

HEALTHCARE PROFESSIONALS' EXPERIENCES IN
APPLYING PRESUMED CONSENT LEGISLATION IN ORGAN
DONATION IN THREE EUROPEAN COUNTRIES: A
PHENOMENOLOGICAL STUDY

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Declaration

I hereby declare that the composition of this thesis and the work therein has been undertaken by myself. This work has not been accepted in any previous application for a degree. All quotations have been distinguished by quotation marks and the sources of information acknowledged.

Barbara L. Neades

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Abstract

The crisis in the numbers of donated organs has featured strongly in the U.K. literature highlighting the growing gap between those waiting for a transplant currently 6,698 and the numbers of organs available for transplant in 2006 numbering 2,195 (UKT, 2006). To address this the new Human Tissue (Scotland) Act 2006 and the Human Tissue Act 2004 (England and Wales) have sought to increase the numbers of organs available for donation, whilst upholding the principle of informed consent to the donation of one's organs contained within the previous legislation. Critics of this "opt in" system however, suggest the adoption of presumed consent legislation or "opt out" as is the case in much of Europe. Little research exists that explores impact on the health care professionals (HCPs), the bereaved relatives, the health care system and society overall of any change to presumed consent legislation. The aim of this study was to explore the views and experiences of the HCPs who utilise this legislation in their practice, identifying implications for these professionals, the bereaved relatives and the health care system of using presumed consent legislation.

Methods

Adopting a phenomenological approach this study utilised the responses to an initial quantitative survey using a questionnaire and combined this with qualitative semi-structured interviews with HCPs who had experience of organ donation in three European countries, Portugal, Norway and Belgium thus capturing the "lived experiences" of the professionals who use this approach to organ donation. A phenomenological framework first identified by Heidegger (1962) and Gadamer (1976) was adopted to structure these interviews and analyse the data developed from these sources.

Results and Discussion

The initial survey of HCPs in the three countries yielded 31 responses (10.6% n=300) from Portugal, 47 (10.4% n=450) from Norway and 44 (35.7% n=123) from Belgium, providing data relating to their experiences in applying presumed consent legislation in organ donation, together with the benefits and challenges of their particular organ donation system. Subsequently, semi-structured interviews undertaken with 14 HCPs in Portugal, 13 HCPs in Norway and 15 HCPs in Belgium demonstrated different approaches to the application of this legislation in these three countries, as a result of varying infrastructures utilised to underpin organ donation. Additionally, there was a dissonance between the requirements of the legislation and the application of this by HCPs within the individual countries resulting from ethical, cultural and professional practice considerations identified by these professionals. Key amongst these considerations was the need to respect the wishes of the donor and involve the bereaved relatives in the organ donation decision-making process.

Conclusion

Implications exist for HCPs, bereaved relatives, NHS and society of any change to presumed consent legislation from ethical, cultural and professional practice perspectives. These require to be explored in more detail and addressed, should this approach to organ donation be considered in the U.K.

Table of Contents

Abstract	1
Chapter 1 Introduction	3
1.1 Background to and Current Organ Donation in U.K.....	3
1.2 Introduction of New Legislation	5
1.3 Barriers to Converting the Consent to Donation into Organs for Transplant.....	6
1.4 Identification of Alternative Approaches to Organ Donation Legislation	8
1.5 Challenges to Presumed Consent Legislation	8
Summary.....	11
Chapter 2 Organ Donation Legislation in U.K.	13
2.0 Introduction	13
2.1 Existing Law and Cadaver Organ Donation.....	14
2.1.1 Common Law	14
2.1.2 Statute	15
2.1.3 Failure to Comply with the Legislation	15
2.2 The Human Tissue (Scotland) Act 2006	16
2.2.1 Ensuring that Life is Extinct	16
2.2.1.1 Diagnosing Death	16
2.2.1.2 Brain Stem Death.....	17
2.2.1.3 Cardiovascular Criteria	22
2.2.2 Preservation of Donor Organs	27
2.2.3. Authorisation to Remove Tissues	32
2.2.4 Appropriate Indication of Wish to Become a Donor	33
2.2.5 Valid Request.....	34
2.2.6 Authorisation to Proceed	35
2.2.7 Preparation of Setting to Support the Family and Undertake Request.....	37
2.2.8 Education and Preparation of HCP for Role in Organ Donation.....	40
2.2.9 Consent to Proceed from Coroner or Procurator Fiscal.....	41
2.2.10 Use of Body Parts for Teaching, Audit and Research Purposes.....	42
Summary.....	44
Chapter 3 Application of Presumed Consent Legislation In Europe	47
3.0 Introduction	47
3.1 Background to the Calls for Presumed Consent Legislation.....	48
3.2 Adoption of Presumed Consent Legislation in Europe.....	48
3.2.1 Strict Interpretation of Presumed Consent Legislation.....	49
3.2.2 Flexible Application of Presumed Consent Using Register of Objection	50
3.2.2.1 Adoption in Belgium	50
3.2.2.2 Alternative Influences Contributing to Belgium Success.....	51
3.2.3 Use of Register of Objections and Limited Family Involvement in Application of Presumed Consent Legislation	52

3.2.3.1 Adoption in Norway	52
3.2.3.2 Adoption in Portugal.....	53
3.2.3.3 Adoption in Italy, France and Spain	54
3.2.3.4 Alternative Influences Contributing to Success in Spain	55
3.3 Impact of Religious Beliefs on Organ Donation Rates	56
3.4 Impact of Spiritual and Family Beliefs on Organ Donation.....	58
3.5 Impact of Health Care Professionals Beliefs on Organ Donation.....	60
3.6 Alternative Rationale for High Levels of Organ Donation	61
3.6.1 Reduced Mortality Rates from Road Traffic Accidents and other Cerebral Injury.....	61
3.6.2 Poor Levels of Preparation for Health Care Professionals for their Role in Organ Donation	62
3.6.3 Development of an Organ Donation Infrastructure	63
3.7 U.K. Views on Presumed Consent Legislation	63
Summary.....	67
Chapter 4 Ethical Principles Underpinning Organ Donation and Ethical Objections to Presumed Consent Legislation	68
4.0 Introduction	68
4.1 Respect for Autonomy and Consent to Organ Donation.....	68
4.2 Right to Control What Happens to Our Bodies after Death and Harm to the Interests of the Dead.....	74
4.2.1 Right to Control What Happens to Our Bodies after Death	74
4.2.2 Harm to the Interests of the Dead	77
4.3 Rescuing Others and Preventing Future Harm	79
4.4 Preventing Harm to the Vulnerable and Incapacitated.....	81
4.5 Doing Good and Preventing Harm Caused to Relatives	82
Summary.....	87
Chapter 5 Research Design	89
5.0 Introduction	89
5.1 Selection of Qualitative Research Approach.....	90
5.2 Defining Qualitative Research	91
5.3 Identifying a Suitable Approach to The Study.....	92
5.3.1 Grounded Theory.....	92
5.3.2 Ethnography.....	92
5.3.3 Phenomenology	94
5.4 Phenomenological Approaches	94
5.4.1 Transcendental Phenomenology	94
5.4.2 Hermeneutics / Existential Phenomenology	99
5.4.3 Interpretation of Hermeneutics Phenomenological Data.....	102
5.4.4 Objectivity of Heideggerian Phenomenological Data	105
5.5 Evaluation of Research Data	109
5.5.1 Overall Concepts of Validity and Reliability of Research	109

5.5.2 Evaluation of Quantitative Research	110
5.5.3 Application of Reflexivity in Qualitative Research.....	111
5.5.4 Selection of Research Approach.....	112
5.6 Application of Phenomenological Approaches to Data Collection.....	113
5.6.1 Development of Research Tools.....	115
5.6.2 Overview of the Research Process.....	117
5.7 Phase 1 Initial Survey of the Application of Presumed Consent Legislation in Europe and Recruitment of Suitable Research Sites	117
5.7.1 Recruitment & Selection of Research Study Sites.....	119
5.7.2 Choice of Participating Countries.....	120
5.7.3 Final Selection of Sites for Study	121
5.8 Ethical Approval for Study.....	121
5.9 Phase 2 Introduction and Site Preparation in Each Country	127
5.9.1 Study Introduction to the Three Countries	127
5.9.2 Final Identification of Study Sites& Research Participants.....	130
5.10 Group 1 European Healthcare Professionals with Access to Presumed Consent Legislation and Utilise the Legislation: Portugal	130
5.10.1 Research Study Sites Portugal	130
5.11 Group 2 European Health Care Professionals with Access to Presumed Consent Legislation not using this Legislation in full: Norway.....	131
5.11.1 Research Study Sites in Norway.....	131
5.12 Group 3 European Health Care Professionals who utilise Presumed Consent Legislation and Bi Lingual Population: Belgium.....	134
5.12.1 Research Study Sites in Belgium.....	134
5.13 Initial Data Gathering Using Questionnaires	136
5.14 Phase 3 Planning and Undertaking the Interviews with Healthcare Professionals.....	137
5.16 Researcher Reflexivity	138
5.17 Identifying and Obtaining Independent Translation Services in Europe .	139
5.18 Transcribing The Taped Interviews.....	142
5.19 Verification of Data.....	143
5.20 Phase 4 Coding of Data and Analysis with Interpretation in Relation to Literature	144
Summary.....	148

Chapter 6 Findings from Transplant Correspondence and Field Work..... 149

6.0 Introduction	149
6.1 Portugal.....	149
6.1.1 Organ Donation Legislation in Portugal.....	149
6.1.2 Cultural and Religious Underpinnings within Portugal.....	150
6.1.3 Application of Presumed Consent Legislation in Portugal.....	150
6.1.3.1 National Organ Non -Donor Register.....	150
6.1.3.2 Relatives Involvement in Decision Making in Organ Donation as Determined by Legislation.....	151

6.1.3.3 Procedure for Organ Donation.....	152
6.1.4 Organisation of Organ Donation and Transplant System in Portugal	153
6.1.5 Organ Sharing System in Portugal.....	154
6.1.6 Funding of National Organ Donation and Transplant System Portugal	154
6.1.7 Education Programmes for Staff in Portugal.....	154
6.2 Norway	155
6.2.1 Organ Donation Legislation in Norway.....	155
6.2.2 Cultural and Religious Underpinnings within Norway	156
6.2.3 Application of Presumed Consent Legislation in Norway	157
6.2.3.1 Procedure for Organ Donation in Norway.....	157
6.2.3.2 Relatives Involvement in Decision making in Organ Donation as Determined by Legislation.....	157
6.2.4 Organisation of Organ Donation and Transplant in Norway.....	159
6.2.5 Organ Sharing Systems Across Scandinavia.....	160
6.2.6 Funding of National Organ Donation / Transplant System Norway ..	161
6.2.7 Education Programmes for Staff in Norway.....	162
6.3 Belgium	163
6.3.1 Organ Donation Legislation in Belgium.....	163
6.3.2 Cultural and Religious Underpinnings within Belgium	165
6.3.3 Application of Presumed Consent Legislation in Belgium	165
6.3.3.1 National Organ Non -Donor Register.....	165
6.3.3.2 Relatives Involvement in Decision making in Organ Donation as Determined by Legislation.....	166
6.3.3.3 Procedure for Organ Donation.....	167
6.3.4 Organisation of Organ Donation and Transplant System in Belgium	169
6.3.5 Organ Sharing System in Belgium	169
6.3.6 Funding for Organ Donation and Transplant System in Belgium	169
6.3.7 Education Programmes of Staff in Belgium.....	170
Summary.....	170

Chapter 7 Findings from Questionnaires and Development of Interviews..... 172

7.0 Introduction	172
7.1 Responses from the Questionnaires.....	172
7.1.1 Demographic Data of the Respondents	172
7.1.2 Question 1 – 4 and 7: Experience of Organ Donation.....	175
7.1.3 Question 5: Knowledge of the Legislation	176
7.1.4 Question 6: Knowledge of Protocols	176
7.2 Question 8: Benefits of the Legislation.....	177
7.2.1 Organ Donation Legislation in Each Country	178
7.2.2 Public Knowledge of the Organ Donation System.....	178
7.2.3 The Recipients and Society.....	179
7.2.4 Organisation of the Organ Donation Services and Infrastructures	180
7.2.5 Professional Practices Used to Support Organ Donation	181
7.2.6 Team working and Communication with Transplant staff.....	182
7.2.7 Involvement of the Family in Decision Making for Organ Donation	183
7.3 Question 9: Challenges of the Legislation.....	184
7.3.1 Public Understanding of Issues Related to Organ Donation	184

7.3.2 Support of the Family of the Deceased During the Organ Donation Event.....	186
7.3.3 Ethical Challenges of Organ Donation Practices.....	187
7.3.4 Requirement for Improvement of the Organ Donation Systems and Infrastructure to Increase Donation Rates	189
7.3.5 Improving Health Care Practices that Underpin Organ Donation.....	191
7.3.6 Overall Findings from Questionnaires.....	193
7.4 Phase 3 of Study: Selection of Staff for Interview and Preparation.....	195
7.4.1 Identification of Suitable Interview Subjects using Questionnaire Responses.....	195
7.4.1.1 Identifying Interviewees in Portugal.....	196
7.4.1.2 Identifying Interviewees in Norway	197
7.4.1.3 Identifying Interviewees in Belgium	197
7.5 Planning the Interviews in Each Country.....	198
7.6 Undertaking the Individual Interview of Identified Staff.....	199
Summary.....	200
Chapter 8 Findings from Interviews.....	201
8.0 Introduction	201
8.1 Responses By Interviewees	201
8.1.1 What is the Impact of the Implementation of Presumed Consent Legislation on the Bereaved Relatives of the Donor using Your Country's System?.....	201
8.1.1.1 Involvement of Relatives in Decision Making Process.....	202
8.1.1.2 Staff Perceived Benefits to Relatives of Involvement in Decision Making.....	205
8.1.1.3 Challenges of Involving Relatives in the Decision Making Process	206
8.1.1.4 Impact of Extreme Presumed Consent Legislation and Potential Harm to Relatives	206
8.1.1.5 Establishing Patient Consent and Relative's Lack of Objection .	209
8.1.1.6 Respect For the Wishes of the Dead and That of Relatives.....	210
8.1.1.7 Level of Public Knowledge of Law and General Education in Society and Ability to Participate in Decision Making Process	215
Summary.....	219
8.1.2 How does Presumed Consent Impact Upon the Relationship Between the donor Families and the Healthcare Professional?	220
8.1.2.1 Level of Knowledge of Organ Donation and Law in Public and Society	221
8.1.2.2 Response of Society to Presumed Consent Legislation.....	224
8.1.2.3 Approach to Relatives.....	226
8.1.2.4. Relatives Understanding of the Concept of Brain Death.....	230
8.1.2.5 Culture & Religion.....	234
8.1.2.6 Protection of the Incapacitated	237
Summary.....	238
8.1.3 Policies and Procedures in Organ Donation.	239
8.1.3.1 Law Application in Practice	240
8.1.3.2 Infrastructure Required to Support the Organ Donation System.	243

8.1.3.3 Protocols for the Identification of Donors by Staff & Types of Donors.....	250
8.1.3.4 Technical Organ Donation Policies & Practices.....	253
8.1.3.4.1 Establishing Brain Death in Portugal	253
8.1.3.4.2 Establishing Brain Death in Norway	256
8.1.3.4.3 Establishing Brain Death in Belgium	258
8.1.3.5 Concerns Relating to Ethical Dilemmas in Donation.....	261
8.1.3.6 Request to Relatives and Relatives Support Practices and Protocols	264
8.1.3.7 Impact of Organ Donation Practices and Protocols on Staff and Resources	267
8.1.3.7.1 Development of New Roles for Staff or Expansion of Existing Roles	267
8.1.3.7.2 Increase in Numbers of Organ Donations with Increase in Staff Workload	269
8.1.3.7.3 Emotional Impact on Staff.....	274
8.1.3.7.4 Financial Impact of Organ Donation on Health Care Systems	278
Summary.....	279
8.1.4 Does the Implementation of Presumed Consent Legislation Require the Provision of Specialist Education or Preparation for HCPs	280
8.1.4.1 Staff Education on the Law and Organ Donation Practices	280
8.1.4.2 Education and Preparation in the Approach and Care of Relatives	286
8.1.4.3 Mentorship and Staff Support in Practice.....	290
Summary.....	294
Chapter 9 Discussion of Study Outcomes.....	295
9.0 Introduction	295
9.1 Drafting and Application of Presumed Consent Legislation.....	296
9.1.1 Establishment of Consent or Objection to Organ Donation	296
9.2 Involvement of the Family in the Organ Donation Process	301
9.2.1 Establishing the Level of involvement of Family in the Organ Donation Process	301
9.2.2 Establishing the Potential Impact of Family Involvement in the Organ Donation Process	304
9.2.3 Family Knowledge and Education in Relation to Organ Donation....	309
9.3 Trusting Relationship between The Public, Family and The Health Care Professional	313
9.3.1 Trust in the Organ Donation Legislation and System	313
9.3.2 Trust in the Health Care Professional's Clinical Practice.....	315
9.3.3 Health Care Professional's Respect for Cultural and Religious Beliefs of the Family.....	316
9.4 Health Care Professionals' Practice in Organ Donation	318
9.4.1 Development of Organ Donation Infrastructures & Networks.....	318
9.4.2 Organ Donation Communication Infrastructure.....	320
9.4.3 Development of Organ Donation Professional Manpower.....	321
9.5. Development of Protocols of Practice in Organ Donation.....	323

9.5.1 Protocols for Brain Death and Donor Management	323
9.5.2 Protocols for Care of the Family.....	325
9.6 Education and Preparation of Health Care Professional for a Role in Organ Donation	328
9.6.1 Education in Legal and Ethical Aspects of Organ Donation.....	328
9.6.2 Education in Organ Donation Clinical Practice.....	329
9.6.3 Education in the Care and Support of Relatives	330
9.6.4 The Research Approach Strengths and Limitations	333
Chapter 10 Conclusions & Recommendations.....	336
10.0 Introduction	336
10.1 The Infrastructures and Administration Required to Support Presumed Consent Legislation.....	336
10.2 The involvement in and Impact of the Legislation on the Bereaved Relatives of the Donor.....	338
10.3 The Impact of the Application of the Legislation on Relationship between the Donor Families and the Health Care Professionals	339
10.4 The Provision of Specialist Procedures, Policies and Resources Enabling the Effective Implementation of this Legislation	340
10.5 The Availability of Specialist Education or Preparation for the HCPs Who Apply this Legislation	343
10.6 Challenges of Research Methodology Adopted.....	344
Summary.....	346
References	350
Appendices.....	366
Appendix 1 The Human Tissue Act 1961 s 1 provides.....	367
Appendix II Human Tissue (Scotland) Act 2006	369
Appendix III Methods of Determining Brain Stem Death.....	375
Appendix IV Research Study Participant Information Sheet.....	378
Appendix V Participant Consent Form	380
Appendix VI Presumed Consent Legislation in Europe : Initial Staff Questionnaire.....	381
Appendix VII Organ Donation Legislation in Portugal	384
Appendix VIII Organ Donation Legislation in Norway.....	393
Appendix IX Organ Donation Legislation in Belgium	408
Appendix X Semi Structured Interview Schedule.....	415
Appendix XI: Codes of Respondents to Questionnaire and Direct Experience in Organ Donation	419
Appendix XII Study Data From Returned Questionnaires and Interviews.....	420

List of Figures

Figure 3.1 Individual Faiths Responses to Organ Donation.....	57
Figure 5.1 The Hermeneutic Circle	104
Figure 5.2 Methodological Interpretations Of Phenomenological Data Van Kaam (1959).....	107
Figure 5.3 Overview of Research Process	116
Figure 5.4 Members of the European Transplant Co-ordinators Organisation ...	124
Figure 5.5 Initial Introductory letter To European Transplant Co-ordinators	125
Figure 5.6 Responses of Initial Descriptive Survey of European Countries	126
Figure 5.7 Coding of Responses.....	145
Figure 5.8 Process For Coding Findings	147

List of Tables

Table 5.1 Distribution of Questionnaires in Three Countries.....	136
Table 7.1 Responses to Questionnaires	174
Table 7.2 Health Care Professional’s Knowledge of Legislation and Policies and Protocols in Organ Donation	177
Table 7.3 Overall of Benefits of Legislation in The Three Countries	180
Table 7.4 Benefits of Organisation of Organ Donation Services and Infrastructure	181
Table 7.5 Benefits of HCP Practices in Organ Donation	184
Table 7.6 Challenges of Organ Donation System Services and Infrastructures..	185
Table 7.7 Challenges Arising from Involvement and Support of Family during Organ Donation.....	188
Table 7.8 Challenges of Improving Organ Donation Systems and Infrastructures	191
Table 7.9 Challenges to Improving Health Care Professional Practices	193
Table 7.10 Returned Questionnaires from Each Country and HCP Interviewed	198
Table 9.1 Research Questions Mapped to Emergent Themes from Participants.	296

Chapter 1 Introduction

1.1 Background to and Current Organ Donation in U.K.

United Kingdom Transplant (UKT) report that as of 31st March 2006 initiatives to recruit organ donors have resulted in 13.1 million people out of a population of nearly 60 million in the U.K., adding their name to the NHS Organ Donor Register (ODR) (UKT, 2006). Additionally, they report that between April 2005 and March 2006, the deaths of 764 people who agreed to donate their organs resulted in 2,195 organ transplants being performed including 125 donations via the newly introduced non-heart beating donation system. These figures reflect a number of different types of organ donations including 1,914 patient receiving kidney transplants 590 of these from live donor transplants, 130 people receiving pancreas transplants, 610 liver transplants and 264 cardiothoracic transplants. Despite the increase in live kidney donations, up by 24% on the previous year, the majority of donations are obtained from cadaveric donations, these are organs donated by the individual following their death. However, UKT (2006) also report that despite their efforts to recruit organ donors and co-ordinate the organ transplant activity within the U.K., as of the end of March 2006 6,698 people remain on the organ transplant waiting list, a 9% increase in the number of people actively awaiting a transplant from the previous year, many of whom will die before an organ that matches their needs becomes available. Cadaveric organ donation rates vary across the U.K. and Ireland however, with 9.1 per million population (pmp) in Scotland, 13.2 pmp in England, 15.2 in Wales and 17.8 pmp in Northern Ireland and 21.3 pmp in the Republic of Ireland (UKT, 2006).

These low numbers of donated organs exist despite the reportedly high numbers of people within the U.K. that support organ donation. UKT (2006) suggest 90% of the U.K. population is in favour of organ donation. This finding supports the British Kidney Association (1992) finding that 71 % of the population are in favour of organ donation. Similar smaller scale studies have also demonstrated high levels of support for organ donation. Gill and Hulatt (1999) report 93% of the members of the public questioned (n=86) agreed with organ donation, with Riad and Banks (1990) reporting that 72% (n=626) of outpatients in two British hospitals also stated that they were in favour of being asked about organ donation. In addition Cantwell (2000) suggested that in a survey of nursing and medical students (n=72) 74% of nursing students and 43% of medical students, claimed that they would be willing to donate their organs.

To resolve this increasing shortfall in organ donation, the U.K. has developed medical, legal and ethical strategies to facilitate the donation of a human organ after death. In 2006 UK Transplant (UKT) merged with the National Blood Transfusion service to form NHS Blood and Transplant Service (NHSBT) with the aim of streamlining donation services throughout the U.K., improving their efficiency and effectiveness. The donation of an organ is often viewed as a voluntary beneficent act undertaken by the individual with the intention of improving the health of another. Many groups within society, save some particular religious faiths, for example, Orthodox Judaism, consider organ donation as being acceptable and desirable. The majority of organs for donation are procured when a living individual has agreed to offer his or her organs for donation following their death, described as cadaver donations. Alternatively, the

individual can agree to offer to donate certain types of organs to another person while they are still alive, described as live donation. Although strategies to encourage live donation of non-vital organs to improve the quality of life of a chronically ill person on the transplant list are being introduced (UKT 2006), within the U.K. the majority of solid organ donations are via the cadaver donation route. Sweeny (1999) suggests that improved survival rates in individuals who suffer a Road Traffic Accident or a Cerebral Vascular Accident which had previously resulted in high numbers of fatalities, may have had a detrimental effect on the numbers of organs available for donation. As a result of this low level of donation the gap between those waiting for a transplant and the numbers of organs available grows every year.

1.2 Introduction of New Legislation

New legislation was introduced in 2006, the Human Tissue (Scotland) Act 2006 (here after referred to as the HT (S) Act 2006), which facilitates the donation of a part of the body of a deceased person for the purposes of transplantation, research, education or training and audit provided that the deceased had authorised this prior to their death, either in writing or having expressed this authorisation verbally. These new legislative powers supersede the previous pieces of legislation that governed the donation of organs and tissues namely the Human Tissue Act 1961 and the Human Fertilisation & Embryology Act 1990. Additionally, the principles of the Human Rights Act 2000 and the Adults with Incapacity Scotland Act 2000 are also upheld within this new legislation where the fundamental principle underpinning the donation of human body parts is the requirement of evidence of individual expressed consent to donation. This “opt in” system allows the individual to choose to donate their organs and notify their

intention to do this prior to their death and is usually facilitated by one of two methods.

Firstly a system exists that allows an individual to record their consent to organ donation via the completion and carrying of an organ donor card. Those who adopt this approach to recording their intention to donate are also encouraged to notify their immediate family and friends of their decision. Secondly, following the establishment of the NHS National Donation Registry (NDR) (UKT, 1995) individuals can register their consent to the donation of Organs and Tissue via the entry of their name on this register. Additionally, by completing the appropriate sections on their driving licence application form with the Driving Vehicles Licence Authority, or completing an application to register with a new General Practitioner the individual can have their intention to be an organ donor communicated to the ODR. Subsequently, major retail pharmaceutical companies have also joined the scheme enabling individuals to register their names on the ODR via part of the application form to join their loyalty card scheme.

1.3 Barriers to Converting the Consent to Donation into Organs for Transplant

Despite these strategies there continues to be a considerable short fall in the number of organs required for transplantation. Some clinicians have attempted to explore the rationale for this by analysing the practice for organ procurement undertaken by HCPs. Kozlowski (1998) and Riley and Coolican (1999) amongst others suggest that the introduction of the concept of organ donation very quickly after the news to a relative of loss of a loved one, as required in the application of presumed consent legislation, may produce psychological harm to the relatives,

resulting in a detrimental effect on their grieving process. Gore et al, (1991) reports HCP difficulties in exploring this delicate issue at a time of great distress for relatives, suggesting that in the U.K. seven out of every ten families would give their consent to donation if approached. She also suggests that a 20% increase in cadaver donations could be achieved if avoidance of organ donation by HCPs was addressed. This lack of willingness to approach the family she views as possibly stemming from two sources i) possible lack of evidence of the individual's wish to donate their organs appears to result in many missed opportunities for organ donation, ii) lack of awareness of the issue by staff within the acute setting coupled with staff reluctance to request organ donation at the time of a sudden death. Gore et al., (1991) also suggest that the provision of improved professional skills in requesting donation might reduce relatives' refusal of consent. Gibson (1996) agrees with this view, suggesting that the non - procurement of organs is a much more complicated issue under the influence of many factors, not least the attitudes towards organ donation held by the public and the professionals involved. She suggests that underlying philosophies must be understood if the problem of shortage of organs is to be resolved.

One of the chief aims of the newly formed NHSBT is to increase the numbers of donated organs by reducing relative's refusal rates from 41% to 30% by March 2009. To achieve this an investment of £1 million per annum has been made in the development of twenty transplant co-ordinator schemes within neurological and other intensive care units through out the U.K. (NHSBT, 2006).

1.4 Identification of Alternative Approaches to Organ Donation Legislation

In an effort to improve the number of organs for donation, some cite approaches undertaken by some European countries as having a potential solution to this problem. In order to increase their organ donation rates countries such as, Austria, Spain, France, Portugal, Norway, Belgium and Italy, have introduced presumed consent legislation (New et al., 1994, Roels et al., 1999). Using this approach to organ donation, it is presumed that most individuals are in favour of organ donation and would wish to donate their organs in the event of their sudden death. Subsequently, under the terms of this “opt out” system, if the individual does not indicate their objection to donation, their organs can be procured for donation. Leading figures within the medical and legal establishments (Kennedy et al., 1998; BMA, 1999) have supported moves to introduce this legislation. The BMA (2005), in a further position statement supporting the introduction of presumed consent legislation in organ donation in the U.K., take the view that this legislation would increase the organs for transplant by reducing the numbers of organs currently lost. This loss most often occurs as a result of the failure of individuals to either register their intent to donate, or notify relatives of this wish. Additionally, UKT (2006) report that a recent survey undertaken by the BBC demonstrated that that 61% of the population surveyed were in favour of the introduction of presumed consent legislation in the U.K.

1.5 Challenges to Presumed Consent Legislation

Opponents of this proposal however raise a number of objections to the introduction of this legislation on an ethical and or professional basis. Kass (1985) and Lamb (1990) challenge the introduction of this type of legislation suggesting that it may result in disrespect for the wishes of the dead. Others suggest that this

legislation is disrespectful to the autonomous choices of the individual (Ellis, 1998, Hill et al 1999), with others warning of the legal and ethical difficulties associated with this system, for example, conflict between the concept of an organ donation as a voluntary gift between one human being and another versus forced removal of organs irrespective of consent (Titmus, 1970, Veatch, 1987). Moreover, Prottas and Batten (1991) support this view suggesting that the principles of informed consent and encouraged voluntarism that underpin the act of organ donation are vital to the organ donation programme and cannot be overlooked. Although there is limited research to support the view, Sque and Pyne (1994) together with Mason and McCall-Smith (1999) fear this may produce a negative impact on the relationship between the HCP and the public. A report of the House of Lords (HOL, 2000) supports this view highlighting the public's increasing mistrust of the health care professionals in general but citing the controversy surrounding the retention of children's organs as a major example of failing confidence of the public in the health care professional.

Whilst there has been considerable literature on the successes of presumed consent legislation approach to organ donation in terms of the numbers of organs produced using this system, to date very little literature exists exploring the impact of this legislation on the families of the deceased or on the HCPs who utilise it in order to procure organs for donation (Neades, 2000). In reporting the limited application of presumed consent legislation by staff involved in organ donation in France, Nowenstien Piery (2004) also highlights the lack of evidence relating to organ donation legislation and the interpretation of this by the HCPs directly involved in this area of practice. Additionally, review of the relevant literature demonstrates the paucity of information detailing the effect on the health

care system of this approach to organ donation in terms of the legal, ethical, financial and professional practice impact it may have.

If the views of Kozloski (1998) and Riley and Collican (1999) can be substantiated, the introduction of presumed consent legislation may increase the numbers of organs for donation but has the potential to produce considerable ethical dilemmas for the HCPs and society at large who would seek to implement it. If supported, this potential conflict between the need to increase organs and the potential harm to the rites of the individual and the public perception of the organ donation system. Public mistrust in the organ donation system engendered by the introduction of presumed consent legislation may not only fail to improve the supply of organs for transplantation but may reduce the numbers currently available. It may in turn produce professional and legal consequences for the HCP. Alternatively, if these suggestions are not supported and the HCPs involved in organ donation within countries that currently utilise presumed consent legislation in organ donation can demonstrate safe effective practice, in not only obtaining high numbers of organs for transplantation, but in addition, demonstrating acceptable professional and ethical practice in the respectful care of the donor and family, then perhaps there is much that can be learned from their practice which can be applied to organ donation practice within the U.K.

As an experienced nurse and educationalist in emergency and intensive care I had considerable personal experience of organ donation within these practice settings. During my career practicing within these settings I had witnessed first hand the difficulties experienced by the HCPs in this clinical areas in balancing the desire to care for the donor and the family in an ethical and professional

manner, with the need to obtain organs for donation. As a joint appointment between a Higher Education Institution and NHS Healthcare Provider, I was also acutely aware of the need to develop explore new legislative and clinical initiatives in order to increase organs for donation. Additionally, a review of presumed consent legislation undertaken as part of M. Phil. degree in Law and Ethics in Medicine, demonstrated to me the lack of information relating to the application of presumed consent legislation in health care practice. In my view in order to make a judgement as to whether adopting this approach to organ donation would be beneficial or harmful to the HCP, the NHS and society as overall, there was a need to develop data that described the practice of the HCPs in Europe who used this approach to organ donation. Once developed these data could be used to inform professionals, legislators and the NHS of the potential impact on practice of this approach to organ donation. I considered the lack of data detailing the application of presumed consent legislation by HCPs to be an important omission in the literature underpinning the debate in the U.K. surrounding the adoption of this legislative approach to organ donation. As such this lack of data required to be addressed and was therefore the stimulus for this study.

Summary

In the face of increasing numbers of people requiring an organ transplant and so many of these people dying whilst on the waiting list, the question of whether some format of presumed consent legislation should form part of a future organ donation strategy within the U.K. continues to be raised and as yet remains unanswered. There is an urgent need therefore to explore the impact of this legislation on the bereaved relatives and the health care professional directly involved in this aspect of care. A study designed to explore these issues would

inform legislators and professional alike and assist in the development of future organ procurement policy in the U.K. In order to design an appropriate research study to address these deficits in knowledge, it was first important to review the legislation in relation to organ donation in U.K. together with that relating to organ donation in Europe, identifying the benefits of and challenges to the two different approaches to organ donation. To achieve this the thesis will be structured in the following manner:

- Chapter 2 and will review the literature relating to the application of the current organ donation legislation within Scotland.
- Chapter 3 will review the literature relating to the application of presumed consent legislation in organ donation within Europe.
- Chapter 4 will discuss the ethical underpinnings of organ donation exploring the ethical objections to presumed consent legislation.
- Chapters 5 will describe the process by which the design for the study was identified, discussing the application of this approach.
- Chapters 6, 7 and 8 will describe the findings arising from the study and their analysis together with a discussion of the implications of this provided in chapter 9.
- Finally, chapter 10 will describe the conclusions formulated by researcher as a result of the study findings, providing her recommendations for future research, practice and education.

Chapter 2 Organ Donation Legislation in U.K.

2.0 Introduction

This chapter is the first of two reviewing the literature published in relation to organ donation legislation and practices within Europe together with the current legislation in the U.K. relating to organ donation. The current legislative provision within the U.K. will be critically appraised from a health care perspective highlighting the benefits and issues presented. The subsequent chapter will appraise the use of presumed consent legislation across European countries, analysing the successes and challenges reported in relation to this approach to organ donation. The U.K. legislation will be reviewed under the following sections:

- **Existing Law and Cadaver Organ Donation**
- **Common Law**
- **Statute**
- **Failure to Comply with the Legislation**
- **The Human Tissue (Scotland) Act 2006**
- **Ensuring That Life is Extinct**
- **Preservation of Donor Organs**
- **Authorisation to Remove Tissues**
- **Appropriate Indication of Wish to become a Donor**
- **Valid Request**
- **Authority to Proceed**
- **Consent to Proceed from Coroner or Procurator Fiscal**
- **Preparing Setting to Support the family and Undertake Request**

- **Education and Preparation of Health Care Practitioner in Organ Donation**
- **Use of Body Parts for Teaching, Audit and Research Purposes**

2.1 Existing Law and Cadaver Organ Donation

Currently the main approach to organ transplantation is cadaver donation, where the individual can determine what they wish to have done with their body tissues following their death. Prior to death an individual can validly consent to the removal of organs after their death for donation, education or scientific purposes both in common law and under statute. This will assist in facilitating cadaver organ donation. The legislation in relation to organ donation in Scotland and England and Wales has recently changed. However, in order to understand the current position in relation to organ donation, it is important to review the development of this new legislation from a historical perspective.

2.1.1 Common Law

Dworkin and Kennedy (1993) suggest that under the terms of the Human Tissue Act 1961 and the Human Organ Transplants Act 1989 in England and Wales there are no property rights in respect to a corpse. In their view the person lawfully in possession of the body or the next of kin have the duty however to arrange for appropriate burial of the corpse. The person lawfully in possession of the body can also authorise the use of the body, for example, they may authorise investigations into the cause of death. However, citing common law in England and Wales as held in *R v Kelly* (1998), and in Australian law citing *Doodewood v Spence* (1996), Price (2000) suggests that ordinarily body parts can not be considered as the property in the possession of a party, i.e. they cannot belong to

an individual unless it could be demonstrated that work had been undertaken on the body parts by that person to “change the character” of the body part. Skegg (1975) however suggested that under common law within Scotland as inferred in *Dewer v HM Advocate* (1945) a corpse may be the subject of property and can be stolen or possessed until such time as it is buried or cremated.

2.1.2 Statute

The first statutory regulation of donation of cadaver tissues was framed within the Anatomy Act 1832 passed as a result of the prosecution of Burke and Hare who supplied corpses to the medical school in Edinburgh in return for payment. This allowed a person to make a declaration donating their body to medical science following their death. The Corneal Grafting Act 1952 allowed for the donation of eyes for therapeutic purposes and was closely followed by the Human Tissue Act (HTA) 1961 (**Appendix 1**). This legislation regulated the use of cadaver organs and tissues until superseded by the Human Tissue (Scotland) Act 2006 here after referred to as HT (S) Act 2006 (**Appendix II**), with the Human Tissue Act 2004 (HT Act 2004) regulating the same in England and Wales. This legislation now governs the use of body parts for transplantation, post-mortem examination, anatomical examination, tissue sampling & retention in Scotland, England and Wales.

2.1.3 Failure to Comply with the Legislation

The HT (S) Act 2006 also identifies a criminal offence may be committed by the individual who removes or uses parts of the body of deceased person for transplantation, education, research or audit without authorisation:

“1) A person commits an offence if the person removes, after the day on which section 3 comes into force, a part of the body of a deceased person for any of the purposes referred to in section 3(1) or uses after that day any part so removed for any such purpose and-

a) the removal or, as the case may be, the use for the purpose in question is not authorised in accordance with section 6, 7, 8, 9 or, as the case may be, 10; or b) any of the requirements in section 11(1) or (4)(a) is not satisfied as respects the part.”

Additionally, the legislation also identified penalties should these offences be committed by the HCP who removes organs or tissues without authorisation thus:

3) A person guilty of an offence under subsection (1) is liable- (a) on summary conviction, to-

i) imprisonment for a term not exceeding 12 months; (ii) a fine not exceeding the statutory maximum; or (iii) both; (b) on conviction on indictment, to- (i) imprisonment for a term not exceeding 3 years; (ii) a fine; or (iii) both.

The power to pursue a conviction flowing from the offences created by this new legislation lies with the Lord Advocate for Scotland. Under the HT (S) Act 2006 and the HT Act 2004, all practices related to organ donation in Scotland and England and Wales will now be overseen by a new authority, the Human Tissue Authority, with powers to inspect and monitor adherence to the legislation.

2.2 The Human Tissue (Scotland) Act 2006

To understand the implications for the HCP of the new legislation, it is important to explore the different aspects in detail. For ease of understanding the HT (S) Act 2006 can be divided into the following sections:

2.2.1 Ensuring that Life is Extinct

2.2.1.1 Diagnosing Death

Under the terms of the HT (S) Act 2006 before the medical practitioner or other person recognised to remove the body parts from the deceased there is a requirement to establish the death of the donor utilising accepted criteria. Part 1 (s) 11 states that:

“4) The requirements are that the person (and, where a registered medical practitioner proposes to authorise the carrying out of the removal by virtue of regulations under subsection (1)(b), the practitioner) must be satisfied- (a) either- (i) by personal examination of the body, that life is extinct; or (ii) that another registered medical practitioner, by such personal examination, is so satisfied.”

This requirement is fundamental to the ethical basis on which the HCPs may practise. However, the legislation does not specify how death should be established or indeed what tests should be used to certify the patient as dead. This is left to the discretion of the medical practitioner and may include the utilisation of brain stem death criteria or the use of cardiovascular criteria to establish death.

2.2.1.2 Brain Stem Death

Brain stem death is said to occur when a person has sustained irreparable, structural or tissue damage to their brain stem usually resulting from the cessation of blood flow to this part of the brain, and its subsequent death (Conference of Medical Royal Colleges and their Faculties in the U.K., 1979). Having established the term brain stem death, the Medical Royal Colleges developed criteria for the diagnosis of brain death that have been used as the basis for this diagnosis thereafter stating:

“It is agreed that permanent functional death of the brain stem constitutes brain death”

and that diagnosis should be considered when:

“ There should be no doubt that the patient’s condition is due to irremediable structural brain damage. The diagnosis of a disorder which can lead to brain death, should have been fully established”.

Brain stem death produces a deeply comatose state within the patient’s brain with the loss of regulatory control of respiratory and cardiac functions. This renders the patient unable to breathe without the assistance of a ventilator or to maintain a cardiac output without the assistance of a range of drugs. Should this assistance be

provided the respiratory arrest and subsequent cardiac arrest that would follow from cerebral anoxia, i.e. resulting from the cessation of blood flow to the brain stem, is prevented. These patients will never regain consciousness and their normal bodily functions require to be supported by medical technology. Patients who are cared for in the intensive care unit who are suspected as meeting the criteria for the diagnosis of brain stem death, are usually subject to testing of their brain stem function to establish if any of this vital aspect of the brain function remains. These criteria established by the Medical Royal Colleges (1979) is recognised internationally to determine brain stem death and is one of several measures currently available to practitioners to certify brain death, with subsequent additional measures being introduced (**Appendix III**).

In the event of the brain stem function being permanently lost, the patient is medically recognised as being dead (the dead donor) but continues to have a cardiac output and respiration with the support of medical technology. Should this respiratory support be removed the patient would quickly sustain a respiratory arrest and subsequently a cardiac arrest and die. The patient sustained in this condition could therefore be described as a heart- beating donor (HBD) i.e. he or she has suffered brain death but cardiac function will continue to function until support is withdrawn, immediately prior to donation. Controversy does exist however with acceptance of this terminology amongst all HCPs. This term was recognised as a diagnosis of death as held in *Re A* (1992). In this case Mr Justice Johnston ruled that it was not in the interests of a child a “continuing indignity” for his body to have to have ventilation, hydration and nutrition continued following a diagnosis of brain stem death. He therefore granted an order permitting these to be withdrawn by the medical staff. If the child in this case had

not been diagnosed as brain dead, clearly withdrawal of these life-sustaining interventions would have resulted in his death, with the medical staff open to accusations of manslaughter. Some debate does exist in relation to the manner in which the tests are conducted i.e. by one or two senior medical professionals, or the predisposing conditions experienced by the patient that could contribute to a false negative response to the tests undertaken on the patient, for example, if the patient had been administered a sedative drug prior to the tests being undertaken.

Robertson (1999) suggests that the determination of death prior to the donation of organs is central to society's respect for persons and human life. Given this, it would therefore be unethical and illegal to remove organs from a donor if this would result in their subsequent death. Public trust in the organ donation system rests on the confidence that all cadaveric donors are certified as being dead prior to the removal of their essential organs and that no person would be killed for their organs. This is termed the "dead donor rule". Despite the reassurance of the acceptance of the brain death criteria by the Conference of Medical Royal Colleges of the U.K. (1979), Hodgkinson (1986) highlights how many medical staff still consider it difficult to accept the technical criteria for brain stem death. Schroeter and Taylor (1998) report that in the U.S. the controversy surrounding the possible different tests to diagnose brain death has had a detrimental effect on donor numbers. This controversy regarding the definition of death resulted in further definitions of death to be developed with the United States of America President's Commission (1982) stating that individuals could be diagnosed as dead who had sustained the irreversible cessation of circulatory and respiratory functions or irreversible cessation of all functions of the entire brain, including the

brain stem. Subsequently the US Uniform Determination of Death Act 1985

defines death as:

“ The irreversible cessation of circulatory and respiratory function or the irreversible cessation of all functions of the entire brain, including the brain stem”.

Elsewhere, the Law Reform Commission of Australia (1977) also suggested that

death was defined by either:

“ Irreversible cessation of circulation of blood in the body of the person, or irreversible cessation of all functions of the brain of the person”.

The addition of these two words of “all functions” of the brain presents many challenges as it infers that a person cannot be defined as dead until all of the cells of the brain have ceased to function, a term known as brain death or “Whole Brain Death.” This term means that in addition to the death of the cells within the brain stem below there should be demonstrable irretrievable cell failure through out the other parts of the brain. Pearson (1997) acknowledges the controversy surrounding these differing definitions of brain death highlighting that despite the advances in technology, there are no objective tests available to demonstrate categorically the total loss of all brain cell function. The technology is available however to measure electrical impulses produced within the brain in response to external stimuli termed Somatosensory and Brain Stem Auditory Evoked Potentials (**Appendix III**). These alternative tests are performed by some clinicians to test for brain death (Sullivan et al., 1999). Additionally, other technology is available to measure blood flow to differing parts of the brain and confirm where this is absent e.g. cerebral angiography. This neuro-radiological examination is also utilised in some countries to confirm the diagnosis of brain stem death by demonstrating a cessation of blood flow within the central brain, for example, in Norway (DHSS, 1973).

The use of other more technical methods of evaluating total lack of brain function and therefore brain death in all patients, as opposed to brain death criteria, whilst preferable, presents a number of problems. Implementing some of these tests is very labour intensive in terms of the time this takes and the numbers of medical professionals required to undertake these tests. If cerebral angiography is employed, there will be a requirement to move the critically ill, possibly unstable, patient to the radiology department to undertake the procedure, with the accompanying risk that the patient will suffer a cardiac arrest whilst undergoing this procedure. Sullivan et al., (1999), suggest however that the measurement of neurological deterioration achieved using commonly used tools to assess neurological status i.e. the Glasgow Coma scale, is sensitive and accurate enough to confirm brain stem death. If the brain stem tests demonstrate the loss of function of this vital part of the brain, even if there is some residual blood flow to the other aspects of the brain, when resuscitative measures are removed the patient will suffer a cardio-respiratory arrest. In practical terms if brain stem death exists the patient is dead and will not recover. Pearson (1997), therefore strongly supports the use of the brain death criteria as both the legally and socially acceptable diagnosis of brain death in use today.

As has been previously suggested, to proceed to organ donation without ensuring that the patient has been certified as dead, Robertson (1999) suggests would bring the professional into conflict with the “Dead Donor Rule” i.e. the ethical and legal rule that requires that donors not be killed in order to obtain their organs. This he views as central to the respect for persons and human life and the linchpin to a voluntary system of organ donation and public trust in the organ donation system. If there was a possibility that all attempts to resuscitate the patient had not been

explored and that some slim chance existed that the patient could have survived, this being overlooked by the HCP in their quest to obtain organs for donation, this would not only destroy confidence in the organ donation system. Additionally, if this was confirmed, it could potentially result in charges of manslaughter or professional misconduct for the professionals involved.

In response to these controversies the Royal College of Anaesthetists (RCA, 2006) sought clarification of the processes for the diagnosis of brain stem death in patients, confirming the protocols for practice used to determine brain stem death in the U.K. At the time of writing these protocols form the basis of a consultation exercise reviewing the Code of Practice for the definition and certification of death currently being undertaken by RCA. This very detailed consultation paper acknowledges the controversies associated with brain stem testing and reviews the available data on these tests in patients. This consultation exercise was due to conclude in early 2007, establishing appropriate protocols for identifying brain stem death testing within the U.K.

2.2.1.3 Cardiovascular Criteria

In addition to the identification of brain dead patients within intensive care units using the RCA (2006) guidelines on brain stem death criteria, in the case of a Non-Heart Beating Donor (NHBD), death that often arises from a cardiac arrest in the emergency department, the patient can be certified as dead using cardiopulmonary criteria i.e. the cessation of cardiac output and respiratory function. Younger et al., (1999) however, report that controversy has resulted from the practice of declaring individuals dead on cardiovascular criteria alone following cardiac arrest. This method of certifying death has most often been used

to declare an individual dead in the so called “Controlled Non-Heart Beating Donor” (NHBD) situation. In the U.S. the use of these criteria to certify death provided the opportunity to move to organ donation very quickly after the cessation of cardiopulmonary functions, without the application of the strict neurological tests required within brain death criteria (University of Pittsburgh Medical Centre (1992).

Concerns have arisen however when it was suggested that in NHBD situations, death is defined using the cardiopulmonary criteria instead of the recognised criteria for brain stem death, to facilitate organ donation. Robertson (1999) together with Younger et al., (1999) describe the anxieties that exist within HCPs relating to the diagnosis of death following a cardiopulmonary arrest and the need to establish the irreversibility of this cardio-pulmonary failure. This irreversibility is usually demonstrated by failure of the patient to auto-resuscitate, i.e. regain a cardiac output with an agreed time period of 5 minutes after cardiopulmonary resuscitation has been withdrawn. When this auto-resuscitation fails to occur within the agreed time, the brain will be starved of oxygen and fail within 3-5 minutes. When this occurs, the patient can be pronounced dead and considered as an organ donor. In this event cardiopulmonary death is viewed as the criteria for death without the use of the recognised brain death criteria (University of Pittsburgh Medical Centre, 1992).

In response to this practice however, some argue that there is a need to establish not only cardiopulmonary death but also brain stem death. Younger et al., (1999) discuss the debate surrounding the declaration of death using the 5 minute rule and argue that there are many issues surrounding the concept of irreversibility that

remain unexplored including, what is the definition of irreversibility i.e. when can the brain be considered dead with no possibility of recovery of spontaneous circulation together with the morality of the decision not to attempt to restore cardiopulmonary function. They highlight that there is even debate amongst the HCPs as to what constitutes brain death in patients, with many questions that remain unanswered relating to the definition of death.

In an attempt to address this issue utilising the terms of the American Uniform Determination of Death Act 1985, i.e. that death can be defined by cardiovascular criteria only once it is irreversible, the Institute of Medicines (IOM) (1997) advised professionals to wait ten minutes after cessation of breathing and cardiac output before preparing to remove the organs. Younger et al., (1999) however note that despite the advice from the IOM to amend all NHBD protocols to include the 10 minute interval, many transplant centres rejected this advice preferring instead to recognise an interval of two minutes after the cessation of cardiopulmonary function, before proceeding to organ donation as recommended by the University of Pittsburgh Medical Centre (1992). Controversially, the organ retrieval protocol in Pittsburgh continues to allow organ retrieval to commence after two minutes of cardiac standstill (De Vita and Snyder, 1993). Hodgkinson (1986) reported that this controversy surrounding the diagnosis of death, that in order to ensure that the donor is in fact dead and there is no possibility that the medical staff are causing the donor's death by removing organs, some professionals would not proceed to remove the organs for transplant until the ventilator has been disconnected and the electrocardiogram demonstrates loss of all cardiac activity. By doing this they ensure that there was no possibility of auto-resuscitation of the donor, thus the medical staff performing the organ retrieval

cannot be accused of causing the death of the patient by moving to organ donation. In Europe this issue has also been debated. Kootstra (1995) discusses that in the Netherlands, in Maastricht the first international conference on non-heart beating donors considered this issue, taking the view, that 10 minutes of cardiac standstill and subsequent lack of perfusion of the brain would be required before any organ retrieval measures should be instigated. This convention of waiting 10 minutes after cardiopulmonary cessation before moving to consider the patient as a donor has been adopted across Europe.

That the issue of declaring an individual dead and procuring organs have been discussed openly in the media together with the uncertainty about brain stem death criteria validity has resulted in fears amongst some members of the public. The view suggesting that the public in general have a poor understanding of the concepts of organ donation is supported by studies of donor family experiences undertaken by Pelletier (1992) and Haddow (2003). These two small-scale studies demonstrated that the donor family did not understand the concept of brain death and the assessments of this, resulting in fear and anxiety for them.

Younger et al., (1999) highlight how the 60 minutes programme broadcast in the US in 1996 cast doubt on the practice of applying the cardiopulmonary criteria for death effectively, with the US programme furthermore suggesting that patients had been given drugs to shorten their life but improve the quality of the organs. Robertson (1999) acknowledges the misunderstandings and confusion that exist relating to brain death even amongst the HCPs involved but suggests that the proper application of brain death criteria including the assessment of brain stem function is the appropriate method of determining death and therefore upholding

the dead donor rule. Despite this assertion Robertson (1999) and Koppelman (2003) still maintain that there remains confusion and some controversy related to the criteria for pronouncing a person dead especially in the non-heart beating donor situation in emergency rooms using cardiovascular criteria rather than the brain death criteria required to determine death. The concern raised here is that in utilising the cardiopulmonary criteria for death, the irreversible loss of all cardiopulmonary function, may not been established. Hurried transfer of the patient to donor status and the removal quickly thereafter of organs could therefore be said to cause the patients death, and clearly unacceptable. In a attempt to clarify the position and end this controversy at least in the U.K., the Royal College of Anaesthetists (RCA, 2006) acknowledge these challenges to the diagnosis and certification of the patient using cardiopulmonary criteria and advises that using a newly identified set of criteria, a patient can be pronounced dead after a five minute period of observation of cardio-respiratory arrest. These proposals currently form part of a consultation exercise being conducted exploring opinions on a code of practice on the diagnosis and certification of death.

The NHSBT (2006) report a major initiative designed to increase the numbers of organ for donation from cadavers, i.e. the introduction of non-heart beating donors in eleven sites within the U.K. Proposals are also being developed to expand the controlled non-heart beating donor programmes to all neurological and other general intensive care units throughout the U.K. It remains to be seen however whether HCPs within these units will feel confident in these new criteria to certify patients as dead and move to consider the patient as an organ donation within five minutes of being pronounced dead. This will require the HCP to re-commence cardiopulmonary resuscitation procedures on the now identified donor and

maintain this until they are transferred to the operating theatre where the organ harvest will be performed. This may present considerable psychological and ethical challenges to the HCPs involved requiring them to move from the resuscitation of their patient to the consideration of them as a donor in a very short time. Additionally, in these sudden death events relatives, if present, could potentially be psychologically traumatised by the death of their loved one under these circumstances and require care and support, the implication of which will be explored later in this chapter.

2.2.2 Preservation of Donor Organs

In order that the organs are maintained in as good a condition as possible following the patient being pronounced dead and identified as a potential donor, whilst authorisation to proceed to organ donation is established, organ preservation procedures must be instigated. Hassan et al., (1996); Magrath (1999) and Sutherland (1995) all report that utilising a system of early retrieval of organs following a sudden death within the emergency setting can be very successful in the procurement of viable organs. These non – heart beating donors are pronounced dead within the emergency department and if no objection to donation is revealed or the deceased carries a donor card providing consent, organ retrieval is undertaken very soon after death. Nathan et al., (1999) reports that in the US the organ donation pool could be increased by 20 to 25% utilising this approach combined with a cold perfusion technique. This procedure involves the infusion of the corpse intra-peritoneally with cold perfusion fluid very quickly following cessation of resuscitation procedures in order to preserve the organs. This procedure adopted by Booster et al., (1993) in the U.S. and Varty et al., (1994) in the U.K. has been successful in procuring organs, especially kidneys

that would otherwise be lost. In some cases the deceased either carries a donor card or relatives are present and after being informed of the death of a family, give permission for the procedure and the donation of the organs. This allows retrieval of the organs almost immediately without the need to take the patient to an intensive care bed if a theatre is available to harvest the organs. This procedure negates the requirement to ventilate the brain dead patient.

Previously, controversy existed as to the role of the public procurator in the granting of permission to insert intravenous cannulae into the body of the deceased in the non-heart beating donor situation (BMA, 2000). This action is required to preserve the organs whilst reasonable enquiries are made to gain the consent of the next of kin to proceed to organ donation even if the deceased has signalled their consent by a signed donor card. The Report of the Scottish Transplant Group (2002) described their attempts to clarify the legal position within Scotland in order to allay the fears expressed by the Emergency Department staff as to the legality of this procedure, without the expressed consent of the deceased and verification of this by the relatives. The DOH (2002) acknowledged the lack of legal clarity on this issue as the insertion of the cannulae could be viewed as interference on the corpse. With the promotion of United Kingdom Transplant (2004) of the non-beating heart donor programme throughout the UK to obtain more organs for transplant there was an urgent need for clarity on this issue.

The HT (S) Act 2006 acknowledges this difficulty with Part 1 s 13 making it lawful for the health authorities to take minimum steps to preserve the organs of a

deceased person while authorisation is sought from the next of kin to remove the organs for transplantation thus:

“Where part of the body of a deceased person lying in premises to which this section applies is or may be suitable for use for transplantation, the managers of the premises may- (a) take steps for the purpose of preserving the part for use for transplantation; (b) retain the body for that purpose, but may not move the part or body to other premises.

(2) Authority under subsection (1)(a) extends only to- a) the taking of the minimum steps necessary for the purpose mentioned in that paragraph; (b) the use of the least invasive procedure.”

This paragraph therefore offers clarification as to the authority of the HCP to undertake procedures required to preserve organs for transplant, such as cold perfusion of organs, when the nearest relative is not immediately available to provide their authorisation to donation. This is a holding procedure to preserve the organs whilst authority is sought and provision can be made to move the donor to theatre. This facilitates the organ retrieval team undertaking this intervention without the fear of being penalised by the procurator fiscal for doing so or being accused of acting without authorisation and interfering with the body. They should first however confirm the patient’s authority to use his or her organs for donation, also confirming with the nearest relative that they have no knowledge of the patient withdrawing their consent to this or the nearest relative raising an objection to this procedure. The HT (S) Act 2006 also identifies that this power to undertake the preservation of organs ceases to apply once it has been established that either the deceased had not provided their authority to remove their body parts, or the relatives raise an objection to donation.

Wijne et al., (1995) however report problems in accessing relatives quickly enough to obtain agreement to remove the organs in optimal condition. They suggest forty-five minute window of time between certification of death and damage to the organs, in particular the kidney, during which the preservation of

the kidneys would be undertaken using this procedure. This would allow time to access relatives and explore if any objection to donation exists and the intervention halted if authority to proceed was not obtained. Wijne et al., (1995) therefore suggest that adopting this procedure provides an opportunity for the Emergency Department staff to address their professional obligations to respect the autonomy of the potential donor by establishing their authority to proceed, without damage to the organs.

A second controversy also exists in relation to the introduction of preservation drugs to the donor prior to them being declared dead. Bell (2003) reports a practice adopted in some settings with heart beating donor (HBD) where the patient is mechanically ventilated in intensive care with a deteriorating cerebral condition. In these situations if the patient demonstrates a negative response to the first set of brain death criteria and as the health care team await a similar result to the second set of tests normally performed to confirm brain death and final authorisation from the family, some centres have developed a protocol where certain drugs can be commenced to conserve the organs, increasing the chance of viable organs should donation subsequently take place. Bell (2003) raises the possibility that the drugs within these protocols designed to preserve the organs, such as anticoagulants and vasodilators administered to the patient prior to death being pronounced, either cause or hasten the death of the donor. This would be legally and ethically unacceptable.

Previously, the suggestion that these drugs introduced to the patient to preserve organs might hasten the death of the donor had been considered and was rejected by the IOM (1993) taking the view as they did, that the administration of these

drugs to the donor was necessary to preserve the organs. Bell (2003) however continues to suggest that there are legitimate concerns that these drugs such as anticoagulants, can aggravate bleeding in the donor, which can in turn impact on the donor's vascular stability. Moreover, other vasodilator drugs used such as phentolamine will by their action lower the donor blood pressure, potentially causing further instability in the already critically ill donor. The issue under debate is that in order to preserve the organs in optimal condition for the future recipient, the donor is in some way harmed. In response to these concerns, the ethics committee of the American College of Critical Care and the Society of Critical Care Medicine (2001) reject this interpretation of the harm done to the donor in instigating these necessary preservation protocols thus:

“ Medications that do not harm the patient and are required to improve the chances of successful donation, are acceptable”

Bell (2003) however views that it is at best a conflict of interests between the care of the donor and the attempt to achieve the best outcome for the potential recipient and at worst an example of active euthanasia. He also questions the suggestion by Ozarks and De Vita (2001) that using this necessary approach to preserve organs, even if this action does cause harm which was not intended, is complying with the donor's wishes and that of their family to donate organs and therefore acceptable under the principle of “double effect”. However, the suggestion that in the desire to help another, i.e. the future recipient, it is ethically acceptable to introduce some drugs to the donor that could potentially cause further deterioration in their condition requires debate. Additionally, as it has been demonstrated that in general the public have a limited understanding of the concepts and practices related to organ donation. Given this it is highly contentious to suggest that this action complies with the donor's wishes. To have expressed a wish in favour of

this action there requires to have been some understanding of the potential for this procedure to be undertaken by the individual agreeing to organ donation. Since evidence suggests the public do not hold this level of understanding of organ donation procedures, to make the assumption that they would wish this is questionable. The public confidence in the organ donation system is built on an understanding of the procedures associated with donation and trust in the HCP that their primary responsibilities will always be to the patient in their care. If it were to be suggested that prior to the patient being certified as dead, the HCP had the interests of another in mind, i.e. the potential donor, this may have a major impact on the numbers of the public who give their authority for donation.

2.2.3. Authorisation to Remove Tissues

Under Part 1 s 3 of the HT (S) Act 2006 the removal of an organ is authorised if there has been a specific request to this effect by the deceased prior to their death for purposes specified. The individual wishing to undertake this course of action usually does so by giving consent in writing prior to their death. This would indicate freely given consent to the use of any organs or tissue including the use of specific organs or tissues. This is commonly known as the “opting in” system where the individual makes known his or her willingness to be a donor. In particular the legislation defines the appropriate authorisation for the use of part of body of deceased person clarifying that:

“Part of the body of a deceased person may be removed from the body and used, for the purposes of- (a) transplantation; (b) research; (c) education or training; (d) audit, only if the requirements of subsection (2) are satisfied as respects the part. 2) The requirements are that- (a) the removal and use for the purpose in question are authorised in accordance with section 6, 7, 8, 9 or, as the case may be, 10; and (b) the removal is carried out in accordance with section 11”.

In this instance sections 7,8,9 & 10 of the legislation relate to the position of authorisation of the removal of body parts in the case of a person who is not an

adult or minor older or younger than 12 years of age, this will be explored further later in this section.

2.2.4 Appropriate Indication of Wish to Become a Donor

Further to this, part 1 s 6 of the HT (S) Act 2006 relating to authorisation by an adult for removal of body parts for the purposes identified in section 3 states that:

*” 1) An adult may authorise the removal and use of a part of the adult's body after the adult's death for one or more of the purposes referred to in section 3(1).
2) Authorisation by virtue of subsection (1) (a) must be (i) in writing; or (ii) expressed verbally; b) subject to subsections (3) and (4), may be withdrawn in writing.
(3) If the adult is blind or unable to write, withdrawal of authorisation by virtue of subsection (2)(b) may be signed by another adult (a "signatory") on the adult's behalf and if it is so signed it must be witnessed by one witness.”*

This section of the legislation clearly indicates that removal of organs can only be authorised by an individual by means of expressed consent. Interestingly, the HT (S) Act 2006 utilises the term authorisation to the removal of organs for the purposes stated rather than the term gives expressed consent to this action. Currently within Scotland, and indeed elsewhere in the U.K. should an individual wish to donate his or her organs, this is demonstrated by adopting one of two methods. First, freely given expressed consent to the donation of organs by an individual can be demonstrated by the carrying of a signed donor card (Ward, 1993). Under the terms of the HT (S) Act 2006 in the event of an individual's sudden death this recognised documentation authorises the medical practitioner or a person authorised to do so in accordance with the regulations made by the Scottish Ministers, to proceed with the removal of the indicated organs as soon after death as possible. The second method, introduced in 1995, allows the individual to express their consent to the removal of organs after death by giving expressed consent to this action by registering him or herself as an organ donor by placing their name on the NHS Organ Donor Register. Currently 13.1 million

people in the U.K. have indicated their consent to be an organ donor in their event of their death by placing their name on this register (UKT, 2006).

The HT (S) Act 2006 also clarifies that at any time before this death the adult can withdraw his authorisation for his / her body parts to be used in this manner thus:

“ Withdrawal of authorisation which is signed by a signatory on behalf of an adult by virtue of subsection (3) must contain a statement signed by both the signatory and the witness in the presence of the adult and of each other that the adult, in the presence of them both, expressed the intention to withdraw the authorisation and requested the signatory to sign the withdrawal on behalf of the adult.” (5) Nothing in subsection (3) prevents an adult who is blind from withdrawing, in accordance with subsection (2)(b), any authorisation by virtue of subsection (1). 6) In subsection (2)(a)(i), "writing" includes, in relation to the requirement there for authorisation to be in writing, representation of a character in visible form”.

Applying the terms of the HT (S) Act 2006 the withdrawal must be made be in writing.

2.2.5 Valid Request

The authorisation to donate organs must have been given by a competent person, who has the capacity to make this decision. The required level of this comprehension has been described by Kennedy and Grubb (2000) as being similar to that which one would require to make a valid will as held in Banks v

Goodfellow (1870) by Cockburn C.J:

“ He ought to be capable of making his will with an understanding of the nature of the business in which he is engaged, a recollection of the property he means to be disposed of, of the persons who are the objects of his bounty, and the manner in which it is to be distributed between them. It is not necessary that he should view his will with the eye of a lawyer, and comprehend its provisions in their legal form. It is sufficient if he has such a mind and memory as will enable him to understand the elements of which it is composed, and the disposition of his property in its simple form”

Additionally, in part 1 (s) 3 the HT (S) Act 2006 reflecting the tenets of The Children (Scotland) Act 1995 recognises the right of a child over the age of 12 years of age to authorise the removal of their organs:

“A child who is 12 years of age or over may authorise the removal and use of a part of the child's body after the child's death for one or more of the purposes referred to in section 3(1). 2) Subject to subsections (3) to (5), authorisation by virtue of subsection (1)- (a) must be in writing; (b) may be withdrawn in writing.”

Further to this, Part 1 of the HT (S) Act 2006 s 9 & 10 provide a facility for the parent or person with parental responsibilities for a child to authorise the removal of organs from a child over the age of 12 if there is no authorisation from the child themselves, or if the child is under the age of 12 years.

Additionally Part 1 s 18 of the legislation mirrors the authority given within the Adults with Incapacity (Scotland) 2000 Act facilitating another adult to give authority for the removal of organs from an adult with incapacity thus:

“This section applies to an adult- (a) who, in the opinion of the Scottish Ministers, is an adult who is incapable in relation to a decision about the removal from the adult of regenerative tissue for transplantation; and (b) in respect of whom a certificate has been issued by the Ministers in accordance with subsection (2) that they are of this opinion.”

This section therefore facilitates the donation of organs by an appropriate individual acting on behalf of the person with incapacity, so long as there is a valid certificate of incapacity in force, with this individual having legal authority to authorise the donation of organ or tissue from the person with incapacity.

2.2.6 Authorisation to Proceed

In the absence of individual authorisation by the deceased prior to their death, Part 1 s 7 (3) of the HT (S) Act 2006 also allows for the nearest relative of the adult to authorise the removal of the body part for transplantation; research; education or training and audit, if:

“a) there is in force immediately before an adult's death authorisation by the adult by virtue of section 6(1) of removal and use of a particular part of the adult's body for transplantation; b) the authorisation does not expressly include removal and use of another particular part, the nearest relative of the deceased adult may, subject to subsection (4), authorise the removal and use of the other particular part which is not so included for one or more of the purposes referred to in paragraphs (b) to (d) of section 3(1).”

Subsequently, in relation to this authorisation the nearest relative Part 4 s 50 clarifies who should be recognised as the nearest relative, identifying a hierarchy of importance for this role within the family thus:

“For the purposes of sections 7 and 30, the nearest relative is the person who immediately before the adult's death was-

” (a) the adult's spouse or civil partner; (b) living with the adult as husband or wife or in a relationship which had the characteristics of the relationship between civil partners and had been so living for a period of not less than 6 months (or if the adult was in hospital immediately before death had been so living for such period when the adult was admitted to hospital); (c) the adult's child; (d) the adult's parent; (e) the adult's brother or sister; (f) the adult's grandparent; (g) the adult's grandchild; (h) the adult's uncle or aunt; (i) the adult's cousin; (j) the adult's niece or nephew; (k) a friend of longstanding of the adult.”

Whilst the family have no power to disregard the freely given authorisation of the deceased to organ donation given in writing or verbally and therefore veto the decision to donate made by the deceased, Mason and Laurie (2006) suggest that it is unlikely that any doctor would proceed with organ procurement, should the relatives object to this action. Kennedy et al., (1998) however challenges the need to approach the family suggesting that if written consent in the form of a signed donor card is available, then there is no requirement to seek the relative's agreement to proceed with organ procurement. Mason and Laurie (2006) agree with this view but see this as an example of the difference between the legislation and clinical practice.

Despite this direction within the legislation, problems do exist in relation to obtaining the appropriate authorisation from the deceased or nearest relative within the emergency setting. Many individuals die every year as a result of a traumatic or sudden event, many of whom were willing to donate their organs after death. The problem arises when large numbers of these individuals do not carry their signed donor card or have not discussed their wishes with their

relatives prior to their untimely death. In addition, often the deceased's relatives are not present or cannot be located in sufficient time to authorise the donation to proceed.

Even when relatives are present difficulties continue to arise. Gore et al., (1991) suggests that in the sudden death situation up to 30% of families who were asked to donate the organs of their dead relative refused, often because they did not know their family member's wishes, or were too distressed at the time of the sudden death to consider this aspect. Stein (1995) supports this view agreeing that there are difficulties for HCPs of approaching grieving relatives in this situation to request cadaver organ donation. As a result of these issues many organs that could be procured in these circumstances are lost because relatives are either not asked to give consent or refuse, worried that this is not what their deceased relative wished. Lack of knowledge of the deceased's wishes combined with absence of agreement from relatives often prohibits the donation of organs for transplant in the event of a sudden death. Clearly, there are problems with the present methods available to record the wishes of individuals in relation to organ donation, which allow opportunities for organ donation to be missed.

2.2.7 Preparation of Setting to Support the Family and Undertake Request

The act of attempting to obtain authorisation from relatives in the event of a sudden death that usually occurs within an Intensive Care Unit or Emergency Department environment also presents challenges. Wright (1991) and Davies (1997) citing the work of Corless, Germina and Pitman (1994) highlight how the grief and mourning after a sudden traumatic death in the emergency situation is a very complicated affair. Miles and Deni (1986) discuss the feelings of fear,

hopelessness, despair and overwhelming sense of chaos that the grieving relative's experience when informed of their family member's death in the emergency situation. In contrast however to these arguments put forward by emergency staff for the refusal to utilise the non-heart beating donor option in the emergency setting, recent reports suggest that utilising this option may not be so potentially harmful and distressing for the bereaved as first thought. Research undertaken by Finlay and Dallimore (1991) related to relatives reactions to the sudden death of a child and personal accounts from Carsdale and Carsdale (1999), suggest that the action of donating an organ for transplant may be beneficial in the long term to the response to a sudden bereavement. Riley and Coolican (1999) acknowledge these responses to the sudden death of a family member and discuss four stages of intervention required to support relatives. Further to this a process of careful relative support, the separation of the communication of the death from the requesting of organs for donation i.e. the de-coupling of these two tasks is recommended by Niles and Mattice, (1996) if successful consent for donation is to be obtained. Clearly, there is evidence to suggest that with the correct preparation of the environment and using the correct approach to relatives, organ donation is possible even in the uncontrolled environment such as the sudden death of a patient in the emergency setting. There are however a number of difficulties with this suggestion.

