Arguments in favour of choosing a young person as a recipient as it is doing the most good with the resources will most certainly be accepted. The rationale behind this solution is because it is probable that they will receive greater benefits from the resource for example survival is higher and they recover faster.³⁷⁴ On the other hand, in the light of fairness and equity, can it be justified to discriminate against candidates based upon their age?³⁷⁵ Some authors, such as Veatch³⁷⁶ believes that discrimination based upon age can be ethically justified, because younger persons have not had the privilege to enjoy a long life as the elderly have been privileged to.³⁷⁷ The Constitutional challenge to this statement is evidently section 9, which prohibits unfair discrimination based upon age. If the test of proportionality is applied, depending on the particular facts of the case, it is difficult to justify discrimination of this kind.

³⁷¹ Mathieu 90.

³⁷² *Ibid.*

³⁷³ *Ibid.*

³⁷⁴ Veatch *Transplantation Ethics* 337.

³⁷⁵ Churchill *Should We Ration Health Care by Age?* *Journal of the American Geriatrics Society* 36 (1998) 644.

³⁷⁶ *Transplantation Ethics* 338.

³⁷⁷ Connected to this factor, is the question whether quality of the life of the recipient would be extended? This quality of life factor which also forms part of assessing how much good is done to allocate an organ to a specific recipient, needs assessment of success on an individual level, depending on the recipient and the life he / she is leading.

(ii) The Beneficial and Harmful Effects for Other Persons

This factor considers a transplant candidate's psycho-social criteria post operation. This is the case where the candidate's ability to cope with a transplant is assessed on a psychological level.³⁷⁸ The criteria taken into consideration includes:

- Whether the candidate has a family or he / she is instead a loner with few social ties?³⁷⁹;
- Does the candidate have a history of drug or alcohol abuse?;
- Did the candidate ever suffer from suicidal tendencies which were cause by stress, depression, or related illnesses?; and
- The candidate's ability to comply with any post operation requirement to preserve the newly transplanted organ?

The application of the psycho -social criteria is probably one of the most important ethical criteria, however, to my comprehension, this criteria should be used with caution, as it only forms a small part of the total assessment of the candidate and each case should be individually assessed to guard against prejudice.

(iii) Patient Sensitisation

Several ethically challenging factors exist that is closely related to both medical and non-medical criteria such as patient sensitisation and urgency of need.³⁸⁰ Patient sensitisation refers to patients who develop antibodies to a large number of different antigens with the result that these patients are incapable of finding a suitable matching donor. Due to this extraordinary situation, some authors argue that these sensitised patients should be given a higher priority if a suitable matching organ(s) can be found.³⁸¹ From a fair and equitable point of view, perhaps it would be permissible to allow, "queue

³⁷⁸ Lamb 130; Mathieu 91.

³⁷⁹ Mathieu at 91, Brock argues that "[t]here seems no plausible reason why the effects on others besides the potential recipients should be excluded from an assessment of the overall benefits and harms done as a result of who is selected for transplantation. Some other ethical considerations is needed to restrict concern only the effects on the patient."

³⁸⁰ Mathieu 92.

³⁸¹ *Ibid* 92.

jumping” to such an unique situation. Certainly, it would be doing the most good with an organ to allow it, however, selection should always be evaluated on a case-to-case basis.

(iv) Ability to Pay

In any developing country where access to health care is limited to the availability of resources, this factor is essentially contention as it confronts patients with the realities of organ transplantation.³⁸² It is a sad fact that a patient’s ability to pay the medical costs involved with the transplantation operation will, in most circumstances, dictate who becomes a recipient and who will not. From an ethical perspective, there is little that could be recommended to better the situation.³⁸³

The legal standpoint is unfortunately in agreement with this view. A constitutional challenge in terms of section 27 to compel the state to take reasonable measures, within its available resources, to provide free access to these health care services, have already been contested. In *Soobramoney v Minister of Health*³⁸⁴, the court dismissed an application to direct a hospital to provide health care services to the applicant on the grounds that they (as a state funded hospital) could not allocate limited resources due to the lack of availability thereof. Although, the court’s decision were based upon the availability of the resource, the decision would in most probability remain the same, if the application were brought against a provincial department of health or the national government to provide free access to these health care services.

Even in developed countries where appropriate state funding is provided to the particular health care system, not every kind of transplant is “universally” funded.³⁸⁵ In the United States, patients are not even referred for transplant

³⁸² Dossetor *Principles Used in Organ Allocation* in Land et al *Organ Replacement Therapy* (1991) 393 at 394 remarks that the ability to pay is the “main allocative factor” in the developing world.

³⁸³ See further The American Medical Association Report on the Ethical Considerations in the Allocation of Organs and Other Scarce Medical Resources among Patients available at www.ama-assn.org/ama/upload/mm/369/ceja_report_049.pdf.

³⁸⁴ 1998 (1) SA 765 (CC).

³⁸⁵ Price 445.

evaluation, if they do not possess over medical insurance or another method of payment.³⁸⁶ In the United Kingdom, the Court of Appeal held, in an action brought against the British government to allocate funds for health care service³⁸⁷, that there was no duty upon the Secretary of State to allocate funds to all patients who are asking for dialyses machines “or for all the new developments such as heart transplants in every case where people would benefit from them.”³⁸⁸

Throughout the course of this chapter, opinions on the ethics of allocation procedures were analysed and which allocation procedures would be considered as unfair and which equitable. However, in reality these theories are just theories on paper that cannot be applied in practice. The current stance is in my opinion a very demoralizing situation that a transplant candidate would be prohibited from receiving an organ due to his / her inability to pay the medical costs. This situation regrettably reflects the poignant realities associated with organ donation.³⁸⁹

3.3 Legislative Framework regulating Organ Allocation Procedures

The ethical theories surrounding organ allocation are important in the government policy-making process, which provides for a framework upon which effective legislation could be drafted. It is important to mention that the evolution of organ allocation laws in South Africa is still in its infancy. Due to this reason, it is necessary to assess foreign legislative principles.

3.3.1 South African Law

Currently, no concrete legislative framework on organ allocation procedures exists. The National Health Act makes provision for allocation and use of human organs in terms of section 61, however, section 61(2) only states that “[h]uman organs obtained in terms of subsection (1) must be allocated in

³⁸⁶ Price 446.

³⁸⁷ R v Secretary of State for Social Services ex parte Hincks (1980) 1 BMLR 93 (CA).

³⁸⁸ Page 95.

³⁸⁹ In the U.S, health practitioners and health care institution are requested to continue to accept patients with limited financial capabilities, and that these patients should not be “systematically” denied simply due to their lower economic status. See further The American Medical Association Report on the

accordance with the prescribed procedures.” The content of these “prescribed procedures” falls within the prerogative of the Minister of Health to draft regulations under section 68 of the National Health Act to regulate supply and allocation of tissue or human cells by institutions and persons.³⁹⁰ As to yet, no regulations have been published in the *Government Gazette*.

3.3.2 Foreign Law

(a) Draft Guiding Principles on Human Organ Transplantation

In terms of organ allocation procedures, the Guidelines declare “[i]n the light of the principles of distributive justice and equity, donated organs should be made available to patients on the basis of medical need and not on the basis of financial or other considerations.³⁹¹ The ethical approach to this guiding principle falls solely within the ambit of the theories discussed, however, the guiding principle is impractical due to the *Soobramoney* effect.

(b) Belgium

In Belgium, allocation procedures are regulated in terms of a form of statute called the Crown Order pertaining to the Procurement and Allocation of Tissue of Human Origin of 1997.³⁹² This Crown Order was promulgated to establish a legislative framework to regulate allocation of human organs and tissue.