Lack of time to access and inform the bereaved relatives of the death and care for them appropriately prior to the request for organ donation is a major issue of concern to the staff within emergency settings. Schroeter and Taylor, (1998) and Ehrle et al., (1999) support this view reporting that lack of specialist training in this area and pressure to care for the surviving patients within the emergency

setting, may mean that HCPs elect not to request organ donation from relatives at all. Erin and Bryant (1992); Cooke et al., (1992) and a joint report by and the British Association of A&E Surgeons and the RCN A&E Association in assessing the facilities and support of grieving relatives in Emergency Department (1995), identified shortcomings in the standard of care provided for these relatives in the emergency situation, highlighting that lack of time to support the family was a major issue. They also demonstrated the poor facilities for relatives in the sudden death situation and the lack of preparation of the HCP to care for these families as a major omission, recommending the introduction of standards of care for the bereaved and additional training for professionals in this setting for this role. Sells (1998); Taylor and Salaman, (1988); Riad and Banks (1990) agree with this view highlighting that the insufficient specialist knowledge and training in bereavement care and in the request for agreement to organ donation, may also hinder efforts to obtain authorisation for donation. They suggest that specialist knowledge and training is required for the HCP to be successful in obtaining consent from the relatives within this distressing time.

It would appear that the provision of legislation facilitating organ donation from intensive care units and emergency departments is one aspect that could assist in the donation of organs. However, it is clear that the provision of appropriate facilities to care and support the family including the appropriate preparation of the HCP to undertake this role, are equally important aspects that must be considered if organ donation is to be achieved.

2.2.8 Education and Preparation of HCP for Role in Organ Donation

Within the U.S. Verble & Worth (1997, 1998 1999, 2000) describe specialist education programmes designed to prepare staff in the emergency setting to undertake challenging role of supporting relatives and making the request for organ donation. Similarly, Singer and Rachmani (1997) and Randhawa (1998) report the existence of specialist education programmes for staff directly involved with organ donation within Israel and the U.K. This education programme is based on a model of training devised by the European Donor Hospital Education Programme (EDHEP) available throughout Europe. Sadly, due to the lack of available education opportunities, access to similar programmes is severely limited within the U.K. and, when available, is reserved for HCPs employed with transplant co-ordinator roles.

In order for families to be adequately supported through the organ donation event and successful requests for donations made in the emergency situation, Sells (1996) recommends access to a Transplant Co-ordinator. These specially trained members of the transplant team, often having undertaken the EDHEP are ideally prepared to address the needs of the suddenly bereaved and provide the information and support required to obtain their consent to organ donation. Unfortunately, these professionals are in short supply and are usually only available within hospitals that have a transplant centre located within their facility. These transplant co-ordinators are often employed on a regional basis and as such have a wide clinical area within which to function. In reality, although often available to support the identification of a donor from within the ITU setting, the likelihood of these professionals being available in every potential organ donation event within the emergency department is very doubtful.

It would appear that the adoption of organ donation in the emergency setting has considerable resource and educational implications for the NHS should there be a decision to develop the organ donation programme to include these clinical settings. Robertson (1998) supports the view that changes in legislation in organ donation require to be supported with an education strategy to support professionals to implement the law. In the U.K at least, the responsibility for the organisation or financing of such an option to support the change in the legislation has yet to be established.

2.2.9 Consent to Proceed from Coroner or Procurator Fiscal

In the event of a sudden death there is a requirement under the Fatal Accidents and Sudden Deaths Inquiry (Scotland) Act 1976 and Coroners Act 1988 (England & Wales) for the medical practitioner pronouncing the person as dead, to notify the local Procurator Fiscal or Coroner's office of the circumstances surrounding the death. He or she will then decide if any enquiry into the circumstances of the death and indeed if a post mortem examination of the body is required. Concerns exist amongst HCPs in the Emergency Department that progressing to organ donation without the permission of the appropriate authorities may present legal and professional challenges to this practice. In the event of a suspicious death however, consent of the procurator fiscal to remove parts of the body for examination is facilitated by Part 1 s 5 of the Act thus:

“1) Where a person knows, or has reason to believe, that an examination of the body of a deceased person is, or may be, required for the purposes of the functions of the procurator fiscal, the person may not, except with the consent of the procurator fiscal, remove from the body any part of it, or authorise such removal, for a purpose referred to in section 3(1).

“2) For the purposes of subsection (1), consent by the procurator fiscal may be given verbally and if so given is to be confirmed in writing as soon as is reasonably practicable.”

Shafer et al., (1999) acknowledged that medical examiners and coroners have a role to play in forming public policy on organ donation and promoting and facilitating organ donation in circumstances where the cause of death could be easily identified and not result in a full coroner's enquiry. Further to this, Mason and Laurie (2006) highlight that the Procurator Fiscal has the power to veto any authorisation to remove organs if he or she deems this necessary. In practice however permission to proceed to organ donation is usually granted by the coroner or procurator fiscal, provided that the organ which has been requested for donation, is not linked to the cause of the deceased's death and would not be relevant to the coroner's enquiry. The consent to proceed with donation given in this manner from the procurator fiscal may reassure the HCP and facilitate consideration of organ donation without fear of being penalised for undertaking this procedure, potentially facilitating an increase in organ donation in sudden death events if the authority to do so can be confirmed.

2.2.10 Use of Body Parts for Teaching, Audit and Research Purposes

The HT (S) Act 2006 also amends the Anatomy Act 1984 providing new regulations relating to the anatomical examination of body parts and their retention and use for teaching and research purposes. Under Part 2 (s) 28 removal during examination and retention of organs and other parts of a body, the legislation clarifies the procedure for the removal and retention of organs at post-mortem examination thus:

” (1) Subject to section 26 and subsection (2), any part of the body of a deceased person mentioned in subsection (5) may, by virtue of the authorisation for the post-mortem examination of the body, be-
(a) removed from the body during the post-mortem examination for the purposes of the examination;
retained and used thereafter for any of those purposes (2) An organ may be- *(a) removed, for the purposes of audit, education, training or research, from the body of a deceased person during a post-mortem examination of the body only if the removal for the purpose in question; b) retained and used thereafter for any of those purposes only*

if the retention for the purpose in question, is authorised in accordance with section 29, 30, 31, 32 or, as the case may be, 33.”

“(3) Any part of the body of a deceased person (other than an organ) which is removed from the body during the post-mortem examination by virtue of the authorisation referred to in subsection (1) forms part of the medical records of the deceased person. (4) Where an organ is removed from the body of a deceased person during the post-mortem examination of the body (whether by virtue of the authorisation referred to in subsection (1) or (2)), samples- may, by virtue of the authorisation, be taken from the organ; and (b) if taken, form part of the medical records of the deceased person. 5) The parts of the body referred to in subsection ((1) are- (a) an organ; (b) tissue sample; (c) blood, or any material derived from blood; (d) other body fluid. (6) A part of the body of a deceased person which is not mentioned in subsection (5) may not be removed from the body during a post-mortem examination of the body”

In the wake of the Bristol Royal Infirmary Inquiry (2000) the Redfern Inquiry (HOC, 2001) and Independent Review Group on Retention of Organs at Post-Mortem (SEHD, 2002) into the events related to the retention of children’s organs at Alder Hey Hospital and in Scotland, controversy arose in relation to the retention of organs for sampling after post mortem. Subsequently, advice from the Chief Medical Officer designed to address this controversy relating to the removal and retention of human organs and tissues (DOH, 2002), perhaps influenced the drafting of Part 2 and Part 3 of the HT (S) Act 2006 which describes the procedures that must be adopted for the sampling of tissue and organs at post mortem examination and their retention for further examination or as part of the patient records. Mason and Laurie (2006) however take the view that the inclusion of this section within the legislation is inappropriate, seeing this as a response to the widely publicised unauthorised retention of tissues at post mortem. This they suggest does little to regulate the therapeutic use of cadaver organs, with its inclusion allowing the need to establish “appropriate consent” to dominate the practice of using these tissues and in doing so altering the focus of the new legislation in organ donation. Similarly, Brazier et al., (2004) criticises the inclusion of the need for formal consent to retain tissue specimens contained in the Human Tissue Act 2004. They see this need for formal consent as having a

potential devastating impact on healthcare research in the future, as formal consent will be required to use any tissue specimens for research. Combining the two aspects of organ donation and organ or tissue retention within the same act is confusing for the public to understand at best. On a more worrying note, given the outcry of the public to the organ retention issue and the mistrust of the healthcare system that resulted from this, the family's suspicion of the HCP motives for requesting organ or tissue retention has the potential to impact negatively on the family's decision to agree to organ donation.

Summary

The donation of organs for transplant is legally permitted both in common law and statutory law. Cadaver organ donation is currently the chief source of organs for transplantation within the U.K. Under the terms of the HT (S) Act 2006, an individual prior to their death can validly consent to the removal of their organs after death for transplantation, education and research purposes. There are conditions that require to be met however, such as the establishment of the patient's death utilising accepted criteria, ascertaining that the deceased has authorised the removal of the organs or that their nearest relative has authorised this procedure. Concerns exist as to how this authority to proceed can be established. In the absence of a donor card providing authority to proceed to donation, this authority can also be established via identification of the deceased's name on the national organ donation register. There are difficulties however. In order to utilise the present legislation to its full potential a large number of the population is required to register to be organ donors, there is a clear requirement to improve the numbers of people willing to do so. This task is not as simple as it may seem. Public confidence in the scientific professions appears to be at a record

low (HOL, 2000, SEHD, 2002). Fears of the power that the medical and scientific professions hold over the individual may impact on the number of people who volunteer as organ donors.

Should there be an absence of the recorded authorisation to proceed via these methods, authority to proceed can be gained from a request to proceed to organ donation being made to the nearest relative, establishing that no known objection to this procedure exists. In an anticipated death, for example, one that occurs in the hospital intensive care setting, although this may be a distressing obligation to fulfil, this may be established with comparative ease. In a sudden death situation however, relatives may not be present, therefore establishing the deceased's or their objection may be difficult. Presented with these practical difficulties in ascertaining the deceased wishes, HCPs often do not consider this option and the opportunity for organ donation is missed. Once these conditions have been addressed the current legislation provides considerable flexibility to procure organs for transplant.

The majority of HCPs employed within the setting where organ donation is an option are in favour of organ donation. Provided with the correct environment and the appropriate circumstances most will attempt to procure organs for donation. Nonetheless, many opportunities to acquire organs are lost every year from cadaver donors either because the staff involved are unaware of the current powers afforded by the legislation to procure organs, or are reluctant to utilise this option as a result of practical difficulties related to lack of time to procure organs for donation.

Difficulties also remain in requesting authority from the immediate family to proceed to organ donation, even in the presence of recognised authorisation from the deceased. This role is both difficult and stressful for the staff and the relatives within the organ procurement situation and requires specialist education and communication skills to be undertaken effectively. Practical measures are required to improve the likelihood of staff making this request of relatives if no prior consent of the deceased can be established. Improved access to information regarding the deceased's wishes prior to death may reduce these perceived difficulties and may make staff more willing to explore this option.

Despite the apparent flexibility to procure organs for transplant afforded by the HT (S) Act 2006 and the HT Act 2004, within the U.K., there are 6,698 people currently in need of urgent organ transplantation (UKT, 2006). In an effort to resolve this crisis and improve the likelihood that these individuals, who are usually in a critical state of health, will receive an organ donation, commentators and professionals have suggested changes to the current organ transplant legislation to include presumed consent legislation. This form of legislation used in many European countries has been suggested by some, to increase the numbers of available organs for transplantation procured from cadaver retrieval. The next chapter will review the literature in relation to presumed consent legislation and analyse the benefits that may accrue from such legislation.

Chapter 3 Application of Presumed Consent Legislation In Europe

3.0 Introduction

Critics of the current approach to organ donation within the U.K. have called for the adoption of presumed consent legislation. Before adopting this concept wholesale and amending the current legislation within the U.K., it is important to review the relevant literature. This chapter will present literature related to the application of presumed consent legislation in organ donation within the European countries who have adopted this and critically review the evidence presented regarding implementation and success of this approach to organ donation, under the following headings:

- **Background to the Calls for Presumed Consent Legislation**
- **Adoption of Presumed Consent Legislation in Europe**
- **Strict interpretation of Presumed Consent Legislation**
- **Flexible Application of Presumed Consent using Register of Objection**
- **Use of Register of Objections and Limited Family involvement in Application of Presumed Consent Legislation**
- **Impact of Religious Beliefs on Organ Donation Rates**
- **Impact of Spiritual and Family Beliefs on Organ Donation**
- **Impact of Health Care Professionals Belief's on Organ Donation**
- **Alternative Rationale for High Levels of Organ Donation**
- **U.K. Views on Presumed Consent Legislation**

3.1 Background to the Calls for Presumed Consent Legislation

Many lives are lost each year in the U.K. which could have been saved had an organ been available for transplantation. Kennedy et al., (1998) discuss that under the WHO (1994) guiding principles, organs may be removed from a body of a dead person if:

- a) any consents required by law are obtained
- b) in the absence of any formal consent given during life, there is no reason to believe that the dead person would have objected to such removal.

In most countries providing that evidence of consent can be established, organs are removed from cadaver donors as soon as possible after death has been pronounced. Unfortunately many people do not register their wish to be an organ donor or inform their nearest relative of their intention to do so. As a result many viable organs are lost every year (New et al., 1995). In an effort to meet this ever increasing demand for organs some European countries namely Austria, Belgium, Spain, Portugal, Norway, Italy and France have changed their organ donation legislation to an “opt out” or “Presumed Consent” legislation (Price, 2000).

3.2 Adoption of Presumed Consent Legislation in Europe

Under this system normally referred to as “contracting out” it is presumed that everyone is in favour of organ donation and would wish to donate their organs in the event of their untimely death. Sommerville (1985) describes this system as one that:

“Allows organs to be taken after death, unless there has been an objection to this before death or in some systems, an objection by a relative of the deceased after death of the proposed donor” (Page 58)

Sommerville (1985) summarises the differences between this and the opt in system used within the U.K. as being the initial presumption of “no organ donation cannot proceed.....unless” i.e. no, organs may not be taken unless certain conditions are fulfilled. Alternatively, in a “contracting out” system used across most of mainland Europe, the initial presumption is that of “yes organ donation can proceed.....but” i.e. yes organs can be taken, but there are exceptions. These exceptions include the situation when the individual does not wish to donate their organs for personal or religious reasons, then they must register this objection or refusal of consent on a centrally held register. In depth analysis of the differing legislation applied across Europe (provided later in Chapter 6 of this work) demonstrates differing interpretations of this concept, often reflecting the religious, political and cultural views of that country. Overall these can be categories under the following groups:

3.2.1 Strict Interpretation of Presumed Consent Legislation

The strictest form of the law or “hard opt out” operates in Austria where organs can be removed provided that:

“In his or her life, the person concerned has not expressed an objection. The views of close relatives are not taken into account”

Conference of European Health Ministers, (1987)

In Austria, provided that the deceased has not registered an objection to organ donation via recording their objection on a centralised register organs are offered for transplant as soon after death as possible even if the relatives have not yet been made aware of the death. Relatives are not requested to donate the organs and their views are not taken into consideration. New et al., (1994) identified that Austria with 51.2 kidney transplants per million population (pmp), is one of the highest donation rates in Europe which Wamser et al., (1994) attribute to the

centralised model of donation adopted in Austria following the implementation of the legislation. Price (2000) reports however that in the early nineties there was a considerable drop in the donation rates with Wamser et al., (1994) identifying that although assisting to increase the numbers of organ for donation initially, that the change in the legislation alone was not the solution to the organ donation shortage. Glass (2003) supports this view suggesting that a historical liberal cultural attitude to organ donation within Austria had much to do with the success rates.

3.2.2 Flexible Application of Presumed Consent using Register of Objection

3.2.2.1 Adoption in Belgium

In Belgium, Michielsen (1992) suggests that a slightly more flexible version or “soft opt out” form of this legislation is available, where two aspects of consent to organ donation require to be recorded on a central register, that in turn produces three options in relation to organ donation. Firstly, the individual who is a Belgian national or who has lived in Belgium for more than 6 months can record their desire to become an organ donor via registration at a public building, for example the town hall. If the individual does this, then at a later date once brain death has also been confirmed, the person will be considered as an organ donor and in this event the relatives are not in a position to object to donation. Secondly, an individual can record their objection to organ donation and in the event of their death this objection will be accessed by the transplant co-ordinators and they will be excluded from donation. Price (2000) reported that only 1.8 per cent of the Belgian population have recorded an objection in this manner. The third option in the Belgian legislation allows that if there is no objection recorded from the deceased on a centralised national registry, and this is confirmed by the transplant

co-ordinators the relative's views on donation are sought by the transplant co-ordinator and they are allowed to object to the organs being removed. However, the medical practitioners involved in this decision are under no legal obligation to seek the views of the relatives. The relatives must initiate the process of refusing consent to the organ removal.

Kittur et al., (1991) suggest that in the years since the "opt out" legislation was enacted Belgium has seen a 119% increase in organ donation. Michielsen (1992) in reviewing the overall numbers of successful kidney retrieval in three different centres in Belgium, also suggests that following the enactment of presumed consent legislation, the numbers of organs made available for transplant did increase significantly. Roels (1999) confirmed that Belgium was one of the first European countries to adopt this legislation in 1986 with the first register being established in 1987 with Roles and Meester (1996) previously reporting the increased numbers of donated organs within Belgium utilising this system. It is presumed that everyone is in agreement with the concept of organ donation. Failure to register an objection by all individuals over the age of consent, would be interpreted therefore as an agreement to this procedure. Roels (1987) suggests that this has been successful in increasing the numbers of organs for transplantation in the countries who have introduced this system.

3.2.2.2 Alternative Influences Contributing to Belgium Success

Some commentators question whether these changes in legislation have increased the availability of organs for transplant. New et al., (1994) acknowledge how in 1987 Belgium did see a significant increase of 37% more kidneys available for transplantation following the introduction of this legislation which can not be

attributed to any other trend within the country. Michielsen (1992) reported that in a Belgian population of 10.1 million, 20.2 donors pmp were provided between 1992-1994 compared to Austria, with a population of 7.6 million, produced 23.4 pmp during this same time period. This is considerably more than countries without presumed consent legislation, for example, the U.K. that in the same time period, with a population of 56 million, produced only 13.1 donors pmp (UKT, 2004).

New et al., (1994) further note that Belgium did enact presumed consent legislation in the middle of a period of growth in kidney transplantation across Europe as a whole, this perhaps suggests that factors other than the enactment of this legislation influenced the rise in kidney donations during this period. New et al., (1994) also suggest that an increased effort to publicise organ donation during the debate on presumed legislation in Austria could have contributed to the reported rise in organs for donation at that time. These alternative rationales for high levels of donation rates will be explored further in this section.

3.2.3 Use of Register of Objections and Limited Family involvement in Application of Presumed Consent Legislation

3.2.3.1 Adoption in Norway

Price (2000) highlights that even within the countries who have access to presumed consent legislation a variety of practices are adopted to apply the legislation and facilitate organ donation. In some, for example Norway, no formal centralised register of objectors has ever been established and the relatives wishes are always considered. Additionally, in Norway the legislation requires that the next of kin of the deceased is informed of the intention to remove organs for

donation and the law requires that the lack of an objection from the deceased must be established. Here the wishes of the next of kin are always sought as a means of clarifying what the wishes of the deceased were in relation to organ donation. The family are approached by the HCP or the transplant co-ordinator to explore if the deceased had verbally, or in writing, prior to his or her death expressed an objection to organ donation. Again any objection from the next of kin is also established and if this is the case then organ donation is not pursued.

3.2.3.2 Adoption in Portugal

In Portugal formal mechanisms are in place for the individual to register an objection to organ donation in life. Legislation was developed in 1995, where following considerable media and press coverage to inform the public of the change in legislation, a central register of objection to organ donation was established (Price, 2002). This legislation allows, that in the event of a sudden death of an adult or a child over the age of two years where no objection to organ donation has been recorded, suitable organs to be used for donation.

Mendes and Alves (1991) suggest however that the family have the right to express an opposition to donation, but they do not have the right to prevent this taking place if the individual has not recorded an objection in life. The practice in Portugal is that the next of kin are informed that the deceased's name does not appear on the register and that the intention is to proceed to organ donation.

Normally, even if the next of kin are not in favour of organ donation, the absence of an objection is viewed as consent from the deceased and organ donation proceeds. Alternatively, if the family raise very strong objections to organ

donation, say perhaps on the grounds of religion or due to extreme distress in parents after the death of a child, organ donation would not proceed.

3.2.3.3 Adoption in Italy, France and Spain

In Italy, France and Spain organs can be removed once it has been ascertained that the deceased has made no indication that he or she objected to donation and relatives do not object. In France and Italy a centralised system of recording an objection officially has been established. Drafting of the legislation however requires that the relatives be consulted to obtain information on the deceased's wishes. Nowenstein Piery (2004) reports that in France using their version of presumed consent legislation 20 donors pmp are produced per year. She suggests however that despite passing of presumed consent legislation in 1976 and a Parliamentary vote in favour of this in 1994, with the subsequent establishment of a central registry for objection, this legislation is not fully applied by the professionals involved. She reports that the professionals directly involved in organ donation hold pragmatic reasons, issues related to personal principles and professional ethical views that prevent application of this legislation in the manner of which it was first envisaged by the legislators. As a result of this presumed consent legislation is not always applied by the HCPs.

In Spain the use of presumed consent legislation produces one of the highest levels of organ donation at 34 pmp per year. Mantez and Miranda (1997) report that following the introduction of this legislation in 1979 donation rates steadily progressed throughout the 1980s. Subsequently, the Organizacion Nacional de Transplantes (ONT) (1989) developed the "Spanish Model" where by a centralised organ donor objection register allowed citizens to register their

objection to organ donation, together with a management structure to co-ordinate the donation and transplantation of organs. Mantez and Miranda (1997) however report that using this model, the family's views on organ donation are always sought and the next of kin can object to organ donation. They report that if the family object their views are respected and organ donation does not progress, reporting refusal rates from families as high as 27.6% in Spain.

3.2.3.4 Alternative Influences Contributing to Success in Spain

Miranda et al., (1997) report that Spain by applying a form of presumed consent involving the relatives participation, combined with the introduction of the "Spanish model" of organisation of their organ donation services, produced the leading numbers of organ donation at 30 donations pmp. Similarly, Portugal and Norway who also utilise a so called "model of presumed consent legislation" where the next of kin are involved in the decision making system also produced high levels of organ donors per million population, with Portugal producing 19.5 donors pmp and Norway 17.5 donors pmp. Abadie and Gray (2004) suggest that the introduction of this approach to organ donation produces a demonstrable increase in the number of organs for donation. Nowenstien Piery (2004) however suggests that whilst this is an important element, this is possibly not the leading ingredient in the increase in the numbers of donated organs across Europe, identifying other factors that influence the decision to donate organs. The following sections will explore these in detail.

3.3 Impact of Religious Beliefs on Organ Donation Rates

Religion involves an organised entity with established rules, practices, beliefs, values and boundaries about a Higher Power or God to which individuals should adhere (Thoreson, 1999). Chapman et al., (1997) affirm that most religious groups support organ donation seeing it as being acceptable and desirable, save some particular religious faiths e.g. Shinto. Gillman (1999) reports that most decision-making surrounding organ donation includes at some point in the discussion, the religious beliefs of the donor and the donor family. He also highlights that the culturally influenced individual beliefs of the donor and the family, coupled with the emotional trauma of the death, have a significant impact on the family's response to the question of organ donation. Increasingly, the altruistic act of a healthy individual giving a non-essential organ to another whilst alive, e.g. a kidney or a part of a liver is contributing to the numbers of people who are receiving organs. The majority of organs for donation however are procured when an individual has agreed to offer his or her organs for donation following their death. As previously suggested, the donation of an organ is often viewed by most religious groups as a voluntary altruistic beneficent act, undertaken by the individual with the intention of improving the health of another. However, within these faiths there are a variety of issues and concerns expressed in relation to organ donation. **Figure 3.1** summarises the responses to organ donation from the major faiths in regard to organ donation. Overall, most cultures and religions view the donation of organs after death as an acceptable act on a moral and ethical basis that preserves the inherent and object dignity of every human being.

Figure 3.1: Individual Faiths Responses to Organ Donation

<i>Hind, Buddhist & Sikh Beliefs</i>	Central belief of reincarnation until liberation is experienced and the dominant theme within these faiths. Hindu mythology holds many stories where human parts were used to benefit humans and society. Nothing in the Hindu religion indicating that organ donation cannot be used to alleviate human suffering. (National Coalition on Donation, 1997). Buddhists have not taken an absolute view on organ donation, suggesting that supporting donation, particularly the Mayahana tradition of Buddhism, places a high value on compassion (Lecso, 1991). Sikh religion the altruistic tradition provides support for the idea of organ donation. Very little negative responses to the question of organ donation from this group (Daar, 1997).
<i>Shinto and Chinese Beliefs</i>	Either opposed to organ donation or at least extremely cautious with regard to organ donation. opposition stems from the Shinto rejection of the concept of Brain Death as the definition of death. This culture is also opposed to the commodification of bodies either in death or when alive (Hardacare, 1994). Until very recently organ transplantation was illegal in Japan, with concerns raised around the issues of possible reanimation of the person who was pronounced dead, with undue haste to pronounce death and move to organ donation Lock (2002). Chinese culture which stems from a Confucian perspective there are also barriers to organ donation with central concept that of Filial piety i.e. our body does not belong to the individual but is a gift or an inheritance from our parents and ancestors (Wei-ming, 1985). Not allowed to damage the body or place it at risk, hence the desire for traditional Chinese medicine to go to great lengths to avoid violation of the body when trying to find a cure for the individual's ills. As a result for many organ donation has been unthinkable, except in the case of criminals who are condemned to death and have been reportedly forced to donation, seen as the final insult to their body. Recently been initiatives in main land China to change this view and promote organ donation (Gillman, 1999)
<i>Christianity: Roman Catholic</i>	Roman Catholic denomination views all medical intervention affecting a human being is subject to limits in what it is technically possible and what the impact of the procedure will be on human nature itself. John Paul II (2000) highlighted the Catholic Church's opposition to any commercialisation of human organs as being a violation of the human person. The key principles that define the ethical issues related to organ donation are: i) The defence of the life of the donor and recipient: the principle of the respect life not acceptable to take one's own life to make organs available to another, nor is it acceptable to kill someone to obtain their organs even if this were to benefit others. It is essential therefore that in the case of a cadaveric donation, to ensure that donor is dead before organ donation can proceed. ii) The protection of personal identity of the recipient and his or her descendants: Problems arise ethically with the transplantation of organs connected to thinking and reproductive biological identity of the donor. Head and trunk transplants together with donation of gonads or organs connected with reproduction would threaten the biological identity of the recipient and his / her descendants and are deemed unacceptable. Transplantation of brain tissue or donation of gametes or eggs in fertility treatment are therefore deemed unacceptable to the Catholic Church. iii) Informed Consent: RC Church views transplantation as inseparable from the human act of donation and therefore the person who is donating an organ or tissue must do this freely. When organs are removed from a corpse, since the corpse in the eyes of the Catholic Church retains a sacred nature, the reference that it provides for those who survive, means that the will of the deceased and those of the surviving relatives must be respected. Relatives' agreement is of ethical importance in the absence of any evidence of a decision to donate by the deceased in life (Gambino, 2003)
<i>Christianity: Protestant</i>	Protestant denomination views the need to love one's neighbour and even sacrifice as some of the main tenets of this creed. Various Protestant authorities have spoken out on organ donation concerned with issues of human suffering and giving. Key concerns of : i) Gift giving: As such it sees as the individual duty of solidarity inherent in the gift of organs to alleviate suffering of people who's health is seriously impaired. As a Christian faith it encourages the voluntary altruistic gesture within organ donation, however they do not accept the property model in the transfer of an organ or tissue and uphold the respect for the freedom of both donor and recipient to choose this option or not. ii) Consent: Of the donor and respect for his or her human dignity: organ transplantation must comply with the spirit of gift giving with respect for the dignity person who had died and the grief of the family. This includes the need not to treat the donor as an object but treating the body with due respect. Acceptance of the gift should be demonstrated by gratitude on the part of the recipient for the gift. It is also important to respect for the wishes of the donor in what he / she wishes to be done to their body, together with the need to consider the grief and mourning of the deceased family and friends in consulting them as what they wish to be done with the remains. It is also important to respect those who do not wish to donate.
	iii) Brain death & the inviolability of the body: Protestant Churches accept to concept of brain death however some theologians have expressed concerns about the dichotomy of the soul (the brain) and the body. Some took the view that diagnosis of brain death and then procedure to organ donation was exploiting the donor who is deprived of ending his / her life as a whole. Publication of the joint German Protestant Church Bishop's Conference manifesto (1990) supported the criteria for brain death where in the agreed that the body remains inviolable, but within limits determined by the suffering of others, this rule maybe infringed. (Collange et al., 1994)
<i>Judaism</i>	Under Judaic law organ removal after death can not be allowed as it conflicts with three main rules of the religion: i) No benefit must be derived from a dead body ii) A dead body must not be mutilated iii) The body must be buried Within the main branches of Judaism, Orthodox, Conservative and Reform, only Orthodox still raise objection to organ donation with Conservative and Reform encouraging organ donation (Dorff, 1996; Mayer, 1997). Guigui (2003) organ removal can be permitted when it is a matter of saving others, where the deceased consented to donation in life, where it is impossible to determine the cause of death and post mortem examination is required, subject to the facts being established by three medical experts or in the case of having to identify a hereditary disease that might impact on the health of close family members. Orthodox Judaism opposition to organ donation stems from the lack of consensus on the criteria for death. Jewish law until very recently had strict criteria for the definition of death using a cardio-respiratory definition of death and has recently recognised brain death criteria and a means of determining death National Donor Sabbath Guidelines Resource Kit, (1997) Live donation of a non vital organ, for example, a kidney provided that the removal does not endanger the life of the donor and their informed consent has been given.
<i>Islam</i>	The majority of Muslim scholars, both Sunni and Shia promote the value of saving human life and hence allows organ donation to proceed. (Daar, 1997; Sachedina, 1998; Mohsin, 1995; Al-mousawi et al., 1997). Hadj-Eddine-Sari-Ali (2003) reports that in Islam the creator manifests Himself in the human body. Recently Islamic countries did not permit the use of cadaveric donation because Islamic law prohibits the mutilation of the body after death believing in the resurrection of the body after death. There are also detailed cultural norms that must be observed in the care and burial of the body after death (Sachedina, 1998). Muslim scholars have recognised exceptions to this general principle and in 1987 a unified Arab Draft law on Human Organ transplants was adopted by the Council Arab Ministers of Health (Daar, 1991) recognising the need to save lives via the provision of organs. Previously, all Muslim countries had presumed refusal of organ donation except in the expressed wish of the donor in life (Michielsen, 1997).

3.4 Impact of Spiritual and Family Beliefs on Organ Donation

Tanyi (2006) suggests that spirituality and religious beliefs are often used interchangeably but are in fact two very different concepts, describing spirituality as a personal search for meaning and purpose in life, which may or may not be related to religion. Additionally, Tanyi (2002) views spirituality as entailing a number of connections to self-chosen and or religious beliefs, values and practices that give meaning to life, thereby inspiring and motivating individuals to achieve their optimal being. These connections in turn result in perceptions of faith, hope, peace, joy, empowerment, and a heightened sense of physical and emotional wellbeing. Further to this, Sperry and Giblin (1996) view family spirituality as a search for meaning and purpose in life, meaningful relationships, individual family member spirituality, family values, beliefs and practices which may or not be religiously based. Tanyi (2006) agrees but adds that family spirituality can be much broader than individual spirituality, as it encompasses an individual's distinct spirituality and that of the family unit.

In reviewing the impact of religious and spiritual beliefs on donation, Verble and Worth (1997) demonstrated that people often do not donate organs because of a "mystical mode of thought" that is culturally ancient and now amenable to the rules of logical contradiction. An example of this may be a fear of mutilation or a blood phobia that may result in a refusal of relatives to consider the donation of their relatives organs. Verble and Worth (1997) highlight how cultural influences can impact upon an individual's decision to donate organs and that of their relatives to authorise the use of their relatives organs for donation. At a time of crisis Gillman (1999) suggests that spiritual questions are also evoked in the

family at the time of a sudden death, such as the search for personal meaning in the death and the perceived value of organ donation at such a tragic time. This may result in the family search for some inner resources to cope with the crisis, with the family responses transcending any view on organ donation expressed by religious groups, if these are known.

Chapman et al., (1997) agree suggesting that any family opposition to donation usually stems from emotional or spiritual issues. They suggest that religious or other spiritual rationale may hinder families from donating their relative's organs. When reviewing decision making by families in relation to organ donation Siminoff et al., (1995) identify that families often make conditions on the donation of specific organs for specific reasons, with Roels et al., (1997) demonstrating that in a study of three Belgium generations attitudes to organ donation, there was a higher reluctance to organ donation in the older age group related to their lack of knowledge about the concept of organ donation specifically related to brain death.

All of these studies suggest that in addition to religious influences, availability of accurate information and the attitude within society to organ donation can have a major impact on the individual or the relatives' willingness to agree to donation. In response to these findings Chapman et al., (1997) suggest that the family requires the careful listening and compassionate support of the health care professional to explore and address these issues if organ donation is to take place. He suggests therefore that the multidisciplinary team should often include pastoral support as part of an approach to exploring the family's religious and cultural views on organ donation. He suggests that the addition of pastoral support

facilitates discussion and interpretation of issues related to religious beliefs and organ donation aiding successful donation.

3.5 Impact of Health Care Professionals Beliefs on Organ Donation

Studies of specific HCPs have suggested that particular groups expressed specific attitudes to organ donation and that whilst these views may well impact upon their willingness to donate organs themselves, they may also have a direct impact on their willingness to approach families to request donation (Kennedy and Farrand, 1996; Cantwell and Clifford, 2000). Verbal and Worth (1997) further highlight that the preferences or aversions of the HCPs who approach the relatives to request organs donation, could impact considerably on the possibility of a positive outcome. They also demonstrated that the content of the discussion with the relatives, for example, the adequacy of the information they were given, the manner in which the diagnosis of brain death of their relative was given and understanding of this concept by the relatives had the potential to directly impact on the levels of objection to donation from the family. This research also demonstrated that the lack of appropriate environment in which to make the request, the lack of knowledge about the benefits of organ donation, together with the lack time given to decide and the insensitivity of the HCP to the family anxieties, all contributed to a negative response to donation.

3.6 Alternative Rationale for High Levels of Organ Donation

3.6.1 Reduced Mortality Rates from Road Traffic Accidents and other

Cerebral Injury

The number of potential organ donations is often linked to the mortality rate in a country from road traffic accidents (RTAs) (New et al., 1994). These incidents, often involving young healthy individuals, provide a supply of suitable organs for donation. Legislation that tightly controls these situations inevitably impacts upon the supply of organs. Deaths from road traffic accidents fell in the U.K. markedly following the introduction of car seat belt and motorcycle helmet legislation. The U.K. road deaths per million population (pmp) in 1990 were 9.4 pmp in comparison to Spain and Belgium who registered 23.0 pmp and 20.2 pmp respectively (DOT, 1990). Whilst acknowledging the high level of RTAs in Belgium, Roels et al., (1996) suggest that less than half of the donors reported in Belgium in 1989 were victims of a road accident. Mortality rates related to deaths from intracranial disorders such as cerebrovascular accident or injury also influence availability of organs for transplantation. The OPCS population survey (1990) and the United Kingdom Transplant Support Services Authority UKTSSA (1999) annual report would suggest a strong relationship between the population mortality rates from these events and the retrieval of organs for transplant.

In the U.K. changes in the management of patients who suffer trauma or cerebral insult have significantly improved survival rates for these patients (United Kingdom Trauma Network, 1999). The combination of these factors may have a significant impact on the apparently poorer numbers of organs donated in the U.K. However, New et al., (1994) suggest that the reduced road traffic accident death rates within the U.K. is one of the most significant factors which result in the low

number of organ transplants undertaken. New et al., (1994) also suggest that population density and the advances in medical ability to resuscitate these normal “pools of potential donors” within a country has a direct effect on the supply of organs for donation.

3.6.2 Poor Levels of Preparation for Health Care Professionals for their Role in Organ Donation

Gore et al., (1991) suggest that it is a lack of medical experience in the diagnosis of brain stem death and requesting of organs for donation that results in loss of organs for transplant, a view supported by Kennedy and Grubb (2000). New et al., (1994) highlights how Spain has the largest number of transplant co-ordinators in Europe, postulating that the immediate availability and daily contact of these co-ordinators with the staff within these units may impact on the other HCPs awareness of, and success in, the procurement of organs for donation. In an effort to address this problem Sells (1998) suggests that there needs to be a radical review of the education of intensive care and other staff within the acute areas in the U.K. to improve their understanding and skills in requesting organ donation from relatives. Additionally, he suggests an increase in the numbers of organ transplant co-ordinators in the U.K. would have a positive impact on the numbers of organs donated. These specially trained professionals, usually former transplant or intensive care nurses, support the professionals within the intensive care or other acute areas to identify the potential organ donor and request the organ donation from the bereaved relatives. New et al., (1994) agree, identifying that the unique system of provision of transplant co-ordinators at both regional and local hospital level which exists in Spain, may be more influential in the high levels of organ donation rates than the presumed consent legislation alone. In Spain, the co-

ordinator is not solely employed as a transplant co-ordinator but in addition practises within their own speciality e.g. doctor or nurse within intensive care or renal units. Currently within the NHS similarly trained staff are few in number and are often only available within the locality of a large teaching hospital with an organ transplant unit. It is suggested by Sells (1998), that an increase in the numbers and availability of these professionals would result in an increase in the numbers of organs offered for donation as is reported to be the case in Spain.

3.6.3 Development of an Organ Donation Infrastructure

Gimbel et al., (2003) suggest that factors other than the introduction of the presumed consent legislation are the key factors to increasing the numbers of donors per population. They note that in all the countries that introduced the legislation and produced high numbers of organ donation, Austria, Belgium, Spain, Portugal and Norway have also developed a very detailed national infrastructure to support organ donation which involved the establishment of national networks of centralised transplant centres and a co-ordinated system of transplant HCPs to support these initiatives. This they view as one of the key factors in the success of the organ donation programmes in these countries.

Nowenstien Piery (2004) supports this view, suggesting that the health care professionals exert a major influence on organ donation rates within a country.

3.7 U.K. Views on Presumed Consent Legislation

In the U.K. in the light of increasing gaps between the supply and availability of organs for transplantation there have been calls for presumed consent legislation to be implemented to resolve the crisis in the numbers of people waiting for organ donation. The British Medical Association (2005) supported calls for a system of

presumed consent to be utilised within the U.K. Together with other supporters of this system, they have lobbied for amendments to the H T (S) Act 2006 to facilitate this approach to organ donation. They suggest that presumed consent legislation would provide an opportunity for people to officially register their objection to organ donation and perhaps reduce the amount of missed opportunities for organ donation that occurs every year. Kennedy et al., (1998); English and Sommerville (2003) suggest that this proposal allows for the appropriate recycling of organs, which in terms of medical and social utility is ethically acceptable, benefiting society as a whole by preventing the waste of organs and providing a better quality of life for the recipient (s).

Public opinion in Britain is divided however, as to the benefits of presumed consent as opposed to the problems it might produce. Research undertaken by the United Kingdom Transplant Co-ordinators Association (1992) suggests that 40% of transplant doctors are in favour of presumed consent legislation. In the early 1990s three major surveys were commissioned to explore public reaction to this proposed change in the legislation. The OPCS survey (1992) further suggested that 40% of those questioned were in favour of presumed consent legislation, 48% were against, with 12 % having no view. The RSGB study (1992) undertaken on behalf of the Department Of Health, demonstrated similar results finding that 46 % of those surveyed were in favour of the proposal with 43% against and 11% didn't know. In these surveys the subjects were asked whether or not they were for or against the new presumed consent proposal. Finally, a similar study undertaken by the British Kidney Patients Association (1992) reported that 60% of those surveyed were in favour of presumed consent with 30% against and 10% did not know. Further analysis of these studies produces some interesting

conclusions. New et al., (1994) suggest that the wording of the question in the BPKA survey which focused more on the use of the organs rather than the implications of the proposed presumed consent legislation may have influenced the outcome of the study. More recently a survey undertaken by the BBC reported that 61% of those surveyed were in favour of the introduction of presumed consent legislation (UKT, 2006).

Opinion on the need to change current legislation in order to improve organ donation rates is clearly divided. Organ donation relies heavily on public support and co-operation for its success. Critics of the presumed consent proposal (Fabre, 1998, Spital, 1998, Ellis, 1998) suggest that adoption of this proposal would be counter productive to the quest to improve organ donation. The analysis of the adoption of presumed consent legislation however, produces a number of key observations. Firstly, research undertaken to evaluate the success of this initiative by Kittur et al., (1991) and New et al., (1994) would suggest that the introduction of presumed consent legislation does appear to have produced an increase in the supply of organs for transplant. The exact source of this success remains unclear. Critical appraisal of these statistics reveals that there are other variables which may have influenced the success of this initiative in improving the supply of organs for transplant. For example, the adoption of this legislation in a variety of formats in countries across Europe makes evaluation of its success difficult to assess and perhaps masks the true extent to which presumed consent legislation can successfully improve the supply of organs for transplantation.

In countries that combine presumed consent legislation with a policy of confirming no objection of the deceased or the relatives by highly trained

personnel, the rates of successful donation are highest. This may have an effect on the outcome. The key to the success rate may lie in the skill of the request and not the legislation. The impact of high mortality rates which result as a consequence of head injuries or multiple trauma may have also had an influence on the high donation rates. Additionally, the provision of a programme of public education raising their awareness of the need for organ donation, prior to implementation of the legislation, may have also influenced the numbers of organs available for donation. Further research into these different variables is required to establish their impact on the overall clinical success rates attributed to presumed consent legislation before it can be said with certainty that the legislation is the key to improvements in the supply of organs.

Other claims made in support of this proposal (Harris, 2003) suggest how this initiative facilitates social and medical utility in that it allows recycling of organs, which not only benefits the individual recipient, but also reduces the demands placed on the health services. This may be viewed as an appropriate use of the resources. While it may be realistically predicted that this would be a desirable outcome of the presumed consent legislation, exact statistics to support the theory that presumed consent impacts on the overall efficiency of the health services is unavailable. Supporters of the proposal also suggest that the presumed consent legislation facilitates the achievement of the wishes of the deceased, in that it provides the individual an opportunity to register their intentions prior to their death. A review of the literature failed to produce any research relating to the views of the surviving relatives as to the suggestion that under presumed consent legislation, the last wishes of the deceased had been fulfilled.

Summary

Presumed consent legislation in organ donation is currently successfully applied in a number of European countries providing considerably higher numbers of organ for donation than the U.K. However, the exact source of the success of the increase of organs for donation in these European countries is difficult to establish. It would appear that there is limited evidence to support the suggested benefits and challenges of applying this approach to organ donation. More research into the merits of this legislation may provide better insight into its function and success in the supply of organs for transplant. Interestingly, Mason and Laurie (2006) suggest that the HT (S) Act 2006 does not rule out the possibility of the introduction of presumed consent approach in the U.K. or at least as they suggest the legislation “leaves the door ajar” for this option to be considered. Many observers in addition to challenging the clinical success of presumed consent legislation in organ donation raise other ethical objections to the proposal. The next chapter will review the ethical framework that underpins organ donation in the U.K. exploring whether the objections to presumed consent legislation can be supported.

Chapter 4 Ethical Principles Underpinning Organ Donation and Ethical Objections to Presumed Consent Legislation

4.0 Introduction

Many observers raise ethical objections to the introduction of presumed consent legislation. This chapter will review the ethical framework that underpins organ donation exploring the ethical objections to presumed consent legislation, analysing these and investigating if these objections can be supported under the following headings:

- **Respect for Autonomy and Consent to Organ Donation**
- **Right to Control What Happens to Our Bodies after Death and Harm to the Interests of the Dead**
- **Rescuing others and Preventing Future Harm**
- **Preventing Harm to the Vulnerable and Incapacitated**
- **Doing Good and Preventing Harm Caused to Relatives**

4.1 Respect for Autonomy and Consent to Organ Donation

Beauchamp and Childress (2001) suggest that respect for autonomous choices of persons is a principle within common morality. They describe autonomy as originally referring to self rule or self governance of independent states, which when used in relation to individuals refers to their self governance, liberty, rights, privacy, individual choice, freedom of will, causing one's own behaviour, and being one's own person. The autonomous person has therefore the capacity of self-governance such as understanding, reasoning, deliberating and independent choosing. Applying this principle in health care suggests that the professional has a fundamental obligation to ensure that patients have a right to choose, as well as

the right to accept or decline information (Beauchamp and Childress 2001). They suggest that respecting an autonomous agent requires the acknowledgement of the person's right to hold views, make choices and to take actions based on personal values and beliefs. Respecting these choices, personal values and beliefs involves attitudes and actions by the professional that do not interfere with the personal affairs of others and enable others' capacity for autonomous choices. English and Sommerville (2003) agree that the principle of self-determination is so highly regarded in health care with autonomy being the key legal and ethical concept, so much so, that competent adults are allowed to refuse care rather than have life prolonging treatments imposed against their wishes.

In acknowledging the fundamental paradigm of autonomy in healthcare as being expressed consent, normally demonstrated by written instructions as identified by Price (2002), Beauchamp and Childress (2001) suggest that another form of consent exists namely, tacit or implicit or implied consent, expressed silently or passively, by omission. As an example of this they cite the lack of objection by the residents of a care facility to changes in the time of dinner, as taken to constitute consent, assuming that the residents in question understood the proposed changes and their requirement to object if they did not agree with this change. Another type of consent Beauchamp and Childress (2001) suggest is implicit or implied consent, this being inferred from an individual's actions, an example being, consent to one medical procedure often being implicit in a specific consent to another procedure. They also suggest that in this situation, voluntarily seeking treatment within a teaching hospital may also imply consent to various roles for the physician or nurse to adopt on their behalf.

Applying this principle in organ donation, Price (2002) states that consensus view prevails that consent to donate organs in one form or another is the underlying principle that underpins all legislation and advice governing organ donation, suggesting that the World Health Organisation state the need for consent to organ donation within Principle 1 of their Guiding Principles (WHO, 1994).

Additionally the third Report of Council of Europe Conference of European Health Ministers (1987) reiterated the view previously expressed in Article 10 of the Council of Europe Resolution (1978), that consent was an important element of organ donation:

“Legislation and practice in all member states in fact acknowledge the right of a person to consent during his lifetime to donate an organ after death for transplant purposes”.....

Conference of European Health Ministers (1987) (Page 6)

The Conference of European Health Ministers also identified that this consent may take the different formats of expressed and presumed consent.

Beauchamp and Childress (2001) take the view that to uphold the principle of self-rule or determination we must respect the autonomous choices of the individual to consent to organ donation or withhold this. These obligations of the need to respect autonomy require to be extended to persons who have the capacity to act autonomously.

Debate however continues as to what constitutes appropriate consent to organ donation by the potential donor and the exact form of consent that is required to authorise the removal of organs from the body of the deceased after they are pronounced dead. From a legal perspective, for consent to any action to be valid a number of elements need to be demonstrated. As held in *Sidaway v Bethlem*

Royal Hospital Governors (1985) and *Canterbury v Spence* (1972) three elements must be present:

- i) the individual giving consent must have the capacity and competence to do so
- ii) the consent must be given freely and without coercion
- iii) the consent given must be based on the provision of adequate information on which to make a decision

To fulfil the first element of this requirement the individual consenting to organ donation must be of the appropriate age to do so and be a person who can act in a sufficiently autonomous manner (Beauchamp & Childress, 2001). Additionally, they should not be coerced or exploited in their decision-making. Erin and Harris (1999) agree with the fundamental right of the individual to make an autonomous choice to donate or withhold their consent to donate their organs enshrined in the “opt in” system, agreeing that we have a duty to respect the wishes of the individual. In their view the requirements for valid consent to organ donation under this system should take the form of the individual registering the intention to donate, either by carrying a card, or consciously placing their name on the donation register. Hill et al., (1999) suggest that adequate legislation in organ donation would require that all potential donors were appropriately knowledgeable about organ donation and informed of their ability to choose to become a donor. This view is supported by Tottoczko (2003), who states that ethically consent to organ donation should be informed, with the potential donor given the relevant information beforehand. An example of these groups of potential donors who must be made fully aware of all aspects of organ donation, would be car drivers as they are a common source of organs should they die as a

result of a road traffic accident. In relation to organ donation, Tottoczko (2003) goes further, suggesting that the absence of explicit consent may mean one of three different options, consent to donation, actual objection to this or indifference, rejecting the idea that consent to organ donation can be presumed as a result of a lack of objection to this procedure.

Veatch, (1991) and Harris (2003) also express the view that presumed consent in organ donation is as valid a consent as expressed consent, in that everyone would have the opportunity to express their autonomy by taking the opportunity to object. From their perspective, failure to object to donation is a form of signalling consent to donation. Harris (2003) further challenges the long held notion that expressed consent is necessary in the removal of organs from cadavers, suggesting that presumed consent is a more appropriate form of consent in this situation. Similarly, Emerson (2003) suggests that it is immoral to require consent for cadaver organ donation seeing the body as a loan from the biomass to the individual during their lifetime. When they die the body is no longer part of the person and returned to the biomass and therefore available for organ donation. On review of the appropriate consent in organ donation, the Conference of European Ministers (1987) endorsed presumed consent, permitting organ removal when there was no evidence of expressed consent and where there was no evidence that the deceased had objected to it or would not have been expected to have objected to this procedure. In this instance the lack of objection to organ donation was interpreted as a form of consent, however Price (2002) highlights that silence is not generally regarded as consent in most legal contexts.

In consideration of this issue Beauchamp and Childress (2001) take the view that is plausible to consider presumed consent as a form of tacit consent, assuming that certain preconditions of understanding and voluntariness are present. They accept presumed consent as a form of non-expressed or implied consent suggesting, that in the situation where there is an absence of expressed consent, consent is presumed on the basis of what we know about a particular person's choices or values. They caution however that consent should refer to the individual's active choices, not a presumption about the choices that the individual would or should make. Further to this, Beauchamp and Childress (2001) suggest that any presumption must be based on proof or well-founded assumptions that the person had been properly informed about the consequences about their decision. This would suggest, that in order for presumed consent to be valid, evidence of the deceased's prior knowledge of the law in relation to organ donation and the required actions in relation to this legislation would be required. If no evidence of tacit consent exists, in that there is no evidence that the deceased was aware of the law and the need to record their consent or objection, Beauchamp and Childless (2001) view the practice of presumed consent in removing organs perhaps expropriates organs without regard to consent at all.

Savulescu (2003) suggests that the need to ensure that the individual has understood the legislation on organ donation and made a specific choice to consent to donation, means that body parts can only be used with the expressed consent of the individual to their removal prior to death. Gillon (1995) and Wilks (1998) supported this view suggesting that consent provided by default where no evidence of agreement or objection by the deceased to organ donation exists as in

presumed consent, is no consent at all and that the adoption of any other form of consent other than expressed consent is ethically unsustainable.

The gift exchange theory first described by Mauss (1993) suggests that the act of giving is structured by a set of societal norms, these being an obligation to give, to receive and repay. The recipient is under an obligation to repay the gift by giving something of equal worth usually by acknowledging the gift and agreeing to care for it appropriately. He suggests that organ donation is governed by the same norms. Accepting these principles, some commentators take an even stronger view of the implications for society of presumed consent legislation. Kass (1985) suggests that presumed consent legislation is a form of coercion and infringes individual civil liberties. Supporting this view Lamb (1990), Ellis (1998) and Hill et al., (1999) repeat the warning that erosion of this right by default under presumed consent legislation may, in due course, have an impact on other rights to autonomous informed decision. This may create a “slippery slope” to people feeling that they are state owned commodities with little autonomy. These concerns in health care are reported by Kittur et al., (1991) who agree with these views suggesting that health care professionals may hold ethical objections to the introduction of this legislation as a result of these concerns.

4.2 Right to Control What Happens to Our Bodies after Death and Harm to the Interests of the Dead

4.2.1 Right to Control What Happens to Our Bodies after Death

Traditionally, although there has never been a legal obligation to donate organs, donation has been viewed as an act of giving (Fox and Swazey, 1974). Dorell

(1991) on behalf of the U.K. government, reiterated the view that there is no obligation to donate nor can there be a claim on the organs of an individual stating that:

“We must accept that nobody has a right to anybody else’s organs. If something untoward happens, our organs may be of value to someone else but that should be the result of an altruistic decision about how we want our bodies to be used when we die. It should not be as a result of a right of the recipient..... It is the responsibility of the living whose organs may be of use to someone else; it is not anyone else’s job to claim the organs”

Lamb (1990) and Kass (1985) claim the right of the individual to determine what happens to their bodies after death. They are of the view that to remove organs without expressed consent or consultation with the relatives would be to disregard the wishes of that person and to regard the disposal of their remains as unimportant. This they see as treating with contempt the individual right to determine how he or she wished their remains to be disposed of. Gillon (1995) and Wilks (1998) also suggest that an individual might lose the right to determine what is to be done with their body after their death, a right they hold as a fundamental expression of individual autonomy.

Further to this view Chadwick (1994) suggests that in death the spirituality of the individual, that even if not felt before, is often acknowledged at the time of their death and that great significance is placed by society upon the symbolic care of the corpse after death. Lamb (1990) and Kass (1985) also agree that part of the symbolic ritual of death is related to how we are cared for immediately after death and whilst acknowledging that the corpse is no longer the man or woman, they suggest it represents the person and must be treated with respect. New et al., (1994) also acknowledge respect for the corpse as being of symbolic importance to the relatives and part of the dignity required surrounding the dying process and death itself.

Building on the principle of autonomous choices, Price (2002) asserts that apart from property, the deceased do retain some rights, duties and interests after death. From a professional nursing perspective in the U.K. the Nursing and Midwifery Council (2004) identify that the nurse has a duty to:

“ Ensure that you promote and protect the interests and dignity of patients and clients, irrespective of gender, age, race, ability, sexuality, economic status, lifestyle, culture and religious or political beliefs” (Clause 2.2)

In relation to the death of a patient, these interests could be interpreted as nurses having an obligation to care for the dying person to the best of their abilities and ensure that even in death no act or omission results in a breach of this duty. This could be interpreted as ensuring that the autonomous wishes of the patient are fulfilled in relation to the dying process and the care of their body after death. Savulescu (2003) agrees, suggesting that respect for the dead means ensuring that the dead have an appropriate burial as per their particular beliefs and values. This includes the process of preparation of the body and disposal of the remains. As reported in Chapter 3, some particular religious groups e.g. Muslims and Orthodox Jews and Japanese Buddhists, have particular rituals surrounding the care of the body following death that must be observed. Often these rituals require that the whole body is intact for burial if their religious beliefs are to be respected. The need to maintain the body as intact may lead particular religious groups not only to object to organ donation that would disfigure the corpse, but also to refuse permission for autopsy after death for the same reason (Lamb, 1990). It is suggested that society as a whole, save particular religious groups, supports, in principle, the practice of donation of organs to help others after death by the individual's beneficent autonomous decision to register as an organ donor. In so doing the person freely gives consent to the use of their organs, thus providing

social and medical utility. Chadwick (1994) further suggests that since the mid – twentieth century the autonomy model of health care had been dominant with the respect for the patient’s autonomous choices being at the centre of all care. Lamb (1990) proposes that loss of autonomy in the power to make this decision about what happens to our body after death is one of the major objections to routine salvaging of organs from corpses. The moral argument raised here is that in respecting autonomous individuals’ choices in deciding what should be done with their bodies after death we uphold the principle of respect for all the autonomous choices of other individuals. Price (2002) agrees, suggesting that in the debate surrounding presumed consent, in the right to avoid certain uses of one’s cadaver, it is the right to object which is critical, not the fact of whether a positive request to organ donation was made or not.

4.2.2 Harm to the Interests of the Dead

Another ethical principle applied in relation to organ donation is that of non – maleficence: *primum non nocere* ; above all do no harm or prevent evil. Applying this principle, Hamer and Rivlin (2003) argue that the dead have interests surviving their immediate death although recognising that usually consciousness of a being is necessary for the possession of interests. Citing Feinberg (1984) they argue that although the deceased is no longer alive, sentient and able to experience anything happening to them, their surviving interests i.e. their autonomous wishes can be harmed. This view was supported by The Law Reform Commission of Canada (1992) who also acknowledged that the dead have surviving interests in the form of their burial wishes and that the deceased can be harmed when their interests are violated. Chadwick (1994) argues these views cannot be discounted although acknowledges the consequentialist view that the corpse cannot be

physically harmed by removal of organs for donation. Whilst acknowledging that different religions and spiritual groups hold particular views on the link between the deceased's soul or spirit and their body, Savulescu (2003) agrees taking the view that the afterlife cannot depend on how the body is treated and that showing respect for the dead could be achieved by giving their organs for donation to help others.

Non-maleficence is a fundamental principle adopted by all health care professionals. In particular the NMC (2004) capture this principle stating:

“As a registered nurse, midwife or specialist community public health nurse, you must act to identify and minimise the risk to patients and clients”(Clause 8.0)

***“ You must work with other members of the team to promote health care environments that are conducive to safe therapeutic and ethical practice.”
(Clause 8.1)***

In upholding this principle and combining that with the guidance provided in clause 2.2 of the Code of Conduct it could be said results in obligations and duties for the nurse, midwife or specialist community public health nurse in regard to the care of the dying and the deceased would necessitate the practitioner upholding the interests of their former patient in death. This could mean respecting their interests in respect to their stated wishes as to how their body should be managed after their death above the benefits potentially accrued by others by the removal of their organs without their stated consent.

Emerson (2003) however challenges these views that the cadaver should be afforded respect, as in his view, after death the soul leaves the body and thus the cadaver is no longer part of the person and undergoes a process of decay. In holding this view he suggests that, as part of the ethics of contemporary society as expressed in law there is no concept of property in the cadaver, with the

appropriate authority charged with the responsibility to dispose of the body. As the person no longer exists and the body of no further use to him or her, Emerson (2003) therefore challenges the right of the person to determine the disposal of their body after death when this cadaver can be a resource and a source of life to others.

4.3 Rescuing Others and Preventing Future Harm

To others, the dead have no interests and cannot be harmed thus giving a strong obligation to take tissues and organs from the dead and recycle the corpse for the benefit of the living. They take the view that there is no need to respect the wishes of the dead. Harris (1985) supports this position suggesting that if we view the need to carry out an autopsy against the relatives' wishes as being acceptable, then it is irrational to allow the relatives refusal of consent to organ donation to prevent the retrieval of much needed organs. Society overall, he suggests, would benefit if we could accept the concept of routine salvaging of corpses. Harris (2003) suggests that in a utilitarian perspective it may seem expedient and ethically correct to utilise all of the resources available to us to prolong lives, especially those of people who are chronically ill with no alternative treatment available. He also suggests is that it is right to provide as many organs as possible to save the lives of those people in end stage organ failure and in danger of dying, therefore acting beneficently. Taking this view further Harris (2003) argues that people may donate organs but in addition, the suitable dead should be obliged to donate suggesting that people who refuse to donate their organs would have to explain why they would let someone die (causing harm) rather than give their organ after their death:

“Organs should be automatically available for donation without the need to consult the owners or the relatives. Benefits of cadaver transplants are so great to the individual and society that any harm done in going against the wishes of those who object are so comparatively small, that we should remove altogether the habit of seeking consent of either the deceased or the relatives.” (Page 131)

Additionally, Harris (2003) also suggests that presumed consent legislation would open the door for routine removal of organs to come into force, benefiting others by saving lives and increasing the quality of life for those in end stage organ failure.

Commonly the principle of beneficence i.e. the wellbeing or benefit of the individual ought to be promoted, underpins the goals of organ donation.

Beauchamp & Childress (2001) describe this principle as being demonstrated in acts of charity, altruism and humanity. Additionally, Savulescu (2003) suggests that in applying beneficence to organ donation, that we have a weak moral obligation of beneficence and a duty to rescue others in need if we can. Taking a beneficent view requires that we should use organs and tissues if doing so does more good than harm, regardless of the individual's desires. Agreeing with this principle Ellis (1998) acknowledges the positive aspects of the presumed consent legislation and society's duty to make available organs for life saving treatments, that being the duty that the dead owe to the living and is morally the correct thing to do. He fears however that the application of this concept in its present form could alienate the public and have a negative effect on organ donation rates. Moreover, he suggests that presumed consent proposals articulate society's view that it is acceptable to do with the body what we feel appropriate where the person has not consented prior to their death. Gill and Hulatt (1999) highlight that between 70 –90% of the public in the U.K. are in favour of organ donation.

However, currently UK Transplant figures indicate that only 13, 994,512 (23%) have transferred that enthusiasm into recording their intention officially on the NHS organ donation register (UKT, 2006). This would suggest that on the whole, the public are not good at registering support for this issue. English and Sommerville (2003) also suggest that the low numbers of individuals registering their consent to organ donation stems from a fear that if consent is expressly given, that organ donation procedures may be commenced when the person is critically ill but before they are really dead. Sque and Pyne (1994) view the HCP in organ donation as the gatekeeper to organ donation who must do two things; optimise the patient's chance of survival and care for the quality of life of the post transplant patient. In this role they must act to ensure that all measures have been taken to save the life of the patient and these measures being exhausted, the HCP must also ensure that when the patient dies they act to ensure that the organs are maintained in good condition and utilised in a fair and just manner.

4.4 Preventing Harm to the Vulnerable and Incapacitated

Gillon (1995) and Wilks (1998) suggest that the adoption of a presumed consent approach to organ donation could infringe the civil liberties of many, not least those within society who may be unable to register their objection as a result of poor information or lack of understanding. Wilks (1998) and Ellis (1998) argue even if the intention to implement presumed consent legislation was publicised, given the experience of the high numbers of the public who have expressed a positive view on organ donation but fail to register their consent, many members of the public would fail to register an objection to this option. In their view many people would lose their right to object. Concerns are particularly related to those within society who may not be able to register their objection due to lack of

understanding of the procedure, incapacity through learning difficulties, mental health problems or communication difficulties. Gillon (1995) and Wilks (1998) fear that these vulnerable groups would lose their right to object and automatically become organ donors in the event of their death should presumed consent legislation be implemented. This may cause the public to lose trust in HCPs to make an unbiased decision, resulting in long term damage to the relationship of trust between the public and the health care professions. Patel (1992) reports an increase of refusal rates for organ donation from relatives following the introduction of presumed consent legislation in France, citing the public's loss of confidence in the transplantation system since the introduction of this legislation as an explanation. The impact of such a break down in trust between the health care professional and the public can only be speculated upon.

4.5 Doing Good and Preventing Harm Caused to Relatives

A second obligation to act beneficently might be owed to the relatives and friends of the deceased ensuring that their physical, spiritual and psychological needs are also met and that they are protected from harm. Chadwick (1994) suggests that the duties regarding the dead also involve the duties towards the living persons, for example, the next of kin who will have preferences as to what should be done with the corpse. She cautions that any benefits to the recipient or society gained by organ donation should outweigh the distress caused to the relatives by donation.

Sque and Pyne (1994) suggest that another obligation enshrined within this role is to achieve the process without social or psychological harm to the donor families, the recipient and significant others. This involves the screening of potential

donors, the selection of the recipient and initiating the transplant process. Harris (2003) acknowledges these views but suggests that in the event of a potential organ donation there are two separate groups who have claims upon us, the deceased and his or her relatives and friends and the potential organ recipient and his or her friends and family. He accepts the potential harm to relatives of the deceased if the organs are taken without consent, but takes the view that this harm is trivial in comparison to the potential harm caused to the recipient of loss of life and the harm to their family and relatives.

Balancing these competing obligations can often provide dilemmas for the staff involved in caring for the competing interests of the grieving relatives and the optimum condition of the organs for transplant i.e. the future benefit to the recipient. Kubler –Ross (1970) and Parkes (1972) highlighted the reactions to sudden death and the stages of the grieving process that bereaved relatives experience in this tragic event. Acknowledging these views, Finlay and Dallimore (1991) suggested that the option of organ donation may assist the relatives to begin the grieving process and therefore come to terms with their loss. They suggest that patterns of grief can be influenced by the support provided at the time of the sudden death. McDonald et al., (1995) in reviewing the care and support of relatives in the emergency situation discuss how new standards of care for these individual have now been developed, aimed at assisting them through the initial critical hours of the grieving process which occur following a sudden death. Using these new standards Wellesly et al., (1997) and Cansdale and Cansdale (1999) support the requesting of organ donation from grieving relatives in the event of a sudden death, for example, within the emergency department. Whilst accepting the need for staff education and training to undertake this difficult role

of meeting the requirements of both groups involved, they encourage emergency staff to consider this option in the event of a sudden death.

Niles and Mattice (1996) however suggest that it is inappropriate to inform the family of the sudden death and request the donation of the organs at the same time. They cite research by Kozlowski (1998) who suggests that the families require to acknowledge the death before they are approached with regard to organ donation. Opponents of presumed consent legislation raise concerns as to how this approach to organ donation may impact on the bereaved in the sudden death situation. They suggest that to rush to obtain organs for donation in the limited time available to facilitate this in the emergency situation, might be detrimental to the grieving process for the family.

In reviewing these practices however, Riley and Coolican (1999) highlight how the timing and the method adopted for a discussion regarding organ donation with the family is vital to respect their needs at this time. They propose that if the news of the death can be separated from the request for the organs to be donated, the harm to the relatives can be minimised and organ donation can be facilitated even in these difficult circumstances. Garrison et al., (1991) suggest that consent rates for organ donation could be improved from the current rate of 18% to a rate of 60% if there was a delay between death and the request for donation allowing time for the family to come to terms with the death before they have to consider organ donation. Cutler et al., (1993) concur with this view concluding that the decoupling of the request for organs from the news of the death can be beneficial to donor rates as well as allowing time for the relatives to adjust. This they suggest will reduce the distress to relatives and ensure that the decision made is the correct

one for the relatives, a decision that they will not regret later. Kass (1985) suggests that this may possibly induce harm to the relatives if they are not allowed time to grieve for their deceased family member. Professionals working in this area would regard this as morally unacceptable. However, the limited time available between the death of the patient and the deterioration of organs presents the HCP with a dilemma if they allow a time delay for the relatives to come to terms with their loss before they are asked to consider the option of organ donation.

In response to this difficult situation, Light et al., (1997) acknowledge how relatives are often unable to cope with the decision making process. They suggest that rather than remove the ability to consent or refuse organ donation from relatives, it is more appropriate to appoint an individual to advocate for them at this crucial time. A potential solution to this problem Light et al., (1997) suggest is the provision of family advocates to support and assist the bereaved to make an informed choice regarding their relatives' organs might increase the numbers of families who gave their agreement to donation.

It can be concluded therefore that there are many relevant ethical objections to presumed consent legislation that as yet remain unresolved, not least the validity of different forms of consent to organ donation. A second concern is the potential harm caused to the individual and society overall by the introduction of this type of legislation, especially vulnerable groups such as those with communication problems, incapacity, learning difficulties or those unable to comprehend the legislation would possibly be open to abuse from this proposal. These individuals and others who are not in a position to express an objection may also fall foul of

this change in the law unless special facilities within the legislation identified and excluded these groups of individuals from having to register an objection. The literature fails to identify a process by which individuals who are excluded from presumed consent legislation as a result of incapacity are identified and protected.

Roels et al., (1996) and Michielsen (1997) report presumed consent systems that use a central register of objectors, which is, facilitated via post offices or local government centres. What is unclear however is the process by which an accurate and up to date register of objections to organ donation would be established. The validity and reliability of any registers of objection is however questionable.

Potentially, if properly established and appropriately maintained, databases of objectors to donation may provide an accurate listing of individuals who object and those who are automatically exempt. The logistics of the development of such a register in the U.K. have yet to be considered. It could be reasonably concluded however that this would be a difficult process requiring a review of the latest population census identifying all individuals over the legal age of consent and those who would be considered exempt, for example, those with severe mental health problems or learning difficulties and those who do not speak English sufficiently to comprehend the legislation. These people would automatically be exempt from the legislation and require to be recorded as such. Even if these data could be collected, a regular system of updating would require to be developed to maintain a “live” register. Whilst this may be a possible strategy to achieve this has as yet to be developed in the U.K.

Other objections to presumed consent relate to the perception held by many that the donation of an organ is an individual’s most precious gift with voluntary organ

donation being an expression of the altruistic bond between one human and another. The introduction of any legislation that makes the voluntary donation of an organ into a state commodity, available to be taken as a resource, would change the relationship between the individual donor and the recipient.

Professionals working within the hospital settings where presumed consent would be applied i.e. intensive care and emergency departments raise genuine concerns regarding the practical application of such a proposal and the implications for their practice. To date little research exists which discusses the impact on the professionals or the relatives involved in the procurement of organs for donation utilising presumed consent legislation. If organs were procured via this method and the lack of an objection to the procedure was confirmed later by the next of kin, the relatives and staff could be happy in the knowledge that the wishes of the deceased had been respected. It can only be speculated that if organs were removed from an individual where it was subsequently found that an objection to organ donation existed, both the relatives and staff involved could be harmed considerably. This would surely hold implications for the organ donation programme and could even reduce the numbers of people who offer their organs for donation (Patel, 1992, Csillag 1998).

Summary

There are clearly ethical and professional implications of an approach to organ donation that uses presumed consent legislation. To some within the U.K. the introduction of such an approach is unthinkable at this present time, as the public are currently inappropriately informed or not willing to address the implications of this proposal to address the organ donation shortage. Others suggest the introduction of this type of legislation, despite its difficulties, may paradoxically

present less ethical and logistical problems than the other initiatives discussed. Any proposed legislation would require to be practicable, provide protection for those most vulnerable in society, and yet offer appropriate opportunity for the professionals involved to identify those people who have properly consented to donation.

To date little research exists reflecting the experiences of professionals who utilise presumed consent legislation and their responses to the many ethical challenges presented by this type of legislation in organ donation. The study that follows seeks to obtain and analyse data that reflects the practices and experiences of HCPs who use this approach to organ donation, to establish the validity of these challenges and identify possible solutions to these dilemmas should they exist.

Chapter 5 Research Design

5.0 Introduction

A review of the literature relating to presumed consent legislation demonstrated the lack of data relating to the potential impact of presumed consent on the bereaved families involved in organ donation. The very limited data relating to the experiences of the HCPs in the application of this legislation in organ donation was also identified. In particular, deficits in the literature detailing to the HCPs experiences in relation to the impact of presumed consent legislation in four areas were highlighted:

- **the involvement in and impact of the legislation on the bereaved relatives of the donor**
- **the impact of the application of the legislation on the trusting relationships between the donor families and the HCPs.**
- **the provision of specialist procedures and policies enabling the effective implementation of this legislation**
- **the availability of specialist education or preparation for the HCPs who use this legislation**

It was anticipated that the research study would provide in depth data in relation to the HCP's experiences of implementation of this approach to organ donation. In doing so it was anticipated that the HCP's perception of major issues that underpin the successful application of presumed consent legislation in organ donation, together with their preparation for this role could be identified. The literature review undertaken failed to provide any evidence of these questions being explored previously with HCPs using any research approach. This suggested therefore that a key gap in the literature existed in relation to the HCPs

application of this legislative approach to organ donation in practice. To address the lack of data in this area of practice, firstly a suitable approach and study design had to be identified that matched the specific parameters of the study. Subsequently, having identified a suitable approach to the development of these data, individual research tools had also to be designed that facilitated the capture of these data. This chapter provides details of the research approach and methods adopted for this study discussing the decision-making process underpinning the selection of phenomenological approach adopted in this study. Additionally, this chapter will operationalise the approach adopted detailing the research process undertaken in 4 phases, the selection of the research sites and the research participants. The strategy adopted for the collection, collation and subsequent analysis of these data will be explained. This chapter will also discuss the procedures undertaken to achieve ethical permission for the study describing the strengths and limitations of the approach adopted.