(i) General Provisions

The Crown Order is divided into five chapters, which respectively provide *inter alia* for the following:

- Establishment of a national transplantation committee;
- Developing of transplantation centres on a national level; and
- Development of a transplantation programme, which is tasked with allocating procured organs.

Ethical Considerations in the Allocation of Organs and Other Scarce Medical Resources among Patients available at www.ama-assn.org/ama/upload/mm/369/ceja_report_049.pdf.

³⁹⁰ Section 68(1)(c).

³⁹¹ Guiding principle 9.

At the centre of this system is the National Transplantation Committee that consists of health practitioners, members of the Belgian Ministry of Health and other government departments.³⁹³ The functions of this Committee consist of providing information to the Government on topics such as increasing organ procurement, better preservation methods to protected procured organs, reforming current legislation pertaining to organ procurement and allocation.³⁹⁴

(ii) Provisions relating to Allocation of Organs

In order to establish a better functioning allocation system between hospitals and transplantation centres, the Crown Order set regulations in place which co-ordinates procurement and allocation of organs to secure the optimal compatibility between of procured organs, transplant candidates and reducing waiting time.³⁹⁵ The Crown Order lays down certain criteria to be followed when considering a transplant candidate's eligibility to receive an organ. These criteria are the following:³⁹⁶

- Compatibility of the organ with the candidate;
- Medical urgency and the effective waiting time of the candidate;
- Assessment of the number of available organs in Belgium; and
- The distance between the transplant centre where the organ is preserved and the institution where the operation would be preformed.

It is the task of each transplantation centres to assess each transplant candidate's compliance with these criteria.³⁹⁷ If a candidate's compliance is satisfactory, an organ is allocated to that candidate for transplantation. Interestingly, in terms of section 8(2), each transplantation centre must record the status of each organ that is procured or transplanted, including the features of the organ pertaining to compatibility, quality and security.

³⁹² *Koninklijk Besluit Betreffende Het Wegnemen en Toewijzen van Organen van Menselijke Oorspong (Besluit 23/12/1997)*

³⁹³ Section 3(2).

³⁹⁴ Section 4.

³⁹⁵ Section 6(1).

³⁹⁶ Section 7(2) 1 to 4.

³⁹⁷ Section 8(1)

(b) United States of America

(i) Uniform Anatomical Gift Act

Developments of fair and equitable allocation procedures have been under scrutiny for many years. Due to questionable practices of transplantation, a range of policies have been developed, however the statutory regulation of allocating human organs and tissue falls within the ambit of two acts: the Uniform Anatomical Gift Act of 1968³⁹⁸ and the National Organ Transplant Act of 1984.³⁹⁹ The Uniform Anatomical Gift Act (UAGA) was promulgated to provide a legislative structure for state governments on procedural arrangements for organ procurement and allocation.

(ii) National Organ Transplant Act

Due to an immense shortage in organs and public rumours of inequitable allocation practices, the U.S. Congress enacted the National Organ Transplant Act (NOTA). The purpose of NOTA was to improve and centralize organ procurement and distribution by allowing transplant candidates throughout the U.S. to have access to organ transplantation “when appropriate and necessary”.⁴⁰⁰ NOTA establish a national organ procurement transplantation network to maintain a central national computer database of potential organ recipients.⁴⁰¹ The organ allocation system allocates organs according to “established medical criteria”.⁴⁰² In 1993, the U.S. Congress amended the NOTA through the Organ Transplant Program Reauthorisation Act of 1993 by redefining the purpose to “assure patients that no matter who they were or where they live[d], they would have a fair chance of receiving a necessary organ transplant”.⁴⁰³ Secondly, the amended NOTA provided that regulations would should be drafted to reform allocation procedures.⁴⁰⁴

³⁹⁸ Section 1, 8A U.L.A 63, 64 (1994).

³⁹⁹ P.L. 98-507.

⁴⁰⁰ McMullen *Equitable Allocation of Human Organs: An Examination of the New Federal Regulation* Journal of Legal Medicine 20 (1999) 405; Geysler *Organ Transplantation: New Regulations to Alter Distribution of Organs* Journal of Law, Medicine and Ethics 28 (2000) 95.

⁴⁰¹ 42 U.S.C. Section 274(a)-(b)(1)(A)(1994).

⁴⁰² 42 U.S.C. Section 273(b)(3)(E).

⁴⁰³ S. REP. NO 103 – 233, at 7-12 (1994).

⁴⁰⁴ *Ibid.*

(iii) United Network for Organ Sharing Policies

The United Network for Organ Sharing Policies (UNOS) is a private non-profit organisation incorporated in terms of the laws of the State of Virginia, which administers the National Organ Procurement and Transplantation Network for the U.S. Federal Government.⁴⁰⁵ UNOS stipulates organ allocation should be based upon scientific and medical factors and practices. Apart from these statutory measures introduced by Federal legislation, UNOS drafted policies to establish guidelines ensuring fair and equitable allocation procedures. These policies establishes a fair and equitable process to those transplant candidates who are registered on the national patient waiting list.⁴⁰⁶ UNOS allocation policies functions through a process of individual assessment depending on the type of organ used. Each policy present various factors that should be used to ensure equitable distribution between transplant candidates, however the final decision remains prerogative of the transplant surgeon.

Excerpt from policy on allocation of deceased kidneys⁴⁰⁷

3.0 ORGAN DISTRIBUTION

The following policies apply to the allocation of organs for transplantation.

3.5 ALLOCATION OF DECEASED KIDNEYS. Deceased kidneys must be allocated according to the following policies. The final decision to accept a particular organ will remain the prerogative of the transplant surgeon and/or physician responsible for the care of the patient. This allows physicians and surgeons to exercise their medical judgment regarding the suitability of the organ being offered for a specific patient; to be faithful to their personal and programmatic philosophy about such controversial matters as the importance of cold ischemia time and anatomic anomalies; and to give their best assessment of the prospective recipient's medical condition at the moment. If an organ is declined for a patient, a notation of the reason for that decision must be made on the appropriate form and submitted promptly to UNOS.

3.5.1 Definition of Expanded Criteria Donor and Standard Donor. For purposes of Policy 3.5 (Allocation of Deceased Kidneys), expanded criteria donors are defined by an "X" in the decision matrix shown below indicating relative risk of graft failure for donors older than 10 years of age > 1.7, based upon the following factors: age, creatinine, CVA, and hypertension.

Standard donors are all other donors. Unless specified as an expanded criteria donor or standard donor, the term donor(s) means all donors, expanded and standard. For purposes of distinguishing expanded criteria donors from standard donors, the most recent creatinine at the time of kidney placement shall be used. Patients who agree to receive expanded criteria donor kidneys shall be eligible also to receive standard donor kidneys according to the policies described below for allocating standard donor kidneys. The program shall obtain consent from patients prior to their being listed for expanded criteria donor kidney transplantation.

⁴⁰⁵ <http://www.unos.org/>

⁴⁰⁶ To guarantee compliance with UNOS policies, the U.S. Congress introduced Medicare and Medicaid reimbursements to transplant centres who obtain OPTN membership and for adherence to the UNOS rules.

⁴⁰⁷ Available at www.unos.org/policiesandBylaws/policies/pdfs/policy7.pdf

Donor Age Categories Donor Condition < 10 10 – 39 40 – 49 50 – 59 ≥ 60

CVA + HTN + Creat >

1.5 X X

CVA + HTN X X

CVA + Creat > 1.5 X X

HTN + Creat > 1.5 X X

CVA X

HTN X

Creatinine > 1.5 X

None of the above X

X=Expanded Criteria Donor

CVA=CVA was cause of death

HTN=history of hypertension at any time

Creat > 1.5 = creatinine > 1.5 mg/dl

3.5.2 ABO "O" Kidneys into ABO "O" Recipients and ABO "B" Kidneys into ABO "B"

Recipients. Blood type O kidneys must be transplanted only into blood type O patients except in the case of zero antigen mismatched patients (as defined in Policy 3.5.3.1) who have a blood type other than O. Additionally, blood type B kidneys must be transplanted only into blood type B patients except in the case of zero antigen mismatched patients (as defined in Policy 3.5.3.1) who have a blood type other than B. Therefore, kidneys from a blood type O donor are to be allocated only to blood type O patients and kidneys from a blood type B donor are to be allocated only to blood type B patients, with the exception for zero antigen mismatched patients noted above. This policy, however, does not nullify the physician's responsibility to use appropriate medical judgment in an extreme circumstance.

3.5.3 Mandatory Sharing of Zero Antigen Mismatched Kidneys. The following policies apply to allocation of any deceased expanded criteria or standard donor kidney for which there is a patient on the UNOS Patient Waiting List with a zero antigen mismatch:

3.5.3.1 Definition. A zero antigen mismatch is defined as occurring when a patient on the UNOS Waiting List has an ABO blood type that is compatible with that of the donor and the patient and donor both have all six of the same HLA-A, B, and DR antigens. A zero antigen mismatch is also defined as a match occurring when there is phenotypic identity between the donor and recipient with regard to HLA, A, B, and DR antigens when at least one antigen is identified at each locus. Phenotypic identity means that the donor and patient each has the same antigens identified at each pair of A, B, and DR HLA loci. Patients with only one antigen identified at an HLA locus (A, B, or DR) are presumed "homozygous" at that locus (i.e. homologous chromosomes are presumed to code for identical antigens at that locus). For example, a donor or patient typed as A2, A- (blank) would be considered A2, A2. A zero antigen mismatch would also include cases where both antigens are identified at a locus in the patient but the donor is typed as being homozygous for one of the patient's antigens at that locus. For example, there would be a zero antigen mismatch if the recipient were typed as A1, A31, B8, B14, DR3, DR4 and the donor were typed as A1.A- (blank), B8, B14, DR3, DR-(blank).

If the donor is homozygous at any A, B, or DR locus, the match can be said to be a zero antigen mismatch, as long as none of the identified A, B, or DR donor antigens are different from those of the recipient.

3.5.3.2 Computer Entry. Information regarding each and every deceased kidney donor must be entered into the UNOS computer system prior to kidney allocation, to determine whether there is a zero antigen mismatch between the donor and any patient on the UNOS Patient Waiting List. Pre-procurement tissue typing is expected consistent with Policy 2.7 (Expedited Organ Procurement and Placement) in allocating expanded criteria donor kidneys. In the absence of pre-procurement tissue typing, allocation of expanded criteria donor kidneys shall proceed pursuant to Policy 3.5.12 according to patient waiting time. If pre-procurement tissue typing is not initiated, the Host OPO shall provide a written explanation of the reasons to UNOS.

3.5.3.3 Mandatory Sharing. With the exception of deceased kidneys procured for simultaneous kidney and non-renal organ transplantation as described in Policy 3.5.3.4, and deceased kidneys procured from Donation after Cardiac Death donors; if there is any patient on the UNOS Patient Waiting List for whom there is a zero antigen mismatch with a standard donor, the kidney(s) from that donor shall be offered to the appropriate OPTN/UNOS member for the patient with the zero antigen mismatch subject to time limitations for such organ offers set forth in Policy 3.5.3.5.

With the exception of deceased kidneys procured for simultaneous kidney and nonrenal organ transplantation as described in Policy 3.5.3.4, and deceased kidneys procured from Donation after Cardiac Death donors¹, if there is any patient on the UNOS Patient Waiting List who has agreed to receive expanded criteria donor kidneys for whom there is a zero antigen mismatch with an expanded criteria donor, the kidney(s) from that donor shall be offered to the appropriate OPTNUNOS member for the patient with the zero antigen mismatch who has agreed to be transplanted with expanded criteria donor kidneys subject to time limitations for such organ offers set forth in Policy 3.5.3.5. If both donor kidneys are transplantable, the recipient center that was offered the kidney for a patient with a zero antigen mismatch does not have the implicit right to choose between the two kidneys.

The final decision as to which of the two kidneys is to be shared rests with the Host OPO. In lieu of the four additional points for a patient with a PRA of 80% or higher and a preliminary negative crossmatch (Policy 3.5.11.3) four additional points will be added to all patients for whom there is a zero antigen mismatch with a standard donor and whose PRA is 80% or higher regardless of preliminary crossmatch results. For kidneys procured from Donation after Cardiac Death donors, if there is any candidate on the UNOS Patient Waiting List for whom there is a zero antigen mismatch with the donor, the kidney(s) from that donor shall be offered to the appropriate OPTN member for the candidate listed locally with the zero antigen mismatch, by blood group identical and then compatible; then to all other local candidates in point sequence according to Policy 3.5.11 (The Point System for Kidney Allocation) or 3.5.12 (The Point System for Expanded Criteria Donor Kidney Allocation) depending upon whether the donor is standard or defined by expanded criteria; then to remaining zero antigen mismatched candidates according to the sequence set forth below. When multiple zero antigen mismatches are found for a single donor, the allocation will be in the following sequence:

¹For purposes of Policy 3.5 (Allocation of Deceased Kidneys), Donation after Cardiac Death donors shall be defined as follows:

(1) A controlled Donation after Cardiac Death donor is a donor whose life support will be withdrawn and whose family has given written consent for organ donation in the controlled environment of the operating room;

(2) An uncontrolled Donation after Cardiac Death donor is a patient who expires in the emergency room or elsewhere in the hospital before consent for organ donation is obtained and catheters are placed in the femoral vessels and peritoneum to cool organs until consent can be obtained. Also, an uncontrolled Donation after Cardiac Death donor is a patient who is consented for organ donation but suffers a cardiac arrest requiring CPR during procurement of the organs.

NOTE: The amendment to Policy 3.5.3.3 (Mandatory Sharing) shall be implemented pending programming on the UNOS system.

3.5.3.3.1 First to identical blood type zero antigen mismatched patients in descending point sequence in the case of standard donor kidneys, and by waiting time in the case of expanded criteria donor kidneys, as follows:

i local patients; then to

ii 80% or higher PRA patients on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to

iii 80% or higher PRA patients on the regional waiting list; then to

iv 80% or higher PRA patients on the national waiting list; then to

v less than 80% PRA patients who are less than 18 years old on the list of OPOs which are owed a payback kidney as described in

Policy 3.5.5; then to

vi less than 80% PRA patients who are less than 18 years old on the regional waiting list; then to

vii less than 80% PRA patients who are less than 18 years old on the national waiting list; then to

viii 21%-79% PRA patients on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to

ix 21%-79% PRA patients on the regional waiting list; then to

x 21%-79% PRA patients on the national waiting list; then to

xi less than or equal to 20% PRA patients on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5, except for patients on the list of OPOs that owe ten or more short-term payback obligations and/or do not meet applicable thresholds for reducing long-term debt (please see Policy 3.5.5.2