5.1 Selection of Qualitative Research Approach

Early in the development of the study it was clear that the research question could be best addressed utilising a qualitative approach as the purpose of the work was to capture and describe the experiences of the HCP's in relation to an aspect of their practice. Qualitative research is a set of interpretative practices that utilise a range of approaches including grounded theory, ethnography and phenomenology. These approaches to research all have the potential to provide important insights and knowledge (Denzin and Lincoln 1994).

5.2 Defining Qualitative Research

Miles & Huberman (1994) describe qualitative research as a rich (or thick) description and explanation of the processes that occur in an identifiable local

context. The principle purpose of qualitative research is to develop, synthesise and analyse descriptions of people or events and therefore add to knowledge of these. Morse & Field (1996) emphasise that when using qualitative approaches, reality is explored from an emic perspective, understanding life from the perspective of the participants in the setting under study. Further to this Denzin & Lincoln (2000) identified qualitative research as a field of enquiry in its own right which can be utilised in a variety of disciplines involving:

“The studies use a collection of a variety of empirical materials: – case studies ; personal experiences; introspective, life stories; interviews ; artefacts; cultural texts and productions ; observational, historical, international and visual texts- that describe routine and problematic moments and meanings in individuals lives.” (Page 3)

Further to this Morse & Field (1996) suggest that life structures can be viewed from different disciplinary perspectives which have developed from the different epistemological underpinnings within the main social science disciplines and give rise to distinct methodologies which they identify as being, Grounded Theory, Ethnography, Phenomenology Ethnological Discourse & Analysis, Participant Observation and Qualitative Ethnology. Morse & Field (1996) suggest that the first three approaches are the most relevant to the development of important information relating to; the meaning of experiences and essence of behaviours, values, beliefs and practices of a cultural group, processes and interactions of groups. These first three approaches will be described in more detail providing the rationale for the approach adopted.

5.3 Identifying a Suitable Approach to The Study

5.3.1 Grounded Theory

Grounded theory a research approach developed in the 1960's and 1970's by two sociologists Glaser and Strauss (1967) who aimed to produce research that

would be of value to professional and lay audiences and to develop solid theory that fitted reality. The primary purpose of grounded theory is to generate explanatory models of human behaviour, which are grounded in the data. Using grounded theory, the researcher seeks to identify patterns and relationships between these patterns. (Glaser,1978,1992). On review of this approach to qualitative it was identified that it was not the intention of the work to generate theories or explanatory models of human behaviour of the HCPs or to generate new theories attempting to explain possible rationale for practice. Rather the aim of the work was to generate data new data relating to the experiences and practices of HCPs involved on organ donation, capturing this for the first time. The grounded theory approach was therefore viewed as being inappropriate for this study.

5.3.2 Ethnography

Ethnography seeks to understand the cultural perspective of the group under study utilising participant observation, interviewing and field notes. With its roots in anthropology the word ethnographic means “portraits of a people” stretching back to the 19th century. It seeks to understand people, their ways of living, ways of believing and ways of adapting to changing environmental circumstances (Burns & Grove 1993). Fetterman (1989) describes ethnography as the art and science of describing a group or culture suggesting that to study culture. To achieve this aim the researcher must spend time in the field, being both participant in and an observer of the group that is being studied. Morse & Field (1994) support this view identifying that a cultural understanding or the emic perspective cannot be developed via one or two interviews, suggesting that time in the culture is essential to obtain a holistic perspective. To obtain the research data the study

often utilises intensive and informal interviews together with participant observation. Diaries, life histories and records are also useful in gathering information (Baillie, 1995). On review of the nature of the data and the type of information being sought within the proposed research, it was considered that the aims of the study appeared to fit well with that described within an ethnographical approach to research. On further consideration it was identified however that whilst the utilisation of interviews was possible to gather data, given the distance between the researcher and the subjects, it would not be possible for the researcher to undertake multiple interviews with the participants or be involved in participant observation of their practice. This made the adoption of the ethnographical approach improbable. In addition, whilst the exploration of the potentially different cultures in the HCPs found in Scotland, Portugal, Norway and Belgium could potentially be highlighted during semi-structured interviews with participants, further in depth interviews work would be required to clarify and develop any theories developed in relation to these. After careful consideration therefore it was identified that whilst these issues may well be the focus of further future ethnographical study in this topic, primarily the focus of this work was to capture the personal experiences of the HCPs who practice in the area of organ donation using presumed consent legislation. As such the aim of the study did not fit well with the principles of ethnographical research and this approach was therefore excluded as a sound basis for the study.

5.3.3 Phenomenology

Phenomenology is viewed by many as not a research method but also as a philosophy (Cohen, 1987). Van Manen (1990) describes phenomenology as a being an approach originating within philosophy and an approach where the

researcher is said to seek a deeper and fuller meaning of the experience of the participants. Van Manen (2002) also suggests that phenomenology offers a descriptive, reflective, interpretive and engaged mode of inquiry. Moran (2002) offers a further description of phenomenology as being:

“Best understood as a radical, anti-traditional style of philosophising, which emphasises the attempt to get to the truth of matters, to describe phenomena, in the broadest sense as whatever appears in the manner in which it appears, that is as it manifests itself to consciousness, to the experiencer.” (Page 4)

Moran (2002) reports that the foundations of phenomenology are attributed to the work of German philosophers, Edmond Husserl (1859-1938) viewed as being the founder of the modern movement and Martin Heidegger (1889-1976) his student, who in turn influenced the work of French philosophers, Jean Paul Sartre (1905-1980) and Maurice Merleau-Ponty (1907-1961). Moran (2002) suggests that here are two frequently utilised approaches to phenomenology arising from the work of Husserl & Heidegger.

5.4 Phenomenological Approaches

5.4.1 Transcendental Phenomenology

Husserl, a mathematician working in Germany in the early 20th century originally utilised phenomenology as a quest for the philosophical foundations of logic and evolved into the analysis of the logical structures of consciousness (Walters 1995). Influenced by the French philosopher and fellow mathematician Descartes (1596-1650) his philosophy represented the model of mind and body split known as Cartesian duality. Koch (1994) reports that Husserl viewed phenomenology as developing from the culmination of Cartesian traditional view, that came to mean the study of phenomena, as they appear through the exploration of human consciousness.

Moran (2000) suggests that Husserlian phenomenology was concerned with providing a clear understanding of the fundamental nature of reality. To explain this in more detail he introduced the concepts of individuals and their interaction within the “life-world” or “lived experience”. Husserl (1962) considered experience as a person’s perceptions of their presence in the world at the moment when things, truths or values are constituted. Husserl (1962) also viewed these experiences as not being readily accessible as they are often taken for granted. In his view it was necessary to return to these “things themselves”, i.e. return to these taken for granted experiences and re-examine them, highlighting the structures of consciousness or “essences” and to evaluate critically the role that structures play in determining the sense of it all (Dreyfus, 1987). Husserlian phenomenological studies are therefore those that utilise an inductive process to capture and describe the lived experiences of individuals. To structure this process, Husserl suggested that four themes were essential to the process of inquiry:

(i) Intentionality

Husserl (1962) held the view that the mind is directed toward objects and this directness is called intentionality, based on the notion that our own conscious awareness is a dependable concept. Our knowledge of reality is then built upon our initial conscious awareness. The intentional content of the mind is like a description of reality. This can be employed to explore experiences.

(ii) Essences

Essences relate to the true meaning of something, i.e. concepts giving common or agreed understanding of the phenomenon under study. Husserl saw phenomenology as a descriptive psychology which would return things to

themselves and to the essences that constitute the consciousness and the perceptions of the human world. He described the process of “eidetic intuiting” by which the phenomenon was scrutinised in order to allow a perception of its “essence” or “eidos” or image to be identified. These can be represented as single essences or in relationship to one another. Eidetic comprehension, or accurate interpretation of what is meant by the description of the phenomenon under investigation, providing a common understanding of this. Streubert and Carter (1995) suggest that in nursing these essences related to the commitment to nursing include, for example, concepts of altruism, devotion, dedication, caring, being there, trust, loyalty and nurturance.

(iii) Phenomenological Reduction

Husserl (1962) emphasised the need for “phenomenological reduction”, “epoche” from the Greek epoch, that is a fixed position in time from where subsequent events can be measured. He believed by eliminating all preconceived notions or bracketing i.e. the suspension of beliefs, assumptions and bias in the “outer world” about the phenomenon under investigation. Schutz (1972) reports that Husserl added that the bracketing was not only of the outer world but also the individual consciousness, and that this was necessary to disregard extraneous features and connotations to allowing the clear perception of the vivid, essential image of the “eidos” to emerge. In adopting this approach the researcher should in theory be able to either come to a topic area with no preconceived ideas and biases about a subject matter, or be able to suspend these and allow the true experiences of the research subjects to be revealed uncontaminated.

In reality however, the achievement of these aims presents many challenges to the researcher, requiring as it does the researcher to set aside any previous knowledge or notions related to the topic under study and to ensure that their ideas and biases do not cloud the experiences of the study participants. Most researchers in study preparation will require to explore previous literature on the topic and therefore hold some knowledge of the topic under enquiry, and in doing so, not unrealistically must have formulated some ideas in relation to the issues and ideas surrounding a particular phenomenon. These generated thoughts and ideas will put into context the new information and experiences that may be generated during their investigation of a particular topic. It is essential however that these previous thoughts and ideas are only used as a reference point and are not allowed to obscure the detail of the phenomenon being observed and recorded. As a safeguard against this occurrence all competent researchers must ensure that a clear audit of the study material is provided and available for scrutiny, with any biases that may impact upon the study results kept to a minimum and where they exist are highlighted and discounted within the results. Koch (1994) supports this view establishing an audit trail with which to record and justify decision making in applying a phenomenological approach to research.

(iv) Validity & Objectivity of Husserlian Phenomenological Data

Husserl (1965) viewed phenomenal reduction as necessary for rigorous enquiry. This view is supported by Koch (1995) who sees this as a method of defending the validity or objectivity of the phenomenological researcher against self-interest. Olier (1982) advises that the phenomenological researcher should examine closely the reasons for selecting particular phenomena to study and take every opportunity to explain the choice, as it is argued that the choice stems from the

researcher's own predispositions and values. Parse et al., (1985) support this view suggesting that the researcher should also clarify these beliefs and positions before generating any data and bracket these, thus drawing on Husserl's ideas to maintain the objectivity of the data. In addition to these suggestions Omery (1993) states that it is a requisite of phenomenology that the researcher approach the study with few or no preconceived notions, expectations or frameworks guiding the researcher in data gathering and analysis.

Olier (1982) suggests the goal of phenomenology is to describe accurately the experience of the phenomenon under study and not to generate models, or develop general explanations. To achieve this objective, she advises that delaying the review of current literature on the phenomenon until the data has been gathered, allowing the researcher to see the phenomenon in "its uncontaminated stage" and comply with Husserl's suspension of belief in the outer world.

In reality this might be difficult to achieve completely as in order to identify the topic for study. The researcher must be familiar with literature identifying the gaps in the knowledge that require research. It would be possible however for the researcher to ensure that prior to undertaking the data collection phase of the study they abstained from reading the most recent literature. It might also be possible to ensure that in undertaking interviews with subjects, the researcher used a semi-structured and open approach to exploring the topic under study and refrained from introducing any new topics to the interviewee. In this way, the influences emanating from the researchers previous knowledge would be kept to a minimum, allowing the subjects to provide relatively "uncontaminated" data.

Walters (1995) suggests that Husserlian phenomenology is primarily interested in epistemological issues and summarises it as placing emphasis on:

- i) analysis of the subject and object as the object appears through consciousness (intentionality)
- ii) emphasis on bracketing or epoche as a method for suspending naïve realist awareness
- iii) emphasis on describing the full (or valid) appearance of the object of enquiry

Different approaches to undertaking Husserlian phenomenology have been developed and applied successfully in nursing research that seeks to explore the epistemological question of knowing for example Hermeneutic Phenomenology.

5.4.2 Hermeneutic or Existential Phenomenology

Walters (1995) suggests that Heidegger (1962) takes a different view of the descriptive approach to phenomenology. In contrast to his former teacher Husserl, his approach considers that an understanding of the person cannot occur in isolation from the person's world. Moran (2002) supports this, suggesting that Heidegger's approach to research was based on an existential perspective focusing on ontological issues relating to what it means to be a person in this world.

Hekman (1986) suggests that this approach is concerned with exploration of the relationship between human thought and human existence in a search for objective knowledge. His seminal work, *Being and Time* (Heidegger, 1962), was a re-interpretation of phenomenology as previously developed by Husserl. Moran (2002) reports that Heidegger regarded Husserl as too Cartesian and intellectualist and decided to abandon the term consciousness and intentionality altogether.

Instead he adopted the term “being- in- the- world” to capture the human moods and experiences which result from the ordinary everyday existence of people. This was a challenge to the Cartesian subject – object dualism and the notion of intentionality favoured by Husserl, shifting the philosophical debate from an epistemological perspective to an ontological one. Reed (1994) suggests that Heidegger:

“Questioned the notion that our experience of things was always subjective (in the sense that we are always subjects) and illustrated this point by identifying situations in which people would engage with the world without the subject-object (intentional) relationships.” (Page 337)

Heidegger (1962) challenged Husserl’s perspective that everything can be viewed as a product of the individual’s consciousness. Heidegger illustrates this by the example of the expert carpenter who uses his hammer without thinking about it a conscious way, the hammer is “transparent” to the carpenter. Heidegger suggested that much of human interaction with the world was conducted in this manner and that the relationship we have to other things, is not of a conscious subject to the independent object. This would suggest that we are primarily in and of the world we inhabit, not subjects in a world. To support this view, Heidegger (1962) refers to human existence as “Dasein” or “being there” (in the world) with his analysis of the human condition, people are in the world rather than subjects in a worlds of objects. In further analysis of the concept of Dasein, Heidegger refers to human existence, identifying three concepts contained within this phenomenon, in-the-world, the quality of existence and the uniqueness of being-in-the-world. He further suggests that consideration of any one of these phenomena has to involve reference to the other two (Heidegger,1962).

The most basic way of being in the world is “sorge” or care, i.e. care is about being and it is about caring for things and other people. Being human is therefore,

a situated activity, a situation in which things are encountered and managed. In addition, Heidegger argued that it was not possible to bracket one's previous thoughts, experiences and attitudes in the process of philosophical enquiry, and any previous attempt to understand this concept, which conceptualised reality including human reality as mere objects, was mistaken. Gelven (1989) suggests that phenomenology, for Heidegger is defined as an analysis by which the meaning of the various ways in which we exist can be translated from language of everyday existence into the understandable and explicit language of ontology without destroying the way in which these meanings manifest themselves to us in our everyday lives.

Heideggerian phenomenology was interested in the origin of knowledge embedded in the experience of our everyday activities. In doing so, according to Heidegger, the researcher using this approach tries to develop a deeper and fuller understanding of the experience of the participants of a particular phenomenon, offering a descriptive, reflective, interpretative and engaged mode of inquiry. The researcher asks the question "what is it like to have a certain experience". To this end, he identified three ways in which we interact with our world focusing on the quality of consciousness:

(i) Ready to hand : the way we engage and interact with the world and exist in a transparent involved form in the environment

(ii) Unready to hand : those which are experienced when things or equipment go wrong and presents us with a problem

(iii) Present at hand : characterised by detachment and objectivity with an ability by the individual to stand outside activities and reflect upon them

Heidegger (1962) viewed these as the basic framework for understanding how we as humans interact with world around us and the basis for understanding and interpreting human experiences. Maggs – Rapport (2000) suggests that the Heideggerian phenomenological approach to research attempts to concentrate on the phenomenon under review through the discovery and interpretation of the meaning embedded in the words of the participant narrative. Moran (2000) suggests that this approach to research provides an unprejudiced descriptive study of whatever appears to consciousness in the manner in which it appears.

5.4.3 Interpretation of Hermeneutic Phenomenological Data

Heidegger (1962) developed a phenomenological method for his analysis of “being –in –the –world”. Hermeneutics or interpretation is one of the processes people use in making sense or understanding of their everyday lives. This includes understanding of the person world and culture by the researcher. Koch (1994) reports that to structure this interpretation, Heidegger developed two essential concepts with which phenomenological data should not just be described but interpreted; (i) Historicity of Understanding and (ii) The Hermeneutic Circle.

(i) Historicity of Understanding contains 3 ideas:

Background : a person’s history or background is what culture gives a person from birth, their background which is handed down to them provides them with a method of understanding the world. This understanding structures what the individual views as real or significant for that person. Heidegger considered that these background meanings, skills and practices which make up the individuals existence cannot be completely explicit.

Pre-understanding : or “fore-conception” is the meaning and organisation of a culture (languages, norms and practices) which exist before we understand.

Human beings always come to a culture with a pre-understanding and this is the structure of our “being in the world” and as such this can not be bracketed or eliminated.

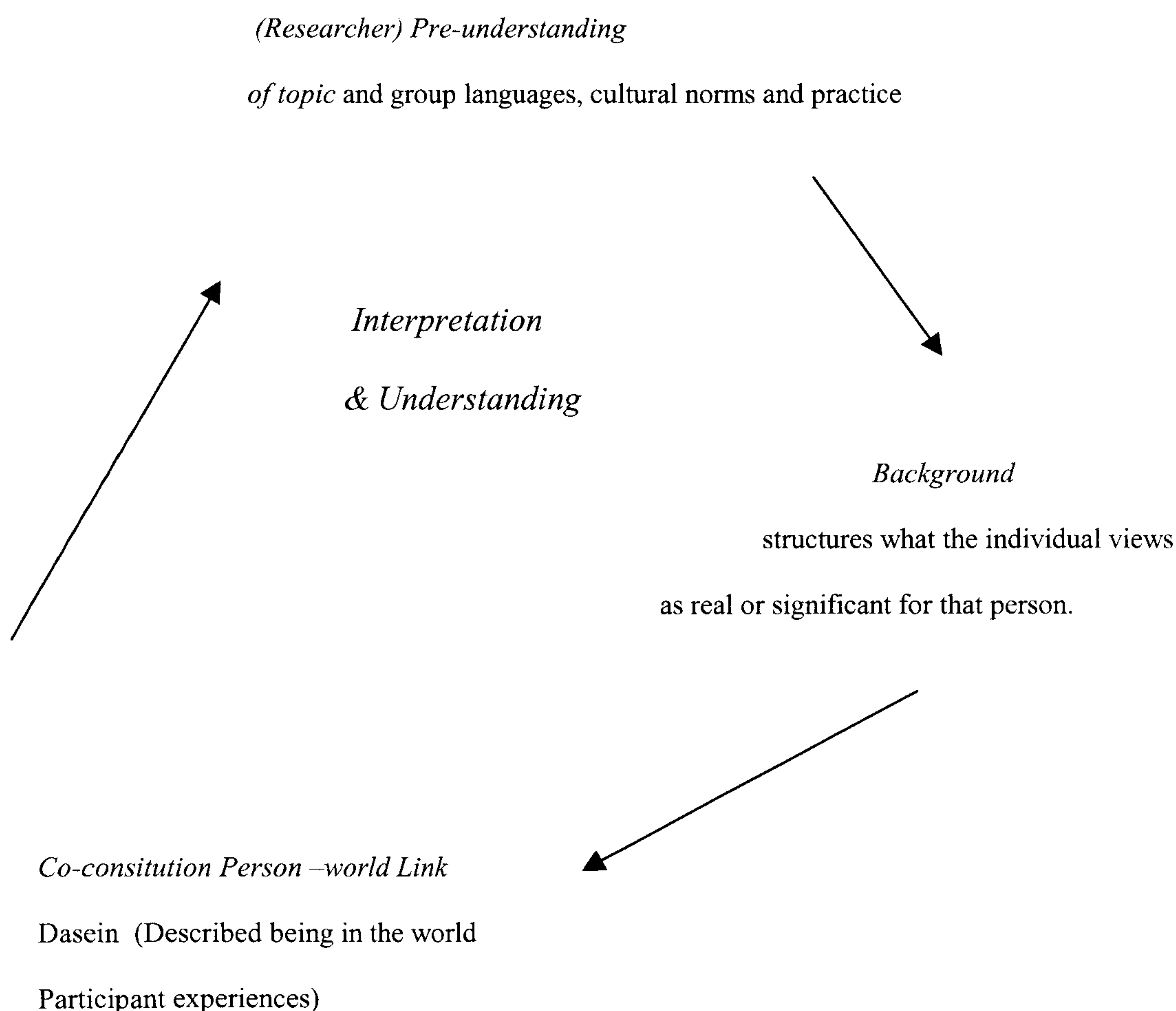
Co-constitution : the philosophical assumption of indissoluble unity (person-world link). This means we are constructed by the world and in-turn we construct the world around us from our own experiences and background. Linked to this is the idea that the person is at home in the world and the world is already there for analysis. The person participates in the world in cultural, historical, and social contexts. Human existence and the world co-constitute each other.

Heidegger (1962) states that nothing can be encountered without reference to the person’s background understanding and that every interaction requires an interpretation in relation to a person’s background in its historicity. He also suggests that the framework that we utilise for interpretation is the fore-conception in which we grasp something in advance. In addition, he takes the view that we cannot have a world and can not exist at a cultural level except via interpretation of the world around us. Understanding occurs because we are born in the world and interpret ourselves and our practices in relation to others, that is to say we are self-interpreting and self defining beings. Heidegger suggests that the real question is not what way “being” can be understood but in what way understanding is “being in the world”.

(ii) The Hermeneutic Circle

For Heidegger (1962) the question therefore to be answered is “what does it mean to be a person” in reference to the concept of Dasein, being already in the world. In his view we are socialised into shared group coping skills, moods, reactions and possibilities with the true experiences of the individual being obscured. The researcher brings a pre-understanding of the situation to the data and utilises this to interpret the experiences as described by the participants and gain new understanding of these experiences, hence the hermeneutic circle (**Figure 5.1**).

Figure 5.1 The Hermeneutic Circle



5.4.4 Objectivity of Heideggerian Phenomenological Data

Whilst not discounting the concepts of Heidegger (1962), the situation where the researcher brings to the study pre-conceived knowledge or understanding of the phenomena may give rise to difficulties. This prior knowledge or involvement with the phenomenon may result in terms of the bias, that cannot be forgotten or bracketed and is therefore generated by the researcher. The Heideggerian view is that the interpreter participates in making data with the concept of co-constitution resulting in the primary data being regarded as contextualized life events. This view was supported and extended by Gadamer (1976), a student of Heidegger, who suggested that philosophy extends the existential – ontological exploration of understanding, providing an emphasis on language as the tool to explore understanding.

Gadamer (1963) suggests that hermeneutics is a reflection about what is going on. He utilises the idea of the hermeneutic circle but acknowledges the concept of language and dialogue as being important elements within this. Gadamer also introduces the idea of prejudices which he uses to refer to Heidegger's notions of background, co-constitution and pre-conceptions. He suggests that we always have traditions in advance of any reflections which result in prejudices. These prejudices he proposes are linguistically conveyed as a forestructure or condition of knowledge that reflect our social reference group and are a product of our gender culture, race etc. These prejudices he views as not being something negative that should be eliminated as we use these to access the world. In Gadamer's (1976) view these prejudices are not necessarily erroneous or distortions of the truth, but that our history of our existence entails prejudices:

“Constitutes the initial directions of our whole ability to experience.... Prejudices are biases of our openness to the world” (Page 9)

He also suggests that in order to counteract the inherent bias within this, the perspectives of the researcher and the person being studied should be being specified within the data. Gadamer (1976) further introduces the concept of “fusion of horizons” i.e. the combining of the contextual life events, with that of the person’s and the researchers perspectives which are specified, which he suggests is necessary to “tolerate the ambiguity of relaxing (not eliminating) ones preconceptions.” Gadamer takes the view that understanding is developed from an interpretation of a range of vision that we see from a particular vantage point. He cautions however that and interpretations of the data that emerge, will be influenced by the conceptual leanings and the interpretive background used when developing the data. Gadamer (1976) suggests that the task of understanding is to identify and explain how fusion has occurred. This is achieved by the researcher showing the way in which the researcher themselves participates in the making of the data, depicting the expression, for example, patient voices, in social context. Given these variables contained within a phenomenological approach to research, that are often difficult to capture and qualify, Streubert and Carter (1995) highlight how several schools have developed frameworks to conduct research utilising this method including, Van Kaam (1959), Gorgi (1985) and Colaizzi (1987) and to simplify phenomenology and help achieve the eidetic intuiting as described by Husserl. A summary of these frameworks utilised to structure hermeneutic phenomenological research can be found in **Figure 5.2**.

Figure 5.2 Methodological Interpretations Of Phenomenological Data

Van Kaam (1959)

1. Obtain a core of common experiences
2. List and prepare a rough preliminary grouping of every expression presented by participants
3. Reduction and elimination
Test each expression for two requirements:
 - a) Does it contain a moment of the experience that might eventually be a necessary and sufficient constituent of the experience?
 - b) If so, is it possible to abstract this moment and label it without violating the formulation presented by the subject? Expressions not meeting these two requirements are eliminated. Concrete, vague and overlapping expressions are reduced to more exact descriptive terms.
4. Tentatively identify the descriptive constituents. All common relevant constituents are brought together in a cluster that is labelled with the more abstract formula expressing the common theme.
5. Finally, identify the descriptive constituents by application. This operation consists of checking the tentatively identified constituents against random cases of the sample to see whether they fulfil a number of conditions:
 - a) It is expressed explicitly in the description
 - b) It is expressed explicitly or implicitly in some or the large majority of descriptions
 - c) It is compatible with the description in which it is not expressed
 - d) If a description is found incompatible with a constituent the former must be proven not to be an expression of the experience under study, but of some other experience that intrudes upon it.

Gorgi (1985)

1. Read the entire description of the experience to get a sense of the whole
2. Reread the description
3. Identify the transition units of the experience
4. Clarify and elaborate the meaning by relating them to each other and to the whole
5. Reflect on the constituents in the concrete language of the subject
6. Transformation of that concrete language into language or concepts of science
7. Integration and synthesis of the insight into a descriptive structure of the meaning of the experience.

Colaizzi (1987)

1. Description of the phenomena of interest to the researcher
2. Collection of the subject's descriptions of the phenomenon
3. Reading all the subjects' descriptions of the phenomenon
4. Returning the original transcripts and extracting significant statements
5. Trying to spell out the meaning of each significant statement
6. Organizing the aggregate formalized meanings into clusters of themes
7. Writing an exhaustive description
8. Returning to the subjects for validation of the description
9. If new data are revealed during the validations incorporating them into an exhaustive description

Adapted from Streubert and Carpenter (1995)

5.5 Evaluation of Research Data

5.5.1 Overall Concepts of Validity and Reliability of Research

In evaluating research Cormack (2000) suggests that a number of key concepts are identified as being fundamental:

- Trustworthiness
- Validity
- Reliability
- Rigour
- Researcher Reflexivity
- External Validity

Cormack (2000) describes validity and reliability as criteria on which the veracity and credibility of research findings are judged. In his view the validity refers to the degree to which the instrument used in the research measures what it is supposed to measure and reliability refers to the degree of consistency and accuracy with which the instrument, used under similar circumstances, measures the attribute under investigation. Denzin & Lincoln (1994) and Guba and Lincoln (1995) suggest that criteria such as validity and reliability can be utilised in quantitative research to provide a degree of objectivity in the evaluation of this research. Whilst these concepts can be applied to quantitative research, problems however emerge when these concepts are applied to qualitative research. Instruments used in quantitative research can often be developed and tested under controlled conditions to ensure the optimum application and even predict the variances of this tool. Cormack (2000) acknowledges that qualitative researchers often experience difficulties with achieving this level of accuracy as application of the instruments that are most frequently used in qualitative research, for example, questionnaires present challenges in their ability to be measured using this

approach. Cormack (2000) agrees that questionnaires can be developed and refined through piloting prior to the study, however when utilised by individual participants, the exact impact of the questionnaire can not be readily ascertained. Additionally, another instruments used in qualitative research, such as the semi-structured interview, by its very nature encourages a dynamic interaction between the participant and the researcher. Despite the appropriate piloting of the interview schedule and adequate preparation for the interviews undertaken by the researcher, the data generated from individual interviews will not be repeated, and is therefore open to challenges as to the validity and reliability of any data generated in this manner. Strauss and Cobin, (1990), Sandelowski, (1993), Koch, (1994) and Popay et al., (1998) question however whether concepts of validity and reliability are appropriate criteria for the evaluation of quantitative research. Similarly, Hammersley and Atkinson (1995) suggests that whilst it is possible to develop criteria for measuring qualitative research, however, as this type of research represents a different paradigm to quantitative, validity and reliability cannot be used as criteria with which to evaluate qualitative research.

5.5.2 Evaluation of Quantitative Research

When discussing the evaluation of qualitative research, Guba and Lincoln (1995) highlight that in qualitative research the findings of these studies are not facts per se, but rather the data has been created via the interaction between the participant, the data, the researcher and the evaluator. As such the findings are dependent upon the values systems of each party and the context within which they operate. Popay et al., (1998) takes this point further suggesting that a good criterion by which qualitative research can be evaluated is the provision of sufficient detail to enable the reader:

“ To interpret the meaning and context of what is being researched and exposes the experience as a process” (Page 347)

Popay et al., (1998) also propose that given the researcher involvement in the research process, the important issue is not whether the data are biased, but what is important is that the process by which the data have been collected, analysed and presented must be transparent. The approaches to phenomenological research described by Van Kaam (1959), Gorgi (1985) and Colaizzi (1987) have been successfully adopted by nurse researchers in the collection, analysis of phenomenological data providing transparency and academic rigor to research using this approach. Koch (1994) however, is deeply critical of these approaches suggesting that these approaches do not adequately address the rigour required in the analysis of this data. She also highlights the need for trustworthiness of the data citing Guba and Lincoln's (1989) need for credibility, transferability and dependability of the data. Koch (1994) suggests that in order to provide academic rigour the approach described by Colaizzi (1987) requires the addition of an audit trail by the researcher to support the data gathering with the use of field notes by the researcher as a useful tool. These notes which contain the researcher experiences, issues, access, settings and prejudices can be recorded as a useful journal of events with which to reflect the data gathered by the researcher, acknowledging their involvement in the data gathering process and justifying his or her decision making.

5.5.3 Application of Reflexivity in Qualitative Research

Hammersley and Atkinson (1995) highlight the need for researchers to acknowledge the role they play in qualitative data collection and rather than try to standardise research procedures as is often the case in quantitative research or try

to soak up all aspects of the culture of the participants within the qualitative study. They suggest that the researcher, should make their thoughts and biases explicit, so as to make their role in the formation of the data clear, and thus strengthen the trustworthiness of the data collected. Horsburgh (2003) further suggests that the term reflexivity refers to the active acknowledgement by the researcher that his or her own actions and decisions will inevitably impact upon the meaning and context of the experience under investigation. Using reflexivity, she argues the researcher realises his or her involvement in the world that is being studied with the result that neutrality and detachment in relation to data collection, analysis and interpretation are impossible. However, combining the concept of researcher reflexivity with the approaches to evaluation of qualitative research as described by Koch (1994) and Popay et al., (1998) where the researchers experiences, prejudices and involvement in the data development are made transparent, the trustworthiness of the data can be established and an academically rigorous approach to the evaluation of this data assured.

5.5.4 Selection of Research Approach

In order to address the research question it was identified that data relating to the “lived experiences” of the HCPs involved in organ donation in three European countries that have access to presumed consent legislation required to be obtained. A review of the literature failed to identify data relating to the experiences of this group of HCPs, and thus a requirement to generate new knowledge was identified. By capturing the reflections and experiences of the HCPs the study aimed to provide information relating to the benefits and challenges of using this approach to the procurement of organs for transplantation.

Analysis of the nature of the data required pointed to the utilisation of the Heideggerian (1962) phenomenological approach to the study as being the most appropriate to answer the research questions. By combining an approach to phenomenological research identified by Gadamer (1976), with the additional adaptations suggested by Colaizzi (1987), Koch (1994) Popay et al., (1998) to structure and evaluate the study, it was anticipated that the exploration of the “lived experiences” of the HCPs in European countries who utilisation of presumed consent legislation could be captured. These experiences and those of the researcher in collecting the data could then be compared with the known literature relating to the legal and ethical practices in organ donation in Europe, forming new insights to this practice and allowing the exploration of the implications in the U.K. of these practices.

5.6 Application of Phenomenological Approaches to Data Collection

The phenomenological approach to research seeks to understand the “lived experience” of the individuals and their intention within the “life-world”. This approach to research and was identified as the most appropriate method of exploring the experiences of the HCPs in organ donation practice in their particular country, allowing as it does rich, in depth data to be generated for analysis. To explore the experiences of these HCPs based in intensive care or emergency settings who used presumed consent legislation, it was first necessary to establish which European countries used this approach to organ donation. Having established which European countries used this approach to organ donation and gaining ethical permission to undertake the study, it was necessary to identify an appropriate sample of professionals in each country who had direct experience of organ donation using and were in a position to address the research

question posed by this study. Acknowledging the logistical problems of the distances between the researcher based in Scotland and these European HCPs a practical approach to the identification these professionals and gain background information to confirm the legislative approach to organ donation used in Europe, had to be devised to develop this initial data. It was quickly realised that this data could not be obtained using a phenomenological approach. It was therefore considered appropriate that in order to establish the legislative approach to organ donation in countries within Europe, an initial descriptive quantitative investigation of members of the European Transplant Co-ordinators Organisation was undertaken yielding contextual and background information. Secondly, it was also established that to identify HCPs within intensive care and emergency settings in these countries with the appropriate experience and recruit them to the study, a further survey of these HCPs using a questionnaire had to be undertaken. This would provide data relating to the range of experience of these HCPs and their initial perceptions of the application of presumed consent legislation. Finally, it was proposed that analysis of these data contained within the questionnaire would enable the researcher to identify an appropriate sample of participants in each country and invite these HCPs to undertake semi-structured interviews to generate further insights into the experiences of these professional's practice in organ donation. It was also anticipated that data from the questionnaire responses would also provide key themes that would be used to develop the interview schedule, adopting a phenomenological approach to address the research questions.

Reflection on the challenges presented by this research study forced the researcher to reconsider the original plan to adopt a purely qualitative approach to the study

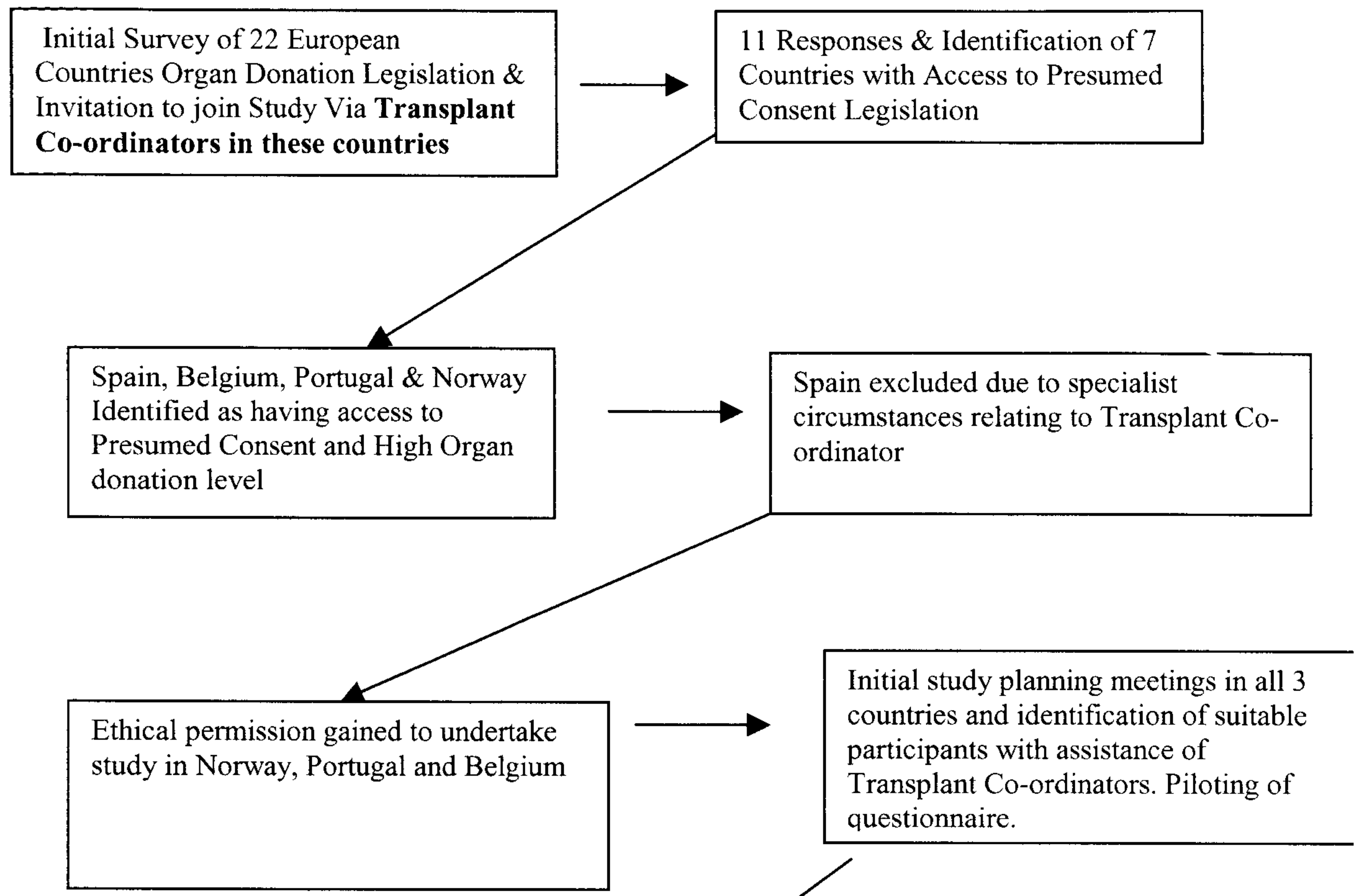
and adopt an approach to data development that combined surveys of European Transplant Co-ordinators and HCP with qualitative data generated using semi-structured interviews.

5.6.1 Development of Research Tools

It was considered that by utilising an initial survey of the European Transplant Co-ordinators Organisation inviting responses to a letter from the researcher, a questionnaire survey of relevant HCPs with direct experience of organ donation combined with individual audio taped semi- structured interviews with selected HCPs , the experiences of these professionals within countries where presumed consent legislation was available, could be recorded and analysed. These questionnaires and semi- interview schedules were developed by the researcher for use in this study.

Figure 5.3 Overview of Research Process

Phase 1



Phase 2

Gathering of initial data via distribution of questionnaire to HCPs in 3 countries involved in organ procurement and return of data to researcher for analysis. Development of interview guide. Selection and recruitment HCPs of in 3 Countries with experience of organ donation, consenting to be interviewed

Phase 3

Planning interviews in 3 countries by researcher and undertaking of audio taped semi- structured interviews. Review these interviews with study participants for verification

Phase 4

Analysis of data by researcher to identify essential or key themes within descriptions. Interpretation and integration of these into exhaustive description of phenomena using literature

5.6.2 Overview of the Research Process

The research process was divided into four phases a summary of which can be found in **Figure 5.3** and comprised of:

- **Phase 1 Initial Survey of the Application of Presumed Consent Legislation in Europe and Recruitment of Suitable Research Sites**
- **Phase 2 Introduction and Site Preparation in Each Country**
- **Phase 3 Planning and Undertaking the Interviews with Healthcare Professionals**
- **Phase 4 Coding of Data and Analysis with Interpretation in Relation to Literature**

5.7 Phase 1 Initial Survey of the Application of Presumed Consent Legislation in Europe and Recruitment of Suitable Research Sites

The literature review undertaken provided some information regarding the reported availability of presumed consent legislation in Europe, proved however to be inconclusive as to the current application of this approach to organ donation across Europe. New information was required to be generated from the major European countries involved in organ donation, exploring if presumed consent legislation was applied in individual countries.

To achieve this, a small descriptive investigation of European countries that have access to presumed consent legislation was undertaken, utilising the assistance of key members of the European Transplant Co-ordinators Organisation (ETCO) from 22 countries. This organisation represents the only countries from within

Europe who are known to be actively involved in organ donation and transplant. **(Figure 5.4)**. Its members are generally Regional Transplant Co-ordinators or Directors of the Transplant Centres within Europe. Each transplant co-ordinator was sent an initial letter in English **(Figure 5.5)**, providing information on the study with its rationale and requesting information relating to the current policies and practices in the procurement of organs within their country. English is the common language of the ETCO to communicate with all members, therefore it was anticipated that the transplant co-ordinators would understand this request for information. They were invited to provide this information in hard copy or electronic format.

Of the initial 22 key members contacted (1 representing U.K.), 9 (43%) responses were obtained. A follow up request was made 6 weeks later providing 1 further response. Thus information was obtained on the practices and legislation within 10 European counties a summary of which can be found in **Figure 5.6**. Responses from transplant co-ordinators in Romania, Slovenia and Georgia reported that these counties operated a policy of informed consent in relation to organ donation similar to that in the U.K. within which the individual must provide positive evidence of their wish to donate organs prior to their death. This is usually in the format of a signed donor card or by registering their consent to donation on a national register. Some co-ordinators indicated their frustration at this approach, suggesting that they would prefer presumed consent legislation to be introduced in their country. The original information that suggested that these countries used presumed consent was therefore misleading and these four countries were therefore excluded from the study. This therefore left the application of presumed consent legislation in 7 counties to be explored.

5.7.1 Recruitment & Selection of Research Study Sites

Of the 7 countries originally contacted, responses from transplant co-ordinators in Belgium, Italy, Portugal, Sweden, Spain, Norway and Switzerland revealed that these countries all had had access to presumed consent legislation in varying formats since as early as 1973. They also demonstrated varying degrees of success in producing organs for donation using presumed consent legislation with Norway, Belgium Portugal and Spain producing the highest numbers of organs for donation; Norway 19 donors per million of population; Belgium 25 donors per million of population; Portugal 22 donors per million population and Spain 33.9 donors per million of population (ETCO, 2004). These numbers of organs for donation are much higher than the average of 13.6 donors per million population obtained from the U.K. Norway, Belgium, Portugal and Spain were considered to be the most likely sites to provide the “rich data” required to answer the study questions. In addition to information on numbers of organs transplanted, the responses from the co-ordinators demonstrated that when present, presumed consent legislation had been developed at different times with or without a public education campaign prior to involvement in this process. The responses also suggested that the level of knowledge of the legislation held by either the public or the HCP was unclear.

To provide knowledge of the legal context in which these countries operate a support copy of the legislation in each country was obtained and translated into English, revealing different approaches to the drafting of the legislation and provisions within each country. Initial responses received by letter or email from the organ donation co-ordinators from these four countries indicated their willingness to participate in the study.

5.7.2 Choice of Participating Countries

To refine the selection of suitable research subjects, the eligibility of the HCP in these four countries to participate in the study was assessed i.e. they could demonstrate experience in organ donation procurement using presumed consent legislation. Research on the practices within Spain, demonstrated the highest levels of organs for transplant in Europe, producing 33.9 organs pmp (ETCO, 2004, Coppen et al., 2005). As described, further exploration of practices related to organ donation revealed that despite having an register of individuals who object to organ donation in place, the staff always seek and respect the wishes of the next of kin before removing organs from the deceased i.e. not fully applying the powers of the legislation.

In addition, it was revealed that Spain's unique system of the provision of large numbers of specially prepared, transplant co-ordinators who work within the critical care settings with a specific role to counselling and supporting the staff and relatives during the organ procurement and transplant process potentially influenced the high organ donation rates (Miranda et al., 1999). As this situation is not repeated in other countries across Europe, an accurate comparison with the other practices relating to organ donation in the other three countries could not be undertaken. For this reason it was considered that Spain would not be an appropriate setting for this research into the application of presumed consent legislation alone, as the direct involvement of the transplant co-ordinators in the procurement of organs for transplantation could bias any data obtained from this country. For this reason Spain was therefore excluded from this study.

The information obtained during the initial survey of members of the ETCO countries from Portugal, Norway and Belgium on their application of presumed

consent legislation was reviewed again revealing that when utilised by HCPs it is being applied using varying approaches, dependent on the views and professional sensitivities of the transplant co-ordinators and HCPs involved in the organ procurement process. To establish their suitability to join the study, the procedures in each country were reviewed in detail.

5.7.3 Final Selection of Sites for Study

Further in depth investigation of the three remaining countries Portugal, Norway and Belgium, details of which will be given in the next section, revealed that when no indication of the views of the deceased was available by the presence of a donor card, absence of recorded objection to donation or name on the donor register, patients were routinely considered as organ donors. Further information from the transplant co-ordinators in each country indicated that routinely, relatives were approached and asked to confirm that there was no known objection to organ donation by the deceased. This approach may or may not result in organ donations as some relatives raised objections to the procedure. Questions were therefore raised as to why different groups of HCPs employed in the same field of practice responded differently to this issue. Some countries appeared to have access to presumed consent legislation and utilise it, whilst others had the same legal facilities and chose not to utilise it to the full. To explore this phenomenon in more detail it was decided that these three countries Portugal, Norway and Belgium would be invited to participate in the next phase of the study.

5.8 Ethical Approval for Study

Ethical approval to undertake this study was sought and obtained from the ethics committee within Napier University and from the participating countries of Portugal, Norway and Belgium utilising accepted ethical research protocols. This

was achieved with the assistance of the Senior Transplant Co-ordinator in each of these countries who presented the study details to their respective ethical approval committee and obtained written consent to proceed. To facilitate the attainment of ethical permission in Portugal, Norway and Belgium further detailed information on the nature and format of the study was then forwarded to the transplant co-ordinators in these three countries by the researcher. As ethical permission in each of these three countries required that all of the study documentation should be translated into the appropriate local language (Portuguese, Norwegian, French and Flemish), the Senior Transplant co-ordinators assisted by undertaking to translate the study information provided by the researcher. They also agreed to undertake the process of applying to their respective hospital and regional ethical committee on behalf of the researcher. This did however require considerable involvement of the researcher to clarify the processes and answer questions posed by the respective ethical committees. These were questions were addressed via the use of the email and telephone systems to provide further details of the study and clarify issues.

Over the course of a two month period in each country, ethical permission was granted by the appropriate authorities to proceed. During the ethical permission process the following key issues were explored with the researcher by the potential participants from the 4 study sites:

- Ensuring that no relatives would be approached to participate in this study
- Ensuring the voluntary status of any staff member who participated
- Clarifying procedures for obtaining individual consent from participants
- Ensuring the confidentiality of data obtained during the course of the study

When these were assured, ethical permission was obtained together with operational approval from the respective hospital management committees and the next phase of the study commenced. This centred on the desire by the researcher to maintain the confidentiality of the subjects and ensure that the proposed work fulfilled the requirements for Research Governance as detailed in the Research Governance Framework for Health and Community Care (SEHD, 2001). To achieve these requirements, detailed study information sheets and consent forms were developed and circulated to all potential study participants prior to their agreement to assist with the study (**Appendix IV and V**).

Figure 5.4 Members of the European Transplant Co-ordinators Organisation

Contacted in initial Survey

Austria	Latvia
Belgium	Moldova
Czech Republic	Portugal
Denmark	Poland
Finland	Romania
France	Slovenia
Germany	Spain
Georgia	Sweden
Greece	Switzerland
Israel	Turkey
Italy	United Kingdom

Figure 5.5 Initial Introductory letter To European Transplant Co-ordinators

School of Acute and Continuing care Nursing
St. John's Hospital
Livingston
West Lothian
EH 54 6PP

0044 1506 422823
b.neades@napier.ac.uk

Date
Name
Address of Transplant Co-ordinator
As Listed on Website

Dear Mr / Ms. ,

Re : PhD Study in Presumed Consent Legislation in Organ Donation

Further to my initial introductory email regarding my research I am now in a position to provide you with more details of my intended study and I therefore enclose a copy of my research proposal and my C.V.

Within the details of the study you will see that in the first phase, I developed a questionnaire with which to survey the staff who work within transplant settings exploring their education of presumed consent legislation and their views and implementation of this approach to organ donation. The next phase of the work would involve interviewing selected staff and explore their views further, exploring the benefits to them of organ donation using this approach. The study itself will be supervised by a team of PhD University supervisors and subject to ethical approval. To attempt to achieve this I will require to know the following:

1. If your area is agreeable to assist with this study
2. The procedure for being granted permission to undertake this study in your country
3. The number of organ transplants undertaken per year in your area
4. The numbers of staff within your area who may be amenable to join the study

If you have any concerns or wish to find out more about my study I would be very happy to supply this to you.

I look forward to hearing from you in the near future.

Yours sincerely,

Barbara Neades
Senior Lecturer

**Figure 5.6 Responses of Initial Descriptive Survey of European Countries
with Access to Presumed Consent Legislation**

European Country	Feedback to Request for Details of Current Application of Legislation
Belgium	Presumed Consent Legislation in force since 1986 applicable to all Belgium citizens and any foreign resident of Belgium of more than six months. Individuals intention to object to organ donation, can be done in writing using an easily obtained form that when completed will be added to a National Electronic Register of those who object. 2% of the 10 million population of Belgium have registered either their intention to donate organs or objection to organ donation using this method. 98% of the population have as yet failed to register their views either for or against organ donation Authorities are unable to give an accurate view as to whether they are in favour of organ donation via this method or not. A recent health survey of three generations of the public (Roles et al, 1996) indicated that 64% of those surveyed did know about the presumed consent legislation in organ donation. The law requires that the surgeon establish that there is no known objection to organ donation before proceeding to procurement. To do this he / she must approach the relatives to enquire if there is any expressed objection to donation.
Portugal	Presumed Consent Legislation since 1993. RENNDA, a register of a variety of health care information on all Portuguese Citizens contains an element where the individual can object to organ donation. If they do not utilise this facility then they will automatically become an organ donor should the correct conditions apply. The individual can also announce their objection to organ donation verbally prior to their death, which will be respected.
Spain	Legislation since 1979 allowing consent to organ donation. Family always approached and asked to confirm the deceased wishes and can also object to organ donation. If so, donation will not proceed. In transplant co-ordinator view legislation not applied fully. New organ donation infrastructure introduced to support organ donation with many more transplant co-ordinators introduced into critical care settings. Chief role of transplant co-ordinators is the education and support of critical care staff to identify potential donors and of bereaved family.
Norway	Presumed Consent Legislation since 1973. The legislation requires next of kin of the deceased to inform the staff of the deceased's views on organ donation. If the family does not agree then organ donation does not proceed as it is viewed that the family can best represent the wishes of the deceased.
Sweden	Position same as that of Norway. National Register established to allow the population to register their intention to donate or not to object to donation. Only 1.5 million of 9 million population as yet registered their views either for or against organ donation.
Switzerland	Mixed picture with regard to organ donation legislation. Switzerland has 26 regions of government called cantons. Of these 7 have no legislation with regard to organ donation, 8 have legislation which requires written consent from the deceased for organ donation and 16 have presumed consent legislation in organ donation. Reports however suggest that this presumed consent legislation has never been enacted to procure organs for transplant. No explanation has been provided as to why this is so other than that the views of the HCPs involved are against the use of this legislation. New national legislation for Switzerland based on the requirement of informed consent of the deceased prior to any procurement of organs for transplant has been passed.
Italy	Presumed Consent legislation since 1999 however, a National Register of Objectors has still to be established. Currently if the deceased has not provided written evidence of their intention to donate, the family is approached and a request for organ donation is made.

5.9 Phase 2 Introduction and Site Preparation in Each Country

Phase 2 of the study involved the preparation of each site in the three countries to undertake the study, the identification of suitable research participants for the study, together with the recruitment of these HCPs to the study. This was then followed by an initial survey of HCPs within intensive care and emergency settings using questionnaires to identifying their direct experiences in relation to organ donation and therefore the suitability of participants for interview. Details of the research process in this phase will be given under these headings, namely:

- **Study Introduction to the Three Countries**
- **Final Identification of Study Sites & Research Participants**
- **Initial Data Gathering Using Questionnaires**

5.9.1 Study Introduction to the Three Countries

To facilitate the next phase that involved the identification of suitable research subjects and distribution of the self report questionnaires (**Appendix VI**), the researcher organised briefing meetings with the transplant co-ordinators and other key professionals involved in organ donation in each country to inform them of the research parameters and clarify the procedure for study. The researcher met with the Transplant co-ordinators at all sites to:

- identify key staff directly involved in organ donation in their countries
- pilot the questionnaires
- explore how to distribute these questionnaires
- explore the collection of the subsequent data
- discuss how this was to be managed to maintain confidentiality.

This required researcher visits to the sites in Portugal, Norway and Belgium, allowing meetings with the transplant co-ordinator in each country and in depth discussion of the study with this key link person. It also allowed the researcher to become familiar with the organ donation network in each country, identifying a distribution system for the questionnaire. During these visits, the researcher had an opportunity to discuss the questionnaire in more detail and undertake a small pilot of the questionnaire with the transplant co-ordination teams. Their feedback in regard to the wording and structure of the questionnaire was utilised in the final version of the questionnaires. These visits also allowed the researcher to explore the ability of the HCPs in each country to understand the questionnaire in English and potential language barriers that these professionals may have had in responding to the questionnaires. These visits identified that although, the majority of medical staff in all three countries were able to understand and communicate in English, for some of the nursing staff this presented a challenge. Using this information from these visits it became clear that in order for the questionnaires to be understood, they would require to be translated into all four languages of the countries, Portuguese, Norwegian, French and Flemish. The visits also demonstrated the need for the researcher to organise translation of any returned questionnaires into English in order to be understood and utilised.

As the researcher's home University did not have access to translation services, assistance was sought and obtained from the language department of another local University. On receipt by the researcher of the completed questionnaire from the HCPs in the respective study sites, these questionnaires had to be again translated back into English for the researcher to be able to utilise this data. Aware of the challenges of minimising the individual variances in interpretation by individual

translators and in order to maintain quality control of the data, each translation was reviewed by two translators from the University language department before being returned to the researcher for utilisation. The confidentiality of this data was maintained throughout this process. This was achieved by the researcher meeting directly with the translators prior to their undertaking any translation, discussing the study and agreeing a strategy to maintain the security of the data. On translation of the completed questionnaires the researcher again met directly with the translators to receive the data personally. As employees of their respective universities, both the researcher and the translators were bound by their University codes of practice in relation to confidentiality and data protection.

Having been translated into the appropriate language for each of the three countries, the initial questionnaire (**Appendix VI**) and information sheet together with a consent form (**Appendix IV, V**) were distributed to HCPs, identified by the senior transplant co-ordinator within the country, as being involved in the procurement of organs for transplant. In each country discussions between the transplant co-ordinator and the researcher established which units were directly involved in organ donation and where the staff most likely to be in a position to assist with the study were located.

During these meetings a system of access to these HCPs was agreed together with a method of distributing the questionnaires and accompanying information and consent form. The information sheet provided the potential study participant with essential information pertaining to the study and the researcher, together with an invitation to participate in the next phase of the study i.e. the interview phase. In addition to providing an ability to select a suitable group of HCPs from each

country for interview, information from the questionnaires was also utilised to develop semi-structured interview schedules used in phase 3. The number of questionnaires distributed in each country depended on the agreement to participate from individual units and the numbers of staff identified by the transplant co-ordinator involved in organ donation within their respective country who would have a high possibility of direct experience of organ donation.

5.9.2 Final Identification of Study Sites & Research Participants

In addition to the introduction of the study to each country, the site visits by the researcher allowed further data regarding the organ donation system in each country to be developed, with the final identification of suitable study sites and HCPs most able to address the aims of the study and eligible to participate in Portugal, Norway and Belgium. Having gained the appropriate permission from the authorities in these three countries, recruitment and selection of research subjects from the following 3 groups was undertaken:

5.10 Group 1 European Healthcare Professionals with Access to Presumed Consent Legislation and Utilise the Legislation: Portugal

5.10.1 Research Study Sites Portugal

Site I Hospital de S J Porto

There were 2 sites selected in Portugal. The Hospital de S J Porto, a 1400 bed university teaching hospital and medical school in northern Portugal, serving a population of 800,000 people was the central base for the study in Portugal. This facility acts as a specialist tertiary referral centre for a wide range of medical specialities for the population of 2,000,000 within the region. The hospital is one

of the 5 regional organ donation and transplant hospitals throughout Portugal. It has a 10-year history of organ donation with the present 4-person organ donation team being together for 7-8 years. This regional organ donation team is linked to the national organ donation programme in Portugal, RENNDA. This hospital provided approximately 100 organs per year to the transplant programme. Some of these are utilised locally but others are offered to the national programme for use.

Site II P H Hospital Matosinhos, Porto

HCPs from the ITU in another major teaching hospital in Matosinhos near Porto were recruited. This 550 bed hospital is one mile to the north west of Porto collaborating with the S. J. Hospital in identifying organs for donation and also forms part of the national network of smaller hospitals which collaborate to form the organ donation and transplant system in Portugal. This hospital is a major trauma hospital and has four ITU units including trauma and paediatrics producing an average of 5 organ donors per year.

5.11 Group 2 European Health Care Professionals with Access to Presumed Consent Legislation not using this Legislation in full: Norway

5.11.1 Research Study Sites in Norway

Site I R hospital in Oslo

This hospital in Oslo is the national transplant centre in Norway where all organ donation transplants are undertaken. In addition, this hospital provides the clinical base and teaching base for the 5 national transplant co-ordinators for all of Norway. This university teaching hospital opened in 2000 and has approximately

540 beds. This hospital services the local population of Oslo, a capital city, with a population of approximately 509,000. In addition to providing healthcare services for the local population, and a regional centre for a large number of other specialist services

Site II U Hospital Oslo : Regional Specialist Centre for South East Norway

U Hospital is the second large university teaching hospital in Oslo with 1000 beds which provides the trauma, maternity, paediatric, including intensive care and emergency services for South East Norway. As such this hospital cares for many patients who subsequently develop brain death and are considered as organ donors.

Site III St O Hospital Mid Norway

St O Hospital is a large teaching hospital with 1600 beds that provides a full range of surgical, trauma, obstetric and paediatric service for mid and west Norway. This hospital therefore cares for many patients who subsequently develop brain death and are considered as organ donors. On the diagnosis and identification of a donor, the organ transplant team travel to this hospital from their base in Oslo to undertake final assessment of the donor suitability and undertake organ retrieval.

Site IV T Hospital South East Norway

This is a 350 bed district general hospital that provides a wide range of general surgical, medical, psychiatric, paediatric and intensive care services to the people of Tonsberg and surrounding district in the south east of Norway. This hospital participates in the national organ donation program, identifying patients within their ITU who develop brain death and are potential organ donors. When this

occurs, HCPs notify the organ transplant co-ordinators in Oslo of the potential donor and assess the patient for brain death. On the confirmation of this diagnosis and agreement of the next of kin, the organ transplant team travel to this hospital from their base in Oslo to undertake final assessment of the donor suitability and undertake organ retrieval.

Site V M Hospital Mid West Norway

This is a 180 bed University clinic is on the west coast of Norway. It provides a wide range of general surgical, medical, psychiatric, paediatric and intensive care services to the people of Molde and surrounding district in the mid West of Norway and participates in the national organ donation program, identifying patients within their ITU that develop brain death who are potential organ donors.

Site VI F Hospital South East Norway

This is a 350 bed district general hospital that provides a wide range of general surgical, medical, psychiatric, paediatric and intensive care services to the people of Fredrikstad and surrounding district in the far south east of Norway. This hospital participates in the national organ donation program, identifying patients within their ITU that develop brain death and are potential organ donors.

5.12 Group 3 European Health Care Professionals who utilise Presumed Consent Legislation and Bi Lingual Population: Belgium

5.12.1 Research Study Sites in Belgium

Site I CUL Clinic of St. L Brussels Belgium

This hospital of 950 beds is a regional University medical school providing many specialist referral centres for the region including the regional transplant centre and a base for the three regional transplant co-ordinators. The hospital has 7 Intensive Care Units; 3 cardiac, 1 paediatric and 3 general medical surgical or trauma intensive care units.

Site II CHR W Boussu Belgium

This is a small district general hospital in the Mons region of Belgium that has an intensive care unit and works in partnership with the university hospital to identify organ donors.

Site III CU De MG Belgium

This is another small district general hospital in the Yvoir region of Belgium that has an intensive care unit and also works in partnership with the university hospital to identify organ donors.

Site IV U H Leuven

This is a 2000 bed level 1 trauma centre and specialist referral centre for all specialities including paediatrics, maternity, neurology, neurosurgery and cardiac situated 20 miles north west of Brussels. It is the lead transplant centre within the region servicing 35 donor hospitals. Over 100 transplants are conducted every

year including cardiac, liver, bowel, lungs, and renal. Within this hospital there are 120 ITU beds to support this wide range of specialist transplant activity. There are 4 transplant co-ordinators employed here to support this hospital and the 35 other donor hospitals. This group have developed their own advanced data base to automate all of the documentation required for transplant activity and the screening of potential donors within Belgium facilitating efficient communication with Eurotransplant, the European transplant co-ordination organisation, thus allowing more time for co-ordinators to support the donor hospital staff and the relatives during a transplantation event.

In the event of a potential donor being identified the co-ordinators do not always go personally to the donor site but support the local staff via telephone or email contact. They also supply standardised organ donation documentation, enabling effective communication of the donor status to transplant centres across Belgium and Europe if organs are to be utilised. A member of this transplant co-ordinator team will however visit donor sites with the transplant team for organ retrieval and make a request to relatives if required to do so by the donor site team.

Sites V R Hospital & Site VI and A Hospital

In addition to the units within the University hospital of Leuven taking part in the study: HCPs within two small donor hospitals within the region were also recruited to join the study at R Hospital and A Hospital. These hospitals are found respectively in the east and west Flanders region of Belgium. These two 350 bed district general hospitals are part of the network of donor hospitals across Belgium contributing to the organ donation programme. They each produce approximately 5 – 10 organ donors per year and have developed very advanced systems for the

support of families in the crisis that results from a family member being admitted to the Emergency Room and Intensive Care Unit, suffering brain death and who is then considered as a potential organ donor. The specially prepared nurse team that supports this initiative have been prepared as nurse counsellors who can provide the relatives with clinical and ethical advice in relation to organ donation. This specialist team has also developed very advanced education programmes to prepare staff in the organ donation situation to care for the family physically and psychologically during this process.

5.13 Initial Data Gathering Using Questionnaires

The questionnaires distributed on behalf of the researcher to the intensive care, the emergency and high dependency units of the hospitals recruited to the study by the transplant co-ordinators. These units were identified by these co-ordinators as being units that participated in the organ donation programme in their country and therefore the HCPs with most experience in organ donation were to be found.

This was considered to be the most effective and economical means of obtaining initial data from the numbers of sample subjects who were spread over a large geographical distance. This questionnaire was returned to the researcher via an international pre-paid envelope. **Table 5.1** summaries the distribution of the questionnaires across the three countries:

Table 5.1 Distribution of Questionnaires in Three Countries

	Portugal	Norway	Belgium French Speaking	Belgium Flemish Speaking
Questionnaires Sent	300	450	70	53
Number of sites	2	6	3	3
Site Codes	P St.J , PM	NR, N St.O, N M, NUN, NUNP, NF, NT	B Bru.	B Lev.

5.14 Phase 3 Planning and Undertaking the Interviews with Healthcare Professionals

All of the interviews with the HCPs who had agreed to be interviewed were planned in advance either by email a month in advance of the field visit, or by telephone call on arrival in the respective country. In order to accommodate the interviewee's work commitments, these interviews that normally lasted 45 minutes to one hour, taking place either in a small quiet room within the HCP's practice setting or occasionally within a room in the transplant co-ordinator's department. The semi-structured interview schedule (**Appendix X**) was constructed using a phenomenological approach to interviewing identified by Patton (1990) and Van Manen (1990). Applying this approach a semi-structured interview format is developed that uses a series of opening questions that are "in the right region" related to important experience of the participant to develop the narrative. These narratives are then developed by the researcher using a series of verbal or non-verbal probes to enhance the participant's description of the lived experience, when the response does not seem clear, complete or relevant to the original question posed by the researcher.

Normally the only people present were the interviewee and the researcher. The exceptions to this were those interviews that required the presence of an interpreter to support the interview. The nursing professionals in all three countries appeared very comfortable with the concept of being interviewed in relation to their experiences in relation to organ donation. Many spoke very freely in response to the researcher's open questions, requiring very little assistance to respond to the questions posed. Some medical staff however, although they had

consented to the process, appeared at times uneasy with being interviewed in regard to this topic. In some of these interviews these medical professionals required the use of more directive questioning by the researcher in order for their experiences to be revealed. Throughout the interviews the researcher augmented the taping of the interview with supplementary notes. At the end of each interview notes were made by the researcher using a structure designed by Loft & Loft (1994), to capture these experiences and the researcher's reflections on the interactions.

5.15 Researcher Reflexivity

At the outset of the study the researcher had informed the study participants of her emergency and intensive care nursing background together with her experience in nurse education within the study information sheet. Before the commencement of each interview, the researcher introduced herself to the participant using a pre-determined brief reminder of the background to the study. There is little doubt that the researcher with a background in emergency care and intensive care had previous experience in organ donation events and, as such, had in Gadamer's (1976) view "prejudices" and "pre-conceptions" of these events. During the interviews however, the researcher attempted to minimise any impact that these previous experiences might have on the responses of the participants, by trying wherever possible, to remain neutral to the responses provided to the questions. Occasionally this was however challenging but her previous experience and understanding of the participant's clinical practice became very useful in assisting the interviewee to clarify some of the more technical aspects of their practice that they were attempting to describe. Within the interview transcripts the opening questions and the probing questions used by the researcher to enhance the

participant's response was identified clearly within the texts. Throughout this process the "prejudices", "pre-conceptions" and involvement of the researcher in the formation of the interview data was captured in detailed field notes. This assisted the researcher to reflect on her own involvement in the data formation, identify where her personal bias may have influenced the participant responses and allowed her to use this information in the data analysis phase of the study to support and validate future interpretation of the data.

5.16 Identifying and Obtaining Independent Translation Services in Europe

The ethos of the study was to capture the experiences and opinions of the HCPs in the three European countries in relation to the application of presumed consent in organ donation with phase 2 of the study inviting identified volunteer staff to be interviewed by the researcher. In order to allow these key personnel to communicate freely, those volunteers who had agreed to be interviewed had been invited to indicate if they were happy to be interviewed by the researcher in English, or if they wished, the services of an independent interpreter for the duration of the interview. Within Norway all of the interviewees indicated that their English language skills were such that they were happy to conduct the interview with the researcher in English and these interviews progressed satisfactorily without the services of a translator.

On arrival in Norway however it became clear that communications with the hospital switchboards in the hospitals across Norway where the interviewees were based was a challenge, as although they spoke English to a reasonable level, the hospital telephonists were not familiar with the researchers Scottish accent. This proved a difficulty and the assistance of the lead transplant co-ordinator was obtained to contact all of the interviewees by telephone within their hospital

bases, arranging suitable times for the interview. As all of the interviewees had a very good command of the English language, all of the interviews in Norway were conducted in English without the requirement of an interpreter.

The interviews with the HCPs conducted within Portugal were more complex with 7 of the interviewees happy to conduct the interview without the services of an interpreter, however the other 8 requiring the support of an interpreter. To allow these interviews to progress, the researcher had also to seek and obtain the services of an interpreter in Portugal. The British Consulate in Portugal provided the researcher with a copy of their accredited interpreter list and contact was made with those near to the study sites in Portugal via email communication. On arrival in Portugal the researcher briefed the interpreter explaining and planning the interviews. The sensitivity of the data generated from the interviews and need for the confidentiality of this data to be maintained by the interpreter was also established. It was established however that as an employee of a local University who was also frequently employed by the British Consulate, the interpreter fully understood these concepts and was bound by contractual agreements to uphold these.

Very quickly, the challenge of the researcher's ability to be understood by the hospital telephone operator staff sufficiently to contact the interviewees personally by telephone arose again. Fortunately, the interpreter and in some cases the lead transplant co-ordinator at the study site assisted in contacting the interviewees by phone and arranging a suitable time and location to undertake the interview. For those who required the services of the interpreter, in some cases across the two hospital sites of the study, complex arrangements had to be made that allowed the interviewee, the interpreter and the researcher to be available to

conduct the interview. Challenges did arise when conducting interviews utilising an interpreter. One of these was the need to carefully manage the interview by the researcher as the enthusiasm of the interviewees to provide responses to the questions, at times prevented the interpreter from providing an adequate translation of their response that could be captured on tape. To achieve the capture of their response clearly via the interpreter, the researcher had to agree a system with the interviewees of allowing the interpreter to translate their response clearly, before the interviewee added any further comments in support of his or her response to questions posed by the researcher. This did allow the translation of the interviewee's responses by the interpreter to be recorded during these interviews.

Another challenge was the need to ensure that the questions being posed by the researcher via the interpreter were those being answered by the interviewee. It became clear during these interviews that the majority of the interviewees who, whilst not wishing to conduct the interview in English, did have a good understanding of English and offered to clarify any misunderstanding of their responses as translated by the interpreter. The researcher acknowledged that her inability to communicate directly with the interviewee in their own language and the subsequent utilisation of the interpreter during the interviews may have resulted in misunderstanding of the questions by the interpreter and therefore potentially different questions being asked of the interviewee. However, the interviewee's ability to at least understand English, even if not fluent, did provide assurance that they understood what was being asked and that their responses via the interpreter in English were accurate.

In Belgium where both the French and Flemish language is spoken in different sectors of the country the researcher had organised access to an interpreter to

support the interviews if required. On arrival in Belgium to plan the interviews it became clear that the use of an interpreter was not going to be required. The researcher initial telephone contact to the HCPs from the Senior Transplant coordinator's office to plan the interviews, demonstrated that these HCPs had a very reasonable command of the English language, in addition to the French and Flemish languages that they utilised in the care of patients in Belgium. This was confirmed when undertaking the interviews, with only one interviewee demonstrating any difficulties in conducting the interview in English. This difficulty centred on the interviewee's ability to understand the researcher's Scottish accent. However the researcher's adoption of a more formal and slower speech pattern facilitated the interviewee's understanding of the questions being posed during the interview.

5.17 Transcribing The Taped Interviews

All the interviews were recorded using a small tape recorder and microphone, with the expressed permission of the interviewee and were reviewed by the researcher using support notes taken during the interviews and then transcribed for the researcher by a typist. The Norwegian tapes were transcribed with relative ease by the typist with only minimal corrections required by the researcher on re-listening to the tapes. Unfortunately however, it became clear that despite being an experienced typist and utilising an appropriate transcription machine, the typist was unfamiliar with the Portuguese accent and some of the tapes presented major difficulties to her understanding of the interviewee's narratives within the tapes. To resolve this difficulty, the researcher had to listen to these tapes and re-dictate the interview in its entirety for the typist to transcribe the interviews. Again after transcription the researcher listened to the tapes again in an effort to clarify any recordings not understood by the typist.

5.18 Verification of Data

To ensure the accuracy of the data, prior to the use of any data obtained from these interviews all of the transcribed interview data were returned to the individual interviewees for verification. Each interviewee was invited, if they wished to do so, to review the data within the transcriptions amending any of the content that they felt was inaccurately recorded. Using this process the information obtained within the course of the interviews was verified as being accurate by 31 of the 42 interviewees. The remaining 11 interviewees were also invited to read their transcripts and verify the information contained within the transcriptions but chose not to do this.

The use of email proved very efficient in the ability to access the individual interviewees with return of the reviewed transcripts in one week but contact with interviewees utilising postal services was less efficient, taking up to 4 weeks for the return of the amended transcriptions to the researcher. Again the interviewees' ability to respond adequately to this request to review the transcriptions depended on the ability of the interviewee to read English or access translation services.

Fortunately free of charge, the interpreter who supported the interviews in Portugal offered to assist any of the Portuguese interviewees who had problems understanding the English translations. When the transcriptions were returned to the researcher by the individual interviewees it was noted by the researcher that very little of the content of the transcripts had been altered. Some issues discussed in the course of the interviews were further clarified by the interviewee and any further detailed explanation of these were added to the transcripts, however the main concern of the interviewees appeared to be their need to correct what they

saw as their poor usage of English grammar during the interviews. Using this process reassured the researcher that the data captured within the interviews was as accurate.

5.19 Phase 4 Coding of Data and Analysis with Interpretation in Relation to Literature

Using a phenomenological approach to data analysis all of the data from the questionnaires and interviews was read several times by the researcher to identify the key issues and concepts being expressed by the participants to describe their “lived experience” of the application of presumed consent legislation in their particular country. These descriptions yielded a number of similar key themes and responses of the participants, with the key theme assigned a code utilising QSR Nvivo computerised data management programme (Copyright QSR, 2002). Initially 52 codes arose from the data contained within the text responses to the questionnaires and the transcripts of the interviews undertaken. These codes were identified from key words of phrases in responses by the participants by the respondents to the questions posed either within the questionnaires (**Appendix VI**) or the discussions that occurred within the semi-structured interview (**Appendix X**). These codes were subsequently reviewed by the researcher and were resolved to form 32 codes presented in **Figure 5.7**.

Figure 5.7: Coding of Responses

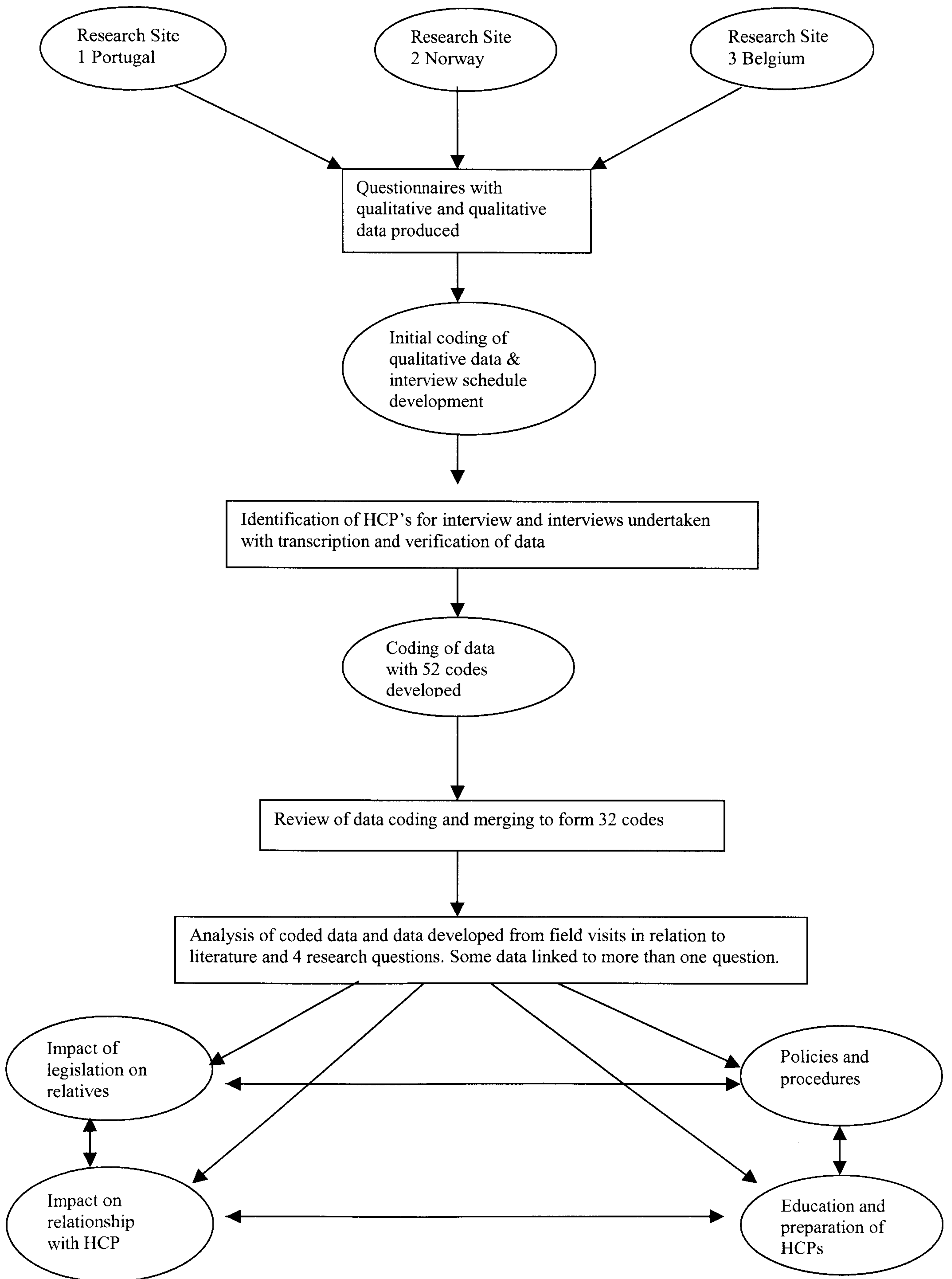
1	General Benefits of Organ Donation	⇒	1	Overall Benefits of Organ Donation System
2	Societal Benefits of Organ Donation	⇒	2	Identification of Donors by Staff
3	Confirmation of Death, Cerebral Angiography	⇒	3	Consent
4	Types of Donor, Identification of Donor by Staff	⇒	4	Autopsy
5	Consent by Deceased	⇒	5	Ownership of Organs
6	Consent of Relative or Next of Kin	⇒	6	Relatives Response
7	Autopsy	⇒	7	Impact of Culture and Religion
8	Ownership of Organs	⇒	8	Staff Role in Organ Donation
9	Relatives Response	⇒	9	Policies and Practices in Organ Donation
10	Impact of Culture and Religion	⇒	10	HLA Typing
11	Staff Role in Organ Donation	⇒	11	Staff Education and Preparation for Role
12	Policies and Practices in Organ Donation	⇒	12	Public Knowledge of Organ Donation Law
13	HLA Typing	⇒	13	Financial Impact of Organ Donation Law and Practices
14	Staff Education in Organ Donation Practices	⇒	14	Ethical and Professional Conflicts in Organ Donation
15	Staff Preparation for Role in Organ Donation	⇒	15	Society's Response to Organ Donation
16	Public Knowledge of Law	⇒	16	Support for Staff
17	Public Education of the Law in Organ Donation	⇒	17	Impact of Organ Donation Practices
18	Financial Impact of Organ Donation Law and Practices	⇒	18	Relatives Involvement in Organ Donation
19	Ethical Aspects of Organ Donation	⇒	19	Trust in Health Care Professionals
20	Ethical and Professional Conflicts	⇒	20	Staff Key Messages in Organ Donation
21	Society's Knowledge of Organ Donation Policies and Practices	⇒	21	Staff Knowledge of the Law
22	Society's Perceptions of Organ Donation	⇒	22	Gift Concept
23	Overall General Perceptions of Organ Donation	⇒	23	Non Heart Beating Donors
24	Support for Staff	⇒	24	Impact of Extreme Presumed Consent Legislation
25	Impact of Organ Donation Practices	⇒	25	Staff Team Communication
26	Relatives Involvement in Organ Donation	⇒	26	Respect for the Wishes of the Deceased
27	Trust in Health Care Professionals	⇒	27	Protection of the Incapacitated
28	Staff Key messages in Organ Donation	⇒	28	Request to Relatives
29	Staff Education in Relation to Organ Donation Legislation	⇒	29	General Levels of Education in Society
30	Staff Awareness of Legislation in Organ Donation	⇒	30	Support of the Family
31	Gift Concept	⇒	31	Overall Benefits of Organ Donation
32	Non Heart Beating Donors	⇒	32	Overall Challenges of Organ Donation System
33	Impact of Extreme Presumed Consent Legislation	⇒		
34	Staff Team Communication	⇒		
35	Respect for the wishes of the Deceased	⇒		
36	Respect for the wishes of the Family	⇒		
37	Protection of the Incapacitated	⇒		
38	Request to Relatives	⇒		
39	General Levels of Education in Society	⇒		
40	Support of the Family	⇒		
41	Overall Benefits of Organ Donation System	⇒		
42	Overall Challenges of Organ Donation System	⇒		

These codes were then analysed by the researcher to identify the key themes that emerged from the data relating to the 4 main areas of investigation of this study:

- **the impact of the implementation of presumed consent legislation on the bereaved relatives of the donors using this system**
- **the healthcare professional's perception of the impact of presumed consent upon the trusting relationship with the organ donor families.**
- **the provision of specialist procedures / policies and resources to enable this to be implemented effectively to the benefit of relatives and staff**
- **the provision of specialist education or preparation for the staff who utilise this legislation**

A summary of this coding process and the identification of the key themes can be found in **Figure 5.8**. These themes were explored again in relation to the data contained within the questionnaire responses and interview transcripts to ensure the trustworthiness of these themes. Evaluation of the possible relevance of themes and responses in relation to the literature was undertaken with the responses of the three study groups responses compared and contrasted. In addition, utilising the approach to academic rigor required for a study of this type suggested by Koch (1994), field notes also made by the researcher during this data-gathering phase were analysed. These notes which contained the researcher experiences, issues, access, and prejudices were recorded as a useful journal of events with which to reflect on the data gathered and justify decision making, were explored to provide possible further insights to the basis for the responses provided by the interviewee to the questions posed by the researcher.

Figure 5.8 Process For Coding Findings



Summary

This chapter reviewed different approaches to qualitative research identifying hermeneutic phenomenology first identified by Heidegger (1962), as the most appropriate qualitative research approach to address the study aims. Additionally, frameworks for hermeneutic phenomenology identified by Gadamer (1976), Colaizzi (1987) and Popay et al., (1998) were selected with which to structure, analyse and evaluate the data developed from the research. A detailed account of the research process adopted to apply a Heideggerian (1962) approach to the phenomenological study undertaken was presented. Within this description the four phases of the work have been explained, together with the rationale and process undertaken for the selection of the research sites and the research subjects. Additionally, the procedures undertaken to achieve ethical permission for the study have been described together with the strategy adopted for the collection of the data, collation of this data and its subsequent analysis. The following three chapters 6, 7 and 8 will present the findings of the work describing the practical adaptation and application of hermeneutic phenomenological theories to the study undertaken.

Chapter 6 Findings from Transplant Correspondence and Field Work

6.0 Introduction

This chapter will describe the findings of the data relating to organ donation gathered either from correspondence with transplant co-ordinators within the research sites in Portugal, Norway and Belgium, or obtained during field work undertaken by the researcher. This information will be presented under the following headings:

- **Organ Donation Legislation**
- **Cultural and Religious Underpinnings**
- **Organisation of Organ Donation and Transplant**
- **Application of Presumed Consent Legislation**
- **Organ Sharing System**
- **Funding of National Organ Donation System**
- **Education Programmes for Staff**

6.1 Portugal

6.1.1 Organ Donation Legislation in Portugal

The current presumed consent organ donation legislation in Portugal was established in 1984 and preceded by a national media campaign to inform the public of the details of this legislation. Under the Republic Assembly Law Nr. 12/93 (**Appendix VII**) all residents of Portugal are subject to this legislation if they are Portuguese nationals or reside in the country for more than two years:

Article 2

- 1- The present law is applicable to the national citizens and stateless persons resident in Portugal.*
- 2- To the foreigners occasionally in Portugal, the jurisdiction of regime of the acts in nr.1 from article 1.*

This legislation requires that all residents of Portugal who have an objection to becoming an organ donor must register this objection and should carry a card notifying the authorities of this objection.

Article 10

- 1- All Portuguese citizens, foreigners and stateless persons living in Portugal who have not demonstrated their intention to be a non-donor are considered as potential donors at post mortem.*
- 2- When the objection to the donation is limited to certain organs or tissues or certain aims, these restrictions must be expressed clearly within the registry or within a non-donor card.*
- 3- The objection to the donation of organs of minors and those with incapacity together with those from minors with the ability to understand and express free will, must be registered, by their respective legal representatives.*

6.1.2 Cultural and Religious Underpinnings within Portugal

Portugal has a population of 10.3 million people where Christianity has been the main religious force underpinning the country's history, with 95% of the population adhering to the Roman Catholic denomination. The remaining 5% of the population recognise other Christian denominations or follow other multi-cultural faiths such as the Jewish or Muslim faiths. Economic growth within Portugal and its membership of the European Community has attracted people of different religions and faiths to reside in Portugal, however the Roman Catholic faith is still powerful and highly respected by the population and the government.

6.1.3 Application of Presumed Consent Legislation in Portugal

6.1.3.1 National Organ Non -Donor Register

Within this legislation there is a requirement for the health authorities to establish and maintain a national computerised register of non- donors:

Article 11

- 1. A national computerised register of non- donors (RENNDA) will be created within the Ministry of Health, and available to all those who have demonstrated their wish to be a non-donor.*
- 2. The government is authorised following the opinion of the National Commission of the Protection of Personal Data, to oversee the organisation*

and the performance of RENNDA and the production of an individual card where the individual's non-donor status is expressed.

3. RENNDA must be regulated and begin its activities from 1st October 1993.

Using this system all adults are required to register their objection to organ donation by means of the completion of the appropriate form available at their local health centre. Failure to record an objection will result in their being considered as a potential organ donor. The individual can however access and amend any personal data recorded on this register.

To ensure that the public were made aware of the changes in the legislation on organ donation, **Article 15** of the Act also specified that the government held a responsibility to undertake a public information campaign with the aim of highlighting the changes in the law on organ donation and the establishment of the non-donor register. Currently only 0.4% of the population has recorded an objection to organ donation in this manner.

6.1.3.2 Relatives Involvement in Decision Making in Organ Donation as Determined by Legislation

Utilising this version of presumed consent legislation, the consent of the individual to donate is established via the absence of their name on the non-donation register. The legislation requires that the non-donor register is consulted by the transplant co-ordinator when an individual has been confirmed as brain dead and therefore is a potential organ donor. The legislation states no requirement for the relatives of the potential donor to be consulted regarding their knowledge of any objection by the deceased in life to the progression to organ donation, or indeed any objections that the family may hold to organ donation, except in the case where the potential donor is a minor or an adult who did not

possess the capacity to consent to organ donation prior to their death. In this circumstance **Article 8** of the Act referring to authorisation to proceed to organ donation requires that:

- 1- In the case of donors who are minors, permission to proceed to organ donation must be given by the parents and their parental powers should not be inhibited, or in the case of the inhibition of these powers, by the court.*
- 2- Tissue or organ donation of minors without the capacity to understand and without the ability to express free will also require the permission of those with parental powers or that of the court.*
- 3- The collection of organs in the elderly, the incapacitated or those with a psychiatric abnormality can only be authorised by the courts.*
- 4- Permission of the donor or of someone who represents him freely is revocable.*

6.1.3.3 Procedure for Organ Donation

When a potential donor is identified, and diagnosed as brain dead by two suitably trained doctors, independent of the transplant team, the national register of objection to organ donation is then consulted by the co-ordinator. Should the name of the potential donor not appear on the non-donor register then organ donation procedures are initiated by the co-ordinator. These co-ordinators are usually either the transplant surgeon or the cardiothoracic anaesthetist. This often entails the HCPs within the Intensive Care Unit caring for the brain dead patient making an initial approach to the family and informing them of the patient's condition, the legislation and the protocols for organ donation. The family are also informed that the review of the non-organ donor register has not produced any evidence that the deceased had registered an objection to the donation of their organs, together with the HCP's intention to proceed to organ donation.

Despite the lack of requirement within the legislation, the procedure adopted by the transplant co-ordinator or the HCP caring for the donor is that the family is then asked if they personally hold any objections to the donation of their relative's organs for transplant. If the answer is negative then organ donation can proceed.

Routinely however, if the family raises an objection to the donation then the HCP will attempt to get them to reconsider and agree to organ donation. If this attempt fails, the staff will not proceed with the organ donation.

6.1.4 Organisation of Organ Donation and Transplant System in Portugal

Since the implementation of the 1983 legislation on organ donation and the establishment of the non-donor central registration system (RENNDA), Portugal has established an increasingly organised national organ donation and transplant system based on 5 regional organ donation and transplant centres to co-ordinate this activity throughout Portugal:

- Two major University donation and transplant hospitals provide services to the north of the country
- One major University hospital provides services to the central region of Portugal and is the centre for paediatric donation and transplant
- Two major University donation and transplant hospitals provide services to the south of the country

Using a decentralised system of organisation and communication these hospitals are supported by a wide network of smaller hospitals across Portugal who will identify potential organ donors within their intensive care or emergency departments. If a potential donor is identified within one of these smaller hospitals an organ retrieval team will be dispatched from one of the 5 regional hospitals to undertake the organ harvest, with the organs being taken to back to one of the 5 transplant centres where the organ transplant will be performed. Using this legislation and system of organ donation and transplant Portugal produces 22 donors per million population, one of the highest levels of organ for donation within Europe.

6.1.5 Organ Sharing System in Portugal

Using a national HLA typing and matching system for all donors with the patients on the organ transplant waiting lists, termed the Lusotransplant system, organs are shared nationally within Portugal. If a match for the organ is not found within Portugal the organ is offered to Eurotransplant and France Transplant to be utilised in Spain or France if an appropriate matched recipient can be identified there.

6.1.6 Funding of National Organ Donation and Transplant System Portugal

The health service within Portugal is a governmental funded public health system with the national computerised register of non-donors established and supported by department of health funding. In addition, the Department of Health funds the organ donation program across Portugal together with the funding for the network of tissue typing and screening centres across Portugal (Lusotransplant). Individual organ transplant co-ordinators are employed by the larger teaching hospitals who in addition to receiving funding from the government, may also be supported by funding from individual University medical academic departments.

6.1.7 Education Programmes for Staff in Portugal

HCPs receive information on organ donation and transplantation within their initial medical or nursing degree. Some staff subsequently undertake masters degree programmes in healthcare ethics in which the legal and ethical aspects of organ donation are discussed. These professionals also receive regular health department circulars regarding changes in practice including changes related to organ donation policies. Additionally, national seminars on ethical practice are

also held by both the medical and nursing professions, where organ donation is discussed frequently.

6.2 Norway

6.2.1 Organ Donation Legislation in Norway

Legislation introducing presumed consent legislation for organ donation has been in place in Norway since 1973. The details of this legislation are contained within The Regulation Regarding the Definition of Death in Relation to the Act Regarding Transplantation, Hospital Autopsies and the Donation of Bodies (Royal Norwegian Department of Health and Social Services, 1973). Subsequently, a Royal Resolution (Royal Norwegian Department of Health and Social Services, 1992) (**Appendix III**) updated the definition of death to support this law and prescribed the use of selective cerebral angiography, together with the criteria in the assessment of the cessation of intracranial circulation and the pronouncement of cerebral death. The legislation Chapter 1 Sub section 2 states that:

“Organs or other biological material may be removed, for the treatment of another person’s disease or injury, from a dead person who in writing or verbally has taken a decision to that effect. Even if such a decision has not been taken, the aforementioned procedure maybe performed on a person who dies in hospital or is brought in dead to the hospital, unless the deceased or his next of kin have expressed themselves against it, or there is reason to assume that the procedure would be in conflict with beliefs held by the deceased or the deceased’s next of kin or if other specific reasons contraindicate the procedure ”

Consent to organ donation after their death should normally be given by a person who is over 18 years of age; however in the case of a minor, then consent to organ donation can be given by their guardian or the person who has parental custody and is responsible for the care of the minor. Further guidance on the regulations for organ donation and consent were issued by the Norwegian Department of Health and Social Services (2004) indicating that consent to organ donation need not be required in writing for organ donation to proceed which states:

“Organs and other biological material may be removed from bodies of deceased persons who have given written or oral instructions to this effect prior to death for the purposes of treatment of disease or physical injury in other persons”.

The guidance also highlights the possibility of taking organs from the deceased even if he has not expressed a specific wish thus:

“Even if the decision has not been made, organs from the deceased can be removed from a person who dies in hospital or is brought to hospital, if the deceased or his next of kin had not opposed or if there is reason to believe that the procedure would have not opposed his or the next of kin’s belief or if other special reasons of contradiction” (do not exist).

This would suggest that organs can be obtained from the deceased once it has been established that they personally did not object to this course of action and that the next of kin raise no objection. However, as no register of objection to organ donation has been established, any objection of the deceased to this procedure must be established via a conversation between the HCP and the next of kin. In addition, under the terms of other legislation relating to patients rights, the next of kin should always receive information relating to the condition of their relative if this is permitted in the clinical situation. Paragraph 5.1 of this Act also states that the next of kin should have access to the medical notes of the deceased, thus emphasising the involvement of the next of kin in patient treatment and subsequent decision to proceed to organ donation in the event of the patient’s death.

6.2.2 Cultural and Religious Underpinnings within Norway

Norway with a population of 4.5 million is mainly composed of people from Nordic and Sami descent who are in the main are educated to a high level with a middle class standard of living. The population is in the main Christian in religious orientation with 83% of Norwegians belonging to the Church of Norway, an Evangelical-Lutheran faith the official religion of the state. Until

recently Norway has had a fairly static population with little immigration to the country. More recently economic migration to Norway has produced a more multiethnic and multicultural society with religious groupings from the Jewish, Muslim, Roman Catholic and other Christian faiths being represented within the population.

6.2.3 Application of Presumed Consent Legislation in Norway

6.2.3.1 Procedure for Organ Donation in Norway

Legislation in Norway is considered to be a weakened form of presumed consent legislation in organ donation (Michielsen, 1997). Here, no register of objectors has as yet been established as this requirement does not form part of the legislation. A view expressed by the transplant co-ordination team is that to undertake this would have a negative impact on donations, as seen in other countries in Europe. Instead the population increasingly is asked to record their intention to donate their organs and to carry an organ donor card.

6.2.3.2 Relatives Involvement in Decision making in Organ Donation as Determined by Legislation

In addition to the individuals agreement to be an organ donor, recorded on this card should be the names of two people they have informed of their intention to donate their organs. These are most often the names of the person's next of kin with whom they should have discussed their intention to donate their organs. This initiative has been launched by a voluntary organisation but is supported by the Department of Health in principle. In practice, in the event of the individual suffering brain death and becoming a potential donor, the HCP would access this card from the individual's personal effects and approach the next of kin to

confirm the individual's intention to donate their organs and in addition, ensure that the relatives do not object to organ donation.

Recently, a Norwegian Department of Health Circular (DHSS, 2004) was issued highlighting that the HCP must make every effort to contact the next of kin and inform them of the death and the intention to progress to organ donation. This new circular also provided guidance on what level of senior medical staff should undertake the approach to relatives, clarifying the level of experience and preparation that these senior doctors should have in order to undertake this request. Utilising this system during 2005, 313 organ transplants were undertaken in Norway. The DHSS (2004) guidance also attempts to clarify the position that should be adopted when there is no clear evidence of the deceased's intentions in regard to organ donation thus:

“Even if a decision has not been made organs from the deceased can be removed from a person, who dies in hospital or is brought to hospital, if the deceased or his next of kin has not opposed or if there is reason to believe that the procedure would have been opposed to his or the next of kin's belief or if other special reasons of contradiction”.

The original legislation also stated the need to approach the next of kin to establish the deceased's wishes on organ donation and ensure that they held no objection. However, the subsequent guidance of 2004 would suggest that the requirement to always do this before proceeding to organ donation, should be weighted against the possibility that this delay might result in the loss of the organs and should be avoided:

“It may happen that the next of kin is unknown or that it is impossible to contact the nearest relative, so that an absolute regulation to contact the family members may lead to the loss of organs for donation which may be viewed as being detrimental, especially when the deceased had given consent for organ donation to proceed”

It can be seen therefore that neither the law nor the regulations make it mandatory for the next of kin to be asked about organ donation. Review of the guidance

would therefore suggest that in the event of the HCP believing that there is no evidence by the deceased of their intention to donate, and if the next of kin cannot be contacted in reasonable time to save the organs from deterioration, then it would be acceptable to proceed to organ donation without the next of kin being able to raise an objection.

6.2.4 Organisation of Organ Donation and Transplant in Norway

Norway has had history of organised donor and organ transplant services stretching back to 1969 since leading transplant surgeons and nephrologists first collaborated to develop an organ donation system. As a result a national alliance of hospitals across Norway was formed to support the identification and donation of organs and the transportation of these to national transplant centre based in Oslo. Following this agreement the donation of organs for transplant was organised into 5 decentralised regional donation centres across Norway:

- South East Norway
- Mid Norway
- West Norway
- Northern Norway
- South West Norway & National Co-ordination Centre

Hospitals in these regions collaborate in this alliance to identify the patients who are diagnosed as being brain dead and therefore have the potential to become an organ donor. In March 2003, to increase the numbers of organs for donation, an additional 28 donor hospitals were identified nationally across Norway. Within these hospitals a key doctor has been designated as the “Donor Responsible Doctor”, this person having responsibility for achieving donor organs for transplant. Donor hospital status is gained in Norway by application to the King (Department of Health and Social Services, 1973). In order to achieve this status,

the hospital must demonstrate that they have adequate numbers of senior medical staff experienced in organ donation, adequate intensive care and specific radiology facilities to manage this role. These specific radiological facilities must include the ability to undertake cerebral angiography, a neuro-radiological test to examine blood flow in the brain using contrast dye (Sullivan et al., 1999). This is essential, as within the regulations of the Norwegian organ donation legislation, cranial angiography must be utilised by the medical staff to establish brain death in the potential donor. According to these regulations a negative result must be obtained demonstrating that no cerebral circulation remains in the patient's brain, before death can be confirmed with the subsequent production of specific type of death certificate, legally allowing the patient to be recognised as an organ donor (Department of Social Services, 1973).

This system of facilitating the retrieval of organs from the deceased has proved to be relatively successful, in that utilising this system Norway has been able to produce on average 15 – 17.6 organs pmp (Hambro Alnes, 2003). This places Norway midway in the European rankings for organ donation using cadaver organs. Norway also has a very active live donation system in which blood relatives will donate an organ usually a kidney, achieving a leading position in the world rankings for organ donation using this system of 18.9 donors pmp (Hambro Alnes, 2003).

6.2.5 Organ Sharing Systems Across Scandinavia

Scandia transplant is an organ sharing system between Norway, Sweden, Finland, Denmark and Iceland (Iceland linked to system in Denmark). In this system there is a sharing of the details of the transplant waiting lists held within the individual

countries. In the event of the diagnosis of brain death the donor will undergo early screening and HLA typing and these results will be matched to all of the names contained within a combined list of names held in these countries. If the organ is not matched to a recipient on the waiting list within the donors' country of origin, then it is offered to the Scandia transplant system. The members of this collaborative give mandatory priority for any patient with acute organ failure. These patients utilise an urgent call system that gives priority of organs to an individual from across these countries for up to 3 days. If a country receives an organ from the Scandia system an agreement is made to have the exchange of an organ returned within a year.

6.2.6 Funding of National Organ Donation / Transplant System Norway

These national and regional organ donation and transplant systems supported by the Norwegian Department of Health include the establishment of 5 national transplant co-ordinators who are based in Oslo. Funding supports their communication with and transport to the network of 27 designated donor hospital across Norway. No financial benefits accrue for the individual hospitals in gaining this status with the Norwegian government requiring that each local health authority should identify money from within their health budget to further the cause of transplant initiatives. Local directors of hospitals have been contacted by the Department of Health to ensure that they are aware of this. Evidence suggests that as yet only 2 hospitals have been provided with additional funding to support their transplant activities. The Norwegian government also funds regular public education and information campaigns designed to raise the profile of organ donation within society. Other new initiatives designed to improve the numbers of organs donated in Norway include the appointment of a National Co-ordinator for

Transplantation to advise the Department of Health on the national organ donation and transplant strategy, ensuring implementation of this.

6.2.7 Education Programmes for Staff in Norway

Information obtained from the transplant co-ordinator team indicated that, in 1992, a specialist education programme was developed for HCPs within intensive care, anaesthetic, paediatric and operating departments to inform them of the key transplant and donation issues. This programme developed by the transplant co-ordinators is based on the European Donor Education Programme and was initially funded by the drug company Novartis. Funding for the delivery of this education programme is now provided centrally by the Norwegian Government. Additional government funding has also been provided to support the five transplant co-ordinator posts within the country. This two day course is provided four times per year across Norway with 25 HCPs attending each course, 50% of attendees being medical and 50% nursing staff. The content of this course includes:

- Specialist information on donation & transplant protocols and procedures
- Information on legislation and ethics of transplantation
- Relative support in donation situation
- Scenario work, role play, small group discussions

There is also specific input to all undergraduate medical and nursing programmes with at least two to three hours within these generic degree programmes designed to ensure that all medical and nursing graduates in Norway have a fundamental understanding of the principles underpinning organ donation and transplantation.

6.3 Belgium

6.3.1 Organ Donation Legislation in Belgium

In Belgium with a population of 10.5 million inhabitants, presumed consent legislation in relation to the donation of organs for transplant was introduced in 1986, (Royal Decision, 1986) and enacted 1987. The introduction of this legislation to increase the numbers of organs for donation was preceded by an extensive public information campaign, funded by the Belgian government, to inform the public of the change in the law, highlighting the benefits of this and the requirement for every individual to register an objection should they not wish to become an organ donor (Executive Legal Advisory Body, 1986). This education campaign raised the profile of organ donation and provoked much public debate on this issue and was the first of frequent government funded media campaigns designed to increase the numbers on the donor register. Other examples of efforts to improve the public knowledge of organ donation issues is the establishment of an organ donation information website.

This legislation applies to all individuals with the capacity to consent (over the age of 18 years) requiring them to make their objection to organ donation known with failure to do this resulting in their being considered as an organ donor. The guidance from the Executive Legal Advisory Body published by Department of Public Health and Environment (1986) states:

“Article 1. Every person (who is either on the Public Register or has been registered for more than six months with the Aliens Registration Office) and is capable of making their wishes known, may contact their local authority in order to register their objection, in the manner set out in article 2, to the removal and transplantation of their organs and tissues after their death. <KB (Royal Decision) 1987-03-26/31, art. 1, 002;

Article 2. § 1. The attached form may be used to register objection and must be appropriately dated and signed. The persons referred to in article 10, § 2, sections 2, 3 and 4, of the Act of 13 June 1986, who wish to register their objection, must also give their names and their degree of relationship to the person on whose behalf they are

acting. §2. The local authorities are obliged to register the objection referred to in article 1 in their files following the accepted protocol and to note this objection in the Public Register. The data registration and the form used for this notification of objection must immediately be sent on to the Centre for Information Processing of the Ministry of Public Health and the Family. § 3. The local authority must provide the persons referred to in §1 with a copy of the transcript of the registered details. § 4. It is the Health Minister's decision how paragraphs 2 and 3 shall be applied.

Article 4. Every person (who is either on the Public Register or has been registered for more than six months with the Aliens Registration Office) and is capable of making their wishes known, may have it noted in their will that they wish to donate their organs/tissues at their death. <KB (Royal Decision) 1987-03-26/31, art. 2, 002: Taking effect from: 24-04-1987> Article 2, with the exception of §1, section 2, and article 3 apply to the declaration referred to in the first section."

Individuals can also amend any personal information held on this register or correct any omissions as expressed in Article 3 of this guidance thus:

"As long as the person in question is still alive, the objection may be withdrawn at any time".

Subsequently, further amendments to this legislation were published in 1987 by the Executive Legal Advisory Body (**Appendix IX**) in an attempt to clarify the terms of the legislation specifically, Chapter III Article 10 on the relating to the Removal from Cadaveric Donors also states:

" Section 1. (Organs, tissues and cells) intended for transplantation as well as for the preparation, under the conditions set out in article 2, of therapeutic parts, may be removed from (all those who are either on the Public Register or have been registered for more than six months with the Aliens Registration Office), except in cases where it has been established that an objection has been registered to such a removal. <W 1987-02-17/31, only article, 002; Taking effect from: 24-04-1987> <W 2003-12-22/42, art. 165, 004; Taking effect from: 10-01-2004> For those persons not included in the definition given above, it is required that they have expressly given their consent for removal.

Section 2. The person, who is 18 years old and capable of making their wishes known, may register the objection referred to in paragraph 1 without an adult witness."

In addition, the individual who is under the age of 18 years and therefore deemed incapable of giving consent to donation together with those over the age of 18 years who are incapacitated are protected by this legislation. In this instance their next of kin or in the case of the incapacitated their legal representative can register an objection to organ donation proceeding thus:

“If a person is younger than 18 but is capable of making their wishes known, the objection may be registered by that person, or, while that person is still alive, by their next of kin who live at the same address. If a person is not capable of making their wishes known due to their mental condition, an objection may be registered, while that person is still alive, by their legal representative, their temporary executor or otherwise a close relative.”

6.3.2 Cultural and Religious Underpinnings within Belgium

Belgium is mainly a country of two groups with different languages and traditions. To the north and west of Belgium in Flanders 60% of the 10.5 million population speak Flemish, excluding Brussels, which although it sits within Flanders, is officially bi-lingual but predominately French speaking and is independently governed in Belgium. In the southwest in Wallonia the majority of the population speaks French with a small section of the country along the German border to the west having a small German speaking population, who also use a different system of government from the rest of Belgium. In addition, Brussels as a major European capital and the centre for the European commission is home to many foreign residents. Many Belgian cities have large immigrant communities with multicultural backgrounds from Europe and Turkey with a large African contingent from the former Belgian colony of Congo. Belgium is therefore a country of many languages and cultures with many of the population speaking 2, 3 or even 4 languages very fluently. From a religious perspective Christianity is the main religion of Belgium with 75% of the population following the Roman Catholic denomination. Protestant, Jewish and Muslim communities also exist within Belgium with Antwerp having the largest Jewish community.

6.3.3 Application of Presumed Consent Legislation in Belgium

6.3.3.1 National Organ Non -Donor Register

The organ donation legislation published by the Executive Legal Advisory Body (1986) stated a requirement to establish a register of donors and non-donors.

Using an appropriate form obtained from the local town hall, all Belgian residents or people living within Belgium for more than six months are obliged to register their intention to or objections against organ donation. As a result of the guidance a register of individuals wishes are recorded in two different ways:

- a) Individuals who have registered their intention to donate
- b) Individuals who have registered their objection to donate

Using this system as of October 2005 33,000 people have placed their names on the donor register while 190,000 have placed their name on the non- donor register.

6.3.3.2 Relatives Involvement in Decision making in Organ Donation as Determined by Legislation

Strictly speaking, as previously mentioned, involvement of the family in the decision making process in relation to organ donation should vary in accordance with the information obtained from the review of the organ donor register by the transplant co-ordinator. If the individual has not recorded an objection in writing on the register, then the organ donation process should commence. However, Article 10 subsection 4 states:

“ The medical practitioner does not have the right to start the removal in the following circumstances:

- 1 If an objection has been expressed in the manner regulated by the King;***
- 2 If a donor has expressed an objection in another way and this information has been relayed to the medical practitioner;***
- 3 If an objection has been communicated to the medical practitioner by a surviving relative.***

This objection must not be accepted if there is a last will, stating that the person in question intended to donate organs/tissues. Next of kin are defined as direct relatives or the co-habiting spouse.”

This paragraph therefore requires that the next of kin be consulted by the medical staff to confirm that they know of no objection expressed by the deceased to organ

donation, even if the individual did not formally record this on the register of objection. This requirement to consult with the relatives in this manner to confirm that there is no known objection by the deceased to organ donation is often considered to be a weakened form of presumed consent legislation. The statement also indicates that if there is evidence that the deceased recorded their positive intention to donate their organs then the objections of the next of kin should not override this expressed wish.

In practice, during the discussion with the next of kin, in addition to exploring if there has been any objection expressed by the deceased, their views on organ donation are also sought. If there are any objections raised by the next of kin to their relative's organs being used for donation, although no provision for their refusal is contained within the legislation, organ donation will not proceed.

Currently the refusal rate of families in regard to the donation of their deceased relatives organs is 15 % in Belgium (van Gelder et al., 2006).

6.3.3.3 Procedure for Organ Donation

Legislation requires that following the diagnosis of brain death of a patient using the latest technology, in Belgium this being interpreted as the application of accepted Brain Death Criteria (**Appendix III**) combined with Somatosensory and Brain Stem Auditory Evoked Potentials (Sullivan et al., 1999) (**Appendix XI**) by three suitably qualified doctors, there is a requirement for the patient's potential to be considered as a donor to be communicated to the regional transplant co-ordinator. This is achieved by a telephone call from the HCP to one of the transplant co-ordinators who is on 24 hour call. When this notification has been received by one of the transplant co-ordinators across Belgium, the co-ordinator

consults the central computerised organ donor register. This is password protected and requires the donor's name, date of birth and national insurance number to search the register. This central register is currently available to transplant co-ordinators via their desktop computer 24 hours per day 7 days per week or if in transit via their hand held palm computer. In the near future it will also be accessible via their mobile phone. When the register of donors or non-donors is consulted by the transplant co-ordinator there are three options for him /her to consider in relation to the donation of organs from the deceased:

- Those individuals who have registered an intention to donate and will become a donor and relatives cannot object to this.
- Those individuals who have registered an objection to organ donation and will therefore be excluded from donation.
- Those individuals who have not registered an intention and therefore by default will become a donor although relatives can object to this.

The result of this consultation of the organ donor register is then conveyed to the intensive care medical staff caring for the potential donor and a decision made as to whether it is possible to progress to the next stage. If the individual has registered an objection to organ donation then no further progress can be made and organ donation will not be attempted. If the potential donor has not registered any intention then there is a potential that this individual could become an organ donor, then as per the legislation the possibility that they have expressed an objection in another manner will be explored with the relatives. If the deceased had registered a positive intention to become a donor then the organ donor process will commence and the relatives are not in a position to object to this process under the legislation. If the deceased had failed to register an intention to donate, or an objection to organ donation, the relatives can object to the donation process.

6.3.4 Organisation of Organ Donation and Transplant System in Belgium

Belgium has a decentralised national system of organ donation and transplantation utilising 8 nationally designated centres across Belgium:

- Two University teaching hospitals in the providing services to the central and south east French speaking sectors
- Two University teaching hospitals in the providing services to the north east Flanders sectors
- Two University teaching hospitals in the providing services to the north west Flanders sectors
- Two University hospital providing services to the south east Flanders and German speaking sectors

These transplant centres across Belgium are the bases for 20 transplant co-ordinators employed by the individual hospitals but with a regional responsibility for transplant co-ordination.

6.3.5 Organ Sharing System in Belgium

All transplant activities undertaken in Belgium are linked to Euro-transplant. If an organ donor is identified and the organs that are produced are not suitable to be utilised locally, these organs will be offered to Euro-transplant to be donated to a suitably matched recipient from elsewhere across the Eurotransplant area.

6.3.6 Funding for Organ Donation and Transplant System in Belgium

Although the register of donors or non-donors is funded centrally by the government finance for transplant activity is provided by the individual University hospitals, who employ the transplant co-ordinators and support the infrastructure for transplants. Expenses are paid to the donor hospital to reimburse them for the donor screening activity from the recipient health insurance scheme. This health insurance is publicly funded via central taxes.

6.3.7 Education Programmes of Staff in Belgium

As members of the European transplant co-ordinators group, the co-ordinators across Belgium provide specialist education to medical and nursing staff within intensive care, emergency and operating room settings to develop their knowledge and skills in relation to donation issues. Utilising the European Donation Hospital Programme format HCPs are provided with information relating to the legal and ethical principles underpinning organ donation and transplantation. Additionally, professionals develop their knowledge in relation to the protocols and procedures that frame the practice of organ donation and transplant. The education programme also includes input from the specialist bereavement counsellors and social nurse specialists enabling the attendees to develop insights and skills in the support of the family during the loss of a relative and subsequent grief process together with the journey through the donation procedures and process. Further information provided during the interviews with medical staff also indicated that these professionals are required to undertake annual specialist updating of key economic and ethical issues to maintain of their professional registration. Transplant co-ordinators also provide input to the undergraduate medical and nursing programmes outlining the principles of organ donation and transplant procedures and protocols to these students.

Summary

Data gathered in relation to the format of organ donation legislation and the application of this in each country were combined with information on the cultural and religious influences together with that relating to the infrastructures for organ donation and education of the HCPs, to form a picture of the context within which

organ donation occurred with each country. This context was utilised as a framework with which to subsequently analyse the data gathered from the participant questionnaires and interviews, the results of which will be presented within the next two chapters.

Chapter 7 Findings from Questionnaires and Development of Interviews

7.0 Introduction

In phase 2 of the study a questionnaire was utilised to identify HCPs within the three countries under review that had knowledge and experience of organ donation practices within their country. This chapter will describe in detail the focus of the different sections of the questionnaire distributed to staff within Portugal, Norway and Belgium together with the responses received within the returned questionnaires. The process adopted enabling the identification of those HCPs interviewed within Portugal, Norway and Belgium will also be described, providing details of the planning and the process that allowed the staging of these interviews.

7.1 Responses from the Questionnaires

Data obtained from the questionnaire responses, full details of which provided in **Appendix XII**, were analysed and identified as providing information relating to the following areas:

7.1.1 Demographic Data of the Respondents

This section of the questionnaire identified the demographic data of the respondents, allowing contact to be made with the respondent and ensured that data for phase 3 would represent as wide a range of practitioners as possible. To obtain a representative sample of the HCPs in each country the data were utilised to identify suitable interviewees in terms of their clinical discipline, their location within a critical care setting that had direct involvement in organ donation,

together with the individual respondent's current practice and experience within organ donation.

A review of these data demonstrated that the response rate to the questionnaires in Norway and Portugal was less than had been originally planned with the small numbers of responses only allowing descriptive statistics to be generated from these responses. The focus of the questionnaire however was to identify HCPs in the three countries who had direct experience of involvement in organ donation and identify an experienced group who would be willing to be interviewed in relation to their practice. In addition, by exploring their views on aspects of organ donation practice, it was hoped to develop an interview guide with which to undertake a more in depth interview in the qualitative phase of the study, based on a representative sample of HCPs involved in organ donation. The explanation for the low response rate to the questionnaires in these countries was therefore considered and a number of possibilities identified.

Firstly, there was a possibility that the senior transplant co-ordinators in both Norway and Portugal had made an over estimation of the amount of HCPs directly involved and experienced in organ donation thus contributing to the low response rate. Secondly, if experienced in organ donation situations, the pressure of work experienced by these professionals who practice in very highly pressured clinical settings may have also prevented their participation in this study. Thirdly, even within particular Intensive Care or Emergency Departments, often only a small group of HCPs became involved in stressful events such as the care of an organ donor and their family. This may have also contributed to the lower than expected numbers of responses. Lastly, there may have been difficulties

experienced by the HCPs in these two countries understanding the questionnaire. Although the questionnaire had been piloted on small groups of HCPs in all three countries by the Transplant Co-ordinators before the start of the study, and amendments made to the structure of the questionnaire to aid understanding, it was possible that some HCPs still experienced difficulties in answering the questions and chose not to respond to the questionnaire. A summary of the numbers of questionnaires sent and the respondents to these can be found in

Table 7.1.

Table 7.1 Responses to Questionnaires

	Portugal	Norway	Belgium French Speaking	Belgium Flemish Speaking
Questionnaires Sent	300	450	70	53
Questionnaires Returned	31 (10.6%)	47 (10.4%)	31 (44.2%)	13 (24.5%)
Respondent Number of Doctors	7 (22.5%)	21 (44.7%)	14 (45.2%)	6 (46.2%)
Respondent Number of Nurses	24 (77.5%)	26 (55.3%)	17 (54.8%)	7 (53.8%)

On review of the respondents from all three countries it was identified that although small in number, the returned questionnaires did represent both medical and nursing professionals who practiced in organ donation. The returned questionnaires also represented a breadth of organ donation practice in terms of the range of experience of the practitioners, together with their particular clinical roles and health care settings i.e. within major teaching hospitals and smaller hospitals who participated in the organ donation system within their country. It was therefore decided that although small in numerical value, the 10.6% responses rate from Portugal (n=31), the 10.6% return from Norway (n=47) together with the 44.2% from the French speaking sector of Belgium (n=31) and the 24% response rate from the Flemish speaking sector (n=13) was a purposeful

(Patton, 1990) and adequate sample of the HCPs in each of the three countries practicing in organ donation and therefore the study could proceed.

7.1.2 Question 1 – 4 and 7: Experience of Organ Donation

As well as exploring the extent of their experience in organ donation, this section also sought to ascertain the HCPs involvement in approaching the family of the donor to explore their views on organ donation. This allowed the researcher to identify a range of HCPs from different disciplines who had a spectrum of personal experience in organ donation practices. Details of the responses to questions 1- 4 and 7 from all three countries can be found in **Appendix XI**, providing information relating to the participant identity codes from each country, information relating to their specific roles and their experience in relation to organ donation practices. To maintain the participants anonymity but allow identification by the researcher each participant was assigned an identity code made up of a combination of; their county of origin, their hospital location and an individual participant number. The full details of all participants were known only to the researcher and maintained in a secure setting throughout the duration of the study.

Analysis of the responses identified that these respondents represented a wide cross section of healthcare professionals from Portugal, Norway and Belgium, currently practising within either a major university teaching hospital or an area district general hospital involved within the organ donation programme within their country. The responses also demonstrated that as either a registered medical or nursing professional in the intensive care, recovery, high dependency or emergency unit of their respective hospital, they had direct experience of caring

for a patient who progressed to become an organ donor, with the majority of respondents also having experience in the care and support of the donor relatives.

7.1.3 Question 5: Knowledge of the Legislation

This section was designed to explore the HCP's knowledge of the legislation relating to organ donation within their country. Their responses would establish if they were familiar with this legislation and also assist the researcher to identify suitable respondents with whom this topic could be explored in more detail in interviews in the next phase of the study. Responses of the HCPs in all three countries indicated that they had a good knowledge of the organ donation legislation in their respective countries. Specifically, these results suggest that in Portugal (n=31) 87.1% (n=27) respondents reported that they had a knowledge of the legislation in their country while 12.9 % (n=4) suggested that this was not the case. In Norway (n=47) a similar pattern was obtained, with 89.4% (n=42) respondents reporting that they had knowledge of the legislation with 10.6 (n=5) suggesting that they did not know of the legislation. In Belgium (n=44) all 100% (n=44) of the respondents to the indicated that they knew of the legislation relating to organ donation in their country.

7.1.4 Question 6: Knowledge of Protocols

This question explored the HCP's knowledge of the organ donation protocols and practices utilised by their hospital in the identification of a potential donor and the subsequent procurement of organs for transplant. This allowed the researcher to identify potential interviewees who would be able to discuss the organ donation practices and protocols used in their country in some depth. Responses suggested that the majority of respondents in all three countries were familiar with the protocols utilised to support organ donation. In Portugal (n=31) the responses

indicated that 96.8% (n=30) respondents had knowledge of the policies and protocols with only 3.2% (n=1) of respondents suggesting that they did not. In Norway (n=47), 87.2 (n=41) respondents reported that they had a knowledge of the policies and protocols used in relation to organ donation, with 12.8% (n=6) indicating that they were unfamiliar with these. In Belgium (n=44) 100% respondents to the questionnaire indicated that they had knowledge of the policies and protocols used in support of organ donation practices in their country. **Table 7.2** summarises these responses to Questions 5 and 6.

Table 7.2 Health Care Professional's Knowledge of Legislation and Policies and Protocols in Organ Donation

Country	Knowledge of Legislation	No Knowledge of Legislation	Knowledge of Policies and Protocols	No Knowledge of Policies and Protocols
Portugal (n=31)	27 (87%)	4 (12.9%)	30 (96.8%)	1 (3.2%)
Norway (n=47)	42 (89.4%)	5 (10.6%)	41 (87.2%)	6 (12.8%)
Belgium (n=44)	44 (100%)	0 (0%)	44 (100%)	0 (0%)

7.2 Question 8: Benefits of the Legislation

This question invited the respondent's views on the benefits of the application of the organ donation legislation in their particular country. A variety of different responses were obtained from the respondents in answer to this question. These were organised and coded by the researcher using the Nvivo copyright QSR International Pty. Ltd, (2002) qualitative data package allowing the identification of similar codes from these respondents. These coded responses were then analysed and similar codes from these respondents reduced to form categories of response. Responses to this question suggested that the respondents from the three

countries considered the benefits of the procedures that they operated in their country in relation to organs donation to fall into the following categories:

7.2.1 Organ Donation Legislation in Each Country

In Portugal 51.6% (n=16) of respondents indicated that they found the legal requirement for the individual to record their objection or be considered as a donor to be beneficial to the organ donation initiative. 9.7% (n=3) of respondents also noted that they viewed the legislation as being clear and easy to understand with 19.4% (n=6) of respondents suggesting that this was instrumental in increasing the numbers of potential organs for donation. Within the responses from Norway (n= 47), 17.0% (n=8) of respondents suggested that they viewed the legislation as being beneficial and easy to understand. 21.3% (n=10) of other respondents, highlighted that they saw the legal requirement to explore the views of the next of kin on organ donation as being a beneficial aspect of the law. In addition, 8.5% (n=4) of other respondents suggested that the legislation facilitated the early screening and identification of potential donors. Responses from Belgium (n=44) indicated that 27% (n=10) of respondents reported that they viewed their legislation as being beneficial to them and easy to understand from the HCP's perspective. Additionally, 20.4% (n=9) of respondents from Belgium reported that in their view the legislation was directly responsible for increasing the numbers of potential donor organs.

7.2.2 Public Knowledge of the Organ Donation System

Responses from Portugal (n=31) suggested that only 3.2% (n=1) of respondents viewed the current level of knowledge held by the public in relation to organ donation to be beneficial to the Portuguese organ donation system. This mirrored

the small amount of respondents from Norway (n=47) where only 10.6% (n=5) respondents and 6.8% (n=3) of the respondents from Belgium (n= 44), viewed the level of public knowledge in relation to organ donation as a beneficial aspect of organ donation systems in their country despite the national public education campaigns undertaken in all three of these countries.

7.2.3 The Recipients and Society

Respondents from Portugal (n=31) suggested that 22.6% (n=7) viewed their current system of organ donation as beneficial in that it facilitates the saving of a life or the quality of life for the organ recipient. They also saw the overall benefit to society of returning a chronically sick person to health as being a benefit of their organ donation system. The responses from Norway (n=47) indicated that only 4.2% (n=2) of respondents identified that there were direct benefits to the organ recipients of their system with another 6.4% (n=3) of the respondents identifying the benefits to the recipient and society that their system produced as noteworthy. Interestingly, in Belgium (n=44), although 20.4% (n=9) respondents considered that their legislation had increased the numbers of potential organ donors, only 2.3% (n=1) of respondents indicated that they viewed their legislation as being beneficial in either saving the lives or improving the quality of the lives of the chronically ill within their society. **Table 7.3** summarises these overall benefits of the legislation as described by the HCPs in Portugal, Norway and Belgium.

Table 7.3 Overall of Benefits of Legislation in The Three Countries

Legislative Benefit	Portugal (n=31)	Norway (n=47)	Belgium (n=44)
Requirement to record objection	16 (51.6%)	N/A	0 (0%)
Public knowledge of legislation	1 (3.2%)	5 (10.6%)	3 (6.8%)
Easily Understood Legislation	3 (9.7%)	8 (17.0%)	10 (27%)
Requirement to involve the family	0 (0%)	10 (21.0%)	0 (0%)
Increased numbers of organs donated	6 (19.4%)	0 (0%)	9 (20.4%)
Overall benefits to recipient and society	7 (22.6 %)	5 (10.6%)	1 (2.3%)
Allows early identification of potential donor	0 (0%)	4 (8.5%)	0 (0%)

7.2.4 Organisation of the Organ Donation Services and Infrastructures

Responses from Portugal (n=31) indicated that 6.4% (n=2) of the respondents viewed the establishment of the non-donor national register as a beneficial aspect of their organ donation organisation, with 6.4% (n=2) of further respondents highlighting the centralised organisation of the donation system using identified hospitals. In Norway (n= 47) 21.3% (n=10) respondents reported that their centralised system of retrieval and transplant teams supported by their national transplant co-ordinator system benefited the organ donation system. In addition, a further 4.2% (n=2) respondents viewed the donor responsible doctor initiative utilised in Norway to co-ordinate the organ donor activities in each donor hospital as being helpful in structuring organ donation throughout Norway. These responses suggested that the requirement for doctors to explore organ donation with the next of kin of all potential donors, was a major benefit of the organ donation system in Norway. Although Norway currently does not have an organ donor register, another 4.2% (n=2) respondents reported that the introduction of a

new initiative to record the wishes of the individual utilising a donor card system was a beneficial aspect of their donation service. In Belgium (n=44) 11.4% (n=5) respondents suggested that they viewed the establishment of the national donor or non-donor register as being a beneficial aspect of their system with a further 6.8% (n=3) identifying that the national transplant co-ordinator system established linked to the European transplant system was a benefit of their organ donation system. **Table 7.4** summaries these findings.

Table 7.4 Benefits of Organisation of Organ Donation Services and Infrastructure

Country	General Benefits	Establishment of Non-Donor Register	Centralised Donor Systems	Identification of Donor Responsible Individuals	Use of Donor Card System
Portugal (n=31)	5 (16.1%)	2 (6.45%)	2 (6.45%)	0 (0%)	N/A
Norway (n=47)	18 (38.3%)	N/A	10 (21.3%)	2 (4.25%)	2 (4.25%)
Belgium (n=44)	20 (45.5%)	5 (11.4%)	0 (0%)	3 (6.81%)	N/A

7.2.5 Professional Practices Used to Support Organ Donation

Review of the responses demonstrated that 16.1% (n=5) of the respondents to the questionnaire from Portugal (n=31) indicated that they viewed the practices and protocols that they employed in the identification and care of the organ donor as being a beneficial aspect of their organ donation system. In Norway (n=47) 38.3% (n=18) of the respondents stated that they viewed the protocols and practices that they utilised in the identification and care of the donor as being a major benefit to the success of the organ donation system in their country. A further 32% (n=15) of these respondents highlighted that they found their procedures for the declaration of brain death in the donor to be easily understood by both family and

the HCP. This they viewed as being a major component of the their successful organ donation procedures. This procedure for establishing brain death in their view clarified the organ donation process for both the next of kin and the HCP. In addition, 8.5% (n=4) respondents indicated that clear procedures for the preservation of the donor following the confirmation of brain death to be a major benefit to their organ donation organisation. Responses from Belgium (n=44) indicated that 45.4% (n=20) of the respondents viewed their protocols and practices utilised within organ donation as being beneficial to the successful organ donation system. Although these responses did not specify any particular protocols and procedures that were particularly beneficial, they did indicate that the use of clear and efficient protocols in relation to the identification and care of the donor, were in their view a benefit to the organ donation systems within Belgium.

7.2.6 Team working and Communication with Transplant staff

Of the respondents from Portugal (n=31) none of the respondents to the questionnaires identified any benefits from their current systems arising from ways of communication and working within the organ donation teams. However, 8.5% (n=4) respondents from Norway (n= 47) indicated that they saw the current communication and methods of working with the transplant teams as being beneficial to the organ donation initiative. The beneficial impact on the organ donation system of having good communication and working relationships with the transplant team was also highlighted by 13.6 % (n=6) of the respondents from Belgium (n= 44).

7.2.7 Involvement of the Family in Decision Making for Organ Donation

Although not required by the legislation, 6.4% (n=2) of the respondents in Portugal (n=31) reported that they viewed the involvement of the family and the respect for their wishes as a beneficial aspect of their organ donation system. This contrasted with the 31.9% (n=15) of the respondents from Norway (n=47) who viewed the involvement of the next of kin in the decision making process as beneficial. A further 10.6% (n=5) of respondents from Norway also suggested that the demonstration of respect for the wishes of the family, by involving them in the decision-making process, was a benefit to their system. A further 2.1% (n=1) of the respondents suggested that the family involvement in this manner allowed them to obtain a positive outcome from their tragic circumstances. Within the responses from Belgium (n=44) 29.5% (n=13) commented on the involvement of the family in the decision making process as a beneficial aspect of their organ donation process, with a further 2.3% (n=1) of respondents agreeing that involvement in the process allowed the family to achieve some positive outcome at a time of loss. **Table 7.5** summarises the benefits of the practices used by the HCPs in each country to support organ donation.

Table 7.5 Benefits of HCP Practices in Organ Donation

HCP Practices	Portugal (n=31)	Norway (n=47)	Belgium (n=44)
General organ donation practices	5 (16.1%)	18 (38.3%)	20 (45.4%)
Protocols for defining death	0 (0%)	15 (32%)	0 (0%)
Protocols for donor preservation	0 (0%)	4 (8.5%)	0 (0%)
Team working and communication	0 (0%)	4 (8.5%)	6 (13.6%)
Benefits of Involvement of family in decision making	2 (6.4%)	15 (31.9%)	13 (29.5%)
Benefits to the family of their involvement	0 (0%)	6 (12.7%)	1 (2.3%)

7.3 Question 9: Challenges of the Legislation

These responses indicated that the respondents viewed the challenges of the procedures that they operated in their country in relation to organ donation fell into the following categories:

7.3.1 Public Understanding of Issues Related to Organ Donation

Reponses from Portugal (n=31) suggested that 22.6% (n=7) of the respondents viewed the poor level of understanding of concepts and issues related to organ donation as a challenge for both the legislators and HCPs in their country. 6.4% (n=2) respondents stated the need to clarify and demystify the legislation on organ donation for the public to improve the numbers of organs that are made available for donation. In Norway (n=47), although 4.3% (n=2) of respondents indicated that in their view occasionally the next of kin were sufficiently informed to raise the topic of organ donation with the HCP, 10.6% (n=5) of respondents agreed that there were poor levels of public knowledge and understanding of the legislation and organ donation processes and it was a challenge to the organ donation system to improve this. Additionally, 6.4% (n=3) of respondents suggested that the

numbers of organs for donation could be improved if the public awareness of the legislation and the need for the individual to indicate their wishes was recorded. This could be achieved either in writing or by conveying this verbally to their next of kin. A further 6.4% (n=3) of respondents linked the lack of knowledge of next of kin in regard to their relative's wishes on organ donation, to their refusal to allow organ donation to proceed seeing this as a challenge to the HCP to manage.

Similarly, 31.8% (n=14) of the respondents from Belgium (n=44) highlighted the poor public awareness of organ donation legislation as a major challenge to the organ donation system in their country. A further 9.1% (n=4) linked the family refusal to allow organ donation to proceed to the overall public lack of understanding of organ donation legislation, together with the failure to discuss individual wishes in respect of organ donation within the family. **Table 7.6** summaries these results.

Table 7.6 Challenges of Organ Donation System Services and Infrastructures

Country	Poor Levels of Public Understanding of Organ Donation	Public Awareness Linked to Increased Levels of Organ Donation	Poor Family Knowledge Linked to Refusals	Multi-Cultural Families Linked to Refusal
Portugal (n=31)	7 (22.6%)	2 (6.45%)	0 (0%)	0 (0%)
Norway (n=47)	5 (10.6%)	3 (6.38%)	3 (6.38%)	0 (0%)
Belgium (n=44)	14 (31.8%)	0 (0%)	4 (9.1%)	3 (6.82%)

7.3.2 Support of the Family of the Deceased During the Organ Donation Event

In Portugal (n=31) 9.7% (n=3) of respondents reported that supporting the family in the event of a potential organ donation presented challenges to them, in terms of having to explain the organ donation legislation to the family at this distressing time. In Norway (n= 47), 19.1% (n=9) respondents cited providing psychological support for the next of kin at the time of organ donation as being a major challenge to them. A further 4.2% (n=2) of the respondents suggested that the next of kin are particularly vulnerable at this time and required a considerable amount of support with a measurable impact on the staff in the time required to support these family and the emotional pressures that this interaction with the family placed on the HCP. A further 6.4% (n=3) of respondents indicated that they found the lack of any structured approach to the care of these relatives at this time, very challenging and stressful for the staff caring for them.

In Belgium (n= 44), the care of the relatives during the organ donation event was also highlighted as a challenge by 18.2% (n=8) of the respondents. In addition, if the deceased had not previously recorded their views, the emotional pressures placed upon the next of kin to decide whether organ donation could proceed was highlighted as a challenge for the staff by a further 9.1% (n=4) respondents. Of particular concern to a further 4.5% (n=2) of respondents were the different cultural responses to organ donation within Belgium, where many people from non-European cultures reside. These respondents reported the existence of different cultural attitudes to organ donation within the Belgian multicultural society and that this presents particular challenges to the HCPs attempting to support the family and gain their permission to proceed to organ donation. The HCPs also indicated that these different attitudes presented particular challenges

to them, in terms of the varying types of support required to be provided for these relatives during the organ donation process. The HCPs indicated that providing this level of support for these families, may take a considerable amount of time to achieve, placing considerable pressures on the staff who were required at this time to care for these relatives, the donor and the other patients within their unit.

7.3.3 Ethical Challenges of Organ Donation Practices

In Portugal (n=31) although not expressly citing ethical challenges, 9.7% (n=3) respondents indicated personal difficulties in having to explain the legislation to the family for the first time when their relative was being considered as a donor. One other respondent 3.2% (n=1) reported that some ethical dilemmas did arise for them in relation to organ donation however this individual did not give any further details of this issue. In Norway (n=47), a key challenge cited by 6.4% (n=3) of respondents was the requirement by law to undertake early screening of the patient as a potential donor. This required blood to be withdrawn from the potential donor to facilitate tissue typing. This would allow a more efficient process to be adopted should the potential donor subsequently be diagnosed as brain dead and relatives agree to organ donation. These respondents suggested that this withdrawal of blood for screening prior to the patient being diagnosed as brain dead and the relatives being informed of this situation, although being required by the legislation and protocols of practice, placed them in an ethical dilemma. They suggested that this requirement for early screening of a potential donor forced them to undertake a procedure that was not to the benefit of their patient, without the consent of the patient or the agreement of the relative.

Ethical dilemmas in relation to establishing consent to proceed to organ donation if the deceased has not registered their views and especially if the relatives were

not aware of the organ donation legislation, were highlighted as a challenge by a further 4.2% (n=2) of the respondents from Norway. Their responses suggest that the respect for the wishes of the family should be the overriding consideration in this situation despite the legislation allowing them to proceed to organ donation. Additional ethical dilemmas relating to the care of the patient as a donor were cited by 6.4% (n=3) of the respondents as presenting challenges to their practice, although again no details of these ethical dilemmas were provided in these responses. One further respondent 2.1 % (n=1) highlighted the professional's lack of preparation to address ethical issues as a challenge. The respondents from Belgium did not report any ethical challenges to their practice in the support of the family during the organ donation event were identified by. **Table 7.7** summarises these results.

Table: 7.7 Challenges Arising from Involvement and Support of Family during Organ Donation

Challenge for the HCP	Portugal (n=31)	Norway (n=47)	Belgium (n=44)
Explaining the legislation to family	3 (9.7%)	0 (0%)	0 (0%)
Providing psychological support	0 (0%)	9 (19.1%)	8 (18.2%)
Impact on HCP workload	0 (0%)	2 (4.2%)	4 (9.1%)
Lack of structured protocols	0 (0%)	3 (6.4%)	0 (0%)
Multicultural family implications	0 (0%)	0 (0%)	2 (4.5%)
General ethical issues	1 (3.2%)	3 (6.4%)	0 (0%)
Ethical issues in early screening of potential donors	0 (0%)	3 (6.4%)	0 (0%)
Lack of HCP preparation for ethical challenges	0 (0%)	1 (2.0%)	0 (0%)

7.3.4 Requirement for Improvement of the Organ Donation Systems and Infrastructure to Increase Donation Rates

Responses from Portugal (n=31) suggested that 19.3% (n=6) of those who replied viewed that their infrastructure and systems could be improved to better identify more organs for donation and utilise these more efficiently. 12.9% (n= 4) respondents described what they saw as the low numbers of donated organs and the resultant long waiting list for organ transplant as a major challenge to their system. In particular, the limited capacity of many hospitals in Portugal to undertake the testing of brain death in patients and to effectively manage the donor if one was identified was seen as a challenge by 9.7% (n=3) of respondents. These 3 respondents reported that in their view, the small numbers of organ donation and transplant centres within Portugal was a limiting factor in the number of organ donations achieved. A further 6.4% (n=2) of respondents suggested that this resulted in potential donors having to be transported considerable distances to be assessed in central hospitals. Alternatively, small numbers of suitably experienced and prepared HCPs had to travel to distant hospitals to undertake organ retrieval. This was viewed as being counter-productive to the organ donation legislation and philosophy.

The majority of the respondents in Norway 84% (n=47) and Belgium 78% (n=44), praised the network of transplant co-ordinators that operate within their systems and the infrastructure that had been developed to support organ donation in there respective countries. 8.5% (n=4) of respondents from Norway did however highlight the need to encourage HCP to apply the protocols of practice already developed to identify and care for potential donors. These respondents suggested although these protocols were available, that work pressures particularly in

smaller hospitals may mean that the detailed tests required to confirm brain death in patients in Norway, may not be possible or undertaken due to lack of resources, with potential donors overlooked and organs lost.

In Belgium, 13.6% (n=6) of respondents highlighted the need to increase the numbers of people registering as organ donors as a challenge, with a further 6.8% (n=3) of these respondents highlighting the work pressures placed on the HCPs to fulfil the requirements of the organ donation policies, i.e. to ensure that every family is asked to consider organ donation, as a challenge. These respondents cited the mandatory involvement of the family in the decision to progress to organ donation in circumstances where the deceased had not indicated their wishes as a challenge. This they viewed as having the potential for the family to refuse permission and therefore organs to be lost. In addition, 18.1% (n=8) respondents highlighted that in their view the recent introduction of initiatives to improve the numbers of organs for donation using a system of Non Heart Beating Donors as presenting particular challenges. These respondents suggested that this method of procuring organs for donation presented challenges in relation to the understanding of this concept and acceptance of this initiative by the HCP and the families of the donor. **Table 7.8** summarises these findings.

Table 7.8 Challenges of Improving Organ Donation Systems and Infrastructures

Improvement Required	Portugal (n=31)	Norway (n=47)	Belgium (n=44)
Development of current donation infrastructure	6 (19.3%)	0 (0%)	0 (0%)
Increase numbers of donations	4 (12.9%)	0 (0%)	0 (0%)
Improve numbers of public registration as donors	0 (0%)	N/A	6 (13.6%)
Improve the capacity of use of brain death tests	5 (16.1%)	4 (8.5%)	0 (0%)
Reduce Pressures on HCP workload	0 (0%)	4 (8.5%)	3 (6.8%)
Consider impact of NHBD protocols	0 (0%)	0 (0%)	8 (18.15%)

7.3.5 Improving Health Care Practices that Underpin Organ Donation

Within the responses from Portugal (n=31), 19.3% (n= 6) of respondents suggested the requirement to standardise the protocols utilised in their country. Of the respondents 6.4% (n=2) suggested that there should be better identification of patients who have suffered brain death. A further 6.4% (n=2) of respondents also suggested that protocols for the preservation of the donor organs when brain death had been confirmed in the patient, was a challenge for the organ donation system. Although these respondents indicated that protocols for these procedures existed, their comments suggested that these required clarification and more effectively applied if organ donation rates were to be improved. Additionally, 6.4% (n=2) of respondents suggested that the education of HCPs in relation to organ donation practices and the psychological support of relatives required to be improved.

Practices associated with the application of brain death protocols, were also raised by some respondents from Norway (n=47) as requiring to be improved. Of these

Norwegian respondents 8.5% (n=4) identified that the late application of the organ donation protocols by HCPs, sometimes led to organs being lost. A further 6.3% (n=3) respondents identified the failure of professionals to identify potential donors early enough and stabilise these patients sometimes resulted in the donor becoming unstable and subsequently dying, without the organs being retrieved. They suggested that work pressures contributed to this situation. Another 4.2% (n=2) respondents also suggested that the poor standard of care in ITU in relation to the care of the donor sometimes resulted in the organs being unusable, suggesting that further education in the timely application of these protocols were required. In addition to comments on the need to improve the practices in relation to the physical care of the donor, 19.1% (n=9) of respondents from Norway cited the lack of protocols to approach and provide the psychological care of the next of kin as being a major challenge to the HCPs. This aspect of the role was reported to be a stressor by these 19.1% of staff, with a further 4.2% (n=2) suggesting the need for specialist education in this area.

Responses from Belgium (n= 44) suggested that 9.1% (n=4) of HCPs saw challenges in achieving more organs for donation from donors who were cared for in the smaller hospital settings. A further 4.5% (n=2) of respondents suggested that there was limited application of organ donation protocols outside of the intensive care units across the country. A lack of understanding of these protocols in the general hospital setting, combined with the work pressures on the HCP was identified by the respondents as contributed to the poor application of these protocols. Additionally, 11.3% (n=5) respondents called for further education in the use of these protocols to be provided for these staff, with another 4.5% (n=2) of respondents calling for the simplification of these protocols to be combined

with additional resources to support the organ donation initiative in Belgium.

Table 7.9 summarises the views of the respondents as to the challenges to the HCPs in improving their practices to increase organs for donation.

Table 7.9 Challenges to Improving Health Care Professional Practices

Country	Standardise I.D of Donors	More Effective Care of Donors	Development of Protocols for Psychological Care of Family	Education of Health Care Professionals in Care of Family
Portugal (n=31)	2 (6.45%)	2 (6.45%)	2 (6.45%)	0 (0%)
Norway (n=47)	3 (6.38%)	2 (4.25%)	2 (4.25%)	9 (20.45%)
Belgium (n=44)	2 (4.54%)	0 (0%)	5 (11.36%)	0 (0%)

7.3.6 Overall Findings from Questionnaires

Although small in number, these returned questionnaires provided some initial information relating to the HCPs experience organ donation in their country in terms of their:

- Particular role in relation to organ donation
- Length of experience in this role
- Knowledge of their country's legislation on organ donation
- Knowledge of their hospital's policies and procedures in organ donation
- Views on the benefits of organ donation in their country
- Views on the challenges of organ donation in their country

Analysis of the responses from the questionnaires allowed the researcher to identify key issues in relation to the application of presumed consent legislation in Portugal, Norway and Belgium. Firstly, responses from the questionnaires clearly

demonstrated the differences in the types and detail of legislation together with the differing approaches to the application of presumed consent in these three countries. The impact of application of the differing types of legislation in each country required therefore to be explored in more detail. Responses also suggested that although the majority of the staff had a level of knowledge in relation to their particular legislation, there were concerns raised that the public were not so fully aware of this legislation. Questions also remained to be answered as to how the staff had gained this knowledge and how the public were educated in relation to the legislation. Secondly, the responses indicated that a range of organisational structures, policies and protocols existed within these three countries to facilitate organ donation, with HCPs indicating both benefits and challenges for the patient, the relatives, society and themselves of these. Further exploration of these structures, policies and protocols that underpin the approach to organ donation adopted in these three countries, required to be undertaken to further explore the views expressed in the responses to the questionnaires. Chief within the key issues that emerged in relation to the policies and protocols was that, although not required to by law, the HCPs included the family in the decision to progress to organ donation. The rationale for this practice and the benefits and challenges that flowed from this demanded further exploration. Finally, the impact on the HCP and the health care system of the legislation and particular approach to organ donation in each country required to be explored in more detail.

Adopting a phenomenological approach to the study, the themes that emerged from these responses to the questionnaire were considered carefully by the researcher and used as a basis to formulate a semi-structured interview schedule (**Appendix X**). This schedule was used as a guide for the interviews with HCPs

identified within phase 3 of the study. The interviewees were selected from the respondents to the original questionnaire from Portugal, Norway and Belgium who had direct experience of the organ donation process and had indicated their willingness and consent to be interviewed.