(Kidney Payback Debt Limit) for definitions of "short-term" and "long-term" debt); then to

xii less than or equal to 20% PRA patients on the regional waiting list, except for patients on the list of OPOs that owe ten or more short-term payback obligations and/or do not meet applicable thresholds for reducing long-term debt (please see Policy 3.5.5.2 (Kidney Payback Debt Limit) for definitions of "short-term" and "long-term" debt); then to

xiii less than or equal to 20% PRA patients on the national waiting list, except for patients on the list of OPOs that

owe ten or more short-term payback obligations and/or do not meet applicable thresholds for reducing long-term debt (please see Policy 3.5.5.2 (Kidney Payback Debt Limit) for definitions of "short-term" and "long-term" debt); then to

3.5.3.3.2 Next (1) in the case of blood type O donor kidneys, to blood type B zero antigen mismatched patients, first, in descending point sequence in the case of standard donor kidneys, and by waiting time in the case of expanded criteria donor kidneys, as set forth in (i) – (viii) below, and, then, to blood type A and AB zero antigen mismatched patients, also in descending point sequence in the case of standard donor kidneys, and by waiting time in the case of expanded criteria donor kidneys, as set forth in (i) – (viii) below, and (2) in the case of blood type A, B, and AB donor kidneys, to all compatible blood type zero antigen mismatched patients in descending point sequence in the case of standard donor kidneys, and by waiting time in the case of expanded criteria donor kidneys, as set forth in (i)– (viii) below:

i local patients; then to

ii 80% or higher PRA patients on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to

iii 80% or higher PRA patients on the regional waiting list; then to

iv 80% or higher PRA patients on the national waiting list; then to

v less than 80% PRA patients who are less than 18 years old on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to

vi less than 80% PRA patients who are less than 18 years old on the regional waiting list; then to

vii less than 80% PRA patients who are less than 18 years old on the national waiting list; then to

viii 21%-79% PRA patients on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to

ix 21%-79% PRA patients on the regional waiting list; then to

x 21%-79% PRA patients on the national waiting list; then to

xi less than or equal to 20% PRA patients on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5, except for patients on the list of OPOs that owe ten or more short-term payback obligations and/or do not meet applicable thresholds for reducing long-term debt (please see Policy 3.5.5.2 (Kidney Payback Debt Limit) for definitions of "short-term" and

"long-term" debt); then to

xii less than or equal to 20% PRA patients on the regional waiting list, except for patients on the list of OPOs that owe ten or more short-term payback obligations and/or do not meet applicable thresholds for reducing long-term debt (please see Policy 3.5.5.2 (Kidney Payback Debt Limit) for definitions of "short-term" and "long-term" debt); then to

xiii less than or equal to 20% PRA patients on the national waiting list, except for patients on the list of OPOs that owe ten or more short-term payback obligations and/or do not meet applicable thresholds for reducing long-term debt (please see Policy 3.5.5.2 (Kidney Payback Debt Limit) for definitions of "short-term" and "long-term" debt); then to

xiv less than or equal to 20% PRA patients on the list of OPOs that owe ten or more short-term payback obligations and/or do not

4. Conclusion

The current South African legislative framework pertaining to the preservation of human organs and allocation procedures show that this framework is not even in its infancy. Although, the promulgation of the National Health Act might be a good innovation to developing these areas, however until a sufficient framework has been established, the path still looks like dark and ominous.

Many ethical and legal problems have been raised in this chapter; however, the most fundamental is the transplant candidate's ability to pay for the transplantation operation. This factor hampers to total organ allocation process, and until government would be able to provide funds to these services, no fair and equitable allocation procedures can be established and are transplant candidates on their own to "pick up the tab".

CHAPTER FOUR

STATUTORY REGULATION OF ORGAN PROCUREMENT SYSTEMS: A DRAFT NATIONAL HEALTH ACT AMENDMENT BILL

1. Introduction

The history of transplantation law indicates no common law authorities exists and these laws are still in the beginning stages of development. When it became necessary to commence regulation of post mortem removal of bodily organs and tissue, legislation were promulgated to regulate such matters. Since 1952, the South African government enacted four statutes, which specially propose to regulate anatomical removal of tissue. These acts are the following:

- the Post Mortem and Removal of Tissue Act 30 of 1952;
- the Anatomical Donations and Post Mortem Examinations Act 24 of 1970;
- the Human Tissue Act 65 of 1983; and
- the National Health Act 63 of 2003.

Currently, the National Health Act regulates South Africa's organ procurement system that has reiterated South Africa's support for organ procurement based upon explicit consent.

The purpose of this chapter is to draft a proposed amendment act which amends section 62 of the National Health Act to incorporate the doctrine of presumed consent. The proposed amendment act is based upon the elements of the doctrine of presumed consent as discussed in chapter two.

2.The History of the Law of Organ Procurement in South Africa (Working Towards a Legislative Framework)

The regulation of organ procurement systems and allocation procedures is a fairly recent concept in the law of South Africa. No common law authorities can be found on the subject. At the time when the first heart transplant operation was performed, the first act dealing with this subject was the Post Mortem and Removal of Tissue Act 30 of 1952. The 1952 Act was later replaced by the Anatomical Donations and Post Mortem Examinations Act 24 of 1970, which was subsequently replaced by the Human Tissue Act 65 of 1983⁴⁰⁸. The Human Tissue Act provided the long-standing regulatory framework on organ procurement and donation.

The National Health Act was signed into law by the President in August 2004, which repeals all previous health related legislation and establishes a single framework for the regulation of organ procurement and transplantation. Chapter 8 contains section 53 to 68 which control the use of use blood, blood products, tissue and gametes in humans. The statutory provisions relating to the removal and use of tissue of both living and cadaveric donors are almost identical to those of the Human Tissue Act.

⁴⁰⁸ Section 10 is an extraordinary provision that regulates the organs and bodily tissue of a destitute may be taken upon death without the destitute person consenting to the removal thereof. During the second reading of the Human Tissue Bill, some members of the *volksraad* pleaded for an amendment to the draft bill to include that any person's body (including organs) may be utilised for *inter alia* transplantation purpose, unless the person prior to death raised an objection against the usage of his/her body. (routine salvaging) The *volksraad* decided not the change the *status quo* due to possible community outrage ("...die meerderheid van die gemeenskap só 'n maatreël aanstootlik sal vind".) For further reading on the drafting of the Human Tissue Act of 1983 refer to *Hansard* 1983 (13) 4 May kol 6500 – 6501.

All previous acts⁴⁰⁹ prior to the enactment of the National Health Act only provided a legislative framework for the removal and transplantation of tissue. None provides for the allocation of organs for transplantation, however, the National Health Act explicitly facilitates allocation and use of human organs.⁴¹⁰ Section 61(2) contemplates that human organs obtained in terms of subsection (1) must be allocated in accordance with the prescribed procedures. Although, this section *prima facie* looks promising, these “prescribed procedures” actually only refers to section 68 which stipulates that the Minister of Health may make regulations pertaining to tissue, cells, organs, blood products and gametes. What the content of these regulations relating to equitable allocation procedures are going to be, only the future can tell.

In paragraph 3, a concept National Health Amendment Act is drafted based upon the principles discussed in the preceding chapters. This concept act proposes the necessary amendments that should be made to section 62 of the National Health Act to incorporate the weak application the doctrine of presumed consent.

3. The National Health Amendment Act

NATIONAL HEALTH AMENDMENT ACT – OF --

[ASSENTED TO -----]

[DATE OF COMMENCEMENT: TO BE PROCLAIMED]

(English text to be signed by the President)

ACT

To amend the National Health Act, 2003, so as to define certain expressions; to amend the donation of human bodies and tissue through the inclusion of the doctrine of presumed consent to certain categories of persons; to amend the age

⁴⁰⁹ Rule 13 of the Guidelines for Good Practice in Medicine, Dentistry and the Medical Science of the Health Professions Council of South Africa (HPCSA) states that a practitioner shall only for research, educational, training or statutory prescribed purposes retain the organs of a deceased during an autopsy with the express written consent of the patient given by him or her during his or her lifetime or, in the case of a minor under the age of 14 years, with the written consent of his or her parent or guardian or, in the case of a deceased patient, who had not previously given such written consent, with the written consent of his or her next-of-kin or the executor of his or her estate.

requirement of minors to consent to removal of organs and tissue; to further regulate the role of the National Department of Health pertaining to the allocation of procured organs and tissue and to provide for matters connected therewith.

Amendment of section 1 of the National Health Act

1 Section 1 of the National Health Act is amended with the insertion of the following definitions:

- (a) “‘cancellation letter’ means a written letter which declares a registered objection void” between “blood product” and “central product”;
 - (b) “‘donor’ means all citizens and permanent residents residing more than six months in the Republic above 18 years of age and who is deemed to have the necessary capacity” between “district health council” and “essential health services”;
 - (c) “‘presumed consent’ means presuming informed consent” between “premises” and “prescribed”; and
 - (d) “‘registered objection’ means any written objection which clearly states a person’s intention not to become an organ donor upon death and registered with any medical practitioner or at any hospital including private or public health establishment”;
- between “rehabilitation” and “relevant member of the Executive Council”.

Amendment of section 62 of the National Health Act

2 Section 62 of the National Health Act is amended by the substitution of the section for the following section:

“62 Donation of human bodies and tissue of deceased persons

(1) All donors who are declared dead by three medical practitioners, whereby two out of the three must have been registered as a medical practitioner for more than five years, are regarded upon such declaration to have willingly consented to the procurement of their organs and tissue, unless such individual provided a registered objection to the appropriate authority prior to death.

⁴¹⁰ Section 61

(2) In the absence of a registered objection, such omission would be considered as an implicit statement of the individual's wiliness to become a donor and it would be presumed that the donor possessed over the necessary information to make an informed decision regarding donating his / her organs and tissue.

(3) No information regarding the identity, race, sex or any other related matter of the donor may at any time be disclosed, subject to section 14 and 15 of the Act.

(4) A medical practitioner who is required to perform a transplant operation, is prohibited from performing such operation, if the medical practitioner becomes aware of the following:

- (a) no registered objections is present, however substantial evidence is present which indicates the individual never would have consented to organ procurement; or
- (b) a family member invokes his / her right of refusal against such operation; provided that the family member has to submit sufficient evidence to support the refusal.

(5) A person who made a registered objection, may at any time prior to his / her death declare such objection void through the registration of a written cancellation letter at the place where the objection was registered, subject to this decision being taken voluntary and the person possessing the necessary capacity.

(6) It is deemed that a donor, who makes a donation as contemplated in section 62(1), nominates the National Department of Health as donee. If any other donee is nomated, such nomination will be null and void.

(7) Human organs obtained in terms of this section may only be allocated in the prescribed manner.

(8) The identity of the recipient may not be disclosed in any manner, unless by a decision of a court.

(9) The National Department of Health is required to establish within a reasonable time to the promulgation of this amendment act, to create an information structure which will serve to inform the public about organ transplantation.”.

3 Short title and commencement

This Act shall be called the National Health Amendment Act, ----, and shall come into operation on a date fixed by the President by proclamation in the *Gazette*.

CHAPTER FIVE

CONCLUSION

1. Introduction

2. Critical Evaluation: Organ Procurement Systems

2.1 The Doctrine of Presumed Consent

If a person is initially confronted with the principles of the doctrine of presumed consent as an organ procurement system, this system might give the impression that it is very apprehensible and infringes the basic human rights. Many reasons contribute to public discontent relating to this doctrine, however to my impression most reasons are based upon the following overarching problem areas:

- An ill-informed public on the general nature of organ procurement, and transplantation; and
- Misperceptions on the nature of consent in the doctrine.

If it would be possible to revolutionize the way people perceive organ procurement and the doctrine of presumed consent; it would lead to an increase of organs.

2.1.1 Findings

The main purpose of this dissertation endeavoured to provide a critical analysis of the doctrine of presumed consent as an organs procurement system as it is applied in various foreign jurisdictions. In this dissertation, an analysis of the doctrine of presumed consent indicates that it can be divided into different elements. Each element contains distinct features that impact the precise functioning of the doctrine and provides possible solutions to current problems experienced within a South African context.

Evaluation of the elements proved that a variety of findings, which can be summarized in the following manner:

(a) Presumed Consent as a Organ Procurement System

- The doctrine of presumed consent establishes a system that purports to procure organs in a faster and effective manner than explicit consent system.
- Organ procurement systems based upon the doctrine of presumed consent operate in a “reserve” manner than those systems requiring explicit consent.
- The application of the doctrine is divided into two types or degrees namely, the “weak” and “hard” application. The difference between the two degrees of application is a right of refusal bestowed on the next-of-kin. In terms of the “hard” application, it will be presumed that, in the absence of an objection, the deceased gave his / her consent to organ donation. If a next-of-kin objects, such objection will be disregarded as only the deceased had the choice to consent or deny organ procurement. The “soft” application functions in the same manner except, the next-of-kin is afforded a right to object / refuse organ procurement on behalf of the already deceased donor.
- Five distinct elements of the doctrine can be identified namely, the donor, consent, capacity, the next-of-kin and the recipient.

(b) The Donor

- The doctrine of presumed consent can only be applied to cadaveric organ donors who are of an adult age with the necessary capacity.
- Deceased patients will not qualify as organ donors if they registered an objection proclaiming their resistance to organ donation.

(c) The Presences of Consent as a Justification Ground in the Doctrine of Presumed Consent

- General requirements for valid consent as a justification ground apply to the doctrine of presumed consent.

- The general nature of consent suggests that consent is a process whereby the patient is required in his / her mind to receive and appreciate information by making his / her intention publicly known. The behaviour or conduct of the patient
- Just as the doctrine of informed consent requires a duty of disclosure upon a health practitioner to inform a patients about risks, advantages and diagnosis of a proposed treatment, in the same manner does the doctrine of presumed consent requires a duty of disclosure to provide information relating to *inter alia* organ transplantation, organ procurement systems and distribution procedures. The nature, scope and accessibility of such information will determine whether informed consent is present in the doctrine of presumed consent.
- The content of the duty of disclosure of the doctrine is exactly the same as the duty of disclosure of the doctrine of informed consent. It is only restricted to information of organ transplantation.
- The nature of the duty of disclosure of the doctrine can be classified as *basisaufklärung*. The reason why this type would be best suited is the manner in which information should be displayed for example general information must be supplied and then more specified information is given.

(d) The Degrees of the Doctrine of Presumed Consent

- The application of the doctrine of presumed consent as a organ procurement system can be classified as either a hard application or a soft application. A strong application declares that upon death a person who did not register an objection to organ donation, will be considered to have given consent to procurement of his / her organs and any interference by the next-of-kin are disregarded. The weak application functions exactly similar to the hard application, with the exception that regardless of whether the donor did or did not raise an objection to organ procurement, the next-of-kin has the right to override the decision.

- Both of these applications have a direct effect on the right of refusal, which might be given to the next-of-kin of proposed donors.