7.4 Phase 3 of Study: Selection of Staff for Interview and Preparation

7.4.1 Identification of Suitable Interview Subjects using Questionnaire Responses

The sampling for phase 3 of this study was dependent on three main factors:

- i) willingness of the healthcare professional to complete the initial questionnaire
- ii) willingness of the healthcare professional to participate in subsequent interviews with the researcher
- iii) demonstrable experience in organ donation

Qualitative research is often criticised for the way in which selection or sampling of the study participants is undertaken (Silverman, 1997). However, utilising a purposeful sample (Patton, 1990) of those who returned their questionnaires from all three countries and identifying the participants who had given their consent, a small selection of these HCPs were then invited to be interviewed by the researcher developing a deeper understanding of the issues and themes raised within the questionnaire in relation to organ donation. The respondents to the questionnaire included medical and nursing staff and ranged from 2 to over 20 years in terms of experience in the care of the organ donor. In making this selection of appropriate staff for interview, the researcher attempted to achieve a mixture of HCPs from both these professions, those who had a range of experience in terms of length of experience and seniority and balance this with a range of HCPs who practiced in a major teaching hospital or in a smaller regional hospital participating in the organ donation programme within their particular

country. This selection was deemed by the researcher as most appropriate to determine the procedures adopted in organ procurement within each country and gain insights as to the impact of the legislation on health care practice.

In addition to attempting to achieve this balance within the three countries, the logistics and practicalities of organising a series of interviews in all three countries had also to be taken into consideration. To undertake these interviews within a reasonable time frame the researcher had to undertake careful planning of field visits to each of the three counties at a suitable time when transplant co-ordinators of each country who were supporting the research were available and combine this with identifying a suitable time frame when the respondents would be available for interview.

7.4.1.1 Identifying Interviewees in Portugal

With the help of a senior transplant co-ordinator medical and nursing staff within 1 of the regional transplant centres or the major hospital sites that most frequently undertook organ donation were identified and sent a questionnaire. Of the 31 questionnaires returned 7 medical staff and 24 nursing staff within two major organ donor sites in Portugal, data were obtained and 15 HCPs identified and agreed to be interviewed by the researcher. Fourteen of these professionals were interviewed, 1 interviewee withdrew at short notice as a result of a family emergency arising.

7.4.1.2 Identifying Interviewees in Norway

It was established from information received from the senior transplant co-ordinator that the legislation to procure organs for transplantation in Norway has been drafted in a different manner to that found elsewhere in Europe. Members of the medical staff and nursing staff who practice organ donation using this format of legislation were identified as being suitable for the study. To identify these professionals, a senior transplant co-ordinator was asked to identify the regional transplant centres or the major hospital sites that most frequently undertook organ transplantation. Of the 47 questionnaires returned, it was identified that these were from the 6 major organ donor hospitals in Norway, with 2 other hospitals failing to return any questionnaires. From within these 21 medical staff and 26 nursing staff who returned the questionnaire, 13 HCP were invited for interview across 3 sites who demonstrated a range of experience in organ donation and were accessible to the researcher using public transport systems in Norway.

7.4.1.3 Identifying Interviewees in Belgium

Professionals within the French speaking sector and Flemish speaking sector of Belgium were identified by the two senior transplant co-ordinators within these sectors as working within the intensive care, the emergency room or the operating room of the major hospital sites which most frequently undertook organ donation. Questionnaires were distributed to staff from both sectors with 31 returned from the French speaking sector of Belgium representing 13 responses from medical staff and 18 nursing staff. Thirteen questionnaires were returned from the Flemish speaking sector representing responses from 7 medical and 6 nursing staff. From these groups 15 interviews were undertaken with HCPs across 3 sites. **Table 7.10**

summarises the responses to the returned questionnaires from each country together with the staff interviewed.

Table 7.10 Returned Questionnaires from Each Country and HCP

Interviewed

	Portugal	Norway	Belgium French Speaking	Belgium Flemish Speaking
Questionnaires Sent	300	450	70	53
Questionnaires Returned	31 (10.6 %)	47 (10.4 %)	31 (44.2%)	13 (24.5%)
Doctor Interviews	5	6	5	5
Nurse Interviews	9	7	2	3
Interviews Conducted	14	13	7	8

7.5 Planning the Interviews in Each Country

Planning these interviews in each of the three counties required co-ordination of a number of steps. Initially, the transplant co-ordinator in each country was contacted and a suitable time frame for a two-week field visit to the study site in each county was explored. With the assistance of each of these transplant co-ordinators a suitable two–three week time scale was identified to undertake the interviews, excluding local holidays and periods of HCP annual leave, together with special hospital events that might have made interviewing of staff difficult. All respondents selected for interview were then contacted by either email or written communication by the researcher to ensure that they still agreed to be interviewed with an offer of a two-week time frame for this interview to take place. On receipt of confirmation of the majority of the interviewees' availability

within a two week time period, final preparations for the field visit were made with the transplant co-ordinators in each country, and confirmation of flights and accommodation undertaken.

On arrival in each site the interviewee was contacted by telephone to finalise a suitable day, time and place for the interview to take place. As the individual interviewees were based at different intensive care, emergency and high dependency units within different hospitals and these hospitals were spread over several different sites within the three countries, careful scheduling of the interviews had to be undertaken by the researcher to ensure that these were achieved within the timescale allowed in each county. With the assistance of very accommodating HCPs who had agreed to be interviewed, together with other colleagues, who although not part of the study facilitated the release of their colleague to be interviewed, only two of the originally planned interviews with these HCPs were not possible due to emergencies arising within the interviewee's work place. Sadly, due to the limitations of time these two interviews one in Portugal and one in Belgium were not possible.

7.6 Undertaking the Individual Interview of Identified Staff

With prior agreement of the individual HCP, interviews were usually conducted within small seminar rooms next to the interviewee's work place, adopting a phenomenological approach utilising the interview schedule (**Appendix X**). The interviewee responses to the questions posed by the researcher were audio taped and supported by contemporaneous notes. The interviews were undertaken next to the HCPs clinical area allowing them to remain within the vicinity of their unit and continue to be available should an emergency situation arise. Although not

always ideal conditions for the interview to be conducted, this did provide a reasonable compromise to the alternative of the interviewee having to undertake the interview within their off duty period. When a suitable room to undertake the interview was not available within the vicinity of the participant's clinical setting, occasionally they took place in the transplant co-ordinators office elsewhere within the hospital. The audiotapes of the interviews were later transcribed.

Summary

This chapter described the responses received from the HCPs within Portugal, Norway and Belgium identifying the key themes that emerged from these returned questionnaires. Adopting a phenomenological approach to the study, these themes then guided the construction of a semi-structured interviews used in the next phase of this study. Having developed the semi-structured interview schedule, this chapter then described the process adopted for the identification and selection of the interviewees in each country, together with the procedure adopted to gather the data from these interviewees. The next chapter will present the findings from these interviews capturing the experiences of these HCPs in relation to their organ donation practice.

Chapter 8 Findings from Interviews

8.0 Introduction

In this chapter using the approach first described by Gadamer (1976) the views of the HCPs interviewed in the three countries under review will be presented capturing their response to the questions posed to them within semi-structured interviews. These reflections of the HCPs on their experiences were used to capture the “lived experiences” of their application of presumed consent legislation in organ donation. The findings of the interviews were analysed using a process described in Chapter 5, which combined an approach to phenomenology first described by Gadamer (1976) and adapted by Colaizzi (1987). This combination allowed the experiences described by the HCPs to be identified and categorised under key themes facilitating the critical analysis of these experiences as described by the interviewees across the three countries under review.

8.1 Responses By Interviewees

8.1.1 What is the Impact of the Implementation of Presumed Consent Legislation on the Bereaved Relatives of the Donor using Your Country’s System?

Initial investigation of this issue within the questionnaire responses combined with communications with the Transplant Co-ordinators, identified that the different legislation governing organ donation in these countries specified in varying detail, the relative’s involvement in the decision-making process. In addition, different legislation described the need to approach the relatives to

establish objection to organ donation by the deceased or the objection of the nearest relative in different formats and in varying detail. An example of this is the legislation in Norway that highlights the need to “make every effort” (DHSS, 2004) (**Appendix VIII**) to approach the next of kin to confirm the lack of objection. However, other guidance within Norway to support the legislation also advises that in the event of the deceased having expressed a view in favour of organ donation and the family being difficult to access, there is no absolute requirement for the family to be involved. In Portugal the legislation (Republic Assembly Law Nr. 12, 1993) (**Appendix VII**) only states the need to involve the relatives within the decision making process if the donor is a child, or an adult who suffers from incapacity and therefore unable to express consent or objection to organ donation.

Utilising a more definite approach the legislation in Belgium (Removal and Transplantation of Organs Act, 1986) (**Appendix IX**) states that should the deceased have not recorded a specific intention to donate their organs, or if the donor was a child, then the closest relative (described as the 1st degree relatives in some legislation) or next of kin, should be involved in the decision making process. Relatives are allowed to object to organ donation in this situation. This legislation also advises that if the deceased has expressed a positive wish to donate their organs then the relatives cannot object to the donation proceeding. In this event there is no requirement to inform the relatives until after the donation has taken place.

8.1.1.1 Involvement of Relatives in Decision Making Process

Despite this information, available literature on the presumed consent legislation demonstrated a lack of evidence as to the role of relatives in the decision to progress to organ donation. The responses from the questionnaires suggested that there were both benefits and challenges associated with involving relatives in the decision- making that required further exploration, namely:

- What is the role of the family in giving consent or objecting to the donation of organs if the deceased recorded a wish to do so?
- Does Presumed Consent Legislation require the consent of relatives if evidence of the donor's wishes are available?
- Could the relatives be excluded from the decision making in organ donation?
- If the relatives are excluded what are the potential benefits or challenges for the relatives as a result of this exclusion?
- If the relatives are involved in the decision making, what are the potential benefits or challenges of involving relatives?

Responses from the participants suggested that despite the various versions of the correct procedures as detailed within the legislation, the interviews with HCPs in all three countries demonstrated their practice of involving the relatives throughout patient care and in particular their desire to keep the family updated in regard to the patient's subsequent deterioration and identification as a potential donor. The family's understanding of the patient's cerebral condition, their deterioration and assessment of brain death, including an understanding of the tests used by the professionals to establish brain death, was viewed as crucial if the eventual agreement of the family to proceed to organ donation was to be achieved. The following comments from interviewees from each country, N R4,

PM 64 two intensive care nurses and B Lev 1 an intensive care doctor, demonstrate this practice:

Document Transcription N R4,

“Yes and the neurosurgical doctor who will bring it up with us, not always,’ but I think it is primarily the neurological doctor who has talked to the relatives brings it up. But many of the other neurosurgeons; they wont speak to the relatives before they have done the cerebral angiography”. Page 2 Paragraph 4.

Document Transcription P M64

“Normally we would contact the transplant team and ask them to check whether or not the patient was on the non-donor list to exclude whether or not this patient had objected to be a organ donor or not. Throughout this process, we will begin to talk to the family and inform them of the situation. We don’t have to do this but we always speak to the family and try to keep them up to date with what is happening with the patient”. Page 2 Paragraph 5.

Document Transcription B Lev 1

“And then secondly we have to inform the relatives although, in Belgium we have the right to take organs without informed consent, we don’t do it”. Page 2 Paragraph 7.

The degree to which relatives were informed of the patient’s condition, throughout the period of the patient’s care and the decision to progress to organ donation, did vary across the three countries. In Portugal relatives were informed of the patient’s deterioration and potential to become a donor, i.e. the relatives were informed of the results of the brain death assessments. Rather than relatives being invited to express their views on organ donation, they were normally informed of the legislation and the intention of the professionals to proceed to organ donation. In Norway, a more determined attempt was made to facilitate the relative’s involvement and gain their agreement to proceed to organ donation, achieved by frequent discussions with the immediate family to identify the next of kin and ensure their lack objection. In Belgium, it was revealed that a unique system of bereavement crisis intervention for relatives had been developed to support relatives in the event of a potential organ donation, involving the provision of specially prepared staff, called Social Nurses, to provide detailed

information and support to the relatives in this event. These staff were involved with the nursing and medical staff caring for the patient, in the communication and support of the relatives from the initial admission in the Emergency room, through the patient's admission and care in the ITU and subsequent deterioration and assessment as a potential organ donor. Using detailed communication and bereavement crisis support these staff helped the relatives to understand the complex issues involved in brain death and organ donation and enabled them to participate more fully in the decision to consider the patient's condition and their potential as an organ donor.

8.1.1.2 Staff Perceived Benefits to Relatives of Involvement in Decision Making

Interviews with all of the HCPs demonstrated the view that despite being distressed at news that their relative was confirmed as being brain dead; and the deceased having not recorded an objection, these patients would be considered for organ donation, the staff felt that the relative would accrue benefit from being part of the decision making process. Two of the interviewees enunciated this point clearly PM 89 a consultant intensivist and PM 72 an intensive care nurse when they said:

Document Transcription P M89

“Once they have come to terms with the fact that the person is dead, once they have understood that the person is brain dead, from the discussion, then most of them understand that something useful can be done as a result of this death and come to terms with this once it has been explained to them” , Page 2 Paragraph 1.

Document Transcription P M72

“.....I don't think that they would do very well with that because to be excluded I think that it is good for them to stay and know. It is good that they know that they can't do anything for their family, and I think that if we give them the information, that ability to be better informed, those who stay with the pain, I have sent them somewhere to think about it. Perhaps later, if then they begin to think about the situation, there is less stress and less pain. Perhaps they can come to terms with this

and say; well O.K. I allow this for my relative. Perhaps they help someone.” Page 6 Paragraph 5.

These comments also suggested that in the view of these professionals there is a potential benefit to relatives of being involved in the decision to identify the patient as an organ donor, in terms of the family’s acceptance of death. In so doing this would be helpful for the family’s bereavement and grief response in the long term. In the views of those interviewed, this involvement suggests that for the family something good can be obtained out of the tragedy of the death of their relative.

8.1.1.3 Challenges of Involving Relatives in the Decision Making Process

Other interviewees acknowledge however, that there was the possibility that relatives could be distressed by being involved in the decision making process and being made aware of the organ donation law, perhaps for first time. It was a common view that most relatives found the concepts of brain death diagnoses and identification of the patient as a potential organ donor very difficult to understand. As a result of this difficulty, explanations of these concepts had to be provided for the relatives by the HCPs to allow them to participate in the decision making process. Despite the possible problems this presented, the importance of the family being involved was identified. PM 89 a consultant intensivist expresses a view frequently repeated throughout the interviews:

Document Transcription P M89

“.....You have to involve the family. They are very emotional and upset at this time but it is very important that they contribute to this discussion. Although the family is upset at this time it would not be acceptable to exclude them from this discussion and they must be involved.” Page 1 Paragraph 8

8.1.1.4 Impact of Extreme Presumed Consent Legislation and Potential Harm to Relatives

Moreover, despite the lack of a formal requirement in law to include the family in discussions regarding the death and organ donation, the majority of the participants thought it potentially harmful to the families to be excluded. They suggested particular negative impact of acceptance of the death if the family were excluded from this decision, as PM63 an intensive care nurse describes thus:

Document Transcriptions P M63

“I don’t think that is a very good idea. I feel that the family would not accept the death and not accept being excluded from this discussion. They perhaps would not be sure that things that could have been done, was done. It would be difficult for the family to accept what was happening and may well be angry if they were excluded from these discussions”. Page 4 Paragraph 13

Another potential problem expressed were the concerns related to the effect on the acceptance by society of the whole transplant enterprise of excluding families from this decision. This they saw as having a negative effect on public opinion.

Two interviewees NR 115 an intensivist, B Bru 102 a former transplant coordinator and B Bru 109 an ER Doctor demonstrated this view very clearly:

Document Transcription N R115

“Yes I think with respect to that, I think that it would be suicide for the transplantation activity to not involve the relatives. If it became public knowledge that organs had been removed and transplanted without explicit consent, I am pretty sure that we would have headlines in the newspapers, like that when there is a war going on. So I am totally and opposed to doing that in a different way.” Page 4 Paragraph 5.

“Yes well that could be perhaps a legal interpretation but we know what has happened when parents have found out that their children have been autopsied without their consent – it is a complete outrage, so this would be even worse. So I think it is totally unrealistic to think that we can do it without explicit consent.” Page 5 Paragraph 7

Document Transcription B Bru 102

“ Excluding families.....I would be very much against such a system because I think that organ donation and transplantation remains a touchy subject and you always hear about things that go wrong abroad in some country’s organ trafficking and things like that. I think that by doing that’s my thought, my vision, by doing things, by hiding things from the family and telling them afterwards will only contribute I think to a negative feeling to organ donation by the general public and only feed this”. Page 5 Paragraph 2.

Document Transcription B Bru 109

“.....We have a clearer opinion about that. The Law authorises us to take the organs without the advice of the family it is written but we never do this. If the relatives do not accept, we won’t take the organs. That’s the way we work and we lose organs, obviously we know that, probably about 50%. But the same procedure in this hospital for normal organ donation is when the patient cannot give any advice, the opinion of the family it is taken into account.” Page 5 Paragraph 10

Data collected across the three countries therefore suggests that staff would not consider exclusion of relatives from this decision making process. They expressed the strong view that despite the challenges of involving relatives and potentially risking the relatives refusing to agree to the donation and perhaps even losing the organs, it was important to involve the relatives in this decision making process. Some staff suggested that a major reason for the requirement of the family to be involved in the decision-making was that to exclude them would be unethical, as this excerpt from PM60 an intensive care nurse demonstrates:

Document Transcription PM60

“ Yes the family if they were excluded would not be able to deal with the death and this situation. You must be honest and it is most important to be honest with them and have them involved in the discussion. To exclude them may well be unethical”. Page 5 Paragraph 7

8.1.1.5 Establishing Patient Consent and Relative's Lack of Objection

Interviews with the HCPs in Portugal and Belgium confirmed that utilising the processes described within the legislation, establishment of the individual's lack of objection to organ donation would be achieved by the transplant coordinator's review of the register of objectors. The absence of the deceased's name on this register would be taken as an indication of consent. The relatives however would be approached to confirm if the deceased had any objections or if they, 1st degree relatives or next of kin, have any objections. Those interviewed suggested that again when approaching the family they are not asking the family to take the responsibility for the decision to progress to organ donation, however they were confirming what the deceased had already indicated by their lack of registration, that they held no objection to organ donation as PM 60 an intensive care nurse again describes:

Document Transcription PM60

"The law, the way it works in Portugal is useful, it is helpful in that it means that the family does not feel as if they have total responsibility for the organs being utilised in this way because the person has not put their name on the register, therefore, they are not having to make this decision on their own and they are not having to say "I am going to give the liver of my father". The legislation helps to do what the patient wanted and this is what is most important". Page 5 Paragraph 3

In Belgium, a register has also been established for individuals to record a positive intention to donate their organs and this would also be consulted in the event of a donation opportunity.

Interviews within Norway revealed that there is currently no register of objectors to organ donation in existence and therefore the next of kin is approached to establish that the deceased at no time expressed an objection to organ donation,

either verbally or in writing to them as N St.O 77 an intensive care doctor explained:

Document Transcription N ST 0 77

“On some occasions we know that the patient wishes or opinion was and maybe what has said that they wanted to be an organ donator in the case of an accident or similar. In these situations the decision is easier to make. And I have also experienced another with a young child about ten years or so and he knew that the mother has an organ donation card but none of the other relatives knew but they found the card. So we ask them”. Page 3 Paragraph 3

The staff in Norway stressed however a view expressed by many of the HCPs in all three countries that they are not asking the relatives to give permission, but rather exploring if the deceased expressed any wishes or objections to organ donation. Using this approach the family are not making the decision on their own, and are using the deceased views prior to their death to guide this decision.

N St. O 77 again describes thus:

Document Transcription N ST 0 77

“Yes. That is a way of asking we always turn it that way – “what would your mother have wanted or what would your father have wanted”. And sometimes they don’t know because they have not talked about it but sometimes they do and in these occasions when the father or mother has said something about it, it is always easy. Because when it is their wish, they want it.” Page 4 Paragraph 8

8.1.1.6 Respect For the Wishes of the Dead and That of Relatives

Interviews with the staff also suggested the view that their respect for the autonomy of the individual to donate or not to donate organs is very important.

Autonomy and whatever decision arises from this, must always be respected as

PM 64 an intensive care nurse suggests:

Document Transcription P M64

“The benefit and most important thing is that we respect the will of the patient. We also respect the view of the non-donors as well as the donor patient” Page 3 Paragraph 12

In addition to the different legislative frameworks specifying the requirement to identify the wishes of the nearest relative, there was a need to accord respect to the patient. This was achieved by respecting the wishes of the family as the representative of the patient's wishes. B. Bru 102 a former transplant coordinator expressed the majority of the interviewees' thoughts on this issue:

Document Transcription B Bru 102

“The Law says that the patient can oppose organ donation not only by the official means which is the national register, national database but, by any other means. Any other means is asking the wife or the children, will they not donate organs? but the only way to know is of course is to talk to the family about the deceased's intention of organ donation”. Page 2 Paragraph 2

HCPs in Norway however did suggest that the traditional idea of the next of kin is increasingly complicated. Complex family relationships exist in a society where levels of divorce has resulted in the loss of the traditional nuclear family, this presented difficulty identifying the next of kin in order to establish that they had no objection to organ donation as suggested by N St. O 77 an intensive care doctor:

Document Transcription N ST 0 77

“I always respect them and their decision because I think that the decision they make they are going to take it with them for the rest of their lives and it has to be right for them. And I also speak to the relatives afterwards; a month after we always take or make a phone call and sometimes earlier too and then we talk about it ourselves. The relatives they always, they don't regret the decision, whether it is yes or no. And that makes me sure about that, the process are right in helping them to decide”. Page 12 Paragraph 9

The majority of responses also suggested that it would not be acceptable to override the objections of the family and proceed to organ donation even if no objection to organ donation had been recorded or expressed. PM 70 and PM 64 two intensive care nurses supported this view:

Document Transcription P M70

“If the family refused and without their support we took the organs; this would not be good. I think that we have the right to put some pressure on the relatives. Where the family is concerned we need to give them some room to say no, but it is not the family’s entire responsibility for the decision and sometimes the family can say no and if they say yes, there is a shared responsibility in making this decision. This is a critical point. The critical point is that you must allow them to say no”. Page 4 Paragraph 5

Document Transcription P M64

“We respect the patient’s wishes if they are confirmed, if they don’t want to donate they can register their objection and that is no problem. The legislation is successful in getting organs so that is something that you should think about. The important issue is that the family view must be respected and if the family says ‘No’ they don’t want organ donation to go forward then that is the view that must be taken by the staff. The ethical aspects of this situation are important”. Page 4-5 Paragraph 9

Within the interviews the staff in all three countries stressed the concept that the donation of organs was viewed as a gift from the donor to society was also challenged. Others challenged the suggestion by some that organs are the property of individuals to give or to withhold consent for donation. These interviewees took the view that the donation of one’s organs was an altruistic act to society and was a demonstration of solidarity with the community from the deceased. B Bru 106 a transplant surgeon articulated a view expressed by many of the participants thus:

Document Transcription B Bru 106

“.....Even if there is an organisation to give organs to somebody, it must be something beside the gift. To help to give the organs to somebody who is waiting for an organ, their lungs working and so on. But I think not in the way property and say well I am the owner and I think that we have to give this to somebody else.Absolutely, the way the Government owning the person who lives in the country, which you are dying you are my property. It is not a good way to think. On the contrary if you are saying well if you are dying, if you can give your organs to somebody, it is more important for the persons to say you can make a gift after your death and another way to think and organise this”. Page 6 Paragraphs 140-142

Some staff also linked the exclusion of the relatives from the decision making process as having the potential to be viewed by the relatives and society as taking

the organs rather than receiving a gift. Other interviews suggested that it is important that organs are viewed as being gifted by the deceased not taken by government. Additionally, some of those interviewed felt that to exclude the relatives from the decision making process would suggest an element of control of organs and not the ability of the individual to gift their organs as expressed by B Lev 1 an intensive care doctor:

Document Transcription B Lev 1

“I would say you have to involve the relatives. Unless you are getting maybe within fifty years that we have the culture where everybody accepts that the Government, that you are the property of the government and nobody cares about your organs or so, that now days I don’t think that anybody here with our western culture wouldn’t accept that all this just can be taken”. Page 10 Paragraph 8

When asked about their views on the claim that presumed consent legislation reduces the individual’s ability to express an autonomous decision, many health staff expressed the importance of balancing the rights of the individual to make an autonomous choice with the needs of the community. B Lev 109 a social nurse demonstrates the views of many of the interviewees on this issue suggesting that not objecting to donate your organs is a method of showing solidarity with the community:

Document Transcription B Lev 109

“Well, we believe that there is always when you want it or not, you must think about the others. You are not living alone so we believe in autonomy to a certain level, but there is also, you are always indebted to the community and we stand for a philosophical way of thinking that people are living for a relation with others.

So solidarity is the main issue, I don’t think that the Government has to decide, we can decide from our own autonomy we hope that people chose in a certain way. I don’t know if you have seen the film “Beautiful Mind”, when Nash sitting in the café and the girl arrive and he says that Adam Smith is wrong that the community does not get on as individuals and does not get the best results when everybody goes for the individual goal. You can go for your own goal but you also have to take notice and think about the importance of the community. When you make that thought then you will have the best of this way of working for the individuals and the community”. Page 7 Paragraph 4

The family's involvement in the decision making process and their lack of objection to the use of their loved one's organs for donation was seen as a demonstration of this solidarity with the community by many of those interviewed. Two of those interviewed however expressed the idea that the views of the family should play little part in the decision making process. They suggested that expressed autonomous choice of the deceased, as demonstrated by the lack of their name on the register of objectors, should be the most important factor in the decision to proceed to organ donation. This they saw as a demonstration of the deceased's beliefs and views in relation to organ donation that should be upheld. This strength of feeling was expressed in the following quote from P St. J 5 an intensive care nurse:

Document Transcription P SJ5

"I think that the problem with my life is with me and I don't, personally I think that my father, my mother my wife or my family if I have reservation, I can register this. So if people in life can afford a decision I don't see why the relatives should be involved in that. The decision is mine after all. Yes. It will be the decision of the person in life, who was alive who says that I know that there is a law that says I am a donator and if I do not want to donate my organs I must register. I will go to the hospital and I sign the list to object". Page10 Paragraph 6

P St. J 103 an intensive care doctor goes further suggesting that even if the family raises an objection to the organs being utilised, this objection should not be allowed to override that of the deceased as expressed by his lack of inclusion on the non-donor register thus:

Document Transcription P SJ 103

"I will take the organs even if the family did not want it. Because in Portugal the law is that each one of us has the right to say that we did not want to be a donator. Because we are healthy and have our life and we say that we do not want anyone to collect my organs. If I do not use this right, it is presumed that I give my consent to donate my organs. Sometimes people did not do this although he has the right, but he did not use his rights to be a donator his family does not have nothing to do with that because he is an adult, he is responsible, he is free and there is nothing the family has got to do with that. So if they have nothing to do with that in the past when he did not say that he wanted not to be a donor then we take the organs." Page 4 Paragraphs 11 and 12

8.1.1.7 Level of Public Knowledge of Law and General Education in Society and Ability to Participate in Decision Making Process

Interviews in all three countries demonstrated that in the views of the professionals, the public's and therefore the relatives' previous knowledge of the law and how it relates to organ donation, was crucial to their ability to participate in the making decisions in relation to organ donation. All three groups reported that over the last 10 years, there had been considerable coverage of the law on organ donation in the media, to ensure that the public are aware of the legislation and its implications for them. This was especially important to increase the public's knowledge prior to the changes in the legislation within the country. It was also reported that in each country the government mounts organ donation campaigns within the media on an annual basis. In addition in Belgium, other initiatives such as transplant co-ordinators delivering organ donation information sessions to school children take place.

Interviews demonstrated a diversity of opinion as to the success of these initiatives. In Norway and Belgium those interviewed suggested that the public and the relatives may have an awareness of the legislation but did not have an understanding of the details or full impact of the legislation in practice. Moreover in the event of a potential organ donation situation, the staff interviewed reported that the majority of the responses of the relatives demonstrated that they did not fully understand the details of the legislation in their country or their personal requirements within this e.g. in Norway to either inform their next of kin of an objection or record this, and in Belgium record their objection or intention to donate on the national register. However B Bru 107 an intensive care doctor

reported that in his experience the majority of the public are informed about this legislation:

Document Transcription B Bru 107

“The first thing is that most of people here in Belgium now know what organ donation is. A couple of years ago many people would have never even heard about organ donation or organ transplantation and people thought that was something from a very small number of patients and they were not involved in the problem. But since the Law was passed, well most of the people know in Belgium know what organ donation is” Page 3 Paragraph 1

In Portugal also, some interviewees supported the view that overall the public had a considerable amount of media coverage of the legislation prior to the introduction of presumed consent legislation in the country and at that time were relatively well informed, as P St. 4 an intensive care doctor suggested:

Document Transcription P St. J 4

“ I don’t really remember but I think that ten years ago when the law was changed in Portugal regarding organ donation, that we had lots of campaigns and information in the public section which helped to educate the public in general about organ donation. I feel that at that time there was a very strong message to everyone given out to the effect that if they did not want to give organs, they must sign on the register to make this quite clear otherwise they would automatically become an organ donor”. Page 5 Paragraphs 12

In the view of the staff interviewed relatives were often distressed at news of death but previous knowledge of law and organ donation issues assisted the family to accept death and the need to consider organ donation. Poor understanding of the legal aspects of organ donation often resulted in the situation that in addition to the relative having to be informed about the technical concepts of brain death and the organ donation process, for the relative to participate in the decision to proceed to organ donation, the professional had to inform the relative about the legislation in the crisis situation as B Bru 103 an intensive care doctor explained:

Document Transcription B Bru 103

“I think that all have heard about it. But they don’t know what it is. They all know it’s the way for their loved ones to stay alive somewhere and they all know that we need organs here and the patient are being with chronic liver disease they need a new organ, but that is all. They don’t know the procedure they don’t know anything sometimes they ask the same question. We heard that you made surgery with her organs..... They have no information, they have heard about it but they don’t really have the knowledge, they don’t really understand what it means in a medical sense”.
Page3 Paragraph 6

Other interviewees challenged this however, reporting that in their experience, relatives were sufficiently aware of organ donation to raise this issue with the HCP as N R 124 and B Bru 107 two intensive care doctors reported:

Document Transcription N R124

“Yes and sometimes they have been thinking about it without we have been daring to mention it in a way. But sometimes this can come as a complete shock so I think that it is very difficult to feel where the relatives are in this nasty situation”.
Page 4 Paragraph 9

Document 'Transcription B Bru 107

“Now, the majority of people are offering by themselves, they are asking and saying so okay well do you think it is possible you can go for organ donation”.
Page 3 Paragraph 11

The experience of many of the HCPs interviewed however was that despite this information, many relatives were not aware of the legislation, had a poor understanding of the legislation in organ donation or had forgotten and this presented considerable difficulties in the acute organ donation situation, presenting challenges to their ability to be involved in the decision making process in organ donation. In the experience of these staff, relatives were distressed to be informed about the legislation for the first time from the HCPs involved in the care of their family member, as PM 60 and PM 63 two intensive care nurses suggested:

Document Transcription PM60

“I don’t really know but I think that they probably do not have any prior knowledge of organ donation before this circumstance arises”. Page 3 Paragraph 7

Document Transcriptions P M63

“I really don’t know. Sometimes it is very difficult because the family are very shocked at the time so it is difficult to know what they may well have known prior to this. It is difficult to say the families probably do know about the situation or the medication but maybe they don’t really know about the law in this situation”. Page 2 Paragraph 1

Not only did this present challenges to the relative being able to participate in the decision making as to whether their family member should become an organ donor but in addition, often resulted in the relative becoming very distressed at this news and suspicious of the HCPs conduct in the care of their family member, as B Bru 107 an intensive care doctor reported:

Document Transcription B Bru 107

“The first time most of the patients are rejecting the news and I think that it is still believe that I don’t think they understand the idea of brain death and the have a kind of aggression”. Page 3 Paragraph 11

In addition to varying levels of knowledge of the law and concepts related to organ donation, some interviewees in Portugal suggested varying levels of general education in society may mean differing abilities to understand legislation with possible lower levels of general education linked to comprehension of organ donation concepts as P St. J 4 an intensive care doctor suggested:

Document Transcription P St. J 4

“The level of education in the country; that perhaps those in the country that are not so well educated and there can be many, these people do have a difficult time in understanding the concept of brain death and organ donation, whereas the better educated person in the country have a much easier time in accepting these concepts and being much more positive towards organ donation as an issue”. Page 9 Paragraph 9

Summary

In response therefore to the question of what is the impact of presumed consent legislation on the bereaved relatives these interviews identified a number of key issues that contribute to this. It has been suggested that the different approaches to drafting the legislation, specifically the role of the family in the use of the deceased's organs for donation is a crucial element in assessing the impact upon the relatives. The professionals interviewed reported that it would be professionally unethical to exclude the family from the decision-making or to override the views of the family, seeing this as both detrimental to the family and the organ donation initiative. The inclusion of the family in the decision to progress to organ donation, presents questions as to the deceased's right to determine the outcome of their organs after death. Questions also arise as to the importance placed on the deceased's stated views and the validity of the "consent" of family to progress to organ donation given in this manner. Questions are therefore raised in relation to the practice of obtaining the family's agreement to proceed to organ donation and the role, function and value of organ registers in the expression of the individual's wishes to consent or object to organ donation. Furthermore, the role of the public education campaigns in providing information to the family, facilitating their involvement in the decision making process in organ donation and therefore the success of presumed consent legislation, also required to be explored. These issues will be examined further in chapter 9.

8.1.2 How does Presumed Consent Impact Upon the Relationship Between the donor Families and the Healthcare Professional?

The responses from the questionnaires suggested that the level of understanding of the legislation and organ donation issues by the family was important in allowing them to participate in the decision making process. These responses also indicated that one of the key challenges to the organ donation programme was gaining support for donation from the family and society as a whole.

Responses from some of the questionnaires indicated that trust and confidence in the organ donation systems and staff was vital if the organ donation initiatives were to be successful. In addition some respondents suggested that there were issues for the public in terms of the information available on the health care practices in relation to organ donation and the transparency of these, inferring that if these practices were not clearly understood by the public, then the relationship between them and the HCPs would be in jeopardy. Questions therefore arose as to the validity of these concerns and impact of this type of legislation on the relationship between the donor families and the HCP, namely:

- Is trust in the HCP impacted upon by the level of knowledge and understanding in relatives / public about organ donation issues and law?
- Is trust in the HCP impacted upon by the level of understanding in relatives or the public about concepts of organ donation and brain death vital to organ donation?
- Is trust in HCP's optimal care for a relative required by the family to facilitate their agreement to organ donation?
- Is public confidence in the diagnosis of patient death and eligibility for donor status required to facilitate organ donation?
- How are the incapacitated protected from automatic selection as donors if unable to give consent?

The interviews undertaken with the HCPs in the 3 countries under review attempted to explore the topic of the family's response in the event of a potential organ donation and the relationship between the HCPs and the family and the public in regard to organ donation. On consideration of these questions those HCPs interviewed suggested that the trusting relationship between the donor families and themselves was based on a number of factors:

8.1.2.1 Level of Knowledge of Organ Donation and Law in Public and Society

As previously suggested the HCPs suggested that the public and the majority of relatives who are involved in the organ donation situation do have a prior knowledge of organ donation issues, if not perhaps the details of the laws in their county. They suggested that the public information campaigns or knowledge of others having an organ transplant had provided information in general terms about organ donation as N ST O 16 a consultant intensivist reports:

Document Transcription N ST O 16

“I don't know if they remember the law personally but they have heard about organ donation and I mean there are lots of people having them all around. Or I have seen that as well, that they know of somebody who is waiting for an organ and there has been something in the media about this several times which I have heard at least”.
Page 7 Paragraphs 6

Staff interviewed acknowledged the view that the public's understanding of the law was poor and that if it was applied rigidly then this would have a negative response from the families as N St. O 16 further suggests:

Document Transcription N ST O 16

“ If you try to pressure somebody or say that you have to think about this, then it might even be a negative thing but I would not try this.” Page 7 Paragraph 6

As previously described in the interviews with staff, changes in the legislation in Portugal and Belgium had been preceded by public education campaigns to provide the public about the changes in the law, however the Norwegian law was developed in 1976 and implemented immediately, with no prior education campaigns. It was reported however, regardless of whether there had been efforts to raise the public's awareness in regard to organ donation issues prior to the implementation of the legislation, on a regular basis all three countries had subsequently been provided with government supported education campaigns to inform the public about the organ donation legislation. Those interviewed suggested that these media campaigns had helped to improve the public knowledge of organ donation as B Bru 103 an intensive care doctor reports:

Document Transcription B Bru 103

“Yes. There are also a lot of campaigns on commercial TV and some of them have somebody in the family who knows about it. So that is a good situation for us, you can say you know somebody in the family you know how it works. They know all the politics around it”. Page 3 Paragraph 8.

Those interviewed considered that if the public and therefore the relatives were informed about organ donation systems and issues, then a relationship built on trust developed between the HCP and the family. This then made the approach to request the family to consider organ donation easier which would be more likely to result in their agreement to proceed to organ donation as B Bru 103 again suggests:

Document Transcription B Bru 103

“Maybe easier to discuss it because, I never felt there was a problem to discuss it, but probably easier to have a yes in this situation. I think that those families they really understand the meaning of organs so you probably have it more easily I guess. Even I say I think 85% would say yes, so I have a high acceptance rate”. Page 3 Paragraph 8

The HCPs in all three countries acknowledged the government-funded infrastructure for ongoing public education in relation to the need for organ

donation, highlighting the benefits of organ donation to society especially since the change in law had been explained. Other educational initiatives such as the provision of education sessions to school children in Belgium, together with public surveys relating to their views on organ donation helped increase the public's knowledge of organ donation. B Bru 102 a former transplant coordinator participant suggested that other accessible media from France on organ donation augmented that available in Belgium and provided education of the public on this issue which they viewed as being linked with the high organ donation rates in their country:

Document Transcription B Bru 102

“Mostly through the media, through the French media, I mean talk shows, the French have a lot of talk shows and things like that, I mean once or twice per year. A few times on Belgian TV but not very common and also I think Belgium is a small country and our transplantation activity is quite high. I mean in correlation with the number of proportion of transplantation per head is the biggest/largest transplantation proportions in the world. So since it is a small country more and more people know acquaintances and people around them who have had a transplant so they know how many patients are waiting. [They know] what is the transplant, how did it happen and things like that and what conditions organ donations are done [under] and things like that so I think yes”. Page 4 Paragraph 5

Despite similar public education campaigns in Portugal, some HCPs reported varying levels of knowledge regarding organ donation or the legislation. This sometimes required detailed discussions about the law and the procedures for organ donation at the time of their relative's death and subsequent consideration as a organ donor. They suggested that the lack of knowledge and understanding of law and organ donation concepts had led to suspicion and mistrust of the team caring for the donor when they approached the donor family to explore whether the deceased objected to donation, as PSJ 4 an intensive care doctor explains:

Document Transcription P SJ 4

“Yes I feel that this would be detrimental to the situation and I know of an experience where families maybe had not been fully informed about what was going on about the

organ donation status. In my view this would lead to questions being posed to the staff, as to what had gone on in this situation, whether all appropriate care had been given to that relative, what exactly had the status of the patient had been prior to a decision of organ donation being made on behalf of the deceased. If we did not do that then the questions raised as to how we would justify what we had done as health care workers and how would we explain our decision making to the families about someone being brain dead, and then someone being an organ donor. I feel the involvement with the families, although difficult, is actually very important". Page 6 Paragraph 9

Many of the interviewees expressed the view that previous knowledge of organ donation concepts combined with the staff's willingness to inform families about their loved one's condition resulted in the development of a trusting relationship between the two groups. This resulted in low refusal rates for organ donation as

B Lev 9 an intensive care doctor reports:

Document Transcription B Lev 9

"I think that that is the reason why we have observed that the percentage refusal rate for organ donation in relatives is very low. The reaction of the responsible relative to this request is positive. Over the one hundred procedures we did the last 10 years I calculated the refusal rate to be about 10% which is very low. We have in this hospital one of the highest donor rates for this country." Page 4 Paragraph 6

"Several people thought that always informing the relatives would increase the number of refusals, we are happy that our experience shows more the opposite. Of extreme importance is of course the way that you bring the message to the relative of the person who died". Page 5 Paragraph 1

8.1.2.2 Response of Society to Presumed Consent Legislation

Some staff also expressed the view that the public today are better educated on law and the procedures related to organ donation. This knowledge in their view helped to develop understanding and positive attitudes towards organ donation within society as B Bru 102 a former transplant co-ordinator explained:

Document Transcription B Bru 102

"It also follows to my knowledge it follows the general trend of surveys, when you ask people in the street "are you in favour of organ donation?" When you ask them in a normal environment no one is stressed 80% of people will say yes . If I can save someone with my organs , of course this is no problem. I think therefore that it also follows the same trend, supposedly that everyone is in favour of organ donation". Page 8 Paragraph 8

The interviewees in the 3 countries expressed the view that society accepts organ donation and that individuals have the choice and individual autonomy to donate or object to the donation of their organs through the systems that are in place and this must always be respected. They suggested that it was important that the underpinning principle that the organ should be viewed as a voluntary gift is upheld. This was in contrast to the perception of government ability to take and control organ supply. B Bru 106 a transplant surgeon voiced the view expressed by many of those interviewed on this point:

Document Transcription B Bru 106

“..... the way the Government owning the person who lives in the country, which you are dying you are my property. It is not a good way to think. On the contrary if you are saying well if you are dying, if you can give your organs to somebody, it is more important for the persons to say you can make a gift after your death and another way to think and organise this”. Page 6 Paragraph 5

A view expressed by some participants was that presumed consent legislation forces the society and thus the individual to take some action on this subject if they object to their organs being donated. This they viewed as being a beneficial consequence of the presumed consent legislation as B Lev 24 a senior intensivist suggests:

Document Transcription B Lev 24

“I think that there are first of all knowing the passive nature of most people in this matter the presumed consent laws, forces the population into the situation where they really have to take a strong option to declare their opposition to the system”. Page 6 Paragraph 3

It was also suggested that there was an acceptance within society that failure to register an objection is taken as a positive response to organ donation as everyone had been informed of their opportunity to register an objection, as PM 64 an intensive care nurse reports:

Document Transcription P M64

“The benefit and most important thing is that we respect the will of the patient. We also respect the view of the non-donors as well as the donor patient. The legislation is good because people do not want to go to the trouble of registering and therefore non-registration sometimes means that there is more organs available so this is a benefit overall. When the legislation was changed everyone was informed and had the opportunity to register their objection to this”. Page 3 Paragraph 12

It was reported by some interviewees that presumed consent systems can be considered by some as demonstrating solidarity with the community by facilitating organ donation which benefits not only the individual but society overall as one participant B. Lev 24 a senior intensivist suggested:

Document Transcription B Lev 24

“I think that the opting out system in some way shows the solidarity of the people. I think that most of the Europeans have this opinion and they take a common sense view that opting out is really something that requires a deliberate act. If you don't do it then there is a possibility you will be a donor”. Page 6 Paragraph 3

Some HCPs in Belgium considered that the level of information available to the public in relation to organ donation was the basis of the positive attitude in their society in relation to organ donation. In the spirit of open communication as much information as possible should be made available to the public including refusal rates, as B Lev 24 again suggests thus:

Document Transcription B Lev 24

“Well I think that the atmosphere of communication has totally changed and there is now a need to be honest with each other with a great sense for openness. I think that we should also keep the public opinion informed. If there is really a problem in the country, the solidarity come into question I think you should always publish the refusal rates, similar to the practices in the U.K. the public should know the refusal rates.” Page 5 Paragraph 5.

8.1.2.3 Approach to Relatives

The participants suggested that previous understanding of the legislation and procedures for organ donation made the exploration of organ donation less traumatic for the donor family and had promoted trust in the HCP. In addition,

many of those interviewed suggested the approach to the relatives adopted by the team caring for the donor to be important in gaining the trust of the family. Many interviewed in all three countries expressed the strong view that confidence and trust in the HCP proposal to consider organ donation, was developed in the family as a result of their involvement in the patient situation at every stage of their care demonstrating an attitude of openness and honesty by the HCPs in relation to organ donation procedures and practices. In the view of the staff the family being kept informed about the deterioration of the patient and efforts made by the multi-disciplinary team to save their life promoted confidence and trust the HCPs. As a direct result of this confidence the family would accept the patient status and not raise an objection to organ donation. B. Bru 108 an intensive care doctor highlights this point:

Document Transcription B Bru 108

“I think that in fact most of the messages rely on the confidence of the family of what happened to the patient before he died. Because in most of the cases if the patient has been correctly treated then the family has the impression that they were correctly approached with the decision by the nurse the staff with an open mind that were able to explain what went on, in most cases they are confident and they will say well we accepted the diagnosis. We know that you did your best to save this patient”. Page 11 Paragraph 3

Those interviewed went further, suggesting that not only was there was a potential for mistrust between HCPs and if the family were not kept fully informed of decision making in regard to their relatives care and subsequent diagnosis of brain death, they also suggested that suspicion of the HCP would impact not only on the relationship with the individual family but could have an effect on society’s response to the organ donation initiative overall as the following participants N R 124, N R 115 two ITU doctors and B Lev 13 a head nurse in intensive care and recovery revealed:

Document Transcription N R124

“Yes certainly and in society it would also be very negative I think. Or people think that they had turned off the respirator and took his organs you know”. Page 5 Paragraph 4

“Yes and you know it is sort of like a contract you know at least they are trying in Norway and in Britain too I guess, they are running down on the vultures or trying to run down the vultures all the time and the consequences in some cases, patients get low quality treatment or care or the other half start to just take organs when it is needed. It is like the contract between society and health care professionals it is destroyed in a way, the trust is destroyed.” Page 8 Paragraph 10

Document Transcription N R115

“Yes I think so, like I say, I think it is a suicidal attitude to try to change that and to take organs in which the donor has explicitly said that you can take whatever you like and the relatives are against it. It does not work”. Page 10 Paragraph 5

Document Transcription B Lev 13

“I don’t think it is very respectful of the relatives nor to the patients because we don’t ask the patient at the moment for his beliefs of this,that’s in the first place. In the second place I think in doing so we get so much bad publicity that you get resentment from the public against us. The people that will have doubts would say “was he really dead” because at the pronouncing of death, to take the organs, you get all sorts of accusations and I don’t think it is a good thing for organ donation. I think straight forward asking, to be direct is better”. Page 4 Paragraph 11

Some interviewees highlighted that families may express views on donating particular organs and withholding others. In their views if this were respected, then the donor family would be more at ease with the concept of organ donation.

N St. O 124 an intensive care and recovery nurse explains:

Document Transcription N ST 0 124

*“Yes I think so. And also they can come with their opinion about which organs that can be taken. Rather than saying you can take all but not the heart or the eye”
“Yes some of them said so. They have special feelings about some things”. Page 5 Paragraph 5*

Many interviewees expressed the further view that the key element in building the relationships with the family was the ability to spend time with relatives prior to the request for them to consider organ donation. In their view the use of the multidisciplinary team approach to conformation of death and request to consider

organ donation, comprising nurses, psychologists and in some situations members of the clergy, promoted a trust in the family, as two participants B Lev 5 a head nurse in intensive care and N St. O 77 an intensive care doctor described how some multidisciplinary team exercise this responsibility when they said:

Document Transcription B Lev 5

“ Absolutely the responsible doctors with the responsible nurses not me, but the nurses who are responsible for caring for the patient. Mostly, it is the social nurse who is caring for the patient. Because they are the confidential person who was with the patient and the family in the emergency unit here and they come here to provide continuing care”. Page 4 Paragraph 18

Document Transcription N ST 0 77

“ But now when the procedure is of good team work where everyone tells each other what we have been informing about, what the reactions were, where the family is in the process. I think they are going to agree or I am not so sure that this family will agree. We talk like that when the family makes their own decision and we also use the priest; very often. Of course if the family wants to but we also use the priest on occasions where we think it is complicated, to support us.” Page 4 Paragraph 15

“But of course some families sometimes also want this religious support as in a blessing before to read some words from the Bible. Yes but the priests are also people who are used to talking to people in a crisis and know something of how to deal with that. So they often help us because we are often two nurses, nearly always, but the practical things take much of our time and then the priest can be with the family and support them and help them. And some families are very traumatised and cry and things and so on. So the priests are a good help there, helping take care”. Page 5 Paragraph 5

All of the HCPs interviewed expressed the need to separate the news of the patient being confirmed as brain dead from the news that they were now eligible to be considered as an organ donor. In their view linking these two concepts was detrimental to the success of the family not objecting to organ donation, as the family would not have been given sufficient time to come to terms with the news of the death and been suspicious of the HCP's motives for pronouncing their relative as brain dead. They suggested that the separation of these two elements allowed the relatives time to come to terms with the death before the

introduction of the concept of organ donation. B Bru 103 an intensive care doctor describes the approach to this adopted by many of the interviewees:

Document Transcription B Bru 103

“Usually we call the family, tell them the situation and give all the explanation regarding brain death and leave the family with the patient”. Page 1 Paragraph 17

“There is a two step procedure of the way I work. First explaining that the patient is dead and that the patient is in quite a strange situation because, the heart is still beating and explaining what brain death is. And then I answer all the questions and then I will leave the family with the patient for half an hour, an hour, sometimes may be more. And usually they come back themselves and come and ask the questions “what is going to happen now?” And then we explain to the family there are two different issues, the first being the donation and the second one being, taking the patient off the ventilator. That the ventilator is now totally useless for this patient”. Page 3 Paragraph 4

8.1.2.4. Relatives Understanding of the Concept of Brain Death

In addition to the families’ poor understanding of the legislation and procedures related to organ donation, those interviewed also highlighted the difficulties experienced by the family in understanding concepts of brain death. If the donor was being cared for on a ventilator in intensive care, they may appear to the family to be merely unconscious, as the resuscitation equipment was supporting their cardiac and respiratory output. Seeing the patient in this condition, the family often had hopes of a recovery for the patient. In these circumstances convincing the family that the patient is brain dead, maintaining their trust and that it is acceptable to consider organ donation is a challenge to the HCPs. B Lev 24 a senior intensivist describes this thus:

Document Transcription B Lev 24

“Well it depends on the educational level. If the subject is quite familiar then they know what is being explained and they respond well. But there are still people who are concerned that that their relative is not dead and there is still some reasonable chance that the patient will recover. And this makes it difficult for them to accept this”. Page 3 Paragraph 5

B Bru 102 a former transplant co-ordinator agrees:

Document Transcription B Bru 102

“Then the most difficult point for donor families is usually to accept the notion of brain death and if they don’t have fully understood this concept of brain death, well then they cannot accept the difficult concept of brain death. The only way to accept brain death diagnosis is for them to be in confidence with the medical team. So it is very much dependent on the initial contact and if they saw and witnessed that the medical team has done everything in their power and that explanation has been given to them, and investigation and why and the results and it will probably be easier for them to accept that brain death is indeed the death of the patient, and death of the individual and for them to accept this before stopping the machines for organ donation.” Page 3 Paragraph 5.

Those interviewed described the challenges of having to undertake very careful explanation of these concepts with the family in order for them to accept the death of their loved one. They agreed that these concepts were not well understood by the public and that the team often had to provide appropriate preparation of relatives to understand concepts. They stressed the need to ensure that the family must be confident that the patient’s best interests were observed prior to their confirmed brain death, in order for them to accept the death and trust the HCPs motives for considering organ donation. PM 89 a consultant intensive care doctor reflects the concerns raised by HCPs caring for relatives in this situation:

Document Transcription P M89

“It is very important that when you go to speak to the family about brain dead criteria you highlight to them that you have nothing to gain in this situation; that you are not connected directly to the transplant team, otherwise they might be suspicious of what you are saying about their relatives and perhaps assume that you have not given them all the care and resuscitation that maybe they required and that you are really just doing this for the organs and not for the benefit of society or them”. Page 8 Paragraph 7

Some staff interviewed in Norway suggested that there were fears held by some of the public that HCPs were guilty of moving to consider organ donation before the patient is confirmed as brain dead. Some of those interviewed supported this

view expressing ethical concerns about covert screening of patients for donor status prior to informing relatives of their condition or potential to be an organ donor. They suggest this practice is not in keeping with an open honest dialogue with relatives and would result in mistrust by relatives if they were to find out. N R 43 an intensive care nurse expressed this concern thus:

Document Transcription N R43

“So you are trying, you might even get told to do tests on the patient, lots of bloods have to be sent away, and you have relatives in the room waiting, wondering what are you doing. I mean if he is going to die anyway, why are you taking these blood tests?”
Page 2 Paragraph 3

“Yes. Sometimes you try to get the relatives out, you do it very quickly when they are out, it is just; I think a very bad situation. So you feel as if you are doing something you should not be doing and really hiding”. ***Page 2 Paragraphs 4***

Whilst other staff in Portugal and Belgium acknowledged the early screening of the patient as a potential donor prior to the conformation of brain death and prior to the next of kin being officially informed, they did not raise a concern in relation to this practice. They accepted that although screening the patient without approaching the relatives was not in keeping with making them fully aware of the patient’s condition, they viewed the early screening of potential organ donors as beneficial in terms of excluding the patient as a donor if the patient’s blood tests demonstrated an abnormality and in terms of the ability to move more quickly to organ donation if no objections were identified by the deceased or the family. B Bru 103 and B Bru 107 two intensive care doctors explained this view:

Document Transcription B Bru 103

“ Yes, that’s when the diagnosis has done. It may happen that diagnosis has not totally made before we are doing it, but usually, only once the diagnosis is made. Sometimes you know you have, the potential of the patient moving into the end stage and is going to die anyway, so sometimes you can go to the transplant team earlier but usually only after the diagnosis.” ***Page 2 Paragraph 12***

Document Transcription B Bru 107

“Before the death has been confirmed. Because you have a small period between the confirmation of the death and organ donation for the organisation for the organ retrieval. If we identified some potential donor, there would be some evaluation from the different organs before this. Of course when the patient is in the critical stages, then we can perform the tests”. Page 3 Paragraph 1

Interviewees in Belgium expressed further concerns related to the introduction of Non Heart Beating Donor systems and protocols that they themselves do not fully understand and feared that the public do not understand these either. Using this approach to organ retrieval in the emergency department following a sudden death, only a short time can elapse between the patient being pronounced dead and the deterioration of the organs, usually kidneys. In order to preserve the kidneys, cannulation of the deceased and infusion with a preservative fluid must take place within 45 minutes. As often the family will not have been informed of the death at this time, HCPs considered the adoption of this procedure, ethically challenging and open to disputes resulting in mistrust of the HCPs. B Bru 108 an intensive care doctor expresses this view thus:

Document Transcription B Bru 108

“On this occasion I think that it is difficult to announce to the family what has to be done. We can only say that we tried to resuscitate the patient but it was not possible, we did not succeed. To say this and then to tell them immediately after that, we still inserted the catheter and used the machine. So we prefer to say well that is the situation, it is awful it happened so suddenly he had died, he has no responses and then to say well, there is still a possibility to remove the kidneys. Page 10 Paragraph 7

“So we can tell them that according to the law when the patient has died we can do that. But, we try to avoid taking the first step to tell the family directly what has been done because then you can cause some problems. Because they will say that you have started something which is not in relation to the patient”. Page 10 Paragraph 8

Other interviewees who practice this approach to organ donation are more comfortable with the idea of undertaking preservation procedures on the potential

donor prior to exploring with the family whether they have any objections to organ donation. B Bru 109 an Emergency room doctor captures this sentiment:

Document Transcription B Bru 109

“We have experience with 1:50 persons. The family will accept and if we have acceptance from the family with or without cannulation. Normally, the cannulation is placed, it’s no problem of putting the cannulae without informing the family. For us, that is not a problem. If the family does not accept they don’t know about the cannulation. For me it’s not a problem otherwise it’s more complicated. But if the family accept okay, after one or two hours the people move the patient into the operating room”. Page 3 Paragraph 8

They express the view that they have experienced family support teams who will explain the organ donation procedures to the family together with the rest of the health care team, that they will understand the need to proceed quickly to organ donation and maintain the trusting relationship with the family and the team. B Bru 109 again:

Document Transcription B Bru 109

“But we have here [in the emergency] team who is working with together with the trauma social team, with the reaction of the family and the wait to discuss with them we have such people certainly. And they will work, in the case of the non-heart beating donor, after the procedure, to meet all the people and explain where busy with the patients and to discuss to see the what they want to say, that’s what we do.” Page 5 Paragraph 5

8.1.2.5 Culture & Religion

Those interviewed in the three counties under review differed in their views on whether religion and culture had a direct impact on organ donation. Those interviewed in Norway suggested that in general terms the Christian culture and Lutheran religion in Norway, did not impact greatly on society’s response to organ donation. N St. 77 an intensive care doctor expresses this view shared by many:

Document Transcription NST 0 77

“ I don’t think that there is a connection there. But I think that when it comes to organ donation I think that religion is a support that gives meaning and strength. But

as a support, the priest is not always doing blessings or prayers or something, he is just a care giver". Page 6 Paragraphs 13

HCPs interviewed in Belgium and Portugal however suggested that the mainly Roman Catholic religion in Portugal and Belgium contributed positively to the promotion of organ donation. B. Lev 16 a senior Anaesthetics summed up a view expressed by many in this respect:

Document Transcription B Lev 16

"Yes because if we have non-religious people, well let's put it this way. Most people in Belgium will be Roman Catholic if not practicing Catholics. Very few people will still go to mass. But they are still Catholics. Now I can only say that in that way religion doesn't play a large role. But if you look at the rest of Europe, I think that as long as Roman Catholicism is concerned, organ donation should not be a problem. Page 8 Paragraph 5.

"What we do see is that if we get patients that come from different religions, patients that we regularly see here are Islamic people and Jews especially orthodox Jews, we have a lot of orthodox Jews here, you will not get organ donation". Page 8 Paragraph 6

"Well I have talked to some of them [people of other religions] and they say that their bodies should be buried intact, nothing should be removed. I know that I have had some encounters with them and they have said no". Page 8 Paragraph 7

One HCP interviewed suggested that previously the Roman Catholic Church's failure to recognise brain death had hampered the organ donation programme in Portugal as PM 89 a consultant intensivist reported:

Document Transcription P M89

"This also had some difficulties in that at that point in the 1970's perhaps, the Catholic religion, [90% of Portugal is Catholic], did not believe in brain death criteria and did not believe therefore in organ donation and therefore the news of this tragic circumstances in this event seemed to support the religious belief of the country and the people at that time. There was no real 'brain death' and the organ donation was therefore in some way wrong and this really did cause great difficulties for those amongst the staff who very much supported the idea of brain death and organ donation, as a result to that." Page 5 Paragraph 6

All the interviewees agreed that different religious or cultural beliefs in regard to death, autopsy and care of body after death had an impact on organ donation practices. They reported that the existence of a more multicultural society in most European countries today including, Norway Portugal and Belgium presented challenges for the organ donation systems as B Bru 108 an intensive care specialist explained:

Document Transcription B Bru 108

“Not only for religious reasons, sometimes and also for people here in Belgium it’s a very difficult for the family in their native country, so very often they ask that the body should be transferred to their country. And I then think they are afraid of the reaction of the families there. What they perform in Europe and maybe they perform an autopsy that’s they are afraid of the reaction when they come back and probably not able to say to the family well we accept organ donation because there is a tradition, that the older people have that’s more complicated.” Page 5 Paragraph 1

As a result of this many of those interviewed recounted experiences where in the case of a potential donor being identified from a non-Christian culture or faith, either organ donation was not pursued or, the request to the family to consider organ donation was rejected on the basis that organ donation was not acceptable to that particular group as B Bru 102 a former transplant co-ordinator commented upon:

Document Transcription B Bru 102

“No 90% of the population in Belgium are Catholic / Christians and they do not have a problem with organs donation, but we do have a problem with those people who come from an African background who do not believe in organ donation. Page 7 Paragraphs 6.

“Yes. I think that they probably use religious motives for their opposition to organ donation. But we know that for most religions there is no opposition to donation. Even in Islam there is nothing in the Koran that is against organ donation”. Page 7 Paragraph 8

Other interviewees however recounted experiences where organ donation was explored and successfully achieved by providing careful support to the family of

a donor from a culture that was not noted as being a group who would have been considered to be in favour of organ donation, as B Bru 103 an intensive care doctor reflected:

Document Transcription B Bru 103

“Muslims, sometimes Jewish families and once I had a family which were Buddhist who were not so for it, but my experience with a Buddhist family was that they accepted this. And it was a difficult case of a young girl of 14 years old and the family agreed and I remember the Dad was younger in years but the Mother older. She immediately they said we will do this. Usually we would say no but we understand you can go ahead. Muslims certainly and Jewish people, they are a problem”. Page 4 Paragraph 2

8.1.2.6 Protection of the Incapacitated

The literature review on the application of presumed consent legislation demonstrated very limited published data on the impact of this legislation on adults who were incapacitated. Questions were raised therefore, as to how this group would be protected and how the family of a potential donor who was incapacitated could ensure that any objections to their becoming an organ donor could be raised.

On review of the legislation in these three countries under review, it was identified that there was some provision in the legislation that detailed the exclusion of the incapacitated or those without the capacity to consent. For example, adults with a learning disability were exempted from the provisions of this legislation. Some of those interviewed however were not always aware of these provisions but described their practice of either excluding an individual who did not have the capacity to consent from being considered as a donor or using the substituted judgement of the family or recognised advocate to make the decision. In the case of a child those interviewed reported the practice of seeking

the parental consent or that of an official guardian to provide consent to proceed to organ donation in the event of a child becoming eligible to be donor, as PM 64 an intensive care nurse explained:

Document Transcription P M64

“I do not know if the law protects these particular people. I know that children are protected in that there is an age limit in organ donation; in that under two and then other than that, the parents must be always asked. The relatives can challenge this if they think that the person did not want to be an organ donor”. Page 4 Paragraphs 1

Others were more informed about the legal protection offered to the child or incapacitated as B Bru 102 a former transplant co-ordinator reported:

Document Transcription B Bru 102

“I would have to go back and read the law again, but to my knowledge it would have to be the same for the patient’s rights bill. This came out in the law two years ago. There is a whole package of decision making in the normal situation, first of all the parents, will be involved in the decision of the child or the mentally incapacitated. If it is not the parents then it will be the first degree relatives, or the legal tutor who has been appointed by the court or what ever, so to my knowledge in the donation process the same process has to be respected, for mentally disabled people or for minors, we still have to ask for permission”. Page 9 Paragraph 6

In the views of the interviewees this system protected the rights of the incapacitated and engendered a trusting relationship with the families concerned as this facilitated them being part of the decision making process and able to object to organ donation on behalf of the incapacitated person.

Summary

In response to the question of how does presumed consent legislation impact upon the trusting relationship between the donor families and the HCP a number of issues arose from the interviews. Those interviewed also suggested that in order for presumed consent legislation to be accepted, the public must understand the law, the procedures for registering their views and know that they have a

choice to register for or against organ donation, with this choice being respected. They also indicated that public confidence in the legislation in organ donation is built on knowledge and understanding of the law and organ donation system. A question arises however as to the levels of education of the public required to provide enough understanding of organ donation to achieve trust in the system.

The HCPs interviewed reported that the success of the organ donation initiatives are dependent society's understanding and trust in their practice. This trust was established by ensuring public understanding of the organ donation legislation and the practices associated with organ donation. These practices of the HCPs must also be open and transparent to the public. Careful strategies for building a trusting relationship with the family by informing them about organ donation procedures require to be developed and undertaken by the health care team to support the family and facilitate organ donation. The implications of these findings will be explored in more detail in chapter 9.

8.1.3 Policies and Procedures in Organ Donation.

An initial review of the responses to the questionnaires suggested that there were a variety of practices and policies adopted in the three countries under review.

These responses also indicated that there were both benefits and challenges to the HCPs, the families and the health care organisations in implementing presumed consent legislation. This indicated that key questions remained to be answered as to the implementation of presumed consent legislation in health care practice. There was also a need to explore the requirement for the provision of specialist

procedures and policies or resources to enable this legislation to be applied in health care practice namely:

- How is the legislation on organ donation applied in practice?
- What policies and procedures are required to apply this law in practice?
- How does the organ donation legislation impact on the staff and resources required to deliver this approach to organ donation?
- What is the impact of presumed consent legislation on the healthcare system?

8.1.3.1 Law Application in Practice

A review of the literature and interviews with the HCPs indicated that different systems of identifying objections to organ donation operate in the three countries.

In Norway a review of the legislation (Department of Health and Social Services, 1973) (**Appendix III**) demonstrated that there was no requirement for a register of objectors to the donation of organs to be established. Interviews with some HCPs suggested that Norway is however currently considering the establishment of an organ donation objection register to facilitate the establishment of an objection by the deceased as N R 124 a senior anaesthetist, reports:

Document Transcription N R124

“Actually they have tried to get a register during the last one or two years with cards that you can have in your wallet and also I think, a form that should be sent in for registering, but in some of the Pharmacies, I think that they tried to set out these brochures but they are not always so keen. Some; you know TV adverts”. Page 4 Paragraph 11

Legislation in Norway requires that individual objections to organ donation must be explored together with any held by the next of kin. Those HCPs interviewed reported that these requirements are met by questioning of the next of kin about

the views of the deceased on organ donation in addition to establishing their views on organ donation as N UNPOP 23 an intensive care nurse, explains:

Document Transcription N UNPOP 23

“.....So the question you ask is; do you know what the deceased think about this and have you ever discussed it? If the relatives are very negative and say no, no we don't want this, we have never gone for the whole of the organ donation, anyway because we let the family decide because their opinion is the most important”. Page 5 Paragraph 5

This statement also highlights a view expressed by all of the professionals interviewed in Norway, where they agreed that they would not proceed with organ donation if there was any indication that the deceased had voiced an objection or, if a family member raised an objection to this.

In Portugal a register of objectors has been established and has been advertised in the media, this being a requirement under the 1984 organ donation legislation (Republic Assembly Law 1993). Under the terms of this legislation all Portuguese nationals and residents over the age of two years are subject to this legislation. In the event of a potential organ donation, the transplant co-ordinator can access the computerised register of objectors available 24 hours a day, in order to establish a recorded objection. Individuals can record their objection to organ donation by using a simple form accessed in their local health practice. They can also amend or update any information recorded on this register by completing a second form. The local health authority has a legal responsibility to organise and manage this register of objectors ensuring that efficient and effective access to this is achievable by the public and that an accurate register is maintained and accessible to the HCPs involved in organ donation.

Having established that no objection has been recorded via the transplant coordinator, the practice of the health care team caring for the deceased is to then approach the family to rule out any objection that they might hold. Although this is not required in law, this a common practice undertaken by the HCPs involved in organ donation. P M 70 an intensive care nurse confirmed that this is the practice in Portugal thus:

Document Transcription P M70

“Yes; despite the legislation it does not require us to ask the family for organ donation, we will always ask the families what their views are on organ donation; this is something that we always do”. Page 2 Paragraph 11

The majority of the HCPs interviewed in Portugal reported that even if the deceased’s name did not appear on the organ donation objection register, if the family raised strong objections, they would not proceed with organ donation as P M89 as senior intensive care doctor, reported:

Document Transcription P M89

“If the family that is present also objects to this, we don’t ever go against the will of the family even although the person is not on the list. If the family says No! they don’t want to go to organ donation then we do not proceed to organ donation”. Page 1 Paragraph 6

Many of those interviewed reported that this did present challenges for the HCP to apply the legislation. If however there was a conflict between the staff desire to procure organs for donation and the family’s objection to their relative’s organs being used, the normal practice would be not to progress to organ donation and respect the family objections as P SJ 4 an intensive care doctor, highlighted:

Document Transcription P SJ4

“Only once in my experience was there a major conflict between the staff and the relatives where the relatives would not accept the organ donation situation for a particular adult who was not on the register and there was many family members

involved and there was many brothers and sisters. Some would say “yes” to organ donation and some would say “no”. In that situation the staff resolved not to progress to organ donation because we thought it was too difficult a situation for the family to live with after this event”. Page 10 Paragraph 6

In Belgium those interviewed confirmed that a national register of those who are in favour of organ donation or who object to organ donation has been established. To register their intention as an organ donor or to register their objection to organ donation, every citizen in Belgium and those foreign nationals who are resident can obtain a form at their local town hall the completion and submission of which allows them to register their views. Alternatively, if they change their views they can also amend their personal details on the register. Amendments to the register can also be made by members of the public using this system. Transplant co-ordinators will also have access to these changes on a 24 hours a day basis.

8.1.3.2 Infrastructure Required to Support the Organ Donation System

Data gathered by discussion with the transplant co-ordination teams within the three countries reviewed, revealed the existence of different degrees of government-funded infrastructures supporting organ donation infrastructures in each country. This support is provided via the establishment of national transplant centres often based within major teaching hospitals and a system of recognised feeder hospitals which are able to undertake organ donation procedures. Subsequently, interviews with the HCPs confirmed the existence of different infrastructures to implement and support organ donation in three countries.

In Norway although a national register of objectors had not been established, a national system of organ donation and transplant co-ordination had been developed using a system of five government funded national transplant co-ordinators transplant co-ordinators. These former critical care nurses based with the central national organ transplant hospital liaise with the key members of the medical staff within the twenty eight donation hospitals across Norway to form a virtual national organ donation network. The transplant co-ordinators advise and support the key HCPs in the donor hospitals to explore if a patient in their care is a potential donor. These “donor responsible doctors” in turn support and advise their staff within the twenty eight donor hospitals, to ensure identification of potential organ donors in patients who die in hospital as N R 124 a senior intensive care anaesthetist reports:

Document Transcription N R124

“Yes it has been quite organised in this hospital because we have transplantation co-ordinators and we have NORAD the organisation for communication for to make it possible for all the hospitals and they revise it every four years or so”. Page 2 Paragraph 4

“Yes it is a national region that we have the organisation for all hospitals of a certain size they are called donation hospitals and then we have this protocol of course and it is always one doctor that they call a transplantation co-ordinating doctor or something like that”. Page 2 Paragraph 6

“Yes a responsible doctor and the responsible doctor has only recently been for the last two years I think”. Page 2 Paragraph 8

The HCPs interviewed reported that this very established system of communication and protocols of practice that assisted the practitioners within the donor hospitals to facilitate successful organ donation and transplantation. This system allows for the potential donors to be quickly identified and communicated to the transplant co-ordinator who authorises initial screening of the patient as a potential donor. If screening of the patient demonstrates that donation is possible,

the transplant co-ordinator will organise an organ retrieval team to be dispatched to that donor hospital to undertake the organ retrieval. The transplant co-ordinator may accompany the retrieval team to the donor hospital anywhere in Norway and provide direct support to the ITU staff caring for the donor and support to the donor family. They will also co-ordinate the delivery of any successfully retrieved organ to the transplant centre within Norway or alternatively ensure that this organ is made available to the Norway or Scandinavian organ sharing system for transplant.