2.1.2 Recommendations

The paragraph provides recommendations if the doctrine of presumed consent were ever introduced in South Africa

- A successful procurement system should apply explicit consent linked with the principle of required response for living donors and the doctrine of presumed consent for deceased donors.
- Organ donor in terms of the doctrine should be restricted to South African citizens and permanent residents residing in the republic for more than six months.
- All information about donors should be subject to a confidentiality clause.
- Donors who are minors and mentally ill should not qualify as donors in terms of the doctrine.
- A objection proclaiming resistance to organ procurement should be in a written form and must be registered with an institution that has the capability to store these information and allow users access to that database.
- A living donor must nominate a donee and the organs of a cadaveric donor under a presumed consent system, will automatically be distributed to a specified institution.
- Prior to reforming South Africa's organ transplantation system, a rigorous information campaign on organ transplantation, organ procurement systems and allocation procedures should be launched to allow the public to familiarise themselves with the true facts of organ transplantation and the doctrine of presumed consent and so on. Government should allow for a transitional period to prepare sufficiently for reforming the current system to that of an organ procurement system based upon presumed consent.
- Government should establish a partnership with the non governmental institutions and a other interested parties to establish and maintain a

information system (i.e. a website) to supply information in an easy accessible manner.

If government wanted to introduce presumed consent in South Africa, a dual system based on the Belgian system should be introduced whereby regulating the living donor through an explicit consent system linked to a policy which employs the principle of required response and deceased donors who did not “opt out” through a presumed consent system. A practical example might be the following:

During a person’s lifetime tissue may only be removed if that person permits it. The level of consent that is required is informed consent. Government policy should be introduced that all persons of a certain age must during a particular event be informed of organ donation for example acquiring an identification document. After a citizen is required to provide a response to organ donation. If the person decides to object to organ donation, an objection must be registered with a central government organ donation department. If the person fails to register the objection, the government may upon death presume that person wanted to become a donor and informed consent is present. The procurement of tissue would be lawful. If reasonable grounds exist to believe that the person would never have consented to becoming an organ donor, the next-of-kin may raise an objection on behalf of the deceased (the right of refusal). If the next-of-kin succeeds, any removal of tissue would be prohibited.

This proposal of a dual system regulating both living and deceased donor would be the most favoured by the public and conform to the provisions⁴¹¹ of the Constitution.

The manner in which all objections are recorded, occur usually *via* registration at a central database of a central donor office. The information gathered is linked to all medical institutions performing transplant operations. Once a patient enters a hospital, the objection is automatically recorded on the

⁴¹¹ Primarily section 12(2)(b).

patient's chart. If the patient passes away, the transplantation operation can commence as soon as possible.

2.2 The Principle of Required Response and Required Request

In the abovementioned paragraphs, the findings and recommendations of the doctrine of presumed consent as an organ procurement system were reflected upon. In the process of developing and maintaining a best practice with the entire transplantation process, it is important that an effective organ procurement system should be established. Measures or incentives have been established to ensure the effective application of procurement system. These incentives should not be classified as organ procurement system *per se*, however as agents which provide a basis whereupon the principles of an organ procurement system can operate. These incentives that are referred to are the principle of required response and the principle of required request.

2.2.1 Findings

(a) General Principles

- The fundamentals of these incentives are established on two principles which are instrumental in securing effectiveness within any organ procurement system. These fundamentals determine patient autonomy through an individual freedom of choice to either opt in or decline organ transplantation; and promotion of active association between donors and their next-of-kin in the decision making process.
- Applying these fundamental principles indicates that both the principle of required response and required request functions through the belief that an informed public will in most likelihood lead to an increase in organ donors. These incentives aim at provoking public discussion on a very controversial topic and encourage decision making at the convenience of an informal discussion between family members and friends. The role of the next-of-kin plays a very distinct and important role in these incentives.

(b) Distinction

- The primary distinction between the principle of required response and required request is in the application. Required response “forces” an individual to consider organ donation, whereas required request only requires a simple enquiry by hospital staff whether a patient would consider becoming a donor. The patient in this case is not in any manner “coerced” to complete an official form requesting compliance or objections to organ procurement.

(c) Incentives in application

- These incentives have mainly been an invention of State legislators in the United States. The first required request legislation was promulgated in 1985 in Oregon and by the end of the 1980’s twenty six states including the District of Columbia had some version of the principle of required request. The outcome of this incentive proved to be dismal and it did not alleviate the demand of organs.

2.2.2 Recommendations

(a) An Incentive linked to a Procurement System

- The principle of required response establishes a good information providing framework that could be utilised with an existing organ procurement system. It is suggested that this incentive should be introduced to provide basic information about organ donation, procurement, allocation procedures etc to the public and during this process also allow an individual to register an objection to organ procurement.
- This process is compulsory for all nationals and occurs during application for identity documents, passports, driver licences, filing of tax returns and elections.

3. Critical Evaluation: Preservation of Tissue and Allocation Procedures

3.1 Preservation of Tissue

Our law severely lacks a regulatory framework, which stipulates the regulating, functioning and executing protocol in respect of the preservation of tissue. The National Health Act does not provide for a particular section which deals with the preservation of tissue of human bodies, however in terms of section 68, the Minister of Health has the authority to draft regulations pertaining to tissue, cells, and the preservation, use and disposal of bodies.

3.2 Organ Allocation Procedures

The issues relating to transplantation jurisprudence creates by nature controversial and contentious debates, however, none so as organ allocation systems. The legal and ethical principles of these systems, created immense debates between medical ethicists, legal scholars and government officials, who have proposed many a possible solution to the following question: which measures should be introduced to alleviate the ever-increasing demand for transplantable human organs and tissue? In order to find a solution to this question, it is necessary to analyse the process of selecting a transplant candidate. This process can be divided into four stages:

- Stage one: which organs are available for allocation?;
- Stage two: who is eligible to receive a transplant of an organ is available?;
- Stage three: a patient must have been accepted as a transplant candidate?; and
- Stage four: the transplant candidate's claim for a particular organ needs to be weighed against the claim of other transplant candidates.

For the transplant candidate to qualify for an organ, he / she needs to pass through each one of these stages complying with various medical and non-medical criteria. The application of the various policies of the last mentioned criteria forms the foundation of all organ allocation systems. The principles of the medical criteria use a medical enquiry based solely on medical techniques

and procedures to select a suitable transplant candidate. The principles and policies of the non-medical criteria use a variety of ethical protocols to select a transplant candidate, subject to the selection being fair and equitable. Various factors are employed in the selection process such as, the age of the recipient, the beneficial and harmful effects for other transplant candidates, and patient sensitisation. Although, an abundance of ethical theories and protocols have been developed to aid in the selection process, the reality of a candidates' ability to acquire funding for the costly medical expenses destroy most candidates chances of obtaining a successful transplant operation. This minute factor, which rarely receives much attention in academic debate, in my opinion, completely annihilates most developments in the legal and ethical issues relating to transplantation and highlights the practical problems of transplatation. The real question is whether this is fair and equitable?