In Portugal five regional organ donation and transplant centres have been established to co-ordinate the activities of 27 donor hospitals across the country (Teixeira et al., 2004). Similar to the system in Norway, a regional system of government-sponsored organ transplant co-ordinators posts has been established throughout the country based in major hospitals that are designated as transplant centres. These transplant co-ordinators have been appointed to support and foster a culture of organ donation amongst the health care professions. They are responsible for supporting organ donation initiatives in their region, accessing the register of objectors and communicating this to the HCPs caring for the potential donor. In addition these transplant co-ordinators advise staff on organ donation protocols, co-ordinating the dispatch of retrieval teams to the donor hospital. These teams of up to four transplant co-ordinators, who are either a transplant surgeon or a senior anaesthetist within the transplant team, act as the transplant co-ordinator for the region on a part time basis, whilst continuing to practice their particular medical speciality. Transplant co-ordinators in Portugal may also be directly involved in the support and approach to the donor families

to request organ donation. Alternatively, they may provide advice and support to those professionals within the ITU caring for the donor, who will approach the families to establish a lack of objection to donation.

Participants reported a very good relationship with the transplant co-ordinators who provided them with support and advice in regards to the identification and management of the potential donor as P M60, a nurse in intensive care describes:

Document Transcription PM60

“Yes I think this is one of the benefits of the system we work. Because the transplant team come from another hospital to the new hospital here, they don’t know each other that well and this feedback that comes after the event of the transplant provides a good working relationship between the transplant team and the intensive care staff who have been involved in this situation. I feel that this builds very good relationships with the transplant team, we have very good relationships with the transplant team and I feel this feedback is a major part of the building of this good working relationship”
Page 4 Paragraph 11

They also described a well-organised system for organ donor identification by the transplant co-ordinator. P M71, an intensive care nurse and P M89, a senior intensive care doctor described the process reported by many of the professionals interviewed thus:

Document Transcription P M71

“During this period we will contact the transplant co-ordinators and ask them to check if this person’s name is on the list of objectors, which would prevent them being an organ donor so the transplant team will consult the list. Even if we do not find this person’s name on the list, we contact the members of the family to discuss this with them”. Page 1 Paragraph 7

Document Transcription P M89

“Normally what happens after the first set of brain death criteria; we suggest the patient is brain dead. Normally we would then contact the transplant co-ordinators at that point and inform them of the ongoing situation with the patient.” Page 4 Paragraph 1

“What normally will happen after the first set of tests, they will ask for the patient’s name and details and they will consult the non-donor list to see if the patient is actually an objector to organ donation and details so that they can actually process them should they eventually be an organ donor. On doing these tests and checking

that that person is not on the organ donor list, a fax of written confirmation that this is the situation will be sent back to the ITU unit for their records, that this person can be an organ donor and is not on the organ donor objectors list". Page 4 Paragraph 9

Should this potential donor prove to be suitable then the retrieval team of transplant co-ordinators from University teaching hospital would be the dispatched to the donor hospital where organ retrieval would be undertaken.

Transplantation of any organs obtained was then undertaken at the nearest regional transplant centre often housed within a large University hospital within Portugal as P M71, an intensive care nurse confirmed:

Document Transcription P M71

"Once we have contacted the transplant team the operation for the organs is undertaken here in this hospital". Page 1 Paragraph 9

"Once the organs have been retrieved from our hospital, from the patients in our hospital then they will be distributed around Porto and Portugal so if it is the liver, they will go to San A Hospital and if it is a kidney it will go to S J Hospital". Page 1 Paragraph 10

Should this not be possible due to the lack of a suitable recipient similar to the process described in Norway, the organ was offered to the local organ sharing partnership established across Europe.

In Belgium a system of eight regional transplant co-ordinator teams has also been established. These teams made up of former critical care nurses or cardiac theatre technicians are employed in a full-time capacity to co-ordinate the organ donation and transplant activities on a regional basis throughout Belgium. This involves the support of the HCPs within the 38 donor hospitals across Belgium to identify a potential donor and in the first instance, explore if the deceased had recorded an objection to donation on the opt out register as B Lev 24 a senior anaesthetist describes:

Document Transcription B Lev 24

“Once this is done we come to the diagnosis of brain death, then we contact the transplant co-ordinator. The first phone call we make is to explore whether the patient has taken the option to “opt out” of the donation or not.” Page 2 Paragraph 7

All transplant co-ordinators have access to a national communication and national computerised register allowing access to register of donors or objectors to donation if available by the transplant co-ordinators on a 24 hour basis. These co-ordinators are responsible for the confirmation of the donor suitability and absence of the patient’s name on the register of objectors, providing advice on the management of the donor, together with the organisation of the organ retrieval and subsequent transplantation of the organs. One interviewee who was previously employed as a senior transplant co-ordinator and now practiced as a senior nurse within the hospital was able to give a detailed account of the infrastructure for organ donation in Belgium:

Document Transcription B Bru 102

“So what usually, we are usually contacted when the first signs of brain death appears but there is no final confirmation of brain death and also mostly before contact with the family has been established talking about organ donation. So we might have a potential donor so we just want to make sure that we have this and that eventually you can start planning something”. Page 1 Paragraph 18

“Depending on the experience of the physician he would either contact us first if he had a potential donor and say well this is the first time, I am confronted with this case what do I have to do, what steps do I have to follow. Or it will be a physician who’s already been confronted with this situation and knows what to do.” Page 2 Paragraph 18

“So usually these steps would be taken already by the referring physician and local referring physician who talk to the family and request organ donation. But what we would also do is at the first stage when the potential donor is referred to us we would also look at the national database to see if the patient opted out or opted in against organ donation. And then once we have got consent of the family and the procedure starts, we contact the transplant coordinator to organise the whole procedure and it’s always our local surgical teams, transplant teams which go to the peripheral hospitals to do the procurement. Always transplant surgeons to go out to at the peripheral hospitals to do the procurement with a fellow surgeon, a scrub nurse and with the transplant coordinator and all the material needed”. Page 2 Paragraph 4

In Belgium those interviewed reported that the transplant co-ordinators are easily accessible and provide advice and support the HCPs in the care of the donor and family. They are also involved in the education and support of the HCPs caring for the donor and family. However, the transplant co-ordinators do not approach the family to explore their views on organ donation unless specifically requested to do this by the staff within the donor hospitals, as B Bru 102 again explains:

Document Transcription B Bru 102

“I would say that I was involved in the donation request in less than 10% of the cases. It has happened that physicians said to me well I don’t feel comfortable with the situation, it is the first time that I have done this or I never done before or eventually it is a difficult situation could you be of assistance to me. And then I would always assist the physician and we would have a joint approach to the family”. Page 3 Paragraph 1

Communication systems within the individual countries are linked to the European organ donation and transplant networks allowing sharing of organs within the individual countries and regions. These systems also allow the sharing and matching of organs across European countries should a match for an available organ not be found in the county of origin, as B Bru 102 again describes:

Document Transcription B Bru 102

“Exactly, and the coordinator contacts Eurotransplant to say that there is a donor available the allocation of the organs is done via Eurotransplant and during the process of donation of the organ harvesting itself or maybe just before the Eurotransplant contacts us and say okay then we have to go there, the lungs have to go there etc. For the thoracic organs it is usually the custom that the thoracic implanting team always comes to the donation centre. So, for example if the heart and lungs go to Austria we would have to contact the local centre and organise a trip with them also make sure they are prepared to organise things there at the same time and organise the facilities there and so forth”. Page 2 Paragraph 6

B Bru 102 also confirmed the establishment of the national transplant co-ordinator system and communications systems within their country together with the funding of these by the government. He also reported a system of reimbursement to individual hospitals of expense in undertaking organ donation

from the recipient's health care insurance has also been established to encourage hospitals to participate in this system as B Bru 102 explains:

Document Transcription B Bru 102

“This is also charged for each organ transplanted to the different user recipients of the different organs and which is refunded to the donor hospital. The donor hospital does not lose money. It is an investment for the donor hospital to have to make, because surely from the time of brain dead diagnoses until the time of organ processing or harvesting in the operating room, there maybe a period of 10, 12, may be sometimes 24 hours. This is still time. Time is still money for a donation hospital. So with this system in place the donor hospital does not make profits but they don't lose money I am sure that this is facilitating the system”. Page 6 Paragraph 2

8.1.3.3 Protocols for the Identification of Donors by Staff & Types of Donors

The early identification of potential donors and notification of this to the transplant co-ordinators was encouraged in all three countries. These potential donors would normally result from patients who developed cerebral death following an injury to their brains, as a result of an accident e.g. a car road traffic accident or fall. Other patients may have developed cerebral death as a result of sustaining a cerebral bleed that could not be controlled as B Lev 1 a senior intensive care doctor and Bru 109 a senior emergency room doctor, described:

Document Transcription B Lev 1

“Normally we quite often have an idea that somebody will be a donor from trauma, accidents and it is our task to identify them and then to first, look to see if they are medically okay, let's say that the potential organs are good if you have somebody with a very bad condition”. Page 2 Paragraph 1

Document Transcription B Bru 109

“Yes we have most of the patients were cerebral trauma patients and I tried to have the accurate information on the origin but, for most of the times, trauma patients. It could be head injury but it could also be multiple trauma with extensive resuscitation”. Page 1 Paragraph 17

Recently, education of staff has been undertaken encouraging them to consider all patients as potential donors and reduce previous exclusion criteria. With this increased understanding of the potential of a patient to become an organ donor, HCPs in ITU and other acute settings are able to detect wider pools of potential

organ donors. Proactive donor identification initiatives for staff have been established with protocols for identification of donors and exclusion criteria for non-donors have been developed. These have recently been extended to include other patients who would have traditionally been excluded from being an organ donor, for example, patients over the age of 80 years were previously excluded as donors, as B Lev 1 a senior intensive care doctor reported:

Document Transcription B Lev 1

“Yes. Because we now want more and more, take a broader criteria, to also look at people over eighty years as possible donors”. Page 2 Paragraph 7

Communication systems with transplant co-ordinators for review of potential donors are in place to support the staff in all three counties allowing the HCPs to identify potential donors and explore this potential at an early stage with the transplant co-ordinator. National donor register networks facilitated effective communication between intensive care, emergency room or operating and recovery units and the transplant co-ordinator. On notification of a potential donor within a critical care area the transplant co-ordinator is able to quickly establish if the potential donors name appears on the register of donors or the register of objectors to donation. Interviewees further reported the establishment of clear protocols for inclusion or exclusion of potential organ donors. The HCPs interviewed in Norway and Portugal reported that they were confident in their protocols for the identification of potential donors and the procedures for organ donation, as N T2 a medical head of intensive care and P SJ 4 an anaesthetist in intensive care suggest:

Document Transcription N T 2

“Yes. So in that way we have a strict brain dead procedure. That is quite strict; so usually there are no problems when to take the patients who are identified”. Page 5 Paragraph 13

Document Transcription P SJ 4

“Eventually the normal procedure is that once they have had a series of very low Glasgow Coma Scale scores, they will progress onto doing brain death criteria in the ITU and we control intracranial perfusion with tomography. If there is a high ICP greater than 40-50 and the patient is not responding to treatment then we consider if they might be brain dead. We will then undertake neurological tests to try to establish this and then we will then decide whether or not the patient needs to go to cerebral angiography to confirm this. However, it could be that the brain dead criteria which they are about to undertake in the ITU, will be sufficient to demonstrate the patient is brain dead. There are no difficulties really. They are quite sure at what they are looking at”. Page 2 Paragraph 6

The HCPs interviewed in Belgium were equally as confident in their protocols for identifying potential organ donors, as B Lev 5 a head nurse in intensive care demonstrates:

Document Transcription B Lev 5

“For instance, it is not when the process is started as a family do not want to donate the organs, when the family want to stop it - it is possible and that is very important. I think it is a fair system. It is not so the patients don't get the maximum therapy, they will have all that also. I have no problems that there are things to do for the deceased, because it is very important to go quickly in that process. It is the time. Time is money. No, time is not money, but time is life. It is very important to go quickly in actual fact”.

“I feel my course is a good system it is very clear. That is important. And the fact of the group have to work together with the procedures. Because we have to start it here because we have to obey the law and that is important for us to more accept it”. Page 8 Paragraph 7

These participants suggest that they are fully aware of the protocols for practice in the identification of potential donors and utilise these in their everyday practice. They are also familiar with organ donation infrastructures and communication systems within their country, utilising them to identify and manage potential donors.

8.1.3.4 Technical Organ Donation Policies & Practices

Within the three countries the HCPs reported clear policies and protocols for technical aspects of organ donation, for example, the identification of cerebral death in the donor had been developed and implemented in large university hospitals. Those interviewed in the three countries however reported that differing practices for the testing of brain death and the confirmation of brain death exist between the three countries explored. These practices utilise international criteria for the clinical establishment of a patient who is brain dead. However, individual countries have developed different additional practices and testing systems to establish cerebral death, the key aspects of which were identified as:

8.1.3.4.1 Establishing Brain Death in Portugal

In Portugal a set of procedures has been established to diagnose the patient as brain dead and therefore as a potential. Here two doctors of at least five years post- registration experience, independent of the transplant team, often an intensive care doctor, a neurologist or neurosurgeon will undertake the first set of internationally recognised bedside tests to establish brain death and agree that the patient has failed to demonstrate any cerebral activity as P M89 a senior anaesthetist in intensive care, explains:

Document Transcription PM 89

“The brain death criteria that we use are under direction of the Royal College of Physicians in Portugal and there has to be two doctors and they must both be senior doctors with more than five years experience. One of which, must be an Anaestheologist or intensivist and the other one must be a Neurologist.

Both these doctors will undertake two sets of test, these brain death tests, to try to establish the patient’s cerebral status. There will be an interval between both these tests. These tests include the reflex responses, apnoea tests, the pupil responses etc. We also highlight the need to exclude any types of sedation or anaesthetic drugs that

the patient might well have on board prior to doing these tests that might influence the results of these tests which we take care to ensure. When we have done two sets of brain death criteria and we get the results of these, then we can make a clinical diagnosis of brain death". Page 3 Paragraph 3

At this point in the process the transplant co-ordinator is notified of the patient's potential donor status and the patient is screened for their suitability as a donor.

In addition the family is made aware of the patient's deteriorating condition and the need to test them for brain death as PSJ 103 an experienced intensive care anaesthetist, explains:

Document Transcription P SJ 103

"We contact the transplant team at the time we are preparing to do the first brain death criteria , diagnosis. We use two sets of tests with an interval between them asking for all the urine analysis, blood analysis and so on". Page 1 Paragraph 2

"So we inform the relatives of the status. Most of the times it is a gradual process. Sometimes there are problems and the death is abrupt..... Page 3 Paragraph 2

They sometimes collapseprobably the relatives have been informed of the deteriorating situation". Page 3 Paragraph 4

If these two sets of tests, which use the internationally recognised brain death criteria, elicit no cerebral activity then the patient is pronounced brain dead and can be considered as an organ donor. In Portugal cerebral angiography is only utilised to confirm brain death should the system of two clinical bedside tests undertaken to diagnose brain death, suggest that there is some dubiety in the test results, as P M89 a senior anaesthetist in intensive care highlights:

Document Transcription P M89

"If there are any doubts we can do a third set of tests; of the brain death criteria or we can move onto to do more advanced tests by taking the patient to the Radiology Department and undertaking either cerebral angiography or angiography with isotopes or CAT scan with contrast, these are further tests that will allow you to actually measure if the patient has any cerebral blood flow present at all and if the patient has cerebral blood flow they would not be classed as being brain dead but if this is absent then the patient is automatically brain dead". Page 3 Paragraph 3

As was described these tests for brain blood flow are undertaken in the radiology department and are not without difficulties as P M89 again highlights:

Document Transcription P M89

“The gold standard is cerebral angiography but it can be a difficult situation if you can not wait for these anaesthetic or sedation drugs, the half life of these drugs to expire, because the patient is unstable through this situation and then you might use some of these other tests to CAT scan with contrast, to try to establish if the patients cerebral blood flow is either present or not”. Page 3 Paragraph 4

In Portugal should the patient be diagnosed as brain dead following the second set of tests or cerebral angiography the family will then be approached to establish that there is no known objection to organ donation. Details of this approach have been described previously and P M64 an experience nurse in intensive care confirms this process thus:

Document Transcription P M64

“Normally we would contact the transplant team and ask them to check whether or not the patient was on the non-donor list to exclude whether or not this patient had objected to be a organ donor or not. Throughout this process, we will begin to talk to the family and inform them of the situation. We don’t have to do this but we always speak to the family and try to keep them up to date with what is happening with the patient”. Page 2 Paragraph 5

Should this be the case then the donor will be cared for on the intensive care unit using organ preservation procedures until the arrival of the organ retrieval team from their base in one of the designated transplant centres and the organisation of a suitable time to undertake the organ retrieval procedure in an available theatre. This may result in the organ retrieval being required to take place in the evening or during night time hours when suitable facilities for this procedure become available. This process may take up to 24 hours to complete.

8.1.3.4.2 Establishing Brain Death in Norway

In Norway, the interviewees confirmed that cerebral angiography is mandatory under the organ donation legislation. This is often viewed as the gold standard in some countries to confirm brain death. This is performed as a final diagnosis of brain death to confirm the results of internationally recognised procedures (**Appendix III**) previously undertaken at the bedside by medical staff caring for the patient. Interviews with the HCPs confirmed that if the first test suggests that the patient is brain dead, screening of the patient for their suitability for organ donation is commenced and the family is informed of the patient's deterioration. Any objection from the deceased or the next of kin to donation is then established via discussions with the next of kin. If no objection is identified and after other investigations to exclude any other factors that may influence the patient's level of consciousness have been undertaken, a second set of brain death tests are performed. In some cases this second set of tests may be augmented by the use of a transcranial doppler, an instrument used to assess the vascular activity in the main cerebral arteries as a senior anaesthetist in intensive care N ST 016 describes:

Document Transcription N ST O 16

“Yes or you could use transcranial doppler. We have two or three persons on this house performing this and we may ask them to do that. From this you can say that from the blood flow situation, it is very, very likely that there is no intra-cerebral circulation”. Page 4 paragraph 7

“It prevents us from going to angiography and getting a negative result because often it happens that you would to have no circulation in the four arteries and you might have a single artery with very little circulation. So if you can avoid going back and forward, that is better”. Page 4 Paragraph 11

Performing a cerebral angiography involves the potential donor being transported to the radiology department to have this test performed accompanied by full resuscitative measures. Should the test demonstrate that the patient has no

cerebral circulation and this is confirmed by the intensive care specialist doctor who will be accompanying the patient to the radiology department, together with the radiologist in attendance, then the patient is pronounced brain dead, as N R124 an intensive care nurse describes:

Document Transcription N R124

“Yes and I always try to follow – if I hear about the patient – I just always try to see if the right things have been done and if someone is; for example if the transplantation co-ordinators think that this time it went too slow or something did not function; I get to know and try to talk with the people and there is always some information that has to be repeated on and on again and that is; especially about the death certificate, we have a special death certificate for the donors, that is not an official death certificate actually but a form that shall be filled out and kept in the notes here where it should be two doctors; often one from the x-ray department the radiologist who does the cerebral angiography and often the anaesthetist who goes with the donor. You know all this paperwork - how it is like every time - it has to be repeated”. Page 2 Paragraph 13

Following this procedure a special death certificate is produced and the patient can be considered as a donor candidate. Practice described in Norway was that the patient’s brain death would be confirmed to the family and a final approach made to establish if any known objection to organ donation. If no objection was identified, the patient’s donor status would be confirmed to the transplant co-ordinator and a detailed protocol for organ preservation would be commenced. The donor would then be cared for in the ITU until a suitable time for organ retrieval could be identified and the organ retrieval team undertakes this procedure. This will be dependent upon the arrival of the organ retrieval team and the availability of an appropriate operating theatre. In total this process may take from 12 to 24 hours to complete.

8.1.3.4.3 Establishing Brain Death in Belgium

In Belgium, in addition to the techniques described as being utilised in Norway and Portugal to exclude any cerebral activity or blood flow in the potential donor, another set of tests to elicit any cerebral function in the potential donor has been developed. This additional test called EVOG potentials (Sullivan et al, 1999) (**Appendix XI**) has been introduced to measure cerebral electrical activity. This neurological examination is designed to measure electrical responses in the brain and neurological system, and is viewed by the HCPs in Belgium as superior to the internationally used tests to establish brain death as it combines bedside clinical testing of brain function with other techniques used in neurology to test electrical impulses in the brain as B Bru 108 the medical head of intensive care, describes:

Document Transcription B Bru 108

“So we know from all experience here, it’s been published in many papers, that evoked potentials are much less sensitive to other factors like hypothermia, sedative drugs and so on, so it is possible to make the diagnosis of brain death, even if the patient actively receives some sedated some opiates a few hours ago. Page 2 Paragraph 12

If the same physician, the same team while that is performing in electroencephalogram and evoked potentials so it’s a type of electroencephalogram with visual tests, somatosensory tests and auditory testing”. Page 2 Paragraph 13

This test is performed by three doctors, an intensive care specialist, a neurologist and a neurosurgeon who undertake different parts of the test in relation to their expertise, who then confer together to agree about the presence or absence of any activity present in the patient’s brain as B Bru 103 an experienced anaesthetist in intensive care, reports:

Document Transcription B Bru 103

“Yes, well we use evoked potentials and clinical examination first of all and then we do evoked potentials we never do an EEG alone. We never do cerebral angiography,

so here we have to go with the results of evoked potentials. So this is clinically clear". Page 2 Paragraph 3

"There are trained doctors signing the documents for the diagnosis of brain death, but usually only one doctor making the diagnosis. There are of course among the three doctors you have may or have another doctor in ITU and you have the doctor who knows the protocol for apnea tests and then there is a third doctor from neurology who undertakes the protocol for evoked potentials and the EEG, and there is a third doctor from here in the ITU who comes to see the patient during the third examination. And we have a diagnosis and we have these three people signing the documents. We cannot go to the operating room without these documents and we cannot be anaesthetist from the operating room (the transplant team) and it cannot be a surgeon or anybody involved in the donation". Page 2 Paragraph 1

In the larger teaching hospitals in Belgium this new test has largely superseded the standard internationally recognised bedside method of testing brain death and is utilised in preference to the cerebral angiography procedure utilised in Norway and occasionally in Portugal, to establish brain death.

Anxiety surrounding brain death diagnosis by different methods was raised as a concern by staff. The use of different techniques to confirm brain death e.g. clinical bed side testing, evoked potentials, with or without cerebral angiography and what they viewed as the varying levels of application of these tests appeared to cause anxiety and confusion in some of the HCPs interviewed as B Bru 107, an anaesthetist in intensive care suggests:

Document Transcription B Bru107

"That is in the diagnosis for brain death, yes three different doctors are involved. And the law in Belgium does not say, the Law says that you have to have confirmed the death with the latest performance technique that you can apply. That is not a problem when you work in a University hospital, but some general hospitals or regional hospitals, we don't have the evoked potential, we don't have the angiography, the transcranial doppler, so it is quite equivocal, you know the statement is not very clear, there is no right way to do this". Page2 Paragraph 7

Although acknowledging these concerns raised by more inexperienced staff in regard to the application of these tests and their reliability, the more senior

members of the HCPs interviewed appeared to have adopted a more pragmatic view in application of these tests, suggesting that the tests were very accurate and appropriately utilised to confirm brain death in the potential donor as B Bru 108, medical head of intensive care states:

Document Transcription B Bru 108

“.....There are no technical reasons to disturb the interpretation of the evoked potentials. In some instances I have to say that it is not very official, but in some instances we are performing only the evoked potentials no more for electroencephalogram because if there evoked potentials is no objective reasons to have cortical activity, that is the rules”. Page 3 Paragraph 7

However, interviews with HCPs within Belgium revealed that not all hospitals had adopted these new tests to confirm brain death and instead used standard internationally-recognised protocol for testing brain death using the two bed side tests together with cerebral angiography to confirm brain death as B Bru 108, further explains:

Document Transcription B Bru 108

“ In other hospitals you will find in Belgium, different policies and I know in some hospitals clinical examination is sufficient to confirm the patient is brain dead and in other hospitals they are performing clinical examinations plus cerebral angiography”. Page 3 Paragraph 8

The interviews within Belgium demonstrated that once brain death had been established in the patient utilising one of these methods of testing and the patient was pronounced dead and the procedures for organ donation followed a similar pattern to those described in Norway and Portugal. In Belgium, the family are approached to inform them of the patient’s status and establish that there was no known objection to the donation of their organs. Details of the family involvement in the decision to move to organ donation have been given previously however, if no objection is raised by the family, care of the newly identified donor in the intensive care unit continued utilising protocols for organ

preservation with arrangements for the organ retrieval procedure being commenced. Organ retrieval would take place as soon as possible. However this is on the availability and arrival of the organ retrieval team from the central teaching hospital, together with the availability of a suitable operating room within which the organ retrieval procedure could take place. Similarly, to the HCP reports from Norway and Portugal this process may take from 12-24 hours to complete.

8.1.3.5 Concerns Relating to Ethical Dilemmas in Donation

Within the interviews in Belgium, concerns of the HCPs were raised in regard to the need to separate diagnosis of death from the transplant procedure to maintain ethical practice. Many of the interviewees highlighted the need to ensure that whilst the transplant co-ordinator and any other member of the transplant team may advise the team caring for the potential donor of the application of the brain death testing protocols, they must remain independent of brain death testing and confirmation of death. Comments made by B Bru 102 a former transplant co-ordinator and B Bru 103 an experienced anaesthetist in intensive care, were typical of those made by many of the HCPs interviewed who felt the need to clarify this point:

Document Transcription B Bru 102

“We believe that it’s not the transplant coordinator who’s to be involved in the diagnosis brain dead”. Page 2 Paragraph 2

Document Transcription B Bru 103

“Yes. There’s never a doctor from the transplant team making the diagnosis of brain dead”. Page 3 Paragraph 2

This was confirmed by one of the participants B Bru 106 a transplant surgeon, who expressed a clear practice in relation to his involvement with the donor thus:

Document Transcription B Bru 106

“No, I am not involved in the brain death diagnosis. I have to be sure of the appropriate use of the law to be sure the patient is dead before I can begin my procedures. So, I am required by law to be sure the patient is dead before I do anything, so I have to look through the papers to be sure all the three physicians signed on paper the patient is dead”.

Page 1 Paragraph 21

“Yes I can’t be involved in the treatment of the patient before they die. So it is important to establish this” Page 2, Paragraph 1

Many of the HCPs interviewed reported the practice of undertaking early screening of the patient as donor prior to brain death confirmation or the discussion of donor status with relatives. This test which involves the removal of a blood sample and analysis of their HLA (tissue) typing is required to match the donor to any potential recipient and is undertaken when the patient has been confirmed as a donor as B Bru 102 explained:

Document Transcription B Bru 102

“At this stage what we do then would be either if it’s in out hospital or peripheral hospital, if it’s in a peripheral hospital we can be dispatch an ambulance to that hospital to get some blood samples from the donor if it’s in our hospital we can go to the unit and get some blood samples from the donor to do the preliminary testing, biological testing, HLA testing and so on”. Page 2 Paragraph 1

Some staff however, in all three countries, reported that this test was undertaken before the patient had been confirmed as being brain dead and prior to the discussion with the family. In Norway, undertaking this intervention did present some staff with an ethical dilemma in that they were performing this test not in the patient’s interests but on behalf of potential recipients. They were also concerned that this test was being undertaken prior to the patient being confirmed as brain dead and before the family had been informed of this fact as N R4, an intensive care nurse, explains:

Document Transcription N R4

“So we know the patient is dead and no doctor has spoken to the relatives and that is the worse situation for the nurses. Because this could be quite an active period in this

unstable situation. We take blood tests and so on and we can't say that we have taken blood to prepare him for the recipient". Page 8 Paragraph 2

"Yes and many have told me that they feel we are doing a bad thing sometimes, while taking these tests without telling the relatives what we are doing because we already know maybe that the patient is dead or is almost dead". Page 8 Paragraph 4

Another interviewee N R 43, an experienced nurse in intensive care confirmed that this view was held by many of the nursing staff:

Document Transcription N R43

"Yes we hate it. I hate it when we have to "creep" around taking bloods and doing blood tests. In this situation you can find yourself wishing that he wasn't going to be a donor because you can be frank with the relatives; you can be honest, you can tell them what you are going to plan to do, things are looking as if so and so and this might happen and you can plan it much more". Page 4 Paragraph 8

Other HCPs in Portugal and Belgium also reported that this was a common practice. However, they did not appear to have the same concerns in relation to undertaking this practice in advance of the patient being confirmed as brain dead or the family being approached to confirm the lack of objection to the patient being considered as an organ donor, as P SJ 2 an anaesthetist in paediatric intensive care and B Bru 107 an anaesthetist in intensive care explained:

Document Transcription P SJ 2

"Generally we contact the transplant team immediately and they ask us to withdraw blood for HLA testing. We have a protocol that we know what they want so immediately we perform a collection of blood samples and we contact the families. Of course most of them are already expecting this. We prepare them when we know there is a possibility of cerebral brain death and we begin the process of telling the parents of the child to expect this kind of the situation. We talk to them but only after we have done cerebral tests we tell them about the possibility of organ donation. We never approach them before the final diagnosis". Page 3 Paragraph 11

Document Transcription B Bru 107

"Before the death has been confirmed. Because you have a small period between the confirmation of the death and organ donation for the organisation for the organ retrieval. If we identified some potential donor, there would be some evaluation from the different organs before this of course when the patient is in the critical stages, that we can perform the tests". Page 3 Paragraph 1

The interviews with these HCPs therefore revealed the need for development of specialist procedures for the diagnosis of brain death and the preservation of donor organs in order to support the organ donation initiative. They also indicated that although there was some anxiety relating to the application of some of these tests, the development of standardised protocols for these procedures was necessary to reassure and assist staff to undertake these procedures with confidence.

8.1.3.6 Request to Relatives and Relatives Support Practices and Protocols

In addition to the practices and protocols developed for the technical identification of care of the donor, the HCPs interviewed reported the adoption of procedures for the approach to and support of family during the organ donation event. Many of those interviewed reported the existence of informal protocols for this role, highlighting the use of a multidisciplinary team approach to relatives. It was reported that some protocols aimed at providing psychological care of relatives at this time were in place as B Bru 103, an experienced anaesthetist in intensive care described:

Document Transcription B Bru 103

“Generally, I never approach the family alone. I would say about 90-99% of the time I have the nurse who takes care of the patient to come with me. It is quite rare that I go alone. Just because sometimes a nurse adds something, he / she has some more information and because sometimes the family does not know the doctor because the nurse is always next to the patient. The doctor comes and morning, afternoon & the evening but the nurse is sometimes they know them better than the doctor. So it’s not because I don’t want to be alone because I am the one who talks to the family and but that’s not really the problem more because I think it is important for the family to see that there is a the team coming, not just like one person. It is the team coming and the team is a nurse and a doctor so you know”. Page 5 Paragraph 4

Some staff interviewed reported the establishment of a multidisciplinary team approach to the discussion with the family that employed specialist input from

crisis counsellor staff, but was led by a member of the clinical team looking after the potential donor as B BRU 109, an emergency room senior doctor explained:

Document Transcription B Bru 109

“Now we have this support, we have the crisis team psychological team, of working in the same geographical area, but the idea is not to use them instead of us. To inform relatives of a death that’s one we have to do every day. That’s our job. If it’s not a disease, if we have to find the words and usually for this procedure according to me there is one person who can coordinate the discussion with the relatives, is the supervisor is the only person”. Page 4 Paragraph 10

Other protocols described by those interviewed highlighted the need to decouple information about death of the patient from the request to the family to consider organ donation. Some staff reported the existence of protocols for the care of the family that had been developed that were designed to ensure that the family had time to accept the death before being asked to consider organ donation, as B Bru 107 an anaesthetist in intensive care and B Lev 1 another senior anaesthetist in intensive care suggested:

Document Transcription B Bru 107

“When cerebral death is confirmed then and first of all we meet the family and firstly confirmed that nothing else can be done to save the patient finding that cerebral death is confirmed and that the patient is dead. Most of the time we try to separate in two different times, confirmation of the death and the request for organ donation.” Page 2 Paragraph 4.

Document Transcription B Lev 1

“So first we first commence with announcing the death. It is mostly traumas. People already know from the first contact at the emergency department that things are not good. Page 4 Paragraph 2

“So then we announce the official deaths. So we did the tests and we have seen that there is brain death. We try to do that quite directly so that is death, you cannot say maybe death, so death is death. And then we always to try not to do that alone, but together with a nurse or with an assistant of the social service and then depending on how some relatives do. Normally we try then to get, to make arrangements for a second talk and then to announce the possibility of donation. But sometimes people ask what will we do next? and then you have to put your cards on the table, but that is not the goal of doing it in one session. The goal is to do it in two separate sessions”. Page 4 Paragraph 5

Interviews with HCPs in Portugal also supported the view that the family would be informed of their relative's brain death and allowed time to come to terms with this before an approach was made to explore their views on organ donation, as PM 64 a experience nurse in intensive care explains:

Document Transcription P M64

“Normally the doctor would say to them gently that it could be that this patient will not survive and all our tests has suggested that they are very ill and they may not survive. After this normally they are given some time to think about this and then we would ask them, we would tell them about the law and that we are considering organ donation and we would try to establish if there is any real objection to this from the families”. Page2 Paragraph 11

In Belgium one of the social nurses interviewed reported that in order to facilitate clear and consistent communication with the family in the stressful event of donation, there was an identified requirement for the documentation of any communication with the family to be recorded in the patient's notes. It was reported that in some instances a clear policy had been developed to structure the communications between the multidisciplinary team and the family, as B Lev 109 a social nurse describes:

Document Transcription B Lev 109

“We have to see organ donations procedures within the total guidance of care. We start with the psychological guidance of the family at the emergency room. When it is not done well there, the rest will be difficult too because one of the main factors is the trust that you have to earn with the family. Another very important item is open communication which has to be honest. Page 1 Paragraph 15

Also the homogeneity in communication is essential. When we say something, it has to be the same as what the other nurses and doctors say. Everybody has to be on the same level of communication with the family. That is the reason why many years ago, I started with the communication papers in the notes of the ICU and now we have it also on the computer notes. Page 1 Paragraph 16

In the paper notes, when we talk to the family, we have to note it down because when you are talking with the family in a very difficult moment a lot of the communication say up to 40-50% of more is up on the air. And an hour later the people don't know what you have just said or they have a different interpretation of what you have said.

So it is very important that all health workers (nurses, social worker, doctor...) write their communication in the notes of the patient, in that way each one knows what the other has said.” Page 1 Paragraph 17

Interviews therefore demonstrated that a variety of good practices exist to guide the approach to informing the family of the brain death of their relative and provide psychological support of the family at this time. In Belgium, clear policies and practices for this had been developed however, in Norway and Portugal no clear protocols of practice had been developed for this role.

8.1.3.7 Impact of Organ Donation Practices and Protocols on Staff and Resources

Interviews with the HCPs in all three countries suggested that organ donation practices and protocols impacted directly on the HCPs and health care system resources in a number of key areas:

8.1.3.7.1 Development of New Roles for Staff or Expansion of Existing Roles

Interviews with the HCPs in each country had confirmed that within each of the health care systems reviewed, the organ donation initiative had required the development of specialist teams of transplant co-ordinators, transplant surgeons and organ retrieval teams available on a 24 hour basis. Discussions and personal communications between the researcher and the transplant co-ordinators in each country further revealed that although there may have been some subsidiary expenses paid to individual hospitals to cover expenses incurred during an organ donation event, these key staff in organ donation were in the main funded by either the individual hospital or the university who employed them.

Interviews with HCPs in Norway had indicated the development of local organ donation champions or co-ordinators termed the “Donor Responsible Doctor” who in addition to their role as a senior member of the intensive care medical staff, promoted organ donation at a local level and provided support and advice to the intensive care staff. These doctors also assumed the responsibilities for implementing protocols for the identification and care of the donor, communicating with the central organ transplant co-ordination team and organising the organ donation events at a local level, as N ST O 16 as senior intensive care specialist confirmed:

Document Transcription N ST O 16

“Yes. I would say so. We have one doctor in charge of the donation process and he is kind of looking after us and telling us a bit about it if we have any problems. If we have such a situation, I will be in charge at least”. Page 1 Paragraphs 2

Further interviews with Donor Responsible Doctors in smaller peripheral hospitals revealed that depending on the availability of specialist anaesthetic personnel within the retrieval team dispatched from the national hospital, they may on occasion also be required to administer the anaesthetic to the donor in order that the organ retrieval procedure could take place, as N T2 a head of intensive care suggested:

Document Transcription N T2

“Usually there is an anaesthetist with the team and they do this preservation but I know the situation and usually I am involved most of the time, yes”. Page 7 paragraph 10

“.....Sometimes we have to work in the operation theatre but most often there are anaesthetists etc and it is not necessary to be involved in the team. So then only the operation nurses are involved from our hospital”. Page 7 Paragraph 16

Interviews with medical staff in Portugal and Belgium also revealed that although there was not such a clearly defined role as the Norwegian “Donor

Responsible Doctor”, medical staff also had to combine their responsibilities as a senior member of the medical staff with that of their roles in organ donation. Bru 106 a transplant surgeon, describes how he combines his role in transplantation with this other role as a general surgeon thus:

Document Transcription B BRU 106

“So, we are working with those centres for many years, more than 20 years so we are only two or three people to perform this kind of procurements, so all the staff usually know us. Well the know that we are the organ procurement surgeons”. Page 2 paragraph 10

“No ,this is not our only role I have also a general practitioner’s clinic because we don’t have enough activity with transplantation to fulfil my contact. So we have to do something else. Also we have to do at least a number of transplants per year to be good enough”. Page 7 Paragraph 10

Discussions with the transplant co-ordination teams revealed that in Portugal this resulted in the transplant co-ordinator’s role being undertaken by a senior member of the surgical or intensive care medical staff who had to combine this role with the responsibilities of their particular medical speciality, resulting inevitably in some increase in work load for these staff. In Norway and Belgium however, the transplant co-ordinator role was more clearly defined and were funded only capacity.

8.1.3.7.2 Increase in Numbers of Organ Donations with Increase in Staff

Workload

In particular staff revealed their perception that since the implementation of presumed consent legislation there had been a demonstrated increase in organ donors within their hospital. This was directly attributed to the introduction of the legislation, as PSJ 18 a nurse in intensive care describes:

Document Transcription P SJ 18

“Without the current legislation I feel there would be very few organs that were actually available and it would be impossible to help the number of people that they currently do under their system”. Page 5 Paragraph 9

As a result of increased identification and management of donors all members of the medical staff interviewed reported a commensurate increase in workload arising from the care of the donor and the family. This view was supported by the members of the nursing staff interviewed who were employed within the intensive care, emergency room or operating theatre areas of the hospital as three nurses, N ST O 140 a head nurse in intensive care, PM 71 a nurse in intensive care and B Bru 102 a former transplant co-ordinator reported:

Document Transcription N STO 140

“Well that sometimes this is a short period but it might be some cerebral situation left if you go to angiography and you have to do that once again. Then everything takes a long time. And then the procedure is quite long it can be days, one, two, three days yes. And very often these patients, well things happen quite quickly. So very often we don’t have very much time to get to know them”. Page 9 Paragraphs 16 and 18

Document Transcription PM 71

“It might take anything from up to six to twelve hours for this to happen. Between contacting the team and them coming and then it might take a long time, maybe all day the family might have to wait while the operation is being undertaken before they have body returned to them and they can undertake the funeral arrangements. So this is quite a long time for them. Page 4 Paragraph 3

“Yes it does give us more work, we have a lot of work to do the tests and to keep the body in good condition for transplant. The longer we wait, the more chance the organs will fail so it is important to get this resolved quickly” Page 4 Paragraph 8

Document Transcription B Bru 102

If you have two or three nurses working in ITU where there are ten beds and you know that the donor process takes a lot of time and it is a big burden , it is a big workload for the nurses and doctors and you have nine other live patients in the ITU who also need care, if it is in the middle of the night, I think that it is only natural that the decision on the actual procedure to organ donation in certain cases, is not taken because there are too few staff. They therefore decide to take care of the other live patient and let the potential donor die naturally”. Page 10 Paragraph 1

These pressures on nursing staff may result from an increase in the procedures required to assess the donor i.e. the support of the patient and medical staff during the brain death tests and additionally, if cerebral angiography was used to diagnose brain death, nursing and medical staff would be required to transport the patient to the radiology department and care for the often unstable patient, as N UN POP 11, a nurse in neurosurgical intensive care explains:

Document Transcription N UNPOP 11

“Yes. There is a lot of documentation and forms which are signed by the doctors and radiologists. Because you have to have this cerebral angiography before you can be absolutely sure. You can’t do anything without that. This angiography procedure is a very hard thing for the nurses, the relatives and for the patient”. Page 3 Paragraph 11

“It is hard for the patient, they might die on that trip because they are so unstable. I have not experienced it, that one of my patients has died on that procedure but some of my colleagues have lost a patient on that trip”. Page 3 Paragraph 13

They may also result from the requirement to care directly for the donor, implementing the detailed organ preservation protocols or, caring for the family of the donor at this time, as N St. O 16 a senior anaesthetist in intensive care, suggests:

Document Transcription N ST O 16

“ Yes we identify a donor and get all the formalities done then they will come as soon as possible. But as I said preserving a donor is not easy. It’s a dead person and it is getting more and more difficult the longer you wait. The first twenty – four hours is the usual way.” Page 4 Paragraph 1

Those interviewed in the three countries reported that although they found this stressful, they considered that they had adequate numbers of staff to manage this situation by re-organising the staff rota within the ITU or by finding additional staff to work in ITU during this event, as P M72 an intensive care nurse, reported:

Document Transcription PM 72

“No, We have very good nurses. We have 1.5 nurses to every patient One of the nurses will only have one patient and therefore we have enough staff to deal with this situation”. Page 6 Paragraph 1

In some cases however, this had resulted in additional resources being required to be found in the short term to fund these additional staff, as N R 43 another intensive care nurse suggested:

Document Transcription N R 43

“Yes very often you get help and support as far as the staff here at work. But I feel that very often they are good at backing each other in that kind of situation..... As long as there is somebody available you will very often get help”. Page 8 Paragraph 2

Whilst staff in larger hospitals had developed an on call rota a system to accommodate this eventuality, smaller hospitals had difficulties due to smaller staff numbers and limited access to other staff to provide additional cover, as B Bru 107 an anaesthetist in intensive care acknowledged:

Document Transcription B Bru 107

“.....But it is right in that increasing potential donors you use a lot of time and energy have I never experienced that but I know that the intensivist from the smaller hospitals, someone in these hospitals he will have a real problem when he has a donor and he is alone as a single physician and he has not time enough to manage the donor and to take care of the other seven people who are alive and who need care and knowledge to survive. ” Page 6 Paragraph 3

When interviewed the medical staff in all three countries who were responsible for the allocation and management of the beds in intensive care areas reported some pressure on ITU beds within their hospitals as a result of their requirement to care for the donor after brain death diagnosis until organ retrieval can be undertaken. As previously reported this process may take 12 – 24 hours to complete. Those interviewed reported that when requested to admit a new patient to the ITU, when some of the beds were occupied by a donor, the normal

procedure would be to triage the patients occupying beds in ITU and placing patients in other units e.g. HDU to make a bed for the new admission, as B Lev 5 a head nurse in intensive care revealed:

Document Transcription B Lev 5

“Sometimes the beds are full with donors but the new patients can go to other units within the hospital. We will review the patients in the unit and transfer some out if this is appropriate or the new patient will be transferred to the other unit. There are sometimes pressures but we manage this as much as possible, as this is important. Page 7 Paragraph 3

One of the HCPs interviewed acknowledged the pressures on the ITU department caused by organ donation initiatives. In doing so he also reported that within his hospital some elective surgery for patients had been cancelled due to the lack of ITU beds that are being used by donors, as B Lev 24 a senior doctor in intensive care reported:

Document Transcription B Lev 24

“It puts pressures on us certainly it does in two ways. Because first you have to take care of the donor and the family and secondly you still have responsibilities for other ITU patients, (100% occupancy in the in the ITU). It represents an extra job”. Page 7 Paragraph 7

“We refuse elective surgery patients. We have a quite huge elective surgery programme in this hospitals and sometimes the surgery has to be postponed for several days. It causes problems with the surgeons but you get used to it”. Page 7 Paragraph 9

Another possibility would be that if all the ITU beds were full and there was an organ donor identified in another area of the hospital, they would negotiate with colleagues to care for the donor in the critical care area, in which the patient was already placed e.g. the emergency room or operating theatre area, providing staff to these areas to manage the donor, as B Bru 103 an experienced anaesthetist in intensive care reports:

Document Transcription B Bru 103

“I think that is going to happen yes, I don’t remember a case precisely, I am quite sure we have had sometimes a brain dead donor waiting to go into the operating room and

another patient has to come. But we have to delay the family and the patient coming to the ITU yes that that happened. I don't remember the name or the case exactly but I am sure it has happened". Page 6 Paragraph 6

"Yes, you have to manage. You go then to the emergency department, you help them, you try to manage the best way you can. Because you don't think we can stop the donation process because another patient is coming because of course it is important for your patient to come but, also important for people to get an organ. So you have to wait and manage what is going on, we never stop a donation process to accept another patient. We try to find another way, even helping another department". Page 6 Paragraph 7

In addition, HCPs interviewed also reported that organ retrieval transplantation procedures were usually undertaken at night as a result of lack of access to operating facilities at other times, as PSJ 1 a senior intensivist in one hospital suggested:

Document Transcription P SJ 1

"If in England you were able to perform so many transplants you would be helping people who are waiting for an organ but you would have to find the time to perform the transplants. In Portugal we never perform the transplants during the day this would be the exception. Some of my colleagues went to London and saw them undertaking transplant operations during the day". Page 5 Paragraph 12

Overall all of the HCPs interviewed within the three countries acknowledged the tension between their desire to get involved in organ donation and pressures on ITU staff, as B Lev 9 an experienced anaesthetist in intensive care suggested:

Document Transcription B Lev 9

"Perhaps this is a little bit difficult to say but I am convinced that a policy for trying to do the best for organ donation can put some tension on the system. When you have a potential brain dead person and you are not considering donation you can stop therapy and the case is closed".

"However when you go for donation you start a procedure which takes lots of time and energy of a lot of health care workers in your ITU service and so puts pressure on the ITU" Page 6 Paragraph 6- 7

B Lev 9 further reported however that despite the pressures on the staff the possibility of organ donation was always considered:

Document Transcription B Lev 9

“So of course the first step is that we give up the person as a patient, when we foresee that any possibility of resuscitation is failing, this is always the first step. But when we do so, when we are agreeing that the patient is lost, we have an attitude in our service that in this situation, you should not let any case escape from the possibility of organ donation. This is one of the most important reasons why we have such good organ donation figures in this hospital. We will never lose a patient who has a possibility of organ donation that is not taken into consideration”. Page 2 Paragraph 3

8.1.3.7.3 Emotional Impact on Staff

Organ donation is an emotional event for relatives, especially if there are delays in the procedure such as long time periods between the patient deteriorating, their diagnosis as brain dead and being transferred to the operating room for organ retrieval. This presents difficulties for both the family and the health care professional's ability to provide them with appropriate physical and psychological support at this distressing time, as B Lev 5 a head nurse in intensive care and N ST O 16 a senior anaesthetist describe:

Document Transcription B Lev 5

“It is not so easy to help relatives through this process, there are many patients who do not have people to help. It is not so easy”. Page 9 Paragraph 9

Document Transcription N ST O 16

“Yes you don't like losing the patients at all and I mean you obviously have a family who have a major loss, and speaking to people which you don't really know them, I mean that you might have known them for a few days only and there is often quite a tragic situation, could be with small children involved and of course that is stressful in many ways but not so that I would stay away from it”. Page 9 Paragraph 17

Facilities to support the family during the process are required to allow them the time and a place to await the outcome of the brain death test process and a suitable environment within which to say to say their goodbyes to the loved one and view the body post organ donation, as P SJ 4 and anaesthetist in intensive care describes:

Document Transcription P SJ4

“Yes this does place additional pressures on the staff because the family do not understand the time delay. They have been told the patient is dead and they want to go ahead and do things and progress and they have to wait around until the organ

harvest takes place and other procedures go forward. This can be very stressful and can place additional pressure on the ITU staff". Page 8 paragraph 7

"Because they will not see the body again after the organ harvest except in the mortuary what the staff will attempt to do is before the donor goes to theatre, we will get all the family into the unit to say goodbye and will give them time to spend with the donor before they go to organ harvest. Again this can place additional pressures on the staff in the unit". Page 8 Paragraph 8

Communication with the family was viewed as the key aspect in the successful donation of organs. Those interviewed reported that the care of the family and the donor was an emotional and stressful event for ITU staff in terms of the additional physical work that results from the care of the donor and in terms of the care of the relatives. HCPs interviewed also reported that they found the breaking of the news of the patient's brain death and the approach to the relatives to explore their views on organ donation did cause some distress to them, as NSt.0 140 a head nurse in intensive care, suggests:

Document Transcription N ST0 140

"Absolutely. If they have not been talking about it before it is stressful. You feel very sorry for them, they have a big loss and then you have to ask them something that makes this a stressful situation for them as well. So this is one of the difficulties for the health workers. And I know that they feel they don't have much time to decide if they have decided already, I think that is one of our stressful situations". Page 5 Paragraph 8

Many staff in Norway and Portugal suggested that they may seek emotional support from within their own multidisciplinary team or from clergy and to manage this stress, suggesting that the development of guidance on the appropriate care of the family at this time would be beneficial, as N UNPOP 11 a neurosurgical intensive care nurse highlighted:

Document Transcription N UNPOP 11

"Yes I think so. After my years of experience I started to use the Priest. We have three priests in this Hospital and they are so lovely. It is not like they come in and teach about religion, it is like a big support, caring thing". Page 4 Paragraph 4

As previously described, interviews also revealed that in some parts of Belgium specialist crisis support teams have been developed to support families in the event of a potential organ donation. These teams have been funded and are supported by the local hospital authorities to provide a 24 hour service to families in need of emotional and ethical guidance during the organ donation event. Specialist staff from within this team also provide advice and support to the HCPs involved in caring for the donor and the family and have developed protocols of practice for this eventuality, as B Lev 109 one of the specially prepared crisis counsellors called social nurses reported:

Document Transcription B Lev 109

“We have to see organ donations procedures within the total guidance of care. We start with the psychological guidance of the family at the emergency room”. Page 1 Paragraph 10

“Therefore in our service there is a possibility, day or night, 24hrs a day, 7 days a week, to contact a social worker who can be in the clinic within 15 – 20 minutes, so that when there is a problem with the patient where the doctors and nurses are working very hard to keep the patient alive that there is also somebody who takes care of the family. It may even be the case that the family is waiting in the waiting room for 2-3 hours, and doesn’t hear anything. People have to be guided in good psychological way and it is essential that the social work takes the time to do so”. Page 2 Paragraph 3

Interviews with the HCPs in all three countries however suggested that despite the increased workload organ donation is viewed as a positive event from the staff perspective, as this provides a sense of achievement in that some good has resulted from the loss of their patient. The additional workload that resulted from this situation appeared to be accepted by the HCPs if feedback was provided on the outcome of the organs after donation. This feedback motivated the staff to be involved with donation and was a vital part of the success of organ donation, as B Lev 24 a senior intensive care doctor reported:

Document Transcription B Lev 24

“Yes in fact we have regular meetings on organ donation once or twice per year where first of all we get feedback on the transplanted organs and then we organise organ donation symposia where all staff members participate. We have a lot of connections across Belgium as strong network. There is strong team communication with the transplant co-ordination team. We receive feedback from the transplant co-ordinators about the organs and the recipients. We do not get personal details but we can keep in touch with their progress”. Page 5 Paragraph 1

8.1.3.7.4 Financial Impact of Organ Donation on Health Care Systems

As previously stated particular financial arrangements have been made in some of the countries reviewed for the donor hospital to claim back some expenses incurred as a result of the donation even from either a central organ donation and transplant initiative, or from the donors health insurance scheme as provided by their local health authority, as B Bru 102 a former transplant co-ordinator reported:

Document Transcription B Bru 102

“So I mean the surgical part of the organ donation is charged to the mutual insurances of the different recipients ok. So nothing is in charge of the donation hospital and nothing is charged of the donor families. So from the moment of brain dead diagnoses until the moment transferred to the operating theatre for organ donation, so all that has still been taken care of for the donor of the different treatments that has been given to the patient, the medical and the nursing supervisor of the donor and the ITU care, all that has taken care by an insurance system”. Page 6 Paragraph 2

Organ donation is viewed as a financially prudent initiative by those interviewed, in that any financial outlay of the health system, is balanced by the reduction in financial outlay required to support the chronically ill individual on the organ donor register. This is considered to be financially more beneficial to the health care system and to society, as N R125 a senior anaesthetist in neurosurgical intensive care, P SJ103 a paediatric anaesthetist and B Bru 102 a former transplant co-ordinator agree:

Document Transcriptions N R125

“There has been no additional resources provided for the implementation of this system except the development of the Donor Responsible Dr system in Norway. There is no official data on how much keeping a donor in the ITU for the additional 24 hours required for the brain death criteria to be undertaken and then moving to organ harvest but one study previously suggested that it costs approximately £6,000 per day to keep a patient in ITU, however this must be weighed against the gain to the other patients and society of having the organs available”. Page 7 Paragraph 10

Document Transcription P SJ103

“Even in a socio-economic view, it is very important that these donators have a room in the ITU. And their stay is short and I believe that if all the process slow down and he is going on, I believe there is no problem with beds still.” Page 7 Paragraph 9

Document Transcription B Bru 102

“Well from a general health policy perspective it is the normal financial thing to do to make sure that every step, every initiative is taken to make sure that all available organs are procured and that all available organs can be transplanted. Because evidently for the health insurance system people on dialysis can cost a lot of money and to have them off dialysis is less expensive for the healthcare system. Paying the routine consultations after transplantations is less costly than keeping them on dialysis. So I think that is probably the one strong argument that we can use. We have to make sure that we take all initiatives possible to make sure that all available organs are used”. Page9 Paragraph 10

Summary

In response therefore to the question of whether the implementation of presumed consent legislation had required the development of any the specialist policies and procedures to support the initiative, those professionals interviewed suggested that although this approach to organ donation had provided an increase in organs for donation, to allow it to be successful, a wide range of strategic, structural, organisational and professional protocols and practices had been developed and implemented to facilitate the identification and supply of organs for donation and the support of the families involved in the process. The participants also demonstrated a need for the development of systems of support for the HCP involved in this stressful and emotional process. The implications of the need to develop and implement these new healthcare structures, systems and

professional protocols of practice to support this form of organ donation requires to be explored in further detail in chapter 9.

8.1.4 Does the Implementation of Presumed Consent Legislation Require the Provision of Specialist Education or Preparation for HCPs

The responses to the questionnaires confirmed that HCPs who cared for the patient who subsequently progressed to being an organ donor had developed specialist knowledge and skills in this area of practice. Some of the respondents suggested that staff found challenges in supporting relatives through this difficult time however no information was given in relation to their preparation for this role. Key questions therefore remained to be answered as to the requirement for specialist preparation for the HCPs who cared for organ donors and supported the relatives through the donor process. Specific questions identified were:

- How do the staff learn about organ donation law and organ donation practices or protocols of care?
- What preparation do they have for technical, ethical and psychological aspects of this role?
- Where do the staff access personal and professional support for their role in organ donation?

8.1.4.1 Staff Education on the Law and Organ Donation Practices

Those interviewed in all three countries reported that they had a good level of awareness of their country's legislation together with the donation organisational systems. They expressed the view that their legislation was very clear as to how they should respond when there was a patient in their care with the potential to become an organ donor. When asked how they had gained this knowledge, most staff reported that this had been achieved by the provision of a range of different educational opportunities. In Norway, HCPs interviewed suggested that their

knowledge had been gained from a combination of personal experience of patient care and personal reading on this subject. Comments made by N R 115, an anaesthetist in intensive care, when asked to explain where they had gained a knowledge of the organ donation legislation in Norway:

Document Transcription N R115

“You learn as you go along. But then again it is not a very big challenge to do this. That is something I would have to had teach myself.” Page 6 Paragraph 8

Some nursing staff in Norway reported that in addition to experiential learning they also received specialist input on the legislation from the transplant co-ordinator teams. This had often taken place during a post-registration intensive care course or, during input to their orientation programmes when they took up a post in the intensive care unit. This input was mainly related to the legislation however, information on the technical protocols and practices that are mandatory under Norwegian legislation was also included. This input related to the requirement in law to confirm the patient’s brain death, together with the protocols of care for the donor. N ST 0 77 a nurse in intensive care confirmed this thus:

Document Transcription N ST 0 77

“When I was taking intensive care education we had a one day at school where we were taught about the practical things. Yes, but in education in intensive care education, it was I remember, only the practical.” Page 10 Paragraph 6

Interestingly, this interviewee did not report any preparation to manage the emotional aspect of this role:

Document Transcription N ST 0 77

“Yes but in education in intensive care education, it was I remember, only the practical and the rest of it, the rest of the coping thing has come in my experience”. Page 10 Paragraph 10

Other HCPs also reported that they had received no formal preparation in the legal or practical aspects of organ donation, but had gained this knowledge from personal discussion with other staff and with the support of the transplant co-ordinator to advise them of the legislation. N STO 140 a head nurse in intensive care describes her education experience:

Document Transcription N STO 140

“The staff here, yes I think so we have been talking about it in this unit a lot of times and this is an issues people care about and talk about.” Page 3 Paragraph 17

Another group of HCPs reported their attendance at a two-day Norwegian organ donation course run by the transplant co-ordinator teams. This programme is a version of a European Donor Hospital Education Programme (EDHEP) provided by the European transplant co-ordinators organisation, during which the health care professional can learn about a variety of aspects of organ donation to assist them with this demanding role. N UNPOP 11 a nurse from a neurosurgical intensive care, reported the experience of many of those interviewed within Norway:

Document Transcription N UNPOP 11

“Yes that is the Neurological Intensive care unit, we knew it because we had the co-operation of the transplant co-ordinator and we had a course that he taught us how to do it and the old laws and we have a contact person [a resource person] in organ donation and they have it in the unit as well but they have not had that many years of relation so they don’t have that experience”. Page 7 Paragraph 2

N R124 an anaesthetist in intensive care reported that there was additional preparation for some medical staff who were undertaking an organ donation co-ordination role within their hospital:

Document Transcription N R124

“It was the NORAD the Norwegian organisation, they have courses in hospitals on a regular basis so I was in these course five or six years ago. They talked through all the basics in a way; just the legislation, the practical or medical things. The things concerning the relatives and one year ago I was on a course for the transplant co-ordinating doctors in different hospitals and for nurses as well and we had some kind of role play you know”. Page 9 Paragraph 6

In Portugal it was reported that preparation on the legal and ethical aspects of organ donation had been obtained during the undergraduate programmes for both medical and nursing staff, where bio-ethical aspects of care was a theme, as P SJ 18 an experienced nurse in intensive care suggested thus:

Document Transcription P SJ 18

“Within the nurses course; they learn all about the organ donation legislation. There is bio-ethics within the degree course that every nurse undertakes and they should be aware at least of the basic information around organ donation. In addition they sometimes discuss that amongst themselves in the unit”. Page 4 Paragraph 9

In addition to this, many of those interviewed suggested that organ donation was a frequent topic of discussion of Portuguese professional conferences, as PM 64 another experienced intensive care nurse highlighted:

Document Transcription P M64

“The staff know about the law and organ donation because this is a frequent topic in nursing conferences. It has also been included in the degree cause. They are taught by bioethics and it is often discussed in the literature in nursing”. Page 3 Paragraph 6

The majority of the professionals interviewed in Portugal, however, reported that they had not received any formal educational preparation in relation to their roles and that any knowledge they had was gained through media coverage or as part of orientation programmes for new staff to the ITU, as PM 60 another intensive care nurse identified:

Document Transcription P M60

“At work it is normally discussed in the unit. We have a law that the public might not know everything. But the staff in the unit, we discuss this and that is how we learn about it. Especially when a new member of staff comes to the unit, this is part of the discussions and the information they are provided with. They learn about protocols, new protocols when new staff come to the unit”. Page 3 Paragraphs 11

Those interviewed in Portugal also suggested that frequent discussions in relation to the issues raised by organ donation took place within the intensive care units involved in organ donation. These discussions helped staff share information regarding the application of the law, as PM 70 a junior nurse in intensive care explained:

Document Transcription P M70

“The staff in the unit learn through the media and through discussion of the topic in the unit. They discuss it amongst themselves and learn about this through this measure”. Page 3 Paragraphs 11

The majority of the HCPs interviewed in Portugal did not appear to have had the opportunity to attend any formal short education courses on organ donation provided by the transplant co-ordinator teams across Europe. Any information on their role in relation to organ donation, including the technical aspects of diagnosing the patient as brain dead and care of the donor prior to transplantation had been gained via experience of working within the multidisciplinary team caring for a patient who became an organ donor. P SJ 4 an anaesthetist in intensive care described the response of many of those interviewed in Portugal in relation to this point:

Document Transcription P SJ4

“I feel that when we come up against the situation about a patient being brain dead and the brain dead criteria and organ donation, I think this is when we begin to think about the law and what the situation is regarding organ donations but I don’t think we have actually had much in the way of education. Certainly there is no formal education or preparations as far as I am concerned in relation to organ donation within the ITU that I know of. Any knowledge that we have gained has been through experience of practice of these situations”. Page 6 Paragraph 4.

The majority of interviewees in Belgium had similar experiences to their colleagues in Portugal where their undergraduate degree had contained organ donation information. Medical and nursing staff interviewed both reported that there was some formal input to the undergraduate degree programmes relating to organ donation, and this provided some level of knowledge for the newly qualified HCP. Additionally, some of those interviewed suggested that this was a more recent development in the undergraduate curricula as B Bru 102 a former transplant co-ordinator and B Lev 16 a senior anaesthetist reported:

Document Transcription B Bru 102

“Not when I did my studies, which was almost 20 years ago, but I think that now most nursing schools there are a few hours for the transplantation and donation process, which are involved. Yes”. Page 7 Paragraph 1

Document Transcription B Lev 16

“When I was at medical school it was not part of the medical programme. I suppose that it is now because I see that our residents know quite a lot about what I am talking about”. Page 8 Paragraph 1

Some interviewees in Belgium also reported that one of their Continuing Professional Development requirements was to undertake updates relating to legal and bioethical aspects of care as B Lev 16 again suggested:

Document Transcription B Lev 16

“Well I think that anaesthesiologists yes. I suspect that all surgeons very if they are not performing transplant are quite aware of what is legally possible and not possible. One of the reasons for this is that we have regular updates in the hospital and other form of postgraduate sessions on organ donation and transplant. There is a yearly symposium that takes place and it is quite well attended. So I think yes also for the nurses.” Page 7 Paragraph 11

B Lev 16 again explained that in order to maintain their registration, medical staff required an annual update on ethics and economics. The legal aspects of organ donation was a major topic of discussion at these sessions:

Document Transcription B Lev 16

“As for staff, already trained anaesthesiologists, we have a system in Belgium where you have to show some evidence that you have been going to some kind of training every year. There is a financial consequence to that. That what makes people go. You have different points of interest. At post graduate level one of them is ethics and economy, some are very well qualified in ethics. Now you can do what you want, you have to get two hundred points per year. Put at least 30 minutes of them have to be ethics and economy, so that will be a session that everyone will have”. Page 8 Paragraph 1

Those interviewed suggested frequent information relating to organ donation contained within the media kept the health care professional aware of the issues related to organ donation. Further to this, the majority of those interviewed reported that they had attended one of the EDHEP short courses on organ donation. They suggested that attending this course had provided them with more detailed information regarding the application of the organ donation legislation to practice. In addition to this the course provided them with information on the technical procedures for organ donation such as the procedures to determine if the patient had suffered brain death and protocols for the preservation of the organs.

There are clear similarities in preparation of the HCPs that provide the organ donation services in Portugal, Norway and Belgium providing them with a good understanding of the legal and ethical principles that underpin organ donation. However, those interviewed also suggested that their knowledge and skill in the technical practice aspects of organ donation was obtained from personal experience or through the additional provision of specialist practice education courses.

8.1.4.2 Education and Preparation in the Approach and Care of Relatives

Despite having a reasonable knowledge of the legislation and organ donation practices gained from access to undergraduate and post graduate information, the role of the HCP in the approach to the family, breaking the news of the patient's brain death and subsequent consideration as a potential organ donor proved the most difficult to manage. Staff reported that applying the legislation and care of the family at this time presented them with difficulties, especially when the family were not aware of the legislation in organ donation or the concepts of brain death. This lack of understanding sometimes resulted in the family's inability to accept the death of the patient believing that they could receive care elsewhere to resolve their problems. The experience of PM 71, a nurse in intensive care was typical of that described by the HCPs who had to care for the family during the organ donation event:

Document Transcription P M71

“Yes they are very distressed about this when they first hear it and some people are very frightened and there are also rumours that they can take the body to another country and they can make them better and that actually they don't understand what brain death is. So this causes many problems for us. The main problem is that they have been told that the patient is dead, but they are in the bed and they are warm and they have not heard about this situation of ‘brain death’. Page 3 Paragraph 4

Applying the legislation therefore meant that not only had the health care professional to explain the reality of brain death to the distressed family and assist them to understand and accept the cerebral death, but also, they have to explain the legislation and provide family support during the donation procedure. The interviewees agreed that the requirement for psychological care and support of the relatives during the organ donation event was one of the most important aspects of their role. Many expressed the following sentiment captured in a statement from B Bru 103, an experienced anaesthetist in intensive care:

Document Transcription B Bru 103

“When you have to talk to a family about death not just about brain death it is stressful so. I don’t know if the stress comes because of you having to tell them that the patient has died or because you are going to ask for the organs. The major problem is when you have a patient that arrived a few hours ago and you diagnose that they are brain dead. You have never seen the family before and so the first time that you meet them you have to say I am sorry that he is dead and then we want the organs. You know that is difficult. But when you have seen the family before it is easier”. Page 9 Paragraph 7

“If you have got somebody who is 35-40 years old and they come in with a brain haemorrhage and you diagnose that they are dead and then the family comes and you have to tell them this, it is hard.” Page 9 paragraph 10

This role was especially difficult for the HCP where the donor in life had recorded no objection to organ donation but this was challenged by the relatives, as B Lev 1 an experienced anaesthetist in intensive care explained:

Document Transcription B Lev 1

“And the other way, taking an organ from somebody who is not, who did not give consent, firstly strictly legally the transplantation co-ordinator from University of Leuven knows the result of the database. Strictly if relatives object, strictly seen by the law, you have the right to proceed because there was no objection by the victim you don’t need approval of the relatives, so strictly legally it would be approved taking the organs from somebody whose relatives did object, no children, but you put yourself in a very difficult position”. Page 8 Paragraph 5

Many of those interviewed expressed the view that their lack of formal preparation in this aspect of their role was problematic and that they saw a need for education in how to approach the family and provide psychological care during the organ donation process. The view expressed by P SJ 2 a paediatric anaesthetist in intensive care was typical of many of those interviewed in identifying the need for education in this aspect of the HCPs role in organ donation:

Document Transcription P SJ 2

“They need to have formal education. I believe we should have formal education; not regarding the technical issue but regarding the approach, psychological situation dealing with the family, it would be helpful.” Page 9 Paragraph 8

As previously suggested many of the professionals interviewed in Norway and Belgium, had undertaken a short course on these aspects of organ donation. These EDHEP courses run by European Transplant co-ordinators group acknowledged these difficulties and provided training to HCPs. Input within these courses helped the HCP understand and manage the organ donation event, especially in relation to breaking bad news to the family and detailing the procedures to be adopted to ensure that there was no objection recorded by the deceased to organ donation taking place. B Bru 102 a former transplant co-ordinator and an instructor on this course explains:

Document Transcription B Bru 102

“Yes, this is a programme that was created by Eurotransplant along with communication professionals back in 1991, which is aimed at addressing bereaved families about the notion of brain death that and how to react as professionals to the emotions and reactions of the families in situations. Also it is about how to bring about the organ donation discussion not that there is a magic formula of course, but it is generally a communication skills awareness programme. Because I mean that we found and Eurotransplant also found out that, when we ask people in the different fields of medicine and nursing is that, we are not if not at all, not at all trained how to communicate with patients and families in critical situations.” Page 7 Paragraph 3

“So this programme is trying to address this of how to deal with the emotions, how to deal with the reactions of the families in these different situations and how to bring up the subject of organ donation”. Page 7 Paragraph 4

In addition to this particular educational input aimed at preparing the staff for the psychological support of the family, it was identified that specifically trained nurses within Belgium, called social nurses, support the family in the crisis event of a patient being admitted to the intensive care unit, providing information and detailed explanations of the patient care. This support enables the family to be involved in the decision making for their relative and in the event of an organ donation situation, they support the family to understand and come to accept the death of their loved one.

In addition to this role, this specially trained team provides education for nurses and medical staff in the psychological care of the family experiencing the organ donation event, as B Lev 109 a social nurse explained:

Document Transcription B Lev 109

“The new nurses (ER and ICU) and doctors (ICU) always get lessons concerning the way we work regarding to organ donation”. Page 4 Paragraph 2

“They know the law, that’s not the problem, but they do not have, from my point of view, a standard good education. When they have a good education it is because they have done one or two years in this hospital that they know already or they were resident in one of the other clinics in which they have also a good procedures. You may have a new doctor who has done a 6 years specialisation who has not a lot of experience with organ donation procedures. So it is important when there is a new ICU-doctor to see if he has had an education in donation management. If it is not the cases, many members of staff will help him/her to get the necessary skills.” Page 4 Paragraph 4

This specialist education programme includes the development of practical skills in providing psychological care to the relatives. This team have also developed a protocol to support the approach to the relatives and the sensitive exploration of the family’s views on organ donation. This short specialist programme is available to medical staff from critical care areas, who would potentially be involved in breaking the news of the donor’s death to the family and exploring organ donation. B Lev 109 explains further:

Document Transcription B Lev 109

“A few months ago together with a ICU-doctor we made an education lesson concerning ‘breaking bad news’ in the ER and ICU. We believe it is important not to bring a lesson and talk about 15 and 20 studies in research. We have made ‘the ten rules of the house’ concerning breaking bad news in an acute a situation. These are 10 practical rules in crisis communication”. Page 6 Paragraphs 1

Those interviewed therefore supported the requirement to prepare the HCP to manage the psychological and emotional care of the family.

8.1.4.3 Mentorship and Staff Support in Practice

In order to develop the confidence and competence required to apply this knowledge in practice, some HCPs described the provision of an unofficial mentorship of junior staff in care of donor and family. This mentorship scheme provided to the junior members of the ITU team experience in organ donation situations guided by more senior, who took the responsibility for the psychological and emotional care of the family. This allowed the junior team members to gain insights and experience in managing these situations, whilst ensuring that the family received a high standard of support, as B Lev 26 a junior anaesthetist in intensive care explained:

Document Transcription B Lev 26

“Yes, you just you join one of the senior staff members who are doing this and next time they say you will lead this. In the last years of training you are usually the person closely involved with people so you can be involved if you want to”.Page 3Paragraph 9

Whilst this placed additional pressures on senior staff, they took the view that this was necessary to ensure the safe standard of care for the donor and the appropriate support for the family involved in the donor situation, as B Lev 1 an experienced anaesthetist in intensive care explained:

Document Transcription B Lev 1

“..... Yes unofficial mentorship happens, depending a bit on the workload because those things very often go at night and at the weekends. Then sometimes we have to divide our efforts when there are only two or three staff at the hospital so that we cannot do the whole procedure together with a resident because there is too much work”. Page 5 Paragraph 14

As well as these schemes it was reported that further unofficial support systems have been developed to assist the team to manage these events. These often occur locally and take the form of discussions with senior ITU team members and other people such as the clergy and psychologists. These sessions provided the

professional with an opportunity to discuss concerns or ethical issues that had arisen and the provision of the much-needed emotional support. PM 123 an intensive care nurse explains the informal support systems that many staff described:

Document Transcription P M123

“Yes we do support each other. There are difficulties that might happen when there are parents involved and maybe the dead person is actually their child and that can be difficult for the parents to make that decision in regards to this. Yes all the staff do try to recognise this problem and we try to support each other and support the family to make the decision. Sometimes we seek help from outside from priests, psychologists or whatever but in the main it is the staff in the unit who try to deal with this and support each other during this difficult situation.” Page 4 Paragraph 4.

Some of those interviewed reported that they found the organ donation process ethically challenging, especially when working with a patient who was undergoing tests for the confirmation of brain death and then being asked to care for the patient who has the potential to become a donor. N R 124 an experienced anaesthetist in intensive care highlighted this issue, also described by many other professionals that were interviewed:

Document Transcription N R124

“I think I find it quite difficult because it is always difficult when the patient is deteriorating; when you see it can take a couple of days or just hours to get to maybe introduce that thought to the relatives that the patient is deteriorating; that he will not maybe survive and this thought about donation. It can be very difficult because you are treating the patient in the same time that you are in a way interested in the organs so it is quite a difficult thing I think.” Page 4 Paragraph 7

The interviewees suggested that discussing these ethical challenges with other members of the multidisciplinary team was helpful in order to clarify their roles and explore conflicts that might arise especially in relation to communicating with the relatives, as N ST0 77 an intensive care nurse suggested:

Document Transcription NST 0 77

“We always communicate freely, the doctor and the nurses so we always know what the doctor has told and we speak together all the time. Earlier on we did not do that so

much and then it causes trouble, insecurity and ethical problems because we did not know what the family knew. So when the team work is better, I think the team work is very good now and that makes it a better situation". Page 4 Paragraph 9

In the three countries explored those interviewed agreed that the opportunity of contact with the transplant co-ordinator teams for advice at any time by the telephone or by email was very supportive. They also reported that feedback from the co-ordinator team to the staff within intensive care, emergency room, or the recovery area involved in donation, about the success of their efforts, was beneficial to motivating staff to continue to be involved in the programme as B Lev 24 a senior anaesthetist explained:

Document Transcription B Lev 24

"Yes in fact we have regular meetings on organ donation once or twice per year where first of all we get feedback on the transplanted organs and then we organise organ donation symposia where all staff members participate. We have a lot of connections across Belgium as a strong network. There is strong team communication with the transplant co-ordination team. We receive feedback from the transplant co-ordinators about the organs and the recipients. We do not get personal details but we can keep in touch with their progress". Page 5 Paragraph 12

Communication and up to date feedback on donation for the HCPs was achieved using a variety of different methods of such as organ donation newsletters and regular organ donation study events, as B Lev 1 an experienced anaesthetist supports this view:

Document Transcription B Lev 1

"The transplant co-ordinator from L gives us all, they help us a lot. They would, I don't know if there are specific training programmes saying how to access relatives but they organise on a regular basis symposia, they have a news letter if you have a problem, you can always ask them, they are very good". Page 6 Paragraph 1

The interviews therefore suggested that whilst there was a clear requirement for specialist education for the HCP to undertake their role, there was an additional requirement for professional and emotional support for the HCP to enable them to provide the required standard of care for the donor and their family. In

addition to this, those interviewed stressed that the development of good multidisciplinary team working relationships were essential to the success of organ donation. This often required the development of regular feedback and communication systems allowing staff involved in organ donation in the minor hospitals to keep up to date with the success of their efforts, as B Bru 106 highlights:

Document Transcription B Bru 106

“To give support for those teams to see what happens after procurement, because they are only things like reports and everybody not seeing it. It is not a good way to motivate the staff. It is important to say that with those organs we transplanted with one donor we transplanted 3, 4, 5,7 patients, it is important to know this”. Page 7 Paragraph 1

Summary

In relation therefore to the question of whether the implementation of presumed consent legislation required to be supported by specialist education and preparation of the health care professional, those interviewed suggested that in order to effectively implement this type of legislation, these professionals require detailed education on this topic at a variety of points in their professional development and practice. Responses also indicated that not only does this education require to contain information aimed at the development of the HCP’s knowledge and skills on the legal and ethical aspects of the donation process and technical aspects of organ donation practice, any education provided must also help the professional develop competence in a challenging area of practice, that of the physical and psychological care of the family during the organ donation process. Chapter 9 will explore the implications of the need to provide this level of education for the HCP in order to support this approach to organ donation.

Chapter 9 Discussion of Study Outcomes

9.0 Introduction

This chapter will discuss the data collected and analysed in the course of this study using a mixed method approach of an initial quantitative survey of HCPs that used questionnaires with qualitative data gathered from semi-structured interviews with these HCP's combined with other data gathered during field visits, as presented in chapters 6, 7 and 8. Analysis of these data was developed from HCPs within Portugal, Norway and Belgium using a phenomenological framework first identified by Heidegger (1962) and adapted by Gadamer (1976) where a pre-understanding of a topic area by the researcher was combined with data from participant experiences of their "lived experiences" in the application of presumed consent legislation in organ donation. From these experiences a number of key themes emerged in relation to the application of this legislation in the three countries under review.

Whilst it is acknowledged that findings generated from this study may not necessarily be transferable to other settings, the mapping of the research areas for enquiry as identified within chapter 5 with themes arising from the data (**Table 9.1**) and the subsequent comparison of these themes with the relevant published literature, provided new insights into the application of this approach to organ donation within the three countries. This chapter will explore these new insights identifying the implications for organ donation practice in the U.K.

Table 9.1 Research Questions Mapped to Emergent Themes from Participants

Research Study areas for Enquiry	Emergent themes from Participants
The involvement in and impact of the legislation on the bereaved relatives of the donor	<p>9.1 Drafting and Application of Presumed Consent Legislation</p> <ul style="list-style-type: none"> • Establishment of Consent or Objection to Organ Donation <p>9.2 Involvement of the Family in the Organ Donation Process</p> <ul style="list-style-type: none"> • Establishing the Level of involvement of Family in the Organ Donation Process • Establishing the Potential Impact of Family • Family Knowledge and Education in Relation to Organ donation
The impact of the application of the legislation on relationship between the donor families and the healthcare professionals.	<p>9.3 Trusting relationship between Family and the Health Care Professional</p> <ul style="list-style-type: none"> • Trust in the Organ Donation Legislation and System • Trust in the Health Care Professional's Practice • Health Care Professional's Respect for Cultural and Religious Beliefs of the Family
The provision of specialist procedures, policies and resources enabling the effective implementation of this legislation	<p>9.4 Health Professional Practice in Organ Donation</p> <ul style="list-style-type: none"> • Development of Organ Donation Infrastructures & Networks • Organ Donation Communication Infrastructure • Development of Organ Donation Professional Manpower <p>9.5 Development of Protocols of Practice in Organ Donation</p> <ul style="list-style-type: none"> • Protocols for Brain Death and Donor Management • Protocols for Care of the Family
The availability of specialist education or preparation for the staff who utilise this legislation	<p>9.6 Education and Preparation of Health Care Professional for Role in Organ Donation</p> <ul style="list-style-type: none"> • Education in Legal and Ethical Aspects of Organ Donation • Education in Organ Donation Professional Practice • Education in the Care and Support of Relatives

9.1 Drafting and Application of Presumed Consent Legislation

9.1.1 Establishment of Consent or Objection to Organ Donation

A review of the legislation within the European countries considered as described in chapter 3 together with data obtained during field visits as detailed within chapter 6 confirmed differences in each country in the manner in which the legislation was drafted, specifically the manner in which the consent to organ donation was established. The literature suggested that controversy exists as to the nature of consent required to allow organ donation to proceed. Price (2002) acknowledged the fundamental paradigm of autonomy in healthcare as being

expressed consent; normally demonstrated by written instructions. Beauchamp and Childress (2001) however highlighted that another form of consent exists namely tacit or implicit or implied consent; expressed silently or passively, by omission. Responses from participants in the three countries as described in chapters 7 and 8 confirmed a range of different approaches established in these three countries to record the consent of individuals in relation to donation:

- In Portugal and Belgium a register of objection to organ donation had been established where an absence of the deceased name on this register, is viewed by the HCP as consent to organ donation.
- In Portugal and Belgium a computerised register has been developed to record this information.
- A facility to record a wish to donate organs was only available within a specific part of the legislation adopted by Belgium, where the individual had the option to express consent to organ donation.
- In Norway no formal register of consent or objection to organ donation has been established however the next of kin of the deceased were approached by the HCP to confirm that the deceased had not expressed an objection to organ donation.

On review of the formats of presumed consent legislation in the three countries, it could be argued that a form of tacit or implied consent as described by Beauchamp and Childress (2001) in chapter 4 is being adopted to facilitate organ donation. That is, those individuals who have not expressed their views either positively or negatively in relation to donation have done so silently or passively by their omission to register an objection. Price (2002) highlights however that using this form of consent to a procedure is unusual, suggesting that silence is not

recognised as consent in most other legal contexts either in the U.K. or elsewhere. Health care practice within in the U.K. normally requires formal written consent from the patient to any invasive procedures undertaken. This raises the question as to whether the lack of an objection to donation can be viewed as the same as consent or authorisation by the individual to this procedure. If this is seen as an acceptable method of recording consent, questions are therefore raised as to whether this method of determining consent is limited to organ donation or transferable to other situations, where consent to a procedure is currently required to be demonstrated by expressed consent. Further challenges to the validity of using tacit or implied consent in organ donation are presented by Lamb (1990), Ellis (1998) and Hill et al., (1999) who argue that the use of implied consent as used in presumed consent legislation is in fact consent by default. In doing so they question if this was consent at all and whether it represents an erosion of the individual's right to determine the outcome of their organs after death. This they suggest may in due course impact on other rights to autonomous informed decision, creating a "slippery slope" to people feeling that they are state owned commodities with little autonomy. Gillon (1995) and Wilks (1998) supported this view suggesting that consent provided by default where no evidence of the deceased's agreement or objection to organ donation exists, is ethically unsustainable.

The responses from the HCPs to this suggestion from the participant interviews as detailed in chapter 8 reported that in their view the public expressed no sense of state ownership of individuals or organs by the application of this form of organ donation legislation. Instead, the respondents in all three countries expressed the view that under their legislation, the individual retains the power to donate their

organs as an altruistic and community spirited act or alternatively to choose not to donate their organs by recording their objection to this on the register should this exist, thus preserving their autonomy. Alternatively, if no register existed the individual could express their views to their family who could in turn represent this view.

When questioned further however as to how those without the capacity to consent, as in the case of a child or those who have lost the ability to consent due to incapacity, would be protected from being viewed as a commodity, the participants were less confident in their responses. In the case of the death of a child the respondents were confident that the parent or the individual with parental responsibility would be asked to consent to organ donation. When the issue of the incapacitated adult was explored however, the HCPs could not confirm that these individuals would not automatically become organ donors as a result of a lack of recording objection to organ donation. They indicated however that the normal practice when notified that the individual may be incapacitated was to either exclude these people from organ donation or to seek the agreement of their advocate or legal guardian. The validity and reliability of this view held by the respondents could be questioned however. Although databases of individuals who object to organ donation have been developed providing an up to date listing of competent individuals who object to organ donation, the participants were not aware of any method of recording the names of individuals with incapacity and therefore securing their exception from the legislation. The logistics of the development of such a register were not considered nor was the manner in which the vulnerable and incapacitated would be protected.

Review of these findings indicates the need to consider the form of consent that is acceptable to society to allow organ donation. Currently in the U.K. the HT (S) Act 2006 and the HT Act 2004 requires the expressed consent of an individual either in writing or verbally to authorise organ donation. Elsewhere in Europe a form of implied consent using registers of objection operates and does appear to function well providing higher numbers of organ donation than is produced in the U.K. The requirement for expressed consent in organ donation in the U.K. as opposed to implied consent as used elsewhere requires to be explored further. The strongly held objections by some that a change in our present method of gaining consent could have much wider ranging consequences require to be considered carefully.

When used, the application of presumed consent legislation in organ donation is in the main facilitated by the use of registers of objection. Whilst these may provide a method for the competent individual to record their consent or objection to donation, questions are raised as to the ability of registers of objection to protect the incapacitated and the vulnerable adequately from automatically being identified as a donor as a result of their inability to record an objection. If this form of legislation was to be applied in the U.K., a systematic infrastructure for recording individual consent or objection to organ donation would require to be established and maintained by the authorities. There is also the need to explore how this form of legislation would protect the rights of vulnerable individuals in society. Potentially this would require a review of all the individuals over the age of consent who would be considered exempt e.g. those with severe mental health problems, those with severe learning difficulties, those who do not speak English sufficiently to comprehend the legislation. A method of exploring these

individuals' wishes in relation to organ donation would require to be established. Alternatively, these people may be considered as automatically exempt from the legislation unless they indicated that they did not wish to be considered as such. If these data could be collected, a regular system of updating would require to be developed to maintain a "live" register. The organisational and financial implications of establishing this system require further exploration before a change in the legislation could be considered.

9.2 Involvement of the Family in the Organ Donation Process

9.2.1 Establishing the Level of involvement of Family in the Organ Donation Process

Literature in chapter 3 related to the application of presumed consent in the three European countries under review indicated that the family had only a minimal involvement in the decision made by the HCP to progress to organ donation. A key research question posed by this study therefore was the exploration of the impact of presumed consent legislation on these bereaved relatives. Detailed review of the legislation of these respective countries within chapter 6 however, demonstrated that a striking feature of the differing legislation was the varying involvement of the family in the organ donation decision-making process. Further analysis of the legislation in Norway demonstrated the requirement for the next of kin to be approached to confirm the wishes of the deceased. Confirmation of this requirement was provided by HCPs during interviews as detailed in chapter 8. Additionally, in Belgium, the legislation specifies that if there is an expressed wish to donate recorded by the deceased, the family cannot object. Respondents interviewed in Belgium indicated that the family is always approached and asked to confirm the deceased's lack of objection. Participants in Portugal also reported

confirming the deceased's lack of objection with the family and exploring their objection to donation proceeding. Despite the terms of the particular legislation in each country, the HCPs reported that if the relatives objected to organ donation, they would find it very difficult to override the wishes of the family and proceed to organ donation, therefore in practice they would always defer to the wishes of the family as to the decision to proceed to organ donation. The routine involvement of families in the decision to progress to organ donation despite presumed consent legislation in Portugal, Norway and Belgium with had not previously been identified or publicised. These data provide new insights as to the "lived experiences" of the HCPs relating to the application of this approach to donation legislation within the three European countries and with its implications for any future adoption of this approach to organ donation within the U.K.

Participants expressed the view that the recording of the deceased's intentions on the register of donors or objectors is not the single most important factor in the decision by the HCPs to progress to organ donation. In their views the indication of the deceased's wishes as recorded on any register of objection, provides the conditions for organ donation to be explored openly with the family. Interviews with participants indicated that exploring the wishes of the deceased as described by the family was an appropriate method of confirming the deceased's consent or objection to donation. Participants however could not identify the process whereby, in the absence of evidence of expressed wishes of the donor either in favour or against organ donation, they were able to distinguish the family's views on organ donation from that of the donor. In addition to raising questions in relation to the validity of the consent to proceed to organ donation, this finding demonstrates that there is a dissonance between the legislation and the

interpretation and application of this by the HCP. It would appear from the findings that the full tenets of the legislation are not applied by the HCP. Rather the HCP interprets the legislation as a guide to practice and the decision to progress to organ donation will be determined by the views of the family. This supports the findings by Nowenstein Piery (2005) in an exploration of organ donation practices in France who also found evidence that the HCP did not use the full powers of the legislation but utilised the views of the family to influence their decision to progress to organ donation.

These findings would indicate that a form of tacit or implied consent is being applied in these countries where if the individual has not recorded an objection, this is viewed as agreement to donation. Alternatively, despite any intention recorded by the deceased, the family are used as a method of proxy authorisation or refusal for organ donation. In Portugal and Norway, objections raised by the family will veto any agreement to donation recorded previously by the donor. Only in Belgium was a positive decision to donate recorded by the deceased in life, upheld in despite any family opposition where the HCPs reported that if the deceased had recorded a wish to donate then the family would not be allowed to object to the donation process. The involvement of the family to in the organ donation decision making process to such a degree in these European countries is very similar to the process adopted within Scotland in applying the HT (S) Act 2006 in as much as in applying the terms of the 2006 Act, even when evidence exists of the wishes of the deceased in favour of organ donation and especially in the absence of any authorisation by the deceased to organ donation, the family can be asked to authorise organ donation. Clearly, the family has a fundamental role

in the authorisation of organ donation in both the European countries and the U.K. irrespective of whether presumed consent legislation is in force.

9.2.2 Establishing the Potential Impact of Family Involvement in the Organ Donation Process

The literature in chapter 2 reflected some divided opinions as to the benefits and problems for the family to be so involved in the decision-making in organ donation. Sque and Pyne (1994) warn that ethically the organ donation process can only be achieved without social or psychological harm to the donor families and significant others. Whilst acknowledging the potential distress caused to relatives by approaching them to authorise organ donation, analysis of responses from the HCPs interviewed as detailed in chapter 8 indicated that it would be professionally unethical to exclude the family from the decision making in organ donation. To explain this stance the HCPs expressed the fear that exclusion of the family from the organ donation decision-making process would be detrimental to the family's grief process and may result in conflict with the ethical principles of the HCP. It appears that in the views of the participants the underpinning ethical principles of beneficence and non-maleficence toward the family, as expressed in professional codes of conduct for example, the International Code of Nursing (ICN, 2006), must be upheld. This is demonstrated by ensuring the family are included in the organ donation decision-making process and supported appropriately during this event.

Further to this view the HCPs also expressed the view that there are benefits to the family of being involved in decision-making process in terms of their acceptance of the deceased's death. They also reported that in their view if the family agree to

donation, they might gain comfort in the knowledge that something positive has been possible despite their personal tragedy. This may take the form of saving the life or improving the life of another individual. Supporting these views expressed by the HCPs, Wellesly et al., (1997) with Cansdale and Cansdale (1999) agreed that there is much to be gained for the family, even at this time of bereavement to be approached and requested to authorise donation. A small scale study of experiences, attitudes and belief systems of donor and non-donor families in Scotland (Haddow 2003) appeared to support this view, demonstrating that families who had agreed to donate of their relatives organs, felt positively about the donation experience and would make the same decision again if asked to do so.

Alternatively, Garrison et al., (1991), Niles and Mattice (1996), Kozlowski (1998) and Riley and Coolican (1999) warn however of the potential harm for the family if they are asked to make a decision in relation to organ donation very soon after being informed of the sudden death of a family member. Haddow (2003) also suggested that families who had refused donation did so on the basis that they did not believe that this is what the deceased would have wanted or inter-family objections to donation prevented this. Additionally, the study suggested that negative beliefs in relation to donation and lack of understanding of the organ donation procedures underpinned their refusal to allow organ donation to proceed.

In response to the view that the family could perhaps be harmed by being approached to consider organ donation or that inter-family objections to donation can arise some HCP expressed the need to separate the communication of the diagnosis of brain death from the request for them to agree to organ donation. To

address the need for the family to have time to consider their response to this the HCPs developed a protocol of practice to guide their response in these circumstances. The details of this protocol will be explored later in this chapter however, the adoption of these protocols in support of the relatives throughout the donation process had previously been unreported and clearly demonstrates the importance placed by the HCPs of ensuring the physical and spiritual wellbeing of the family in addition to obtaining organs for donation as suggested in the literature reported in chapter 2.

The interviews with the HCPs did indicate however, that the bereaved family's ability to participate in the decision making process may be dependent on their prior knowledge and understanding of the law and organ donation. Roels et al., (1997) demonstrated different attitudes to organ donation across three generations, however little other data exist in relation to the family's knowledge in relation to organ donation, prior to being involved in this experience. Interestingly, participants also express the view that exclusion of the family from the decision-making holds the potential to develop negative publicity in the general population. They saw this as "suicidal" to the organ donation system. In their opinion if this occurred suspicion and fears would be raised in the minds of the public of unacceptable practices in organ donation. This supports the suggestion made by English and Sommerville (2003) in chapter 2 that the public may hold a number of fears in relation to organ donation often based on lack of understanding of the practices and protocols in organ donation, specifically in relation to the identification and certification of brain death. This lack of understanding and fear may lead large numbers of the families involved in an organ donation event to object to the donation.

In response therefore to the question posed by the study to explore the involvement in and impact of the legislation on the bereaved relatives of the donor, it has been identified that the legislation in the three countries specifies the need for the involvement of the family in the organ donation process to varying degrees. Analysis of responses from the participants together with other evidence gathered by the researcher during field visits in the three countries clearly demonstrated that the family are always involved in the decision to accept the deceased as an organ donor. In particular, data presented in this study suggest that the family are not only invited to confirm the deceased's views on organ donation, but in addition despite the lack of requirement to do so from a legislative perspective, the family are asked if they hold any personal objection to organ donation. Analysis of responses from participants also demonstrated that if any family objections were identified, the organ donation process would be halted. Exploration of the rationale for this practice demonstrated that, in the views of the participants, the family represents the best interests of the deceased and their views are upheld, especially if no record of the deceased's wishes are recorded. This supports the view expressed in chapter 4 by Feinberg (1984), The Canadian Law Reform Commission (1992) and Hamer and Rivlin (2003).

Allowing the family to object to organ donation in this manner if the deceased has indicated their wish to donate poses questions however, as to the deceased's right to determine the outcome of their organs after death. Participants viewed this practice of allowing the family to override the wishes of the deceased as acceptable, as they saw the respect for the wishes as being a very important aspect of the organ donation process. Failure to do this they viewed as potentially

harmful to the family in the long term. It is questionable however if respecting the wishes of the family at this time, demonstrates respect for the wishes of the dead another very important concept described by the participants. The deceased may have been unaware of the law. Alternatively, they may have known the law but failed to register views or discuss these with their family. It is very difficult to support the view expressed by some participants that the family will be in a position to present evidence of the deceased's wishes in relation to organ donation, without concrete evidence of the deceased consent to donation. It could be said that this practice of seeking the views of the family, unless this aspect is required under the legislation, does not achieve establishment of the deceased's view in relation to organ donation. It could be suggested that this practice may instead seek authorisation to proceed rather than consent from the family, in order to prevent the likelihood of challenges being raised later by the family. The role of immediate family in representing the deceased's wishes and validity of any consent given by the family to progress to organ donation therefore requires to be clarified.

Questions also arise in relation to the rationale for HCPs seeking the family's authorisation to progress to organ donation and the potential benefits and problems for the family taking this action. The implications of involvement of the family in the decision-making process to this degree require to be explored in more detail. Involvement of the family in the decision-making process may be less challenging than excluding them from the process, but the benefits and consequences of the family's involvement in this decision making require to be researched further. Given this view, the role and function of registers of the

consent or objection to organ donation as a means of authorisation for the HCP to proceed to organ donation require to be considered further.

9.2.3 Family Knowledge and Education in Relation to Organ Donation

In defining tacit or implied consent, in Chapter 2 Beauchamp and Childress (2001) clarify that this form of consent expressed silently or passively, by omission can only be acceptable if it can be demonstrated that the individuals were fully informed of the need to consent or object to an action and fully aware of the consequences of failing to act. This would suggest that in order for presumed consent to be valid, evidence of the deceased's prior knowledge of the law in relation to organ donation and the required actions in relation to this legislation would be required. If no evidence of tacit or implied consent exists, in that no evidence that the deceased was aware of the law and the need to record their consent or objection, then the practice in presumed consent of removing organs perhaps expropriates organs without regard to consent at all (Beauchamp and Childress, 2001). If, as Beauchamp and Childress suggest to be valid consent, tacit or implied consent must be supported by a level of knowledge and understanding as to the need to register an objection. The individual must also be aware of the consequences of failure to do so and therefore for this form of consent to be valid there must be evidence of adequate education of the public to this end.

A review of the legislation within the three countries reported in chapter 3 indicated that public knowledge and education in relation to the organ donation was viewed by the legislators as being vital to the success of organ donation. Subsequently, on review of the legislation of Portugal (Republic Assembly Law Nr. 12/93) and Belgium (Royal Decision, 1986), these laws demonstrated a clear

requirement to educate the public in relation to this legislation and the potential benefits of organ donation. Further to this, although not a requirement of the original legislation in Norway (DHSS, 1973), information later from the Norwegian Department of Health (DHSS, 2004) highlighted the requirement to educate the public in relation to organ donation.

In chapter 8, the necessity of public education was confirmed by the participants who repeatedly stated that public knowledge of this legislation and organ donation processes was vital to facilitate the family's full participation in the decision-making process, and therefore in the success of this format of organ donation. They reported widespread legal and political debate relating to the proposed changes in law and its benefits, prior to implementation in each of the three countries under review. Responses from the questionnaires in chapter 7 and interviews with the HCPs in chapter 8 reported that in their opinion the public education campaigns in their individual countries in relation to the benefits of organ donation, had resulted in the donation of organs being the accepted norm in the population. Field visits to the three counties under review by the researcher as reported in chapter 6 also provided evidence of major public awareness campaigns funded by government using a variety of media to raise the awareness of organ donation legislation and issues. Further to this, the participants reported the use of education in schools in order to promote understanding and discussion in society of organ donation (Roels, 1997). In the views of the HCPs public education via the media promoted acceptance of presumed consent as the normal contribution by the individual to society. Participants also expressed the view that the government funded frequent public education and communication initiatives

highlighting the issues related to organ donation using all types of media available, were vital to success of organ donation.

Questions arise, however, as to whether better public education of organ donation concepts does increase understanding in the HCP's practice and increase the numbers of people agreeing to donate organs. Chapter 3 reported a number of public surveys that were undertaken to explore public opinion in relation to organ donation legislation with Roels (1997) and UKT (2006) reporting education initiatives to increase understanding in relation to organ donation. As also reported in chapter 2 that public confidence in the scientific professionals in the U.K. is at a low level (HOL, 2000) perhaps as a result of poor levels of understanding by the public of health care practices and poor coverage of organ donation practice in the media. Robertson (1999) and Koppelman (2003) suggest confusion in relation to definitions of death also results in misunderstandings between HCPs in relation to practices in organ donation. This confused picture presented from the HCPs combined with public fears that organ donation might commence prior to the patient being pronounced dead as suggested by English and Somerville (2005) raises questions as to what exactly the public understand in relation to organ donation. Limited research exists in relation to public understanding of organ donation concepts (Haddow, 2003, Pelletier, 1992).

What remains unclear however is what level of understanding the public has in relation to these concepts and legislation and what, if any, impact public education campaigns on organ donation have on public knowledge and understanding of these issues. Addressing this gap in the data would be required before a public education strategy aimed at improving public knowledge and understanding of

organ donation legislation and practices could be developed. Using these data a national public education campaign could be developed to provide understanding of concepts associated with organ donation such as brain death. The level of public education that is required to ensure the required public knowledge and understanding in order to allow them to participate fully in the organ donation process is a matter of speculation.

Currently in the U.K. the national organ donation register holds the names of 13.1 million people who are willing to be organ donors (UKT, 2006). Recruitment of individuals to this register relies on the altruistic behaviour of individuals in society and their knowledge and understanding of organ donation. Given as reported in chapter 2 that studies report large numbers of the population are in favour of organ donation (UKT, 2006) perhaps the low number of people registering on the organ donation register results from either a poor understanding of the need for organ donation or how the individual might register their authorisation to this. A national strategy to improve the numbers of people placing their names on this register has been commenced by UKT (UKT, 2006). The public have also been asked to consider adding their name to the organ donor list when visiting their G.P.'s surgery or when they register for a major retailer reward card. UKT have also developed an education pack for school children explaining the issues surrounding organ donation (UKT, 2006). This pack has been made available to all schools within the U.K. for use by children over the age of 16 years of age during their social and religious studies course to help them understand the issues and make an informed choice with regard to organ donation for themselves.

These initiatives are only possible with considerable public funding to underpin them. This has been undertaken by UKT requiring a considerable financial and organisational undertaking from the DOH. Currently the organisation of blood transfusion and organ donation services within the U.K. falls within the remit of the NHS Blood and Transplant (NHSBT) and as such funding is provided from central government. With the advent of devolution across the four countries of the U.K. and with it the devolved responsibility for health matters, it is unclear how the funding of these national organ donation initiatives may be managed in the future by the respective devolved administrations. The organisation and funding of future organ donation structures throughout the U.K. therefore is a matter of importance.

9.3 Trusting Relationship between The Public, Family and The Health Care Professional

In response to the question of how presumed consent legislation impacts upon the trusting relationship between the donor families and the HCPs, a number of issues arose from the analysis of the participants responses:

9.3.1 Trust in the Organ Donation Legislation and System

As reported in chapter 9 in the views of the HCP's interviewed public education campaigns have a major role to play in the success of presumed consent legislation in achieving public trust and confidence in this approach to organ donation. The formation of a trusting relationship between the public and the HCP was described by the participants as being based on respect for individual autonomous choice and knowledge of the organ donation process, and echos the components necessary for tacit or implied consent to be as valid as described in

chapter four by Hill et al., (1999) and Beauchamp and Childress (2001). In the view of the HCPs understanding of organ donation concepts facilitated an open and honest discussion of issues related to death and organ donation within society. Clarity of information and open discussion of organ donation legislation and associated administrative processes provided the public with transparency in the process of registration, building confidence in the public that they have a choice to register for or against organ donation, with this choice being respected.

Interestingly, some participants cited breakdown of a trusting relationship between the public and the HCP that arose in the U.K. in the wake of the retention of children's organs (HOC, 2001) as reported in chapter two, as an example of what may happen when the public are not informed about health practices and afforded the opportunity to participate in decision-making in health care. They warned against any changes to practices in organ donation being attempted without full public knowledge and involvement.

Should presumed consent legislation be considered in the U.K. the implications of the need to develop a system of public education to support the implementation of such legislation requires consideration. The question arises however as to the levels of education of the public required to provide enough understanding of organ donation to achieve trust in the system. Furthermore, exploration of the role of the public education campaigns in providing appropriate information to the public and family, facilitating their trust and involvement in the decision-making process is also required.

9.3.2 Trust in the Health Care Professional's Clinical Practice

Data analysis discussed in chapter 8 provided evidence that the HCPs interviewed reported that the success of the organ donation initiatives are dependent upon society's understanding and trust in their clinical practice. These practices of the HCP in organ donation must be open and transparent to the public. Those interviewed reported that poor levels of knowledge of organ donation concepts and practices may lead to suspicion and mistrust of the HCP. Participants suggested that trust in the HCP is based on information provided previously on organ donation together with the communication and support provided to the family by the HCP during the organ donation process. In the views of the participants the HCP's knowledge of law and procedures in organ donation and willingness to explain these to the family in a sensitive and respectful manner promoted trust in organ donation procedures.

Participants highlighted that a key aspect of the development of a trusting relationship between the family and the HCP, is the family's confidence in the resuscitation efforts of the HCP prior to the death of their relative. This includes the ability of the family to understand the concept of brain death and accept their relative's death. This confidence and acceptance of the death of their relative by the family, in the views of the HCPs promotes trust and may prevent objections to organ donation being raised by the family. Haddow (2003) supports the views expressed by the HCPs that the family experiences difficulties in understanding concepts of brain death. Donor families in Haddow's study demonstrated that the lack of understanding of this concept and other procedures related to organ donation, may result in mistrust of the HCPs caring for the donor. In chapter 2 this poor understanding of these concepts was suggested by English and Somerville

(2005) as having the potential to lead to fears that their relative is not dead and being inappropriately identified as an organ donor. Gore (1992) also highlighted that the level of support provided by the HCPs at this time was very important in facilitating the families understanding of the procedure for diagnosing brain death and the decision to consider their family member as an organ donor. If this level of support is not provided this may increase the levels of family objection to organ donation.

Participants also stressed the need to involve the family sensitively in the diagnosis of brain death by providing them with detailed explanation of the care and assessments undertaken. This should be combined with enough time for the family to understand and come to terms with the diagnosis of brain death, allowing trust in the HCP to develop, thus echoing the need for this expressed by Riley and Cooligan (1999). Further to this, some participants expressed reservations in relation to the introduction of non-heart beating donor (NHBD) initiatives. In their view the lack of time to prepare relatives for the death and move to organ donation status that results from this procedure, has the potential to prevent the development of the trusting relationship between HCP and the family. If this does occur there may be detrimental consequences for the family and indeed for the organ donation initiative overall supporting the views on this issue previously expressed by Niles and Mattice (1996).

9.3.3 Health Care Professional's Respect for Cultural and Religious Beliefs of the Family

Participants also highlighted the requirement for sensitivity in relation to different cultural beliefs in relation to death, autopsy and care of body after death as being

vital to the success of organ donation initiatives. Some participants cited the controversy surrounding the retention of organs at post mortem examination in the U.K. as an example of problems that may arise as a result of the HCPs failure to take cognisance of the public's sensitivities in relation care of the body after death. To this end the participants recommended the involvement of clergy or other relevant religious or spiritual advisor in the request to the family to authorise the progression to organ donation. In their view the inclusion of religious colleagues in the multi-professional team at this time allowed sensitive exploration of the family's cultural and spiritual beliefs allowing these to be addressed and thus aiding trust in the HCP and organ donation. This view of the HCPs that if organ donation is to progress respecting the religious and cultural views of the donor and family is vital, mirrors the views of Chapman et al., (1997) and Gillman (1999) and who suggested that pastoral support was a key element of the multidisciplinary team caring for the donor and the family.

In response therefore to the question posed by this study to explore the impact of the application of the legislation on the relationship between the donor families and the HCPs, analysis of participant's responses suggests that a trusting relationship can be established between these two groups using a number of methods. These include providing the public with education in relation to the legislation and concepts surrounding organ donation in particular the diagnosis of brain death. The provision of this education supports trust in the HCP's diagnosis of death and reduces public fears that organ donation is being considered at the expense of the patient care. This would indicate that in implementing a change in organ donation legislation, in addition to providing the public with education in relation to the legal and administration aspects, there is also a need for a public

information and education campaign in regards to the technical aspects of organ donation and eligibility for donor status.

Any education strategy developed would also require to acknowledge the religious and cultural sensitivities related to this issue, contributing towards establishing trust in the organ donation system as a prelude to amending the organ donation legislation within the U.K. Additionally, the introduction of pastoral support to the multidisciplinary team caring for the donor and supporting the family during the organ donation event may also address religious and cultural needs of the donor family and establish a trusting relationship with the multidisciplinary team and perhaps facilitating successful organ donation.

9.4 Health Care Professionals' Practice in Organ Donation

Presumed consent legislative procedures have provided an increase in organs for donation; however they require the development of new systems, protocols and practices to facilitate the identification and supply of organs for transplant.

Detailed exploration of the specialist policies and procedures required to be developed to support implementation of presumed consent legislation, data gathered from the literature, data from field work and interviews with participants identified the following key issues for discussion:

9.4.1 Development of Organ Donation Infrastructures & Networks

As reported in chapter 6 strategically, evidence gathered during field visits to the three countries under review, demonstrated a development of national and international infrastructures to identify potential donors and support the supply of organs utilising a network of smaller and larger hospitals. These strategically-

placed organ donation centres, often based within large University teaching hospitals, co-ordinate organ donation activity throughout a region, developing expertise and supporting smaller hospitals to participate in the organ donation initiative. This supports work undertaken by Grimbel et al., (2003) who also suggested that considerable infrastructures had been developed to underpin organ donation in European countries that had adopted presumed consent legislation. Clearly, this has required considerable organisational financial investment in the organ donation system to support the implementation of the legislation in terms of medical, nursing and administrative staff.

To develop a similar organ donation network in the U.K. to that existing elsewhere in Europe, this system or a network of larger organ transplant centres linked to small donor hospitals would have to be replicated. Work in this area is already underway with UK Transplant developing a network of regional transplant centre hospitals throughout the U.K. linked to smaller hospitals within their regions. Initiatives have been implemented aimed at promoting organ donation within these regions, however organ donation numbers using this network remain low.

Whilst these initiatives are welcomed, consideration of the impact on the NHS of adopting a more strategic and systematic approach to organ donation in terms of the organisational change and financial change required should be considered. In particular, consideration has to be given to the overall organisational and financial impact on intensive care units, operating theatres and emergency departments of increase in organ donations in U.K. including increases in medical professionals; anaesthetists and transplant surgeons, nursing staff, transplant co-ordinators and

intensive care nurses. Consideration is also required by the Department of Health and Scottish Executive Health Department in relation to the impact on already pressured NHS, of increased organ donation with the subsequent increased requirement of suitable operating theatre and intensive care facilities.

9.4.2 Organ Donation Communication Infrastructure

As reported by the HCPs, to facilitate the application of the presumed consent legislation, a national communication and information technological system was established to develop a register of donors or objectors to donation. To allow this co-ordination of the donation and transplant activity, transplant co-ordinators also require to access this database on a 24 hour basis. In chapter 8 it was also established during the interviews with the HCPs, that in order to facilitate optimum use of any organs donated, not only did the transplant co-ordinators require to communicate with colleagues within their own region or country, but additionally, require to be able to communicate with colleagues on an international basis. Systems that facilitated effective communication between the transplant co-ordinators and the staff within transplant organisations within each country had been developed, together with an ability for them to communicate with transplant colleagues across Europe. This international communication and collaboration facilitates effective and efficient identification and use of available organs across borders allowing effective use of these vital organs and resources.

UKT (2006) report the establishment of a database of organ donors accessible by all transplant co-ordinators on a 24 hour basis, facilitating more effective application of the new HT (S) Act 2006. The development of this database has required a considerable financial and organisational undertaking from the

Department of Health. Any expansion of this facility to link with all neurological and general intensive care units throughout the U.K. in an effort to expand the pool of donors would require careful consideration. To assist in access to established systems for comparison, an exploration of other regional transplant systems in Europe, for example, Eurotransplant should be considered.

9.4.3 Development of Organ Donation Professional Manpower

The participants interviewed were not able to describe in detail the implications of establishing the organ donation system within their particular country. Some of the HCPs interviewed however alluded to the impact on their health care system overall in terms of the increased workload and impact on local facilities such as intensive care, operating theatres and emergency room by an increase in organ donations. Some also briefly discussed the identification of specialist staff to support the organ donation initiative including increase in medical staff, such as anaesthetists and transplant surgeons, together with specialist nursing staff.

Participants suggested that fundamental to the organ donation initiatives within all their country, was the establishment of a national system of transplant co-ordinators. Subsequent interviews with some of these transplant co-ordinators, also demonstrated that these professionals, not only as their title suggests co-ordinate the donation and transplant activity on a local and national basis, but in addition provided specialist information and support to the HCPs based in the intensive care units and emergency rooms, allowing them to undertake the organ donation process. Those interviewed praised these systems seeing them as a key element in the organ donation initiative allowing the co-ordination of the donation activity and increasing the numbers of organs identified for donation. When asked, however, those interviewed were unable to clarify the impact of

establishing such a system of transplant co-ordinators in terms of the financial or organisational structures required to support these professionals.

As reported in chapter 1 the newly formed NHSBT has invested in the development of 20 transplant co-ordinator schemes within neurological and other intensive care units throughout the U.K. (NHSBT, 2006). Whilst these initiatives are welcomed, consideration of the impact on the NHS of adopting a more strategic and systematic approach to organ donation requires to be undertaken. Any development of this initiative would require an increase in the availability of specially prepared staff to support this request e.g. transplant co-ordinators or organ donation link nurses to make requests to relatives for authorisation to undertake organ donation.

Any changes in legislation that produced the increase in organ donation in the numbers reported within the European countries reviewed, would therefore require considerable organisational and financial investment in organ donation system. The provision of the additional personnel to support an expansion in organ donation would require considerable resources both in terms of recruitment, training and financial remuneration. Developing these roles often results in the loss of these specialist nurses from an already over-stretched critical care area. In addition, the cost of providing the co-ordinators is currently borne by the individual trusts that employ these staff. There is currently very little central funding available to develop and resource these personnel. This option would therefore require considerable financial resources in addition to organisational restructuring to make this viable. It could be argued, however, that the provision of resources for organ donation, although expensive initially, could have a long term

benefit in reducing the burden on the NHS of high levels of chronically ill people on the organ donation list. Questions remain, however, as to the overall organisational and financial impact of introducing such an organ donation system and assessment of the cost benefit analysis of this investment requires further exploration. An analysis of the impact of this change in the legislation together with the investment required in the NHS to support such a change requires to be undertaken.

9.5. Development of Protocols of Practice in Organ Donation

9.5.1 Protocols for Brain Death and Donor Management

As reported in chapters 6 and 8 data analysed from participant interviews and other data from field visits demonstrated that a variety of different assessment tools and procedures were in use across the three European countries to diagnose brain death in the patient. These assessments ranged from the application of a set of tests applied at the patient's bedside such as EVOC tests (Sullivan et al., 1999) (**Appendix IV**) to the employment of assessments that transfer of patients to the radiology department for Cerebral Angiography (Sullivan et al., 1999) (**Appendix V**). It was also identified that to promote efficient and effective organ donation at operational level a number of protocols and procedures had been developed in each country. Chief amongst these were protocols developed by expert bodies such as Eurotransplant for the reporting of brain death in patients and protocols for the maintenance of the donor in optimum condition prior to the organ harvest procedure. These protocols can only be applied by senior medical staff with a minimum of five years post registration experience. In an effort to improve donation rates, there had also been a systematic communication of these protocols

to professionals within intensive care and emergency room settings during educational events planned and delivered by the European transplant Co-ordinators Organisation. The aim of this education was to facilitate understanding of these protocols by the HCPs and address fears that surround organ donation, especially those related to diagnosis of brain death (Robertson, 1999, Pearson, 1997).

Whilst many of the participants expressed confidence in the assessment protocols used in their particular country, some however suggested that they were concerned that these protocols were not always fully understood or applied appropriately by some medical staff. In some instances nursing staff reported being concerned that the patient had not been diagnosed as brain dead correctly by some medical staff leading to fears that some patients were moved to donor status in a hasty manner with all resuscitation measures not fully exhausted, giving rise to ethical dilemmas for nursing staff caring for the potential donor. This fear held by the public had also been identified by English and Sommerville (2003).

The existence and the validity of such a wide range of different assessments to diagnose brain death in patients is a cause for concern, as is the reported variances in the application of different tests to determine brain death across these three countries. These tests differ from those used in the U.K. to diagnose brain death (**Appendix II**). Uncertainty in relation to the diagnosis of brain death may present ethical dilemmas for the HCPs in intensive care and emergency settings in applying these protocols, inevitably leading to their reluctance to diagnose brain death and consider organ donation. The work of the Royal College of Anaesthetists (2006) in reviewing the Code of Practice for the diagnosis of death and the management of potential organ donors is welcomed. If this consultation

could facilitate a standardised approach to these issues, which includes the diagnosis of brain death, HCPs may be more likely to consider organ donation in patients who have the potential to become an organ donor and are currently overlooked. Establishment of these standards for the diagnosis of brain death and the communication of these to the professionals and the public would help to develop understanding of these standards and address fears held by both these groups, potentially increasing the numbers of people willing to place their names on the organ donation register.

9.5.2 Protocols for Care of the Family

Participants reported that organ donation presents considerable challenges for the HCP psychologically in terms of the emotional aspects of care of donor and support of the family. Many of these professionals stated that they found it very stressful and emotionally draining to balance the needs of exploring organ donation with the family and ensuring their welfare during the organ donation process. Some of the HCPs interviewed identified the development of clear policies and protocols for the involvement of the family in the organ donation process that provide direction on the management and the psychological care of family involved in the organ donation event. A key element of these protocols has been the separation of confirmation of death and request for organ donation utilising the recommendations of Riley and Coolican (1999), Cutler et al., (1993), in the support of the family and the appropriate approach to request donation.

This research recommended the separation of confirmation of brain death from the request for organ donation, allowing the family time to accept these before request for organs was made and address the ethical requirements of the HCP to prevent

any potential harm to the family and manage their different cultural requirements in relation to death.

Further to the development of these protocols, echoing the suggestions made by Light et al., (1997) in an effort to support the family at this very distressing time and reduce levels of refusal by relatives, participants in Belgium reported the availability of specially prepared staff i.e. social nurses, to support the family. These nurses with a background in bioethics, have developed guidelines in advising and supporting the family in the organ donation event, assisting with the difficult decision-making process for the HCP and the family at this time. The addition of these specialist nurses to the multidisciplinary team to support the relatives and HCPs was highly praised by the participants and regarded as an important innovation in the care of the family during the organ donation event.

Participants within Belgium also reported the exploration of new initiatives such as non-heart beating donor (NHBD) initiatives to identify more donors. In the opinion of those interviewed here, whilst providing new opportunities for obtaining more organs for donation, this new initiative presented challenges for them from a practical perspective in relation to the increased work pressures and the need for new protocols of practice to be developed. Additionally, participants also highlighted the ethical challenges presented by this initiative in relation to the limited time available to address the needs of the family and the difficulties experienced in defining death using cardiac death without the use of brain death criteria (Koppelman 2003; Robertson, 1999), a common practice in NHBD events.

In response therefore to the question posed by this study in relation to the exploration of the provision of specialist procedures, policies and resources enabling the effective implementation of this legislation, a number of discoveries have been made. The findings suggest that the implementation of this approach to organ donation requires the development of a range of specialist procedures, protocols and policies at a strategic, organisational and professional practice level. In the U.K. currently some specialist clinical protocols do exist for the diagnosis of brain death and are applied relatively uniformly (Royal College of Anaesthetists 2006). Transplant co-ordinators are available to advise staff within intensive care and emergency departments on the approach to relatives to consider organ donation and if the co-ordinator can travel to the hospital or unit where the donor and family are located, they will undertake the approach to and support of the family. Unfortunately, because of the distances between the transplant co-ordinators and the units where the donor may be cared for, inexperienced and unprepared medical and nursing staff within these units often have to approach the family themselves to ask them to consider donation.

Currently no detailed protocols or procedures for the approach to, or the subsequent care of, the family involved in organ donation exist within the U.K. Careful strategies for approaching the family in relation to organ donation require to be developed that address the requirements of a multicultural society. The appointment of specially prepared “social nurses” with responsibility to provide psychological support and ethical advice to the family during the donation event merits further exploration. No data were identified that supported their successful role in organ donation. However, if evidence could be found to support their achievement of reduced levels of family refusal and an increase in donation dates

as a result of their intervention, despite the manpower implications, the development of this role may be cost effective in increasing the levels of organs for donation. Furthermore, if a wider range of HCPs within these settings are expected to be directly involved in the identification and care of organ donors on a regular basis, detailed protocols of practice and procedures relating to this care would be required to be identified and implemented on a national basis. These requirements clearly hold resource implications for the NHS in terms of the potential need to identify additional professionals to implement this initiative, together with the equipment and finance to support this strategic plan.

9.6 Education and Preparation of Health Care Professional for a Role in Organ Donation

9.6.1 Education in Legal and Ethical Aspects of Organ Donation

Participants reported that in order that the HCP understands the legislation and the application of this in practice, there is a requirement for this group to receive education on the legislation and their role in its application. Interviews also revealed that organ donation presents considerable challenges for the staff in terms of the ethical dilemmas and emotional challenges it presents. To address this requirement the curricula of both nursing and medical undergraduate programmes in all three countries now include some education relating to the fundamental legal and ethical aspects of organ donation. This education in the principles of organ donation legislation is augmented by the availability of continuing professional development events exploring bioethical aspects of care, developed by the ETCO using the European Donor Hospital Education Programme. The importance of these education programmes to underpin organ donation has been highlighted in chapter 2 by Singer and Rachmani (1997),

Randhawa (1998) and Verble & Worth (2000). These educational opportunities are often organised and funded via regional organ donation organisations established and supported by central government within the three countries. Data analysed also highlighted that in Belgium the Continuing Professional Development requirements of the medical professionals specify the need for education on ethics and economics as a mandatory requirement of annual re-registration. No details were provided, however, in relation to the organisation or funding of these continuing professional development events or their success in providing this education.

In the U.K. the curricula for medical and nursing students do contain some fundamental preparation in relation to the legal and ethical aspects of practice. These education courses however often do not explore the bioethical aspects of organ donation. The question arises therefore for the HCP bodies such as General Medical Council and Nursing and Midwifery Council to consider the addition of this topic to the initial preparation of doctors and nurses. Additionally, it may be worth considering if there is any benefit to ensuring that education in this area of practice forms part of a mandatory requirement for HCPs in the U.K.

9.6.2 Education in Organ Donation Clinical Practice

Participants suggested that education of HCPs who care for patients in critical care settings also requires more detailed education relating to the protocols and practices used in the care of the donor. The interviews suggest that this is most often provided during the HCPs initial induction programme on commencement of a post within these clinical settings. Local preparation and education relating to the technical and clinical aspect of the professional's role in organ donation is also

provided by the transplant co-ordinators, the aim of which is to develop the knowledge of the HCPs and skills in the clinical practice of organ donation. Although not mandatory these courses are recommended for staff working in an area that undertakes organ donation. As previously indicated these courses are organised and structured by the European Transplant Co-ordinators group. Participants also described that in addition to their organisational responsibilities, the transplant co-ordinator provided much of the ongoing support to the staff in the intensive care units, offering support and advice in managing the donor and educating junior HCPs in organ donation protocols and practices.

9.6.3 Education in the Care and Support of Relatives

As previously reported, interviews with the HCPs revealed that organ donation challenges the HCPs in terms of the emotional aspects of care of the donor and support of relatives. Gore et al., (1992) supports the view that lack of preparation and support in this task either produces reticence to undertake the role at all in many staff, or may influence the rates of refusal. In some cases specialist staff may be available to support the family however, normally the HCPs within the intensive care or emergency room undertake this role. Although HCPs in Belgium had access to specialist education to develop knowledge and skills in this demanding role, many reported no formal preparation in this. Given that the professionals involved feel obliged to proceed with the approach to the family to ensure no objection exists it would be logical to assume that the professional undertaking this request was suitably prepared for this difficult task. This preparation might include information on organ donation legislation, clinical aspects of identification and management of the donor together with education and training in the request to the family including their psychosocial support

throughout the donation process. This education and training which would prepare the professional for this role might increase the frequency with which the task was undertaken. The HCPs who undertake this difficult role also require support and guidance from their peers and supervisors to manage the emotional aspects of this challenging task. Senior participants within the study also suggested that competence and confidence in managing donor and family in the potential organ donation situation may lead to the increased numbers of organs being obtained. Building competence and confidence of the junior HCPs in these areas of practice requires specialist education and mentorship from senior colleagues. This mentorship of junior colleagues is undertaken by these senior professionals in addition to their already considerable workload as they view this as essential to the care of the family, the development of the junior staff member and the successful achievement of organ donation.

Ideally, in order to obtain the best outcome in terms of successful authorisation rates and appropriate support of the relatives at this crucial time, this role would be undertaken by specially prepared transplant co-ordinators. Although there has been a national initiative in the U.K. to improve the numbers of transplant co-ordinators funded by the DOH, continued limited access to these professionals results in the staff within the intensive care and emergency environments having to undertake this role unsupported. Resources designed to improve the rate of requests of relatives to proceed to donation are urgently required. These include both an increase of the numbers of transplant co-ordinators available to make the request and the preparation of the intensive care and emergency staff that may find themselves in the position of having to make the request. Whilst NHSBT has announced an initiative to increase the numbers of transplant co-ordinators in

certain neuro-intensive care units across the U.K., more specialist preparation for this role should be included in the education of medical and nursing staff working within these environments as a matter of urgency.

In relation therefore to the question of whether the implementation of presumed consent legislation required to be supported by specialist education and preparation of the HCP, analysis of the lived experience of the participants suggests that implementation of presumed consent legislation requires considerable specialist education to be provided for the HCPs in order that they can fulfil their role in the care of the donor and the support of the family during the organ donation process. Educational, communication and mentorship strategies are also required to support staff in the organ donation situation and encourage their engagement in this role. Educational opportunities within the three countries do appear to be planned, organised and funded via regional organ donation or transplant organisations and supported by central government. Participants however did not provide information as to the financial or organisational implications of providing specialist education for staff. Those interviewed also commended these education programmes and opportunities in providing them with the necessary preparation for undertaking their role in organ donation. However, an evaluation of these programmes is required to establish their effectiveness in preparing HCP for their role in the care and support of relatives involved in the organ donation process.

Clearly, there are considerable educational requirements for HCPs in the U.K. if their current limited role in organ donation is to be developed. This will mean the requirement to provide these HCPs with detailed education of the legislation and their role in this. Much of the education in relation to organ donation appears to be

provided by the transplant co-ordinators organisations across Europe who are supported by some funding from central government in each country. Whilst an evaluation of these programmes is required to establish their outcomes and effectiveness in preparing staff, participants report perceiving these programmes to be very successful in supporting them in their role.

Education for HCPs in the UK is mainly provided under the direction of UKT. It is debatable if the new organisation of NHSBT is able to facilitate this work or if indeed a national education body requires to be identified to lead this work.

Strategic consideration of the education and practice development implications for the NHS must therefore be undertaken with an appropriate response developed, if HCPs within the U.K. are to participate more meaningfully in the pursuit of an increase of organs for donation.

9.6.4 The Research Approach Strengths and Limitations

This study used a phenomenological approach combining a questionnaire survey of HCP professionals in three European countries who use presumed consent legislation with adaptation of a Heideggerian approach to phenomenology as described by Gadamer (1976) and Colaizzi (1987) involving in depth interviews of a purposeful sample of HCPs who had experience of the care of donors and relatives, to capture the “lived experiences” of these professionals. By analysing the data obtained from these sources in the light of the published literature relating to organ donation together with data gathered by the researcher during field visits to Portugal, Norway and Belgium, some detailed insights to application of presumed consent legislation in these three countries and the impact of this

approach to organ donation on the HCPs and the families who have experienced this have been identified.

The approach adopted within this study to develop the data presented many challenges. Although the approach adopted using a questionnaire to identify the HCPs in each country who had direct experience of organ donation produced smaller than expected numbers of responses, given the distances involved between the researcher and the participants, this appeared the most cost effective method of identifying these specialist groups of HCP and exploring their initial views in regard to organ donation in their country. The subsequent selection of the smaller numbers of HCPs from within these respondents for interview, and the use of data from this small group on which to base the study findings could also be challenged. However, interviews could only be undertaken with participants who consented to interview and it was viewed that these small groups of HCPs from each county demonstrated a sufficient range of rich experience of organ donation and could therefore provide insights into the practice of organ donation in that particular country. A wider study of the experiences of HCPs in these three countries may be required to support these findings. Additionally, the adoption of a qualitative approach to the development of data using a phenomenological approach could also lead to challenges to the study findings as the circumstances within which the data was gathered would be difficult to reproduce. However, as the aim of the study was to capture the “lived experiences” of the HCP, the adoption of this approach provided detailed information describing the practice and the experiences of these practitioners, much of which had not been described before.

The adoption of the approach described by Gadamer (1976) to the development of the data where the researcher was directly involved in the interview process and potentially influencing the development of these data could also be challenged. To address this potential bias as highlighted in chapter six, throughout the collection of these data the researcher was aware of the potential impact on the data of her own “prejudices and preconceptions” in relation to organ donation. In an attempt to minimise the bias that this may have had on the participants, the researcher validated raw data obtained during the interviews with the participants, allowing them time to reflect on their transcript and amend any inaccuracies. As was also reported previously minimal amendments to the transcripts were requested by the participants, thus providing reasonable assurance that the content of the transcripts accurately reflected the views and experiences of the participants. By presenting the data obtained from field visits by the researcher and combining this with findings from participants questionnaires and semi-structured interviews together with the process adopted for the gathering of this data and the subsequent management and analysis of this, it is hoped that the trustworthiness of the findings and academic rigor of the study are assured, enabling a number of conclusions and recommendations to be reached. These will be presented in the concluding chapter of this work.

Chapter 10 Conclusions & Recommendations

10.0 Introduction

A number of general conclusions have been reached after a review of the data analysed, albeit that a number of questions arose during the study, which had not been originally envisaged. This chapter will present these conclusions arising from the study and proffer some recommendations that the researcher suggests should be considered by the public, legislators and the NHS in Scotland, England and Wales when contemplating the possible adoption of a presumed consent approach to organ donation legislation. This chapter will also reflect on the research approach adopted in this study identifying the strengths and limitations in the methodology and methods adopted. Using the mixed methods approach adopted by the researcher in this study, in answer to the research questions posed by this study, analysis of the data presented together with the published literature has resulted in the following conclusions being reached:

10.1 The Infrastructures and Administration Required to Support Presumed Consent Legislation

When utilised, the implementation of presumed consent legislation in organ donation contributes to the identification of large numbers of organs for donation. However, the findings of this study clearly indicate that implementation of this form of legislation in relation to organ donation is only one element that contributes to the supply of organs for donation. This study demonstrates however that the implementation of presumed consent in organ donation across Europe is not uniform. There are common elements of legislation as applied in Portugal, Norway and Belgium such as the acceptance of tacit or implied consent as an acceptable basis for the individual to authorise the use of their organs for

donation. Public trust, confidence and support of this form of legislation in organ donation have been established by the provision of public information and education campaigns enabling understanding of the concept of presumed consent.

Recommendation

- Should presumed consent legislation be considered within Scotland, England and Wales there is a need to provide a public education campaign, sufficient to inform the public of the change of the legislation. Any public education campaign devised would require to inform the public about the administrative process associated with the individual recording an objection to organ donation, however this educational input would require to be repeated on a regular basis.

Currently legislation in Scotland, England and Wales only recognises evidence of expressed consent as a method of authorising organ donation. There are wider implications of accepting tacit or implied consent to organ donation not only for the public, but that other methods of consent currently applied would require review. Additionally, the adoption of this method of authorisation not only holds major implications for those with the capacity to understand the requirements of this legislation and respond appropriately, it also presents major challenges for individuals with incapacity to understand this legislation and make their views known.

Recommendation

- Should Scotland, England and Wales consider a change to the current approach to organ donation the wider implications of accepting this

approach to consent for the individual with capacity must be considered.

Additionally, the particular implications to the individual with incapacity of adopting this approach to authorisation of organ donation should also be considered carefully.

Different countries have adopted varying forms of this legislation resulting in different interpretations of this approach to organ donation. Key differences in the formulations of the legislation currently used within Europe, centre on the establishment of a register of consent to, or objection to organ donation allowing the recording of the individual's intentions.

Recommendations

- If Scotland, England and Wales should consider adopting this form of legislation regarding organ donation, the logistics of establishing a register of the public's intentions would be necessary.
- The problems accruing from the implementation of this database such as its availability to the appropriate HCPs in the NHS on a 24 hour a day basis would require to be taken into account by the Scottish Executive Health Department and the Department of Health.

10.2 The involvement in and Impact of the Legislation on the Bereaved

Relatives of the Donor

A striking feature within the differing legislations of the three European countries reviewed was the varying role for the family in the authorisation of the organs of the deceased for donation. Despite the terms of the legislation, the practices of HCPs in organ donation are governed by the need to confirm the wishes of the

deceased as represented by the family. The study demonstrated that HCPs **always** involve the family in the organ donation decision-making process. The level to which this participation happens was not acknowledged and has not been well publicised previously.

Even in the absence of an objection from the donor, should the family raise objections the HCP will not progress to organ donation. This results in a dissonance between the legislation and the practice of the HCPs and requires further scrutiny. The implementation of presumed consent legislation does therefore have implications for the bereaved families of the deceased.

Recommendations

- The rationale underpinning the HCPs perceived requirement to involve the family so directly in the decision making process requires to be investigated in more detail. Further research is needed to clarify the factors that may contribute to the HCP adopting this approach.
- Given that the family are so directly involved in the decision making process undertaken by the HCPs to identify suitable organ donors, any legislation related to organ donation must acknowledge their involvement in the process and facilitate it.

10.3 The Impact of the Application of the Legislation on Relationship between the Donor Families and the Health Care Professionals

Fundamental to the application of presumed consent legislation by the HCP is the need to ensure that the tenets of it do not conflict with their ethical and professional requirements to provide appropriate care for the donor and the

family. The HCPs in the study strove to establish a trusting relationship between themselves and the donor family believing that it is beneficial to their grieving and future well-being to be involved. The development of this trusting relationship and the ability of the family to participate in the decision-making process is achieved by the provision of detailed information relating to the resuscitation of their loved one and their subsequent diagnosis of brain death by the HCP. The respect paid by the HCPs to the religious or cultural views of the family in relation to organ donation also impacts on the family's trust in the HCP and may impact upon whether the family raise objections to the donation process.

The family's prior knowledge and understanding of the organ donation legislation and processes contributes to confidence placed in the HCP practices and the organ donation system. This prior knowledge developed as a direct result of the public education campaign and debate that accompanied the introduction of this legislation in the three countries under review.

Recommendation

- There is a requirement to develop and provide a culturally sensitive and comprehensive public education campaign to sufficiently inform the public of the organ donation concepts and clinical practices and facilitate trust in the organ donation system.

10.4 The Provision of Specialist Procedures, Policies and Resources Enabling the Effective Implementation of this Legislation

The implementation of presumed consent legislation has had a considerable impact on the health care systems of the countries that apply this approach to organ donation. Although it was impossible within this study to determine the position of the health services prior to the implementation of this legislation, the

data suggest that the application of this approach to organ donation has been accompanied by the development of a strategic organ donation and transplant infrastructure on a national and regional level to underpin and support policy and practice in this area.

The development of such an infrastructure may itself provide a means by which higher than average numbers of organs are identified, donated and used efficiently. Each of the three countries reviewed demonstrated the reliance on these infrastructures to deliver effective and efficient organ donation provision. The establishment of these infrastructures also allows effective cross country communication and efficient use of any available organs elsewhere in Europe. An organ donation infrastructure does already exist within the Scotland, England and Wales under the auspices of NHSBT. However, if organ donation numbers were to be increased in a similar manner to those demonstrated in the European countries reviewed, a radical review of the organ donation infrastructure regionally and nationally would require to be undertaken. This review would inevitably require to consider the impact of any changes in organ donation legislation and strategy on the sections of the NHS involved in organ donation namely, the emergency departments, intensive care units and operating departments in terms of staffing and the provision of adequate resources to enable these clinical specialities to utilise any additional donated organs. There are clearly organisational, financial and logistical implications for the NHS in developing a system similar to that established elsewhere in Europe.

Recommendation

- The Scottish Executive Health Department and the Department of Health in England and Wales require to undertake a feasibility study designed to establish the impact on the NHS of an increase in the supply of organs for donation, identifying the resources required by the NHS in order to effectively and efficiently utilise these organs.

In order to apply a standardised approach to the diagnosis of brain death and the care of the donor, as witnessed in the three countries under review, detailed protocols of practice have been developed to direct practice in this area. This allows effective and efficient identification and care of the donor together with ease of communication between units and across regions. Standardisation and communication of these protocols also facilitates collaboration between HCPs regionally and internationally to identify and use organs. Protocols of practice have also been developed to care for and support the family involved the organ donation event, ensuring their wellbeing. In some areas new roles have been developed to support and advise the family during the organ donation process. Work has already commenced in the U.K. by the Royal College of Anaesthetists (2006) to develop a standardised approach to the definition of death and the care of donors. Much work remains however to implement any protocols of practice in this area.

Additionally, in one of the European countries reviewed a new role has been developed to provide advocacy and ethical support for the families involved in organ donation. Although no data were identified that explores this role, the description of this role appears not unlike the role of the ethical advocate

previously described in the U.S. Further research to clarify this role is required to be undertaken.

Recommendations

- Protocols and practices related to the definition and diagnosis of brain death should be standardised and implemented throughout Scotland, England and Wales.
- Protocols for the support of families involved in organ donation should also be developed and implemented.
- Further research is required to explore the impact of the “social nurse” or family advocate in organ donation identifying their role in the support of the family during this process.

10.5 The Availability of Specialist Education or Preparation for the HCPs

Who Apply this Legislation

The availability of presumed consent legislation creates the conditions within which HCPs will more frequently consider organ donation. However, the application of this legislation is dependent upon the preparation and education of HCP in critical care settings for their role in organ donation. Effective and efficient application of presumed consent legislation by HCPs requires the development and implementation of an education strategy that not only includes clinical and technical aspects of donor identification and care, but must also provide preparation in the legal and ethical aspects of organ donation.

Education and preparation of the HCPs for their role in organ donation must include the development of knowledge and skills in the approach to, and care of,

the family during the organ donation event. Within Scotland, England and Wales very limited education for HCPs in their role in the care of the donor and family is available. There are a small number of specialist organ donation and transplantation modules throughout Scotland, England and Wales. Organ donation however, is a topic that most often appears as a very small aspect of an intensive care course or in the format of CPD study days mainly exploring brain death criteria and donor selection. Specialist education in the care of the relatives is normally only available to the transplant co-ordinators group. Little education is available to the intensive care or emergency department professionals relating to the legal and ethical aspects of organ donation or the care and support of the family during the organ donation event.

Recommendations

- Qualitative research is required to survey the levels of current knowledge of the HCPs within emergency and intensive care settings in Scotland, England and Wales in relation to organ donation.
- Using the findings of this research, an education strategy requires to be developed enabling these HCPs to develop the necessary knowledge and competencies with which to apply the current organ donation legislation effectively, facilitating an increase in organ donation.
- This education strategy also required that takes account of the cultural and religious views of the population in relation to organ donation.

10.6 Challenges of Research Methodology Adopted

Exploration of the experiences of HCPs who were directly involved in the application of the legislation related to organ donation in three European

countries, proved to be a bigger challenge than the researcher originally envisaged. At the outset of the study, it was planned to adopt a qualitative approach using an underpinning phenomenological framework to obtain rich, in-depth data relating to these HCP experiences. This approach proved inadequate to achieve the study objectives alone, in that the relevant HCPs had first to be identified in each of the three countries under review. This requirement demanded that the original approach to the study had to be augmented with the addition of a survey of HCPs in Portugal, Norway and Belgium to identify these groups of specialist HCPs and recruit them into the study. Additionally, administration of this survey presented another challenge in that access to these groups of specialist HCPs was only possible with the co-operation of the transplant co-ordinators in each of these three countries. Fortunately, having gained the co-operation of the transplant co-ordinators in all three countries the survey was successfully undertaken, providing not only valuable data relating to the experiences of these HCPs but also providing qualitative findings which were used to inform the qualitative semi-structured interviews undertaken in the next phase of the study.

This modification of the original approach to the study to include this additional element although requiring considerably more effort did prove a successful method of identifying the appropriate HCPs to participate in the study. The data gained from the questionnaire proved invaluable in the subsequent development of the semi-structured interview schedule, facilitating the adoption of a phenomenological approach to these interviews.

The adoption of this approach did indeed provide rich, in-depth data that described the experiences of the HCP that would not have been achieved using other approaches to data development. However, reflecting on the process of the study overall, it is clear that larger than anticipated volumes of data were generated by the study and this was at times challenging for the single researcher to manage. The study was achieved however with the application of considerable time and commitment to the project producing valuable data. It is reasonable to conclude therefore that the phenomenological approach can be profitably adapted to explore the lived experiences of HCPs.

Recommendation

- Although requiring considerable planning and time allocation, a mixed method approach can be successfully applied to explore the experiences of HCPs in European countries providing rich in-depth data.

Summary

The lived experiences of the HCPs involved in organ donation as presented within this thesis indicate that the introduction of presumed consent legislation in Portugal, Norway and Belgium has helped to establish the conditions whereby the numbers of donated organs has increased in these three European countries. By exploring the lived experience of these HCPs, this thesis has identified a number of implications of presumed consent legislation for the HCPs, the bereaved families and the organ donation system, making a number of recommendations for the authorities in Scotland, England and Wales to consider should they contemplate the introduction of this legislation.

This study has also demonstrated however that the introduction of this approach to organ donation legislation is only one element in the strategies developed in these three countries to increase the numbers of organs available for donation. There are many other elements and factors within these strategies that have also contributed to the high levels of organ donation in these countries. This study has identified some of these elements such as, the education and involvement of the public in the support of the legislation and the development of an organ donation infrastructure with which to support this approach to organ donation. As a result of the study findings the following recommendations are made:

- Should presumed consent legislation be considered within Scotland, England and Wales there is a need to provide a public education campaign, sufficient to inform the public of the change of the legislation. Any public education campaign devised would require to inform the public about the administrative process associated with the individual recording an objection to organ donation, however this educational input would require to be repeated on a regular basis.
- Should Scotland, England and Wales consider a change to the current approach to organ donation the wider implications of accepting this approach to consent for the individual with capacity must be considered. Additionally, the particular implications to the individual with incapacity of adopting this approach to authorisation of organ donation should also be considered carefully.
- If Scotland, England and Wales should consider adopting this form of legislation regarding organ donation, the logistics of establishing a register of the public's intentions would be necessary.

- The problems accruing from the implementation of this database such as its availability to the appropriate HCPs in the NHS on a 24 hour a day basis would require to be taken into account by the Scottish Executive Health Department and the Department of Health.
- The rationale underpinning the HCPs perceived requirement to involve the family so directly in the decision making process requires to be investigated in more detail. Further research is needed to more clearly identify the factors that may contribute to the HCP adopting this approach.
- Given that the family are so directly involved in the decision making process undertaken by the HCPs to identify suitable organ donors, any legislation related to organ donation must acknowledge their involvement in the process and facilitate it.
- There is a requirement to develop and provide a culturally sensitive and comprehensive public education campaign to sufficiently inform the public of the organ donation concepts and clinical practices and facilitate trust in the organ donation system.
- The Scottish Executive Health Department and the Department of Health in England and Wales require to undertake a feasibility study designed to establish the impact on the NHS of an increase in the supply of organs for donation, identifying the resources required by the NHS in order to effectively and efficiently utilise these organs.
- Protocols and practices related to the definition and diagnosis of brain death should be standardised and implemented throughout Scotland, England and Wales.
- Protocols for the support of families involved in organ donation should also be developed and implemented.

- Further research is required to explore the impact of the “social nurse” or family advocate in organ donation identifying their role in the support of the family during this process.
- Qualitative research is required to survey the levels of current knowledge of the HCPs within emergency and intensive care settings in Scotland, England and Wales in relation to organ donation.
- Using the findings of this research, an education strategy requires to be developed enabling these HCPs to develop the necessary knowledge and competencies with which to apply the current organ donation legislation effectively, facilitating an increase in organ donation.
- This education strategy also required that takes account of the cultural and religious views of the population in relation to organ donation.
- Although requiring considerable planning and time allocation, a mixed method approach can be successfully applied to explore the experiences of HCPs in European countries providing rich in-depth data.

These recommendations should therefore be considered by the public, legislators and the NHS in Scotland, England and Wales when contemplating the possible adoption of a presumed consent approach to organ donation legislation.

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Appendices

Appendix 1 The Human Tissue Act 1961 s 1 provides

1. (1) If any person, either in writing at any time or orally in the presence of two or more witnesses during his last illness, has expressed a request that his body or any specified part of his body be used after his death for therapeutic purposes or for purposes of medical education or research, the person lawfully in possession of the body after his death may, unless he has reason to believe that the request was subsequently withdrawn, authorise the removal from the body any part or, as may be, the specified part, for use in accordance with the request.

(2) Without prejudice to the foregoing subsection, the person lawfully in possession of the body of the deceased person may authorise the removal of any part from the body for use for the said purposes if, having made such reasonable enquiry as may be practicable, he has no reason to believe

a) that the deceased had expressed an objection to his body being so dealt with after his death, and had not withdrawn it; or

b) that the surviving spouse or any other surviving relative of the deceased objects to the body being so dealt with.