4. Final Conclusion

It is possible to do hundred's hours of research in respect of the issues relating to transplantation jurisprudence and ethics; and it is possible to write thousands of pages on these issues and develop numerous policies and legislative frameworks to guide and regulate, however until the current stance of socio-economic rights are developed to realise the ability to afford the medical costs associated with the transplantation', **all that have been developed is worthless.**

BIBLIOGRAPHY

South Africa

Monographs

Almeida *Market Failure in Health Care: The Effect of Altruism on the Supply of Blood and Human Organs in South Africa* (Unpublished Masters Dissertation 2001 University of the Witwatersrand)

Barnard, Cronje and Olivier *Die Suid-Afrikaanse Persone –en Familiereg* (1994)

Curran et al *Health Care Law and Ethics* (1998)

De Waal, Currie and Erasmus *The Bill of Rights Handbook* (2000)

Potgieter and Visser *Introduction to Family Law* (1998)

Snyman *Criminal Law* (2003)

Strauss and Strydom *Suid-Afrikaanse Geneeskundige Reg* (1967)

Strauss *Doctor, Patient and the Law* (1991)

Strauss *Toestemming tot benadeling as verweer in die strafreg en die deliktereg* (Unpublished LLD Thesis, University of South Africa 1961)

Van Oosten *Medical Law: South Africa – International Encyclopedia of Laws* (1996)

Van Oosten *The Doctrine of Informed Consent in Medical Law* (Unpublished LLD Thesis, University of Pretoria 1989)

Articles

Barnard *South African Medical Journal* (1967) 1271

Blackbeard *Consent to Organ Transplantation* *Tydskrif vir die Hedendaagse Romeins Hollandse Reg* 66 (2003) 45

Blackbeard *Organ Donation for Profit* *Obiter* 52 (2002) 57

Fick and Els *Legal Status of the Mentally Disabled Person in South African Law* *Medicine and Law* (1995) 601

Van Der Walt *Artikel 10 van die Wet op Menslike Weefsel 65 van 1983 in 'n Juridiese, Etiese en Filosofiese Perspektief* Tydskrif vir die Suid Afrikaanse Reg 2 (1984) 154

Van Oosten *Castell v De Greef and the Doctrine of Informed Consent: Medical Paternalism ousted in Favour of Patient Autonomy* (1995) De Jure 164

Case Law

Administrator Natal v Edouard 1990 (3) SA 581(A)

Castell v De Greef 1994 (4) SA 408 (C)

Castell v De Greef 1994 (4) SA 408 (C) 425

Clarke v Hurst 1992(4) SA 630 (D)

Correira v Berwind 1986 (4) SA 60 (Z)

Estate Rehne v Rehne 1930 OPD 80

Estherhuizen v Administrator, Transvaal 1957 (3) SA 710

G v Superintendent Groote Schuur Hospital 1993(2) SA 255 (C)

Lymbery v Jefferies 1925 AD 236

Oldwage v Louwrens [2004] 1 All SA 532 (C)

Phillips v De Klerk 1983 (T) unreported

Pienaar v Pienaar's Curator 1930 OPD 171

R v Swiggelaar 1950 1 PH H 61 (A)

R v Taylor 1927 CPD 16

Rompel v Botha 1953 (T) unreported

S v Makwanyane 1995 (3) SA 391

Soobramoney v Minister of Health 1998 (1) SA 765 (CC)

Van Wyk v Lewis 1924 AD 438

Statutes/Legislation

Anatomical Donations and Post-Mortem Examinations Act 24 of 1970

Anatomy Act 20 of 1959

Births, Marriages and Deaths Registration Act 81 of 1963

Constitution of the Republic of South Africa Act 108 of 1996

Human Tissue Act

Inquests Act 58 of 1959

National Health Act 61 of 2003

Occupation Disease in Mines and Works Act 78 of 1973

Guidelines

The Guidelines for Good Practice in Medicine, Dentistry and the Medical Science of the Health Professions Council of South Africa (HPCSA) (2002)

European Countries

Monographs

Andreas *Neue Tendenzen in the Rechtsprechung zur Aufklärungspflicht* (1987)

Bockelmann *Strafrecht des Artzes* (1968)

Deutsch *Artzrecht und Arzneimittelrecht* (1983)

Giesen *Artzhaftungsrecht* (1990)

Kern und Laufs *Die Ärztliche Aufklärungspflicht* (1983)

Kohlhaas *Medizin und Recht* (1997)

Kuhnert *Die Vertragliche Aufklärungspflicht des Arztes – Insbesondere bei der Anwendung und Verschreibung von Arzneimitteln* (1982)

Lamb *Organ Transplants and Ethics* (1990)

Nys Medical Law in Belgium (1997)

Price Legal and Ethical Aspects of Organ (2000)

Taupitz Zivilrechtliche Regelungen zur Absicherung der Patienten automatic an Ende des Lebens (2000)

Case Law

Belgian Cour de Cassation decision of October 4 1973

Statutes/Legislation

Austria

The Federal Law of 1 June 1982

Belgium

The Law on the Removal and Transplantation of Organs of 13 June 1986
The Crown Order pertaining to the Procurement and Allocation of Tissue of Human Origin of 23 December 1997

France

The Law of December 22 of 1976

Spain

The Law No 30 of 27 October 1979
The Royal Decree of 1980

Guidelines

Draft Guiding Principles on Human Organ Transplantation (1987)

Other Countries

Monographs

Beauchamp and Childress *Principles of Biomedical Ethics* (2001)

Brock *Ethical Issues in Recipient Selection for Organ Transplantation* that forms part of Mathieu (Editor) *Organ Substitution Technology* (2000)

Davies *Textbook on Medical Law* (1996)

Davis Tabor's *Cyclopaedic Medical Dictionary* (1989)

Hiller *Medical Ethics and the Law, Implications for Public Policy* (1981)

Humber et al *Biomedical Ethics and the Law* (1979)

Kennedy and Grubb *Medical Law: Text with Materials* (1994)

Lamb *Organ Transplant and Ethics* (1990)

Land et al *Organ Replacement Therapy* (1991)

Mathieu (Editor) *Organ Substitution Technology* (2000)

Pence *Classic Cases in Medical Ethics* (2000)

Smith *Medical Ethics Series* (1991)

Sullivan *The Uniform Anatomical Gift Act, in Organ and Tissue Donation: Ethical, Legal and Policy Issues* (1996)

Veatch *Death Dying and the Biological Revolution* (1976)

Veatch *Transplantation Ethics* (2000)

Veath *Medical Ethics* (1997)

Youngner, Fox and O'Connell *Organ Transplantation: Meanings and Realities* (1996)

Articles

Alcorn and Harris *To Solve a Deadly Shortage: Economic Incentives for Human Organ Donation* *Issues in Law and Medicine* 16 (2001) 213

Anderson and Copeland *Legal Intricacies of Organ Transplantation: Regulations and Liability* *Journal of the Missouri Bar* 50 (1994) 139

Arnold and Siminoff *Increasing Organ Donation in the African-American Community* *Annals of Internal Medicine* 130 (1999) 607

Bailey *Should The State Have Rights to your Organs? Dissecting Brazil's Mandatory organ donation law* *University of Miami Inter-American Law Review* 30 (1999) 707

Banks *Legal and Ethical Safeguards: Protection of Society's Most Vulnerable Participants in a Commercialised Organ Transplantation System* American Journal of Law and Medicine (1995) 45

Barber *The Tell-tale heart: Ethical and Legal Implications of In Situ Organ Preservation in the Non-Heath-Beating Cadaver Donor* Health Matrix 6 (1996) 471

Blumstein *The Use of Financial Incentives in Medical Care: The Case of Commerce in Transplantable Organs* Health Matrix 3 (1993) 1

Butler *The Law of Human Organ Procurement: A Modest Proposal*, Journal of Contemporary Health Law and Policy 1(1985) 195

Caplan *Current Ethical Issues in Organ Procurement and Transplantation* Journal of the American Medical Association 272 (1994) 1708

Caplan *Organ Procurement: It's Not in the Cards* Hasting Centre Report 14 (1984) 9 (5)

Caplan, Siminoff, Arnold, Vernig and Seltzer *Public Policy Governing Organ and Tissue Procurement in the United States* Annals of Internal Medicine 123 (1995) 10 at 17

Chen *Can Same-Sex Partners Consent To Organ Donation?* American Journal Of Law and Medicine 29 (2003) 31(14)

Churchill *Should We Ration Health Care by Age?* Journal of the American Geriatrics Society 36 (1998) 644

Cohen *Increasing the Supply of Transplant Organs: The Virtues of a Futures Market* George Washington Law Review 58 (1989)1

Cookson *Principles of Justice in Health Care Rationing* Journal of Medical Ethics 26 (2000) 326

Csillag *Brazil Abolishes "Presumed Consent" in Organ Donation* The Lancet 352 (1998) 1367(1)

Cwiek *Presumed Consent as a Solution to the Organ Shortfall Problem* Journal of the American Medical Association 4 (1984) 81

Dennis et al *An Evaluation of the Ethics of Presumed Consent and a Proposal Based on Required Response: A Report of the Presumed Consent Subcommittee And United Network for Organ Sharing (UNOS) Ethics Committee*

Dukeminier and Sanders *Organ Transplantation: A Proposal for Routine Salvaging of Cadaver Organs* New England Journal of Medicine 279 (1968) 413

Dukeminier *Supplying Organs for Transplantation* Michigan Law Review 68 (1970) 811

Erin and Harris *Presumed Consent or Contracting Out* Journal of Medical Ethics 25 (1999) 365

Galen *Organ transplantation at the Millennium: Regulatory Framework, Allocation Prerogatives, and Political Interests* Southern California Interdisciplinary Law Journal 9 (1999) 335

Geysler *Organ transplantation: New Regulations to Alter Distribution of Organs* Journal Of Law, Medicine And Ethics Spring 28 (2000) 95

Geysler *Organ Transplantation: New Regulations to Alter Distribution of Organs* Journal of Law, Medicine and Ethics 28 (2000) 95

Indech *The International Harmonization of Human Tissue Regulation: Regulatory Control over Human Tissue Use and Tissue Banking in Select Countries and the Current State of International Harmonization Efforts* Food and Drug Law Journal 55 (2000) 343

Jefferies *The Body as Commodity: The Use of Markets to Cure the Organ Deficit* Indiana Journal of Global Studies 5 (1998) 621

Kane *Information is The Key to Patient Empowerment* Annals of Health Law 11 (2002) 25

Katz *Increasing the Supply of Human Organs for Transplantation: A Proposal for a System of Mandated Choice* Beverly Hills Bar journal, Summer (1985) 152

Keller *The Bed of Life: A Discussion of Organ Donation, Its Legal and Scientific History, and A Recommended "Opt-Out" Solution to Organ Scarcity* Stetson Law Review (2003) 855

Kevorkian *A Controlled Auction Market is a Practical Solution to the Shortage of Transplantable Organs* Medicine and Law 11 (1992) 47

Kolber *A Matter of Priority: Transplanting Organs Preferentially to Registered Donors* Rutgers Law Review 55 (2003) 671

Krueger *Life Coming Bravely Out of Death: Organ Donation Legislation Across European Countries* Wisconsin International Law Journal 18 (2000) 321

Kurtz and Saks *The Transplant Paradox: Overwhelming Public Support for Organ Donation versus Under-Supply of Organs: The Iowa Organ Procurement Study* Journal of Corporation Law 21 (1996) 767

Liddy *The New Body Snatchers: Analysing the Effect of Presumed Consent Organ Donation Laws on Privacy, Autonomy and Liberty* Fordham Urban Law Journal (2001) 816

Mackey and Kjerulf *The Ethics of Organ Donation: Examining Consent Policies and Donor Criteria* University of Toronto Medical Journal 78 (2000) 51

Markenstein *An Analysis of the State of the Debate on Further Use of Human Tissue in Various European Countries* European Journal of Health Law 2 (1995) 125

Matas, Arras, Muyskens, Tellis, and Veith . *A proposal for cadaver organ procurement: Routine removal with right of informed refusal* Journal of Health Politics, Policy and Law 10 (1985) 231

McMullen *Equitable Allocation of Human Organs: An Examination of the New Federal Regulation* Journal of Legal Medicine 20 (1999) 405

Mehlman *Presumed Consent to Organ Donation: A Reevaluation* Health Matrix 1 (1991) 31

Merril *The Control of Living Body Materials* Annals of Internal Medicine 75 (1971) 631

Molzen and Sokol *The Changing Standard of Care in Medicine: E-Health, Medical Errors, and Technology Add New Obstacles* Journal of Legal Medicine 23 (2002) 449

Naylor *The Role of the Family in Cadaveric Organ Procurement* Indiana Law Journal 65 (1989) 167

Redmond-Cooper *Transplants Opting Out or In –The Implications* New Law Journal 134 (1984) 648

Roberts *Presumed Consent for Organ Procurement – Does It Have a Future in the U.S.?(Ethical-Legal Perspectives)* Journal of Neuroscience Nursing 35 (2003) 107(7)

Robertson et al *Concentrated Professional Education to Implement Routine Referral Legislation Increases Organ Donation* Transplantation Proceedings 30 (1998) 214

Spital *In the Balance, Mandated Choice for Organ Donation: Time to Give it a Try* Annals of Internal Medicine 125 (1996) 66

Stuart et al *Brain Death Laws and Patterns of Consent to Remove Organs for Transplantation from Cadavers in the United States and 28 other Countries* Transplantation 31(1981) 238

Wells *Overview of FDA Regulation of Human Cellular and Tissue-Based Products* Food and Drug Law Journal 52 (1997) 401

Williams *The Regulation of Human Tissue in the United States: A Regulatory and Legislative Analysis* Food and Drug Law Journal 52 (1997) 409

Newspapers

Cassell *Health and Wellbeing: Options for Organ Donors* The Daily Telegraph (London) July 16 1999

Newsletters

Caplan *Organ Procurement and Transplantation: Ethical and Practical Issues* Centre for Bioethics, University of Pennsylvania Newsletter 2 (1995)

Reports

American Medical Association (AMA) *Strategies for Cadaveric Organ Procurement*

GAO Special Publication On Organ Donation

Johnson *A Study of the United States' Organ Donor Programs* Report prepared for the United States State Departments of Motor Vehicles (May 1993)

New York State Task Force on Life and the Law, *Transplantation in New York: The Procurement and distribution of organs and tissues* (1988)

U.S Department of Health and Human Services: Office of Organ Procurement: *Report of the Task Force on Organ Transplantation: Issues and Recommendations* 27 (1986)

Case Law:

Brotherton v Cleveland (1991) 923 F 2d 482

Doodeward v Spence (1908) 6 CLR 406

Georgia Lions Eye Bank, Inc v Lavant (1985) 335 SE 2d 127

Meek v State (1933) 185 N.E. 899

R v Secretary of State for Social Services: Ex Parte Hincks (1980) 1 BMLR 93 (CA)

Ravenis v Detroit General Hospital 234.N.W.2d 411 (1975)

Regina v Sharpe (1857) 169 Eng Rep 959

Siver v Rockingham Memorial Hospital (1999) 48 F Supp 2d 608

Statutes/Legislation:

United States of America

Federal Legislation

National Organ Transplant Act of 1984

Omnibus Reconciliation Act of 1986

Public Health Service Act of 1994

Uniform Anatomical Gift Act of 1987

Federal Regulations

58 Federal Regulation 65,514 (December 14 1993)

Interim Rule and a Final Rule of the Public Health Service Act of 1994

62 Federal Regulations 40, 430-31

State Legislation

Pennsylvania

Pennsylvania Consolidated Statutes

Required Request Law of 1985

New York

Required Request Law of 1985

Oregon

Required Request Law of 1985