(3) Subject to subsection (4) and (5) of this section, the removal and use of any part of a body in accordance with an authority given in pursuance of this action shall be lawful.

(4) No such removal shall be effected except by a fully registered medical practitioner, who must have satisfied himself by personal examination of the body that life is extinct.

(a) No such removal of an eye or part of an eye shall be effected except by a registered medical practitioner, who must have satisfied himself by personal examination of the body that life is extinct; or

(b) a person in the employment of the health authority or the NHS trust acting on the instructions, be satisfied that the person in question is sufficiently qualified and trained to perform the removal competently and must either

(i) have satisfied himself by personal examination of the body that life is extinct; or

(ii) be satisfied that life is extinct on the basis of a statement to that effect by a registered medical practitioner who has satisfied himself by personal examination of the body that life is extinct. [Inserted by Corneal Tissue Act 1986].

(5) Where a person has reason to believe that an inquest may be required to be held on any body or that a post-mortem examination of any body may be required by the coroner, he shall not, except with the consent of the coroner

(a) give authority under this section in respect of the body; or

(b) act on such authority given by any other person.

(6) No authority shall be given under this section in respect of the body by a person entrusted with the body for the purpose only of its internment or cremation.

(7) In the case of a body lying in hospital, nursing home or other institution, any authority under this section may be given on behalf of the person designated for that purpose by the first management thereof by any officer or person designated for that purpose by the first mentioned person.

(8) Nothing in this section shall be construed as rendering unlawful any dealing with, or with any part of the body of the deceased person which is unlawful apart from the Act.

(9) In the application of this section to Scotland, for subsection (5) there shall be substituted the following section

“(5) Nothing in this section shall authorise the removal of any part from a body in any case where the procurator fiscal has objected to such removal”

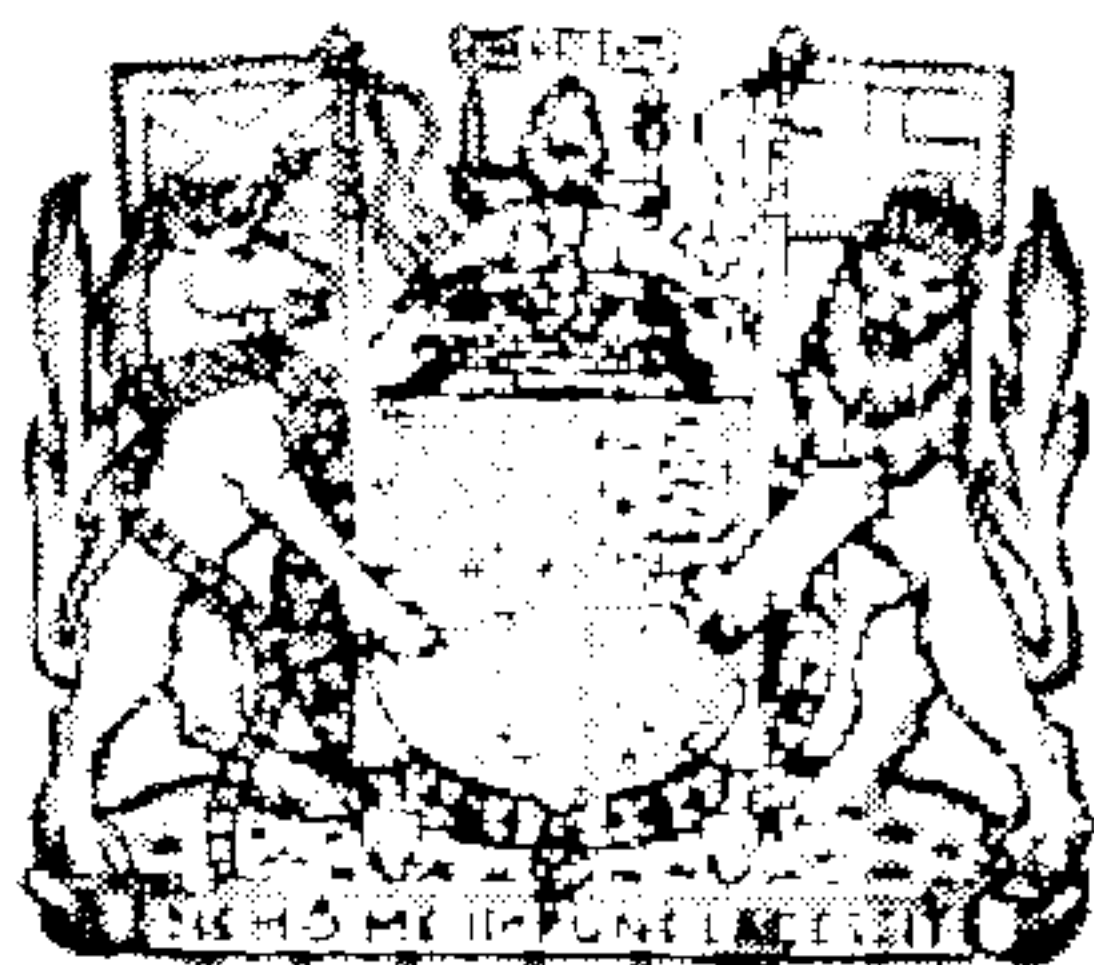
2 (1) Without prejudice to section fifteen of the Anatomy Act 1832 (Which prevents that Act from being construed as applying to post-mortem examinations directed to be made by competent legal authority), That Act shall not be construed as applying to any post - mortem examination carried out for the purpose of establishing or confirming the causes of death or of investigating the existence or nature of abnormal conditions.

(2) No post-mortem examination shall be carried out otherwise than by or in accordance with the instructions of a fully registered medical practitioner, and no post-mortem examination which is not directed or requested by the coroner or any other competent legal authority shall be carried out without the authority of the person legally in possession of the body; and subsections (2),(5),(6) and (7) of section one of this Act, Shall, with the necessary modifications, apply with respect to the giving of that authority.

3. The provisions to be made and the certificate to be transmitted under section thirteen of the Anatomy Act 1832, in respect of a body removed for anatomical examination may, instead of being provision for and certificate of burial, as mentioned in that section, be provision for the cremation of the body in accordance with the Cremation Acts 1902 and 1952, and a certificate of the cremation.

4. (1) This Act may be cited as the Human Tissue Act 1961

Appendix II



Human Tissue (Scotland) Act 2006

2006 asp 4

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Human Tissue (Scotland) Act 2006

2006 asp 4

CONTENTS

PART 1

TRANSPLANTATION ETC.

General functions of the Scottish Ministers

Section

- 1 Duties of the Scottish Ministers as respects transplantation, donation of body
- 2 Assistance and support

Use of part of body of deceased person for

- 3 Use of part of body of deceased person for transplantation, research etc.
- 4 Disapplication of sections 3, 6 to 11 and 16 in certain circumstances
- 5 Consent by procurator fiscal to removal of part of body
- 6 Authorisation: adult
- 7 Authorisation by adult's nearest relative
- 8 Authorisation: child 12 years of age or over
- 9 Authorisation as respects child who dies 12 years of age or over by person with
- 10 Authorisation as respects child who dies under 12 years of age
- 11 Removal of part of body of deceased person: further requirements
- 12 Removal of tissue sample to determine viability of transplantation
- 13 Preservation for transplantation

14 Part of body removed before day on which section 3 comes into force

15 Existing request by adult not acted on before commencement of sections 3 and 6

16 Offences: removal or use of part of body of deceased person for transplantation, research etc.

Restrictions on transplants involving live donor

17 Restrictions on transplants involving live donor

18 Meaning of adult with incapacity for purposes of section 17(1)(c) and (2)(c)

Records, information etc.: removal and use of parts of human bodies for transplantation etc.

19 Records, information etc.: removal and use of parts of human bodies for transplantation etc.

Trafficking

20 Prohibition of commercial dealings in parts of a human body for transplantation

Summary proceedings for offences under section 17, 19(4) or 20(2)

21 Summary proceedings for offences under section 17, 19(4) or 20(2)

Authorisation for transplantation to have priority

22 Authorisation by virtue of Part 1 for transplantation to have priority

PART 2

POST-MORTEM EXAMINATIONS

23 Meaning of post-mortem examination for purposes of Act

24 Disapplication of sections 23 and 27 to 37 as respects procurator fiscal

25 Disapplication of sections 27 to 35 and 37: bodies of persons dead for at least 100 years

26 Consent by procurator fiscal to post-mortem examination

27 Requirements for carrying out post-

mortem examination

- 28 Removal during examination and retention of organs and other parts of a body
- 29 Authorisation of post-mortem examination etc.: adult
- 30 Authorisation of post-mortem examination etc. by adult's nominee or nearest relative
- 31 Authorisation of post-mortem examination etc.: child 12 years of age or over
- 32 Authorisation of post-mortem examination etc. as respects child 12 years of age or over by nominee or person with parental rights and parental responsibilities
- 33 Authorisation of post-mortem examination etc. as respects child under 12 years of age
- 34 Nomination of person under section 30(1) or 32(1): additional provision
- 35 Post-mortem examination and removal and retention of organs: further requirements
- 36 Organ or tissue sample removed before day on which section 27 comes into force
- 37 Offences: post-mortem examinations

PART 3

TISSUE SAMPLE OR ORGANS NO LONGER
REQUIRED FOR PROCURATOR FISCAL PURPOSES

- 38 Tissue sample becoming part of medical records of deceased person
- 39 Use of tissue sample which has become part of deceased's medical records
- 40 Use of organ no longer required for procurator fiscal purposes
- 41 Notice under section 38(2) or 40(2)(a): further provision
- 42 Authorisation of use etc. after examination: adult
- 43 Authorisation of use etc. after examination: adult's nearest relative
- 44 Authorisation of use etc. after examination: child 12 years of age or over
- 45 Authorisation of use etc. after examination: person with parental rights and parental responsibilities for child 12

years of age or over

46 Authorisation of use etc. after examination: person with parental rights and responsibilities for child under 12 years of age

47 Use of tissue sample removed before day on which section 38 comes into force

48 Use of organ removed before day on which section 40 comes into force

PART 4

PARTS 1 TO 3: SUPPLEMENTARY PROVISION

49 Conditions attached to authorisation

50 Nearest relative

51 Witnesses: additional provision

52 Power to prescribe forms and descriptions of persons who may act as a witness

PART 5

AMENDMENT OF THE ANATOMY ACT 1984

53 Amendment of the Anatomy Act 1984

PART 6

MISCELLANEOUS

54 Arrangements by the Scottish Ministers for assistance with functions under section 1, 2, 17(3), (4) or (5), 18, 19(2) or 20(3)

55 Power to give effect to Community obligations

56 Bodies corporate etc.

57 Amendment of the Adults with Incapacity (Scotland) Act 2000

PART 7

GENERAL

58 Ancillary provision

59 Regulations or orders

60 Interpretation

61 Repeals

62 Short title and commencement

Schedule - Repeals

Schedule - Repeals

[Other Acts of the Scottish Parliament](#) | [Home](#) |
[Acts of the UK Parliament](#) |
[Her Majesty's Stationery Office](#)

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Appendix III Methods of Determining Brain Stem Death

i) Brain Stem Death Criteria and Testing

The Royal Colleges' Statement (1979) identified three general conditions which have to be satisfied before brain stem death testing can be considered:-

1. The patient is deeply comatose
2. The patient is maintained on a ventilator because spontaneous respiration is inadequate
3. There is no doubt that the condition of the patient is due to irremediable structural brain damage

If these conditions are satisfied then the following diagnostic tests for brain stem death should be undertaken:

- The pupils are fixed in diameter and do not respond to sharp changes in the intensity of light.
- There is no corneal reflex
- The vestibulo-ocular reflexes are absent (a test involving injecting ice-cold water into the ear and observing eye movement)
- No motor responses within the cranial nerve distribution can be elicited by adequate stimulation of any somatic area
- There is no gag reflex or reflex response to bronchia; stimulation by suction catheter passed down the trachea
- No respiratory movements occur when the patient is disconnected from the mechanical ventilator for long enough to ensure that the arterial carbon dioxide tension rises above the threshold for the stimulation of respiration.

Source New et al., (1994)

ii) Somatosensory and Brain Stem Auditory Evoked Potentials

Evoked potentials are a measure of the synchronised activity of a group of neurons in the brain and add background information to that obtained from the electroencephalogram. There are three main modalities of stimulation of the neurons in the brain :

Visual response – used to diagnose problems with the optic nerve

Brain stem auditory responses- used to diagnose hearing ability and the presence of brain stem pathology

Somatosensory – used to diagnose disorders in the spinal cord and the brain (Weber, 2006)

Testing for somatosensory evoked potentials is undertaken at the bedside with a portable instrument that provides bilateral stimulation of the median nerves.

Studies of patients with brain death demonstrate that most patients had no responses to tests for somatosensory and brain stem auditory evoked potentials (Sullivan et al, 1999).

iii) Transcranial Doppler Sonography

In transcranial doppler sonography, intracranial arteries are insonated bilaterally (ie, the middle cerebral artery through the temporal bone above the zygomatic arch). 10% of patients may not have temporal insonation windows. Therefore, initial absence of Doppler signals cannot be interpreted as consistent with brain death. Findings consistent with brain death indicate high vascular resistance associated with greatly increased intracranial pressure and include absent diastolic or reverberating blood flow, systolic – only blood flow or retrograde diastolic flow and small systolic peaks in early systole. Blood flow velocities may be influenced however by marked changes in the oxygen content of the blood the hematocrit levels and cardiac output.

iv) Cerebral Angiography

Selective four-vessel angiography will be performed in the neuroradiology department. In patients with brain death, intracerebral blood filling is absent at the level of the carotid bifurcation or the Circle of Willis of the brain, whereas the external carotid circulation may be patent. If there is no circulation within the Circle of Willis then there can be no oxygenation to the brain and therefore the patient is cerebrally dead (Sullivan et al, 1999).

Appendix IV Research Study Participant Information Sheet

Presumed Consent Legislation in Europe : An Investigation of the Experiences of Staff

Researcher Information

My name is Barbara Neades and I am a lecturer in Nursing in Edinburgh Scotland and am currently conducting a doctoral research study in the School of Acute and Continuing Care Nursing at Napier University. I am an independent researcher therefore you can be assured that any information that you provide will be kept in the strictest confidence.

Background to the study

You are invited to take part in the above mentioned study. Little is known about the practical aspects of application of presumed consent legislation in Organ Donation for example the policies and structures that are required to implement this approach to organ donation. Little is also known about the role of the health care professional in organ donation using this approach. Scotland and the U.K. are currently reviewing the structures that support organ donation. One of the suggested options is the adoption of presumed consent legislation as it applies in Europe. This study aims to explore the experiences of staff in Europe whose legislation is currently based on presumed consent in organ donation to learn about their views and practices in organ donation. This information would be utilised to inform Organ Transplantation Specialists and legislators in Scotland of the structures and policies required to be developed if presumed consent legislation were to be adopted. Discussion with individual staff as to their preparation for this role may also inform nurse educators and to the educational programmes required to be developed for staff who would be expected to apply this legislation should it be introduced.

What would your participation involve?

Initially you would be asked to complete a brief questionnaire designed to identify staff willing to participate in the study and in a position to assist with this research. Later a sample of these staff who give their consent will be interviewed in confidence by the researcher using a tape recorder, unless any objections to this approach are identified. These tapes will be stored in a secure place and only reviewed by the researcher to extract the data for transcription. At the completion of the degree these tapes will be destroyed.

Your decision to participate in this study is completely voluntary and you are under no obligation to take part in the study. Even if you do decide to participate in this study, any participants can withdraw from the study at any time without prejudice by contacting the researcher.

Anonymity and Confidentiality

All information gained during the course of this research will be anonymised by the researcher and treated as completely confidential. The final report will not identify any individuals who participated in the study.

Researcher Contact Details

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Email b.neades@napier.ac.uk

Appendix V Participant Consent Form

Your assistance in this research study to explore presumed consent legislation in Organ Donation is very valuable. It is important however that you do give any information freely and without any prejudice. To demonstrate this I would be grateful therefore that you complete the following details. This should be returned to the researcher with your questionnaire in the self-addressed envelope provided.

Section A

I will be able to participate in this research

Name.....

Address.....

.....

Place of Work.....

.....

Contact Telephone Number.....

Section B

Please sign only if you agree with the following statements and have decided to participate in the study :-

I have agreed to participate in this study voluntarily and I understand that I have the right to withdraw from the study at anytime without prejudice.

I have been provided with adequate information about the research and have been able to ask questions to clarify any issues.

I understand that I will not benefit financially or otherwise from my participation in the study.

I understand that my participation in this study will be tape - recorded but remain anonymous and will be treated in the strictest confidence.

Signature:

Date

Appendix VI Presumed Consent Legislation in Europe : Initial Staff Questionnaire

Name.....Qualification(s).....

Place of work.....

Contact Address.....

.....

Telephone Number.....Email Address.....

Current Post.....

1. Have you personally been involved in procuring organs for transplant from a donor?

Yes No

2. Have you personally been involved in requesting organs for donation from relatives?

Yes No

3. How long has your experience been in seeking organs for donation ?

Years Months

4. Approximately how many times has this occurred?

1-5 Occasions

6-10 Occasions

More than 10 Occasions

5. Do you have a knowledge of the legislation related to organ donation in your country?

Yes No

6. Do you have a knowledge of your hospital a) policies and b) procedures related to organ donation?

Yes No

7. What has your role been in the organ procurement process? Please give details of this role (please utilise additional information sheet if required)

8. What do you consider to be the benefits of the organ donation procedures that you currently operate in your country & unit? (please utilise additional information sheet if required)

9. What do you consider to be the challenges of the organ donation procedures that you currently operate in your country & unit? (please utilise additional information sheet if required)

10. Would you be willing to be interviewed by the researcher to gain further insights into your knowledge and experience of organ donation?

Yes No

11. If you were willing to be interviewed by the researcher would you require the services of an independent interpreter?

Yes No

Thank you very much for your help in completing this questionnaire. If you could place this in the sealed pre paid envelop and return this together with the completed consent form to the researcher. The next phase of the study will involve interviewing individuals to gain further insights in to their experience. Utilising this information I will contact those individuals who have agreed to be interviewed and arrange for these to take place.

If you have any further questions about this study please contact:

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Please attach your consent form with this questionnaire and return this to the researcher in the self - addressed envelope provided thank you.

Additional Information Sheet Attached

Appendix VII Organ Donation Legislation in Portugal

Republic Assembly

Law Nr. 12/93

April 22

Collection and Transplantation of Organs and Tissues of Human Origin

The Republic Assembly decrees, in the articles 164., e), 168, no.1,f) and 169 no.3, the Constitution, the following :

Chapter I General Rules

Article 1 material application

1 – The present law is applicable to acts which have for object the donation or collection of tissues or organs of human origin, to diagnosis or therapeutic goals and for transplantation, as well as the interventions themselves.

2- Blood transfusion, eggs and sperm donation and the transference and manipulation of embryos are objects of special law.

3- Donation and collection of organs for scientific investigation have also special law.

Article 2

- 1- The present law is applicable to the national citizens and stateless persons resident in Portugal.
- 2- To the foreigners occasionally in Portugal, the juridic regime of the acts in nr.1 from article 1, rules for persona; status.

Article 3

Authorized establishments and qualified persons

- 1- Acts referred to in article 1, nr.1, could only be done under direct responsibility of medical vigilance, according to the respective *leges artis* and in public or private hospital establishments.
- 2- Tissue for therapeutic purposes can be collected during autopsy examinations within recognised medical institutions.
- 3- Transplant centres are authorised by the Ministry of health and subjected to the periodical evaluation of its activities and results for the same ministry.
- 4- Transplant centres already functioning do not require previous authorisation, but they are subject, as well, to a periodical evaluation, referred in the same number.

Article 5
Confidentiality

- 1- Unless with the permission of the person in charge, it is forbidden to reveal the identity of the donor or the recipient of an organ.

Article 5
Payment

- 1- Tissue or organ donation with therapeutic outcomes of transplantation can not be under any circumstance the subject of any payment. It is also forbidden to trade in organs.
- 2- It is illegal to pay expenses or damages or make any other payments that arose as a result of the acts referred to in article 1, nr.1.
- 3- Agents of those acts referred in article 1, nr.1 and the establishments authorised to realise tissue or organ transplants can receive a remuneration for its services, but in the calculation of this it can not attribute any value to the transplanted tissues or organs.

Chapter II
Live Donation

Article 6
Admissibility

- 1- Without prejudice of the disposed in the next number, only the organs capable of regeneration in life are authorised.
- 2- Donation is possible between the donor and the recipient who are related at level 3.
- 3- Donation of the organs not capable of regeneration in life in minors or in the incapacitated is forbidden.
- 4- Donation of organs is forbidden if the health or physical integrity of the donor is at any risk.

Article 7
Information

The physician must inform the donor and the recipient, in a loyal, adequate and accessible way, of the possible risks, the consequences of donation and of the treatment and collateral effects of any transplant as well as the after care required later.

Article 8
Authorisation

- 1- The agreement of the donor and the recipient must be free, clear and unequivocal and the donor can identify the individual who is to benefit.
- 2- Permission must be granted by the clinical director of the establishment where the collection of the organs is to take. This doctor should not be part of the transplant team.

- 3- In the case of donors who are minors, permission to proceed to organ donation must be given by the parents and their parental powers should not be inhibited, or in the case of the inhibition of these powers, by the court.
- 4- Tissue or organ donation of minors without the capacity to understand and with the ability to express free will also require the permission of those with parental powers or that of the court.
- 5- The collection of organs in the elderly, the incapacitated or those with a psychiatric abnormality can only be authorised by the courts.
- 6- Permission of the donor or of someone who represents him freely is revocable.

Article 9
Assistance rights and indemnification

- 1- The donor has the right to medical assistance until he is completely re-established and to be indemnified for damages suffered, independently of fault.
- 2- Obligatory insurance for the donor must be created, supported by the establishments referred in nr.1 of article 3.

Chapter III

Article 10
Potential Donors

- 1- All Portuguese citizens, foreigners and stateless persons living in Portugal who have not demonstrated their intention to be a non-donor are considered as potential donors at post mortem.
- 2- When the donation is limited to certain organs or tissues or certain aims, these restrictions must be expressed clearly within the registry or within a non-donor card.
- 3- The non-donation of organs from minors and those with incapacity together with those from minors with the ability to understand and express free will must be registered, by their respective legal representatives.

Article 11

National Registry

1. A national computerised register of non- donors (RENNDA) will be created within the ministry of health, and available to all those who have demonstrated their wish to be a non-donor.
2. The government is authorised following the opinion of the national Commission of the Protection of Personal data, to oversee the organisation and the performance of RENNDA and the production of an individual card where the individuals non-donor status is expressed.
3. RENNDA must be regulated and begin its activities from 1st October 1993.

Article 12
Certification of Death

- 1- The physician undertaking the certification of death must be registered within the National Council of Ethics for life Sciences according to the regulations and criteria for the medical legal verification of cerebral death, and update these scientific requirements for registration.
- 2- The physician must communicate the certification of death to the Ministry of Health affixing details of the criteria undertaken to certify death as stated in nr. 1 for the publication within the registry.
- 3- The first publication of this information will be available after 1st October 1993

Article 13
Certification Formalities

- 1- The physicians that collect organs must undertake two things, a) report the identity of the deceased, the day, date and time of verification of the death mentioning the consultation of the RENNDA registry and the consultation of the deceased individual non-donor card if this exists, together with the lack of opposition to organ and tissue donation expressed by the deceased within these. The respective destination of the organs and tissues must also be provided.
- 2- The verification of death must not be undertaken by a Dr. who has been part of the transplant team.
- 3- The collection of the organs and tissues must be undertaken by a medical team authorised by the medical director of the establishment, where the collection will take place.
- 4- The regulations referred to in nr. 1 must be signed by the participating physicians and the clinical director of that establishment.
- 5- One of the copies of these regulations must remain in the archives of that establishment where the collection of the organs has taken place, and the other sent to the Information Services within the Ministry of health for statistical analysis.
- 6- When it has not been possible to identify a corpse, one presumes the intention to non-donation if no further evidence to the contrary is provided.

Article 14
Taking Care in the Collection of Organs

- 1- When undertaking the collection of organs the unnecessary dissection or mutilation of the body should be avoided limiting the dissection to only that required for the recovery of the organs or tissues.
- 2- The medical legal requirement of a autopsy in certain cases notwithstanding, the doctor undertaking the collection of the organs should make note of any observation that may be useful to implement the autopsy regulations that may apply.

Chapter IV Complementary Dispositions

- 1- The government must provide an information campaign promoting the social solidarity, the health politics and the therapeutic benefits of organ and tissue collection and the subsequent organ transplantation.
- 2- The information campaign must explain also about the possibility to register the intention to be a non-donor *post mortem*, and the existence of the national registry of non-donation and the use of the individual cards that notes this fact.

Article 16 Responsibility

- 1- Infractions of this laws dispositions fall into civil responsibility, penal and discipline law in general terms.

Article 17

Revocable Norm

The decree of law no. 553/76, from June 13th, is revocable.

Article 18
Beginning

- 1- Article 11 and 12 of the present law begin in general terms
- 2- Other dispositions of this law begin in the day after the publication in the first series of the Republic Diary of the criteria and rules referred to in article 12 and the communication of the Ministry of health declaring the beginning of RENNDA

Ordinance – Law no 244/94
26th September

When instituting the new regime of gift of fabrics or organs of human origin for prognosis or therapeutic ends, the law no 12/93 of April 22 foreseen the existence of a national register of Non Givers expressly, as well as the emission of an individual card of a non giver.

It matters, in consequence, to regulate such mechanisms, to make possible an effective opposition right to the gift that assures and gives consistency to the excelled of the will and of the individual conscience in this matter.

Being a right dependent procedure, it urges the institutionalisation of mechanisms that , for its simplicity and effectiveness, be within reach of all of those who's convictions determine that it is in this possibility for the post mortem of organs or tissues.

Acknowledging the difficulties that the consultations to the national register of Non Givers can raise, the obligation of the register and file of such consultations are concentrated , as well as of the respective text, for a temporary defined period.

The National Commission for the protection of Computerised Data has held :

In the development of the judicial regime established by the law no. 12 / 93 of April 22nd and in terms of the alignments a) and c) of the nr.1 of the article 201st of the Constitution, the Government decrees the following :

Article 1

Objection

- 1- The present diploma seeks to regulate the organisation and the operation of the National Register of Non – Givers (RENDA) and the emission of the respective individual card.

Article 2

Manifestation of the unavailability for the Gift

1 – Total or partial unavailability for the gift post mortem of certain organs or tissues or for the use of those organs or tissues to certain ends is manifested in the ministry of health, through the registration in RENDA by means of the completion of the form by the individuals or their legal representatives and recorded in triplicate.

- 2- The model of the printed form that one makes reference in number 1 will be approved by the Ministry of Health.

Article 3
Registration in RENNDA

- 1- The registration in RENNDA is accomplished through the presentation, for the interested parties or for those who represent them, in any health centre or extension, of the form referred to in the previous article.
- 2- The completion of the form is required, at the moment of its presentation, for the employee receiving this, to consult documents proving the identity of the individual mentions within the text.
- 3- The reception of this form by the appropriate authority will be confirmed by an immediate delivery of a copy to the individual and the signature of an appropriate employee or responsible agent. This statement of non giver will take effect immediately and will be automatically processed by RENNDA.
- 4- The registration in RENNDA will take effect within 4 working days of the receipt of the completed form.

Article 4
Purpose of the File

The automated file of RENNDA has the purpose to organise and to maintain an up to date register of citizens, stateless persons and resident foreigners in Portugal who have made their organs and tissues unavailable for donation.

Article 5
Collection of Data and is Method of Collection

- 1- The personal data collected for automatic use referring to the citizens registered in RENNDA, in terms of the present diploma, they are the name, the address, the nationality, date of birth, sex, national insurance number and its dates of identity, note of the unavailability personal organs or tissues for donation.
- 2- The change to the unavailability of the gift, as well as the update of the collected data mentioned in the pervious number, are accomplished via the completion of an appropriate form by the individuals or their legal representatives.

Article 6
Purpose of the Data

The data and personal details of the automated file are designed as per the law to verify before the collection of organs or tissues at post-mortem the existence of an opposition to or a restricted gift of organs.

Article 7
Communication of the Data

- 1- Communication of this data will be through the uninterrupted I.T. connection to the automated system of RENNDA to authorised pathology centres and to the offices of the transplant co-ordinators within the recognised medical institutions, allowing them to consult this data referred to in article 5.

- 2- In the case of it not being possible to consult the data referred to in the previous point. Information relating to the RENNDA register will be communicated by fax.

Article 8
Safety of the Information

The responsible person for the automated file and the authorised entries to the file, in terms of the previous article, will adopt the necessary technical measures to guarantee that the information cannot be obtained improperly or used for another ends that consented not them in the present diploma.

Article 9
Conservation of the Data

The personal data will be conserved for 10 years after the title holder's register of death.

Article 10
Right to the information and Access to the Data

- 1- Any person is entitled to know the content of the register or registers of the automated file of RENNDA in their own respect.
- 2- Without infringement of the conditions attached in terms of the alignments in f) of no. 1 of article 8 of the Law no. 10/91 of 29th April, the exact reproduction of the registers referred to in the previous number, with the indication of the meaning of any codes and constant abbreviations of them, is supplied free of charge, to the solicitors of the title individuals or their legal representatives.

Article 11
Correction of Possible Inaccuracies

Any person is entitled to demand the correction of possible inaccuracies, the suppression of data improperly registered and the addition of omissions, in the terms foreseen in the goods 30th and 31st of the law no. 10/91 of 29th April.

Article 12
Responsible Entry

The responsibility of the entry for the automated file of RENNDA is the management Computer Science Institution and Financial of the Ministry of Health.

Article 13
Confidentiality

- 1- all those that become aware of the data personal details within RENNDA in the exercise of their functions are forced to observe professional confidentiality, even after the terms of their respective functions.
- 2- The violation of the duty that is referred to in the previous number will be subject to civil and professional discipline procedures.

Article 14
Emission of the Card

- 1- All of the citizens who have registered in RENNDA in terms of the non-giving of organs and tissue will be issued with a card signifying this approved by the ministry of health.
- 2- The Management Computer Science Institute and Finance within the ministry of Health will produce this individual non giver card and send this to the addressee within 30 working days of the reception of the notification of non donor status.
- 3- This card will contain the identification elements of the person that it represents.
- 4- In the case of the unavailability of the donation to be limited to just certain organs or tissues or to certain ends, these should be recorded on this card.

Article 15
Consultation to RENNDA

- 1- The public or private hospital establishments who in terms of the law are recognised as being allowed to proceed to organ harvest at post mortem, before initiating the organ harvest should consult the RENNDA register of the restrictions on organ donation or opposition to this, via the offices of the transplant co-ordinator.
- 2- For the effective determination of the previous number, the offices of the transplant co-ordinators and pathology centres should be directly linked to the automated RENNDA file.
- 3- The harvest of organs and tissues within the institutes of medicine , in terms of the law, can only be undertaken after the verification that there has been no expression of opposition to the same, via the consultation of the RENNDA file.

Article 16
Opposition

Without damage of the determination of the previous article, the opposition to the gift can be proven by the copy of this that he /she refers in number 3 of Article 3 or via the production of a non givers card, found within the possessions of the deceased before the organ harvest.

Article 17
Certification of the Consultation of RENNDA

The consultation of the automated RENNDA register are registered in a magnetic support in terms that the consultation has been undertaken, as well as one in respect of the text.

Appendix VIII Organ Donation Legislation in Norway

The Royal Norwegian Department of Health and Social Services

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The Hospital Administration

Hospitals

The Norwegian State Health Inspectorate

The County Doctors

Circular no.1 – 39/97

Our ref.: 94/04154 SAJ/MARS

Date: 8.10.97

REGULATION REGARDING THE DEFINITION OF DEATH IN RELATION TO THE ACT REGARDING TRANSPLANTATION, HOSPITAL AUTOPSIES AND THE DONATION OF BODIES ETC.

- I Introduction
- II Regulation of 10.June 1977 no 2
- III Guidelines regarding the definition of death

I INTRODUCTION

According to Act of 9.february 1973 no. 6, regarding transplantation, hospital autopsies and donation of bodies etc, § 4, a royal resolution of 10.June 1977 established a definition of death in relation to the aforementioned law.

§ 2 of the regulation gives the criteria that should be fulfilled in order to set the diagnosis of death at the total destruction of the brain when respiration and heart activity is maintained by artificial means.

In the guidelines concerning the definition of death, § 2 section 6 of the regulation regarding cerebral angiography, is described as so called selective cerebral angiography, i e the insertion of a plastic tube in the 4 main arteries to the brain followed by an injection of contrast medium. In an addition to this section, arcography is mentioned as an alternative method to selective cerebral angiography in the assessment of the cessation of intracranial circulation.

In the case of arcography the guidelines demands a 30-minute interval between injections. Because this interval is seen as unnecessary the department has decided to abolish this condition.

An addition has been made in the guidelines regarding the competence requirements of the two doctors that are responsible for making the diagnosis of death: neurology has been included as an alternative specialisation in addition to internal medicine, surgery, neurosurgery, anaesthesiology, clinical neurophysiology and radiology.

This circular will replace circular I of 07/93.

Your sincerely

Kari Sønnerland

[signed]

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[signed]

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The National Hospitals

The National County Doctors

Circular no.1 – 07/93

Our ref.: 92/01232 HJ HJS/-

Date: 5.01.93

REGULATION REGARDING THE DEFINITION OF DEATH IN RELATION TO ACT REGARDING TRANSPLANTATION, HOSPITAL AUTOPSIES AND THE DONATION OF BODIES ETC.

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In the guidelines concerning the definition of death, § 2 section 6 of the regulation regarding cerebral angiography, is described as so called selective cerebral angiography, i.e the insertion of a plastic tube in the 4 main arteries to the brain followed by an injection of contrast medium. In an addition to this section, arcography is mentioned as an alternative method to selective cerebral angiography in the assessment of the cessation of intracranial circulation. Technological advances have made arcography a simple and reliable method that will be available 24 hours per day in Norwegian hospitals.

Regulations regarding the definition of death in relation transplantation, hospital autopsies and donation of bodies etc were last issued in the circular I-31/92, at the Department of

Social Services. Because of an inadvertence, parts of the circular had been obliterated. This has now been corrected. Circular I-31/92 is thereby made invalid.

Oslo, January 1993

Harald E. Hauge e.f.

[signed]

Kari Holst

[signed]

II

REGULATION REGARDING THE DEFINITION OF DEATH IN RELATION TO THE ACT REGARDING TRANSPLANTATION, HOSPITAL AUTOPSIES AND THE DONATION OF BODIES ETC.

Established by royal resolution of 10.June 1977 pursuant to Act of 9th February 1973 no.6 regarding transplantation, autopsies etc § 4.

§ 1

A person is dead when certain signs of the total destruction of the brain are present, with the complete and irreversible cessation of all functions in the cerebrum, the cerebellum and the brainstem.

§ 2

The following criteria must all be fulfilled for the diagnosis of death by the total destruction of the brain, when respiration and heart activity are maintained by artificial means, to be set.

1. An established course of intracranial disease (i.e., disease or injury inside the vault of the skull).
2. Complete unconsciousness.
3. Cessation of breathing by individual means.
4. Cessation of all brain reflexes.
5. Cessation of all electrical activity in the brain (i.e. no apparent electrical activity during electroencephalography (isoelectric or "flat" EEG)).
6. Cessation of blood supply to the brain, established with the use of cerebral angiography (i.e. x-ray images of the brain after injection of contrast medium into the main carotid arteries).

§ 3

The time of death is formally the moment in time when the diagnosis of the total destruction of the brain is set.

§ 4

When the diagnosis of death is set in cases where respiration and heart activity is not maintained by artificial means, an ordinary medical certificate regarding death should be used (an ordinary death certificate).

When a diagnosis of death is set based on the total destruction of the brain according to the defined criteria, while respiration and heart activity are maintained by artificial means, a specific medical certificate must be completed in addition to an ordinary death certificate. This certificate should be completed in two or three (see below) identical copies using the prescribed form and be signed by two doctors. One copy should be enclosed with the deceased's medical records. The other copy should be filed by the chief physician at the ward where the death took place. If organs are removed for transplantation, a third copy should constitute part of the record that must be kept for procedures that are carried out according to § 4 in the Act of 9. February 1973, regarding transplantation, hospital autopsies and the donation of bodies etc.

These regulations came into force on 1st July 1977.

III GUIDELINES FOR THE DEFINITION OF DEATH

The death of an individual has traditionally been established based on the cessation of respiration and heart activity, sometimes with secondary changes like rigor mortis, blotches on the skin and a body temperature that is close to the surrounding temperature.

Because new forms of treatment have become available in medicine, it is apparent that the cessation of respiration or heart rate over a short period of time (minutes) is not a conclusive sign of death, but that the diagnosis of death must be based on the cessation of brain function. Some patients may resume a worthwhile existence after a short cessation of respiration and/or heart activity after a successful resuscitation. During open-heart surgery, the heart and lung function can be suspended over a longer period of time (hours) with the use of technical equipment like a heart/lung machine and cooling of the body. However, the requirement for continued presence of life after a temporary cessation of respiration and heart rate, is that the brain function is preserved.

On the other hand, the function of the heart, the kidneys and some other organs may be maintained by artificial means even after the total destruction of the brain. But it is rare that the function of these organs can be maintained for longer than 3-4 days after the cessation of brain function, even with maximum medical input and proper care. In these situations, which only occur where the use of artificial breathing (respirator) has commenced, it is the cessation of brain function that is the reason why a continued existence is not possible. A universal definition of death must therefore be based on the cessation of brain function.

The diagnosis of death is to be based on the following definition:

Death has occurred when a total destruction of the brain has taken place, with complete and permanent cessation of all function in the cerebrum, the cerebellum and the brainstem (the mesencephalon, the pons Varolii and the medulla oblongata).

This definition of death is universal and covers all causes of death.

The signs of total destruction of the brain are either permanent cessation of heart rate and respiration, or the criteria listed in § 2 of the regulations, which must be fulfilled if heart rate and respiration is to be maintained by artificial means.

1. Established process of intracranial disease

Complete destruction of the brain occurs if there is an increase in pressure inside the skull vault to the same level as the blood pressure, with the result that the blood supply to the brain ceases.

THESIS CONTAINS

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Increase in pressure inside the skull vault is caused by restriction of space due to disease processes and/or swelling of the brain (i.e. brain oedema or increased fluid content in the brain).

The destruction of the brain may be caused by disease or injury inside the skull vault, like haemorrhages, tumours, infections or head injuries (primary causes) or if disease and injury outside the skull vault causes a lack of oxygen in the brain (secondary causes).

2. Complete unconsciousness

There should be an absence of reaction to light, sound, touch or pain inducement. The spine – that is outside the cranium – may have reflexes even if the brain itself is destroyed.

Spine reflexes (i.e. muscle contractions during impact against the ligaments) may take place even if death has occurred.

3. Cessation of breathing by individual means

This is an absolute criterion for the diagnosis of death to be set.

4. Cessation of all neuro-reflexes of the brain

Reflexes that pass the brainstem – that is inside the skull vault – should not be possible to release. The pupils must not react to light, and it must not be possible to induce the cornea reflex (blinking at touch against the cornea) and the vestibulocochlear reflex (movement of the eye when cold water is sprayed into the ear).

5. Cessation of electrical activity in the brain

An isoelectric or “flat” electroencephalogram is usually a sign of the total destruction of the brain. An EEG-examination on its own is not sufficient proof of the total destruction of the brain, because patients suffering from barbiturate or drug poisoning, or low body temperatures (hypothermia) or acute lack of oxygen, may show a temporary isoelectric electroencephalogram. If a x-ray examination (cerebral angiography, see next section) already has confirmed the cessation of blood supply, the EEG-examination may be omitted.

6. Confirmation of the cessation of blood supply to the brain with the use of cerebral angiography.

Confirmation of the cessation of blood supply to the brain with the use of angiography is the definite sign of total brain destruction. To establish the cessation of blood supply to the brain either 1) selective cerebral angiography or 2) arcography, may be used.

1) The injection of contrast medium must be carried out in all four main arteries to the brain, both arteries of the neck (the carotid arteries) and both arteries of the cervical vertebra (the vertebral arteries). If the injection of contrast medium in both carotid arteries show that none of these supply blood to the brain, it is sufficient to inject contrast medium

into one of the vertebral arteries in case the contrast medium flows back into the other artery without the arteries in the skull vault being filled with contrast medium.

2) In the case of aortography, contrast medium is injected into the ascending aorta with subsequent examination of intracranial and extracranial circulation, either using ordinary full format film technique or subtraction angiography. If a conventional technique is used, photographic subtraction should be carried out.

Injection of contrast medium should be undertaken twice with an interval of 30 minutes. 40 – 50 ml of contrast medium should be given with an injection rate of at least 20 ml per second. The blood pressure should be measured before, during and after the examination.

Conclusion

When all the criteria from 1-6 are fulfilled, the patient may be declared dead. A medical certificate regarding death (ordinary death certificate) and a particular medical certificate regarding death when the diagnosis is based on the total destruction of the brain, should be completed. Procedures according to the Act of transplantation § 2, see §§ 3-5, may be carried out.

Other requirements

Act no.6 of 9th February 1973 regarding transplantation, hospital autopsies and the donation of bodies etc chapter 1, does not set any demands for the competence of the two doctors that are responsible for the diagnosis of death according to § 4. One of the two doctors should have a superior position and be competent in either interior medicine, surgery, neurosurgery, anaesthesiology, clinical neurophysiology or radiology. One of the two doctors should be the one who treated the deceased during the last illness.

Act relating to transplantation, hospital autopsies and the donation of bodies etc.

Ref. Previous act of 20.May 1899 no.1

Chapter 1. Transplantation

§ 1¹

Organs or other biological material may be removed from any person who has given written consent thereto for the treatment of another person's disease or injury. Such a procedure may only be performed when it does not present any obvious risk to the donor's life or health.

Consent may be given by a person who has reached 18 years of age. When special circumstances indicate this, persons below 18 years of age may give their consent with the endorsement of their guardian² and the person who has the parental custody and is responsible for the care of the minor³. In which case the procedure must be authorised by the department⁴.

Before consent may be given, the donor must have been informed by a doctor⁵ about the nature of the procedure and the possible consequences. The doctor is under obligation to ensure that the person concerned has understood the content and significance of the information.

1. Altered according to the acts of 8.April 1981 no.7, 30.July 1992 no.101.- Ref. §§ 5 and 14.

2. See Act of 22.April 1927 no.3 chapter 2.

3. See Act of 8.April 1981 no.7 chapter 5

4. The Department of Social Security

5. See Act of 13.June 1980 no.42

§ 2

Organs and other biological material may be removed, for the treatment of another person's disease or injury, from a dead person who in writing or verbally has taken a decision to that effect.

Even if such a decision has not been taken, the aforementioned procedure may be performed on a person who dies in hospital or is brought dead to the hospital, unless the deceased or his next-of-kin have expressed themselves against it, or there is reason to assume that the procedure would be in conflict with beliefs held by the deceased or the deceased next of kin, or if other specific reasons contraindicate the procedure.

The deceased next of kin should, as far as it is possible, be informed about the death before the procedure takes place.

§ 3

Procedures pursuant to § 2 must not¹ be performed in cases where there is a question of forensic autopsy² and the procedure may have a bearing on the outcome of this.

1. Ref. § 14

2. Ref. Act of 22.May 1981 no.25 § 228.

§ 4

Before procedures pursuant to § 2 may be performed, death¹ must be confirmed by two doctors who will not themselves perform the procedure or the transfer to the recipient. A record of the procedure must be kept. The record should state the time of death, the cause of death, the names of the doctors who confirmed the death and in what way this was done.

The procedure must not be carried out by the doctor who treated the deceased during the final illness.

1. Regulation regarding the definition of death, laid own by resolution 10.June 1977

§ 5

Procedures pursuant to §§ 1 and 2 may only be carried out at hospital approved by the king for this purpose.

§ 6

The withdrawal of blood, the removal of small pieces of skin or other minor procedures of a similar nature may be carried out notwithstanding the provisions of this act.

Chapter II. Hospital autopsies

§ 7¹

On medical grounds an autopsy may be performed on a person who has died in hospital or other health institution as stated in the Hospital Act of 19. June 1969 no 57 § 1, first paragraph, or on a person who is brought in dead to such an institution.

Nevertheless, an autopsy may not be performed if the deceased or his next-of-kin have expressed themselves against it, or there is reason to assume that that such a procedure would be in conflict with beliefs held by the deceased or his next of kin, or if other special reasons contraindicate this.

The autopsy may not be performed before the deceased next of kin have been notified of the death and a period of 8 hours has elapsed since the death occurred. If the deceased or his next-of-kin have given their consent, the autopsy may be performed earlier.

If special reasons render it necessary to ascertain the cause of death without delay, the autopsy may be performed without regard to these conditions.

Necessary training in the use of treatment and operation techniques may be carried out on the body and on organs that are removed during autopsy in autopsies pursuant to paragraph 1.

The King² may approve regulations regarding autopsy and the donation and use of autopsy material.

1. Altered in Act of 12.June 1987 no.66

2. The Department of Social Security according to resolution of 18.March 1988 no.231

§ 8

An autopsy pursuant to § 7 must not be performed if there is reason to assume that a forensic autopsy¹ will be required.

1. Ref. Act of 22.May 1981 no.25 § 228

Chapter III. The donation of bodies

§ 9

For use for teaching purposes and research in anatomy and other medical subjects at the universities and other places of learning, such institutions as the King decides may require the donation of:

- a) the body of any person who after 18 years of age has made a written statement concerning the donation of the person's body for such purposes,
- b) a body which is in the keeping of the public authorities when the deceased next of kin consent to such surrender or do not undertake the responsibility for the burial.

Surrender according to letter b) must not take place if there is reason to assume that surrender would be contrary to beliefs held by the deceased or if the deceased next-of-kin forbid such surrender.

§ 10

The expenses in connection with the donation of bodies pursuant to § 9, as well as the cost of the burial should be carried by the institution to which the body is donated.

Chapter IV, Miscellaneous provisions

§ 11

Anyone who in pursuance of this Act obtains knowledge of a confidential nature is subject to the pledge of secrecy regarding such circumstances unless duty or service require otherwise.

§ 12

The Public Administration Act¹ – with the exception of Chapter VII regarding regulations – is not applicable to matters under this Act.

1. Act of 10.February 1967

§ 13

The King issues regulations to implement and supplement this act.

§ 14

Anyone who makes a decision to remove any organ(s) or other biological material that is not subject to the conditions prescribed in this law will be punished by fines, unless the case is punishable under stricter penal prohibitions.

§ 15

The Act shall enter into force from the date defined by the King. The King may decide that the various chapters in the Act shall enter into force at different times.¹

1. According to resolution of 3.May 1974, chapters II and IV, apart from §§ 14 and 16, came into force on 1.Oct 1974. According to resolution of 16. June 1977 chapters 1 and § 14 came into force on 1. July 1977. According to resolution of 11. Jan 1985 no.18, chapter III came into force from 1.March.

§ 16

From the date when Chapter III of the Act enters into force¹, Act no 1 of 20 May 1899, relating to the Donation of bodies for use in the University's Teaching of Medicine, is repealed.

1. Se note 1 to § 15, above.

Regulations

§ 4	SHD 1977-06-10 2	Regulation regarding the definition of death in relation to Act regarding transplantation, hospital autopsies and the donation of bodies etc.
§ 7	SHD 1988-03-18 230 SHD 1988-03-18231	Regulations regarding autopsies etc. Authority given to the Department of Social Services according to the autopsy act.
§ 13	KUF 1985-01-11 19	Regulation regarding the donation of bodies for the teaching of and research into anatomy and other medical subjects at the universities and other places of learning. Altered 11.December 1992 no.-1062

The Health Department of Norway Regulations for Organ Donation and Consent (2004)

The intention of this circulation is :

- to promote the donation of organs from the deceased at every possible opportunity
- to ensure that health care workers raise the question of organ donation at every possible opportunity with the NOK
- to help secure that the decision of the deceased has been followed if he has expressed a wish
- to clarify if there is a difference between the views of the deceased and the next of kin

When there is Consent from the Deceased

If a person before death has decided that his or her organs can be used for transplantation, organs can be removed on the basis of the will of the deceased. This follows the law relating to transplantation:

“Organs and other biological material may be removed from the bodies of deceased persons who have given written or oral instructions to this effect prior to death for the purposes of treatment of disease or physical injury in other persons”

It is not necessary that this consent of the deceased was committed to paper, as the situation within a family is often that this consent is provided verbally. If this consent has been given the doctor responsible for the organ donation process could put this consent forward and it must be a major factor for putting through an organ donation. If however the next of kin strongly objects to organ donation, even though there is consent from the deceased, the Dr. responsible must evaluate the situation and make the final decision if it is the last wish of the deceased that is to be followed or if it is the wish of the Next of Kin. If consent is put in writing by the deceased, it should be placed in the medical notes.

When there is No Consent from the Deceased

The law of transplantation, § 2 provides for the possibility of taking organs from the deceased, even if the deceased has not expressed a specific wish. Following the Transplantation Law §2:

“Even if a decision has not been made organs from deceased can be removed from a person, who dies in hospital or is brought to hospital, if the deceased or his next of kin has not opposed or if there is reason to believe that the procedure would have opposed his or the next of kin belief or if other special reasons of contradiction.”

Following the Transplantation Law §2 third point, every attempt must be made to contact the Next of Kin and proclaim death before the procedure is done. In the work up before the law was put in act shows that doctors are expected to bring on the question of donation. However neither the law or the work up makes an absolute claim that the next of kin is to be asked. In the work up of Ot.prp.nr 52(1971-72) it is written:

“It may happen that the next of kin is unknown or that it is impossible to contact the nearest relative, so that a absolute regulation to contact the family members may lead to the loss of organs for donation which may be viewed as being detrimental, especially when the deceased had given consent for organ donation to proceed”

In the normal situation the healthcare professionals would always ask the next of kin if they knew the decision of the deceased in relation to organ donation. This practice supports the ethical codes that underpin organ donation and are part of the new laws of Norway relating to the guard of health and person. This new health and person guard law places considerable emphasis on the individuals right to obtain information and the right to autonomous decision making.

If the deceased as previously expressed an opposition to organ donation this must be respected by the next of kin organs should then not be removed for transplantation even if the next of kin wished this to happen.

If they believe that the deceased would have opposed organ donation, then this must be respected. However, if the next of kin expresses that they do not know the deceased wishes in relation to organ donation, and they after being provided with a adequate information are not opposed, donation should proceed.

Provision of Information to the Next of Kin and Requesting of Organ Donation within Appropriate Medical Conditions

Under the terms of the Law on Patient Rights paragraph 3-3, the next of kin should always receive information relating to the condition of their relative if this is permitted in the clinical situation. In addition, as stated within paragraph 5.1 of the Law on Patients Rights, the next of kin also has a right to have access to the medical notes of the deceased. It is the wish of the Department of Health that these regulations should be applied and that the next of kin must also be provided with information to organ donation and be requested to participate in organ donation. The information given at this time must be provided in a caring and competent manner. The health care professionals, must ensure that the next of kin has fully understood the information provided and understand the extent.

The health care professionals should raise the question of organ donation on behalf of the deceased, to enable their wish to donate their organs to be respected. If consideration is made of the shortage of organs for donation and the many patients on transplantation lists who are waiting for the life saving organ, the question of organ donation is to be raised with the hope of receiving a positive response. Health care professionals that are given the task of making a request, must have empathy and a high level communication skills. They must also ensure that the question of organ donation is raised demonstrating that the decision of the next of kin will be respected, irrespective of whether their response is positive or negative. In addition, the Hospital Administrative Authorities also holds a

responsibility for developing infrastructures and procedures that ensure that every potential family is informed and asked in relation to the possibility of organ donation.

Who is The Next of Kin

The Next of Kin of the deceased are those who the deceased has previously indicated as fulfilling this role when he/she was alive. If the deceased did not indicate who was to be recognised as they next of kin, then the next of kin should be the person who has had the most and frequent contact with the deceased prior to their death. Normally the next of kin would be the spouse or partner of the deceased, followed by the children of the deceased. Subsequently, the parents of the deceased should be recognised as the next of kin. Further, siblings, grandparents and other close family members should be viewed as being the next of kin as held in the Law relating to Patient Rights paragraph 1.3b. If there are multiple claims from individuals to the role of next of kin, it is enough that one of these individuals raises an objection to organ donation, for this procedure to be abandoned. However, if consent from the closest member of the family can be obtained, then the opposition to the organ donation form the other members can be overruled.

Police Request for Post Mortem Examination in Organ Transplant

In the event of a request for a post mortem examination of the body is made by the police authorities, organ donation can proceed. The police should be contacted before organ extraction is done.

Appendix IX Organ Donation Legislation in Belgium

JUSTEL - Consolidated Legislation

End First word Final word Amendment(s)

Introduction

Table of Contents 2 Implementation Orders

Registered

Version

French

Version

belgiëlex.be – Kruispuntbank Wetgeving

Raad van State (Executive Legal Advisory Body)

Title

30 OCTOBER 1986. Royal Decision concerning regulation of the manner in which the donor or the persons referred to in Article 10, §2, of the Act of 13 June 1986 pertaining to the removal and transplantation of organs make(s) their wishes known.

Source: JUSTICE. PUBLIC HEALTH AND ENVIRONMENT

Publication: 14-02-1987

Taking effect from: 24-02-1987

Dossier number: 1986-10-30/34

Table of Contents Text Start

Art. 1-5, N

Text Table of Contents Start

Article 1. Every person (who is either on the Public Register or has been registered for more than six months with the Aliens Registration Office) and is capable of making their wishes known, may contact their local authority in order to register their objection, in the manner set out in article 2, to the removal and transplantation of their organs and tissues after their death. <KB (Royal Decision) 1987-03-26/31, art. 1, 002; Taking effect from: 24-04-1987>. The persons referred to in article 10, § 2, sections 2, 3 and 4, of the Act of 13 June 1986 concerning the removal and transplantation of organs may register their objection in the same way.

Article 2. § 1. The attached form may be used to register objection and must be appropriately dated and signed. The persons referred to in article 10, § 2, sections 2, 3 and 4, of the Act of 13 June 1986, who wish to register their objection, must also give their names and their degree of relationship to the person on whose behalf they are acting. §2. The local authorities are obliged to register the objection referred to in article 1 in their files following the accepted protocol and to note this objection in the Public Register. The data registration and

the form used for this notification of objection must immediately be sent on to the Centre for Information Processing of the Ministry of Public Health and the Family. § 3. The local authority must provide the persons referred to in §1 with a copy of the transcript of the registered details.

§ 4. It is the Health Minister's decision how paragraphs 2 and 3 shall be applied.

Article 3. As long as the person in question is still alive, the objection may be withdrawn at any time.

Article 4. Every person (who is either on the Public Register or has been registered for more than six months with the Aliens Registration Office) and is capable of making their wishes known, may have it noted in their will that they wish to donate their organs/tissues at their death. <KB (Royal Decision) 1987-03-26/31, art. 2, 002: Taking effect from: 24-04-1987>
Article 2, with the exception of §1, section 2, and article 3 apply to the declaration referred to in the first section.

Article 5. The Minister for Justice, the Home Secretary, the Minister for Work and Pensions and the Undersecretary of Health are, in those areas relevant to their duties, responsible for implementation of this decision.

Article. N. Model. < For technical reasons this model has not been included. See B.St. 14-02-1987, p. 2134>

Introduction Text Table of Contents Start

Bearing in mind the Act of 13 June 1986 concerning the removal and transplantation of organs, particularly article 10, paragraphs 3 and 4, 3°;
Taking into consideration that it is appropriate to regulate a procedure prescribed by law in such a way that people's convictions are combined with efficiency in the removal and transplantation of organs and tissues at their death;
Paying attention to the advice given by the Raad van State (Executive Legal Advisory Body);
On the recommendation of the Minister for Justice, the Home Secretary, the Minister for Work and Pensions and the Undersecretary for Health,....

Amendment(s) Text Table of Contents Start

AMENDED BY

.ROYAL DECISION OF 26-03-1987 PUBLISHED ON 14-04-1987

page 1 of 6

JUSTEL – Consolidated legislation

End First word Final word Amendment(s)

Parliamentary Activity

Table of Contents 19 Executive 3 Registered

Decisions Version

French

Version

Raad van State (Executive Legal Advisory Body)

Title

13 June 1986. – Law relating to the removal and transplantation of organs.-

(NOTE: Having consulted earlier versions starting from 14-02-1987 and updated the text up to 31-12-2003.)

Source: JUSTICE. PUBLIC HEALTH AND ENVIRONMENT
Publication: 14-02-1987
Taking effect from: 24-02-1987
Dossier number: 1986-06-13/37

Table of Contents

CHAPTER 1._	General Conditions
Art. 1-4	
CHAPTER II._	Removal from Living Donors
Art. 5-9	
CHAPTER III._	Removal from Cadaveric Donors
Art. 10-14	
CHAPTER IV._	Final Conditions and Determination of Punishment on Contravention
Art. 15-19	

Text

CHAPTER 1. General Conditions

Article 1. § 1. (This law applies to the removal of organs, tissues or cells from the body of a person, referred to as the ‘donor’, in view of the transplantation for therapeutic purposes of those organs, tissues or cells to the body of the same person or a different person, referred to as the ‘receptor’.) <W 2003-12-22/42, art, 156, 004;

Taking effect from: 10-01-2004>

The transfer of an embryo, the removal and transplantation of testes and ovaries, the use of egg-cells and sperm are not regulated by this law.

§ 2. The Act of 7 February 1961 concerning therapeutic parts of human origin does not apply to the removal and transplantation of organs and tissues in accordance with this law.

§ 3 (The King has the right to lay down rules and conditions and to impose restrictions concerning removal, storage, preparation, import, transport, distribution and delivery of organs, tissues and cells.

Each implementation of the first section after the Programme Act of

22 December 2003 has come into effect will take place subsequent to a decision reached after discussion by the Cabinet.) <W 2003-12-22/42, art. 157, 004: Taking effect from: 10-01-2004>

Article 2. After consultation with the National Health Council, the King has the right to extend the application of this law to removing the organs and tissues after death which he decides on in order to prepare therapeutic medicines which are indispensable for the treatment of serious illnesses or conditions.

Article 3. Each removal and transplantation (of tissues, cells or organs) must be carried out by a medical practitioner in a hospital, as determined in the Hospital Act of 23 December 1963. <W 2003-12-22/42, art. 158, 004; Taking effect from: 10-01-2004>

Article 4. §1. Donation (of organs, tissues or cells) may not be undertaken with a view to financial gain, regardless of the parties involved. <W 2003-12-22/42, art. 159, 004; Taking effect from: 10-01-2004>

Neither the donor nor his/her next of kin will have the right to make any claims against the receptor.

§ 2. The King will set out regulations for awarding compensation to a living donor paid for by the government or the social security institutions which the King will appoint.

This compensation is to cover expenses as well as the loss of income directly related to the organ donation.

CHAPTER II. _ Removal from Living Donors.

Article 5. Without prejudice to that which has been set out in article 7, removal (of organs, tissues or cells) from living donors may only be carried out on donors who are 18 or over and have given their prior consent. <W 2003-12-22/42, art. 160, 004; Taking effect from: 10-01-2004>

Article 6. § 1. In situations where the removal from living donors could have serious consequences for the donor or where the removal involves (organs, tissues or cells) which will not regenerate, it may only be carried out if the receptor is in a critical condition and the transplantation (of organs, tissues or cells) from a cadaveric donor cannot produce an equally satisfactory result. <W 2003-12-22/42. art. 161, 004; Taking effect from: 10-01-2004>

§ 2. For the removal referred to in § 1 the following is required:

1° if the donor is married, the permission of the cohabiting spouse;

2° if the donor is under 21, the permission of the persons or person who, in accordance with the statutes in the Civil Code, would have to give their permission for the marriage of the minor in question.

Article 7. §1. In situations where the removal from living donors would as a rule not have serious consequences for the donor (and when it concerns) organs and tissues which will regenerate and where the removal is intended for a transplantation for a brother or sister, the procedure may be carried out on persons who are under the age of 18. <W 2001-12-07/75, art. 2, 003; Taking effect from 10-01-2004>

(In situations where the removal of cells from living donors would as a rule not have serious consequences for the donor, this procedure may be carried out on persons under the age of 18). <W 2003-12-22/42, art. 162, 004; Taking effect from: 10-01-2004>

§ 2. For the removal referred to in § 1 the following is required:

1° if the donor has reached the age of (12), their prior consent; <W 2001-12-07/75, art. 2, 003; Taking effect from: 10-01-2003>

(1° b. If the donor is under the age of 12 , they should be given the opportunity to express their opinion;) <W 2001-12-07/75; Taking effect from: 10-01-2003>

2° if the donor is married, the permission of the cohabiting spouse;

3° the consent of the persons or person who, in accordance with the statutes in the Civil Code, would have to give their permission for the marriage of the minor in question.

Article 8. §1. Consent for removal (of an organ, tissue or cell) from living donors must be given freely and consciously. It can be retracted at any time. <W 2003-12-22/42, art. 163, 004; Taking effect from: 10-01-2004>

§ 2 Consent must be given in writing in the presence of an adult witness. It must be dated and signed by the persons or person giving their consent and by the adult witness.

§ 3. The proof of consent must be handed over to the medical practitioner intending to carry out the removal.

Article 9. The medical practitioner intending to carry out a removal (of an organ, tissue or cell) must make sure that the conditions of articles 5 to 8 have been met. <W 2003-12-22/42, art. 164, 004; Taking effect from: 10-01-2004>

The medical practitioner must clearly and comprehensively inform the persons whose consent is required of the physical, psychological, familial and social consequences of the removal. He/she must establish that the donor's decision has been taken judiciously and for entirely altruistic reasons.

CHAPTER III. _ Removal from Cadaveric Donors

Article 10. §1. (Organs, tissues and cells) intended for transplantation as well as for the preparation, under the conditions set out in article 2, of therapeutic parts, may be removed from (all those who are either on the Public Register or have been registered for more than six months with the Aliens Registration Office), except in cases where it has been established that an objection has been registered to such a removal. <W 1987-02-17/31, only article, 002; Taking effect from: 24-04-1987> <W 2003-12-22/42, art. 165, 004; Taking effect from: 10-01-2004>

For those persons not included in the definition given above, it is required that they have expressly given their consent for removal.

§ 2. The person, who is 18 years old and capable of making their wishes known, may register the objection referred to in paragraph 1 without an adult witness.

If a person is younger than 18 but is capable of making their wishes known, the objection may be registered by that person, or, while that person is still alive, by their next of kin who live at the same address.

If a person is not capable of making their wishes known due to their mental condition, an objection may be registered, while that person is still alive, by their legal representative, their temporary executor or otherwise a close relative.

§ 3. The King will regulate the manner in which the objection by the donor or the persons referred to in § 2, against the removal, can be expressed.

He has been authorized to do so under the conditions and in a way which he is to determine:

- a) at the request of the person involved, to register the objection by means of the services of the State Register;
- b) to arrange access to this fact in order to inform the medical practitioners who are preparing to undertake the removal, of the registered objection.

§ 4. The medical practitioner does not have the right to start the removal in the following circumstances:

1° If an objection has been expressed in the manner regulated by the King;

2° If a donor has expressed an objection in another way and this information has been relayed to the medical practitioner;

3° If an objection has been communicated to the medical practitioner by a surviving relative.

This objection must not be accepted if there is a last will stating that the person in question

intended to donate organs/tissues. Next of kin are defined as direct relatives or the co-habiting spouse.

Article 11. The death of the donor must be established by three medical practitioners, excluding the medical practitioners who are treating the receptor or will be carrying out the removal or the transplantation.

In order to establish death these medical practitioners must be led by the latest scientific knowledge.

These medical practitioners must note, in a dated and signed record, the time of death and the way in which it has been established. That record and, if any, the attached documents will be kept for a period of ten years.

Article 12. The removal (of organs, tissues and cells) and the closing up of the body must take place with respect for the cadaver and concern for the family's feelings. <W 2003-12-22/42, art. 168,004; Taking effect from: 10-01-2004>

The undertaker must prepare the body for burial as quickly as possible giving the family the opportunity to pay their last respects to the deceased at the earliest possible opportunity.

Article 13. § 1. In the case of a violent death, the medical practitioner who intends to carry out the removal (of organs, tissues or cells), must write a report that must be immediately sent to the Procurator Fiscal. <W 2003-12-22/42, art. 167, 004;

Taking effect from: 10-01-2004>

In this report, the details concerning the condition of the cadaver and the body parts that have been removed which could be important in determining the cause and the circumstances of death, must be recorded, in particular those which will not be able to be examined subsequently as a result of their removal.

§ 2. In a death due to unknown or suspicious causes, no removal (of organs, tissues or cells) may be carried out, unless the Procurator Fiscal, in whose district the institution where the removal is to take place is located, has first been informed and does not object. <W 2003-12-22/42, art. 168, 004; Taking effect from: 10-01-2004>

In such cases this magistrate may instruct a medical practitioner of his/her choice to immediately proceed to the institution to attend the removal and to make up a report of the procedure.

Article 14. The identity of the donor and the receptor may not be communicated.

CHAPTER IV. Final Regulations and Determination of Punishment

Article 15. The King determines the rules concerning the manner in which the consent referred to in the articles 5 to 9 is to be expressed.

Article 16. The medical practitioners appointed by the King are to be in charge of the monitoring of the application of this law and the decisions pertaining to its implementation.

They must be allowed access to the hospitals at all times.

Without prejudice to the authority of the police officers of the court, they will uncover crime and record it in official reports which will be used in evidence until the opposite has been proved.

Within 48 hours of discovering a criminal offence, the offender will be sent a copy of the official report.

These medical practitioners may have any necessary information or documents delivered to them for the carrying out of their task and may proceed to drawing any useful conclusions. In the case of a violent death or if the cause of death is unknown or suspicious, the medical practitioner selected for these duties may take samples and carry out analyses under the conditions and in the manner decided by the King.

Article 17. § 1. Contravention of article 3 is punishable by a prison sentence of three to six months and with a fine of between 500 and 5000 Franks or with either one of these punishments.

§ 2. Contravention of article 14 and of the decisions pertaining to the implementation of article 1, § 3, are punishable by a prison sentence of between eight days and six months and with a fine of between 100 and 500 Franks or with either one of these punishments.

§ 3. Contravention of the articles 4 to 11 and 13 as well as the decisions pertaining to their implementation, is punishable with a prison sentence of between three months and one year with a fine of between 1000 Franks and 10 000 Franks or with either one of these punishments. The person who deliberately prevents knowledge of the objection to removal, referred to in article 10, in whatever way this might have occurred, from being made available, will be punished with these same punishments.

Article 18. If the same offence is committed within five years of the day of the Judge's final decision of conviction for contravention of this law or of a decision pertaining to its implementation the penalties may be doubled.

Article 19. Chapter VII of Book I and article 85 of the Penal Code are applicable to contravention of this law or of a decision pertaining to its implementation.

Amendment(s)

AMENDED BY

ACT OF 22-212-2003 PUBLISHED 31-12-2003

(AMENDED ARTICLES: 1;3;4;5;6;7;8;9;10;12;13)

ACT OF 07-12-2001 PUBLISHED 31-12-2002

(AMENDED ARTICLE: 7)

ACT OF 17-02-1987 PUBLISHED 14-01-1987

Appendix X Semi Structured Interview Schedule

Key Questions For Health Care Professionals

Theme 1 : Exploring the Policies / Procedures for Organ Donation

Key Question

From your experience to date can you tell me about your knowledge and role in the procurement of organs for transplant?

(Further exploration of comments within question 7 of questionnaire)

Possible Supplementary Questions

Can you tell me your role in the organ procurement and transplant procedure?

If this happens in your unit, do you have identified protocols and policies for the efficient and safe management of this procedure?

What are the exact procedures for organ procurement in your hospital / unit?

Who identifies the potential organ donor and commences the process or procurement?

How do staff then notify the transplant co-ordinator / team?

Is the transplant co-ordinator or other transplant staff easily accessed?

How long does the procedure normally take from identification of the donor and donation of the organs?

Where does the organ harvest normally take place?

If relatives are present what is the normal procedure for informing them of the potential / actual organ donation?

If it is used, how do the staff access the “opt out” register to ensure the deceased does not object?

How is this accessed in an emergency situation?

Theme 2 : Exploring the Benefits of Presumed Consent for Relatives and Society in General

Key Question

What do you see as being the benefits of utilising your countries current approach to organ donation (presumed consent if used) in for the deceased, the relatives and the transplant programme?

(Developing responses to question 8 of questionnaire)

Possible Supplementary Questions

(If used) What impact has your countries current legislation had on overall numbers of organ donation in your country?

To the best of your knowledge has there been an increase in organ donation using this approach ?

Has there been a requirement to increase resources to facilitate an increase of organ donation using this approach?

What benefits do they think the utilisation of presumed consent legislation has on the relatives of the deceased if utilised?

In your experience do you feel that the use of presumed consent policies assist the relatives during their difficult bereavement period?

Have you had any experiences, which best illustrate these benefits?

Key Question

What do you see as being the challenges of utilising your current approach in organ donation programmes (presumed consent if used) for the deceased, the relatives and the transplant programme in your country?

(Developing responses to question 9 of questionnaire)

Possible Supplementary Questions

Has there been any problems for the relatives of the deceased by utilising this legislation / current approach ?

If so what have these been in relation to?

Do you anticipate any potential problems for the relatives arising from presumed consent legislation?

What if any impact do they think the utilisation of this legislation has on their relationship with the relatives and the public?

Has there been any difficulties identified for the staff or organisation in the utilisation of this approach?

If so what have these been in relation to?

Have you had any experiences, which best illustrate these difficulties?

Themes 3 : Impact on Healthcare of Organ Donation Legislation and their / Ethical Perspectives of Current Policy

Key Question

From your knowledge and experience can you tell me about your knowledge in relation to organ donation law & procedures in your country / unit and their impact?

(Developing responses to question 5 of questionnaire)

Possible Supplementary Questions

What do you know about the law in your country in relation to organ donation?

If a presumed consent / opt out register is in use , how is the register established / maintained / updated?

What procedures exist to ensure that people unable to give consent, for example, any minors, vulnerable / incapacitated / individuals with learning difficulties are excluded?

What role do you think relatives of the deceased should have in potential organ donation situations?

In their view does presumed consent legislation ensure the wishes of the deceased are honoured?

If so how is this achieved?

If not why not?

If available, do staff always utilise this option to obtain organs?

If not, why do staff not utilise presumed consent law if already in place?

In some cases why do they prefer to utilise informed consent of relatives?

What influences do you think the culture of the region / country impact upon your and the relatives response to organ donation practices in your area?

Key Question

What do you see as the Impact of your current Organ Donation Procedures on staff from a Professional / Legal perspective?

Possible Supplementary Questions

What implications does it have for the staff if any?

Does this impact on recruitment and retention of staff in critical care settings?

Are there any fears in relation to possible litigation arising from the adoption of current approaches / presumed consent approach to organ donation?

If this has been used, to your knowledge has there ever been any legal or professional difficulties for staff who have applied this legislation?

Themes 4 : Preparation of Healthcare Staff / Organisation in relation to Organ Donation Legislation

Key Question

Can you tell me about the specialist / additional policies & procedures or resources required to support your current approach to organ donation?

Possible Supplementary Questions

Are there any specialised policies or procedures utilised in your unit for organ donation using your current approach to organ donation?

Are there additional resources in terms of finance, staff or equipment that have been required to make this work efficiently?

Key Question

Can you tell me how you were prepared for your role in organ donation procedures?

Possible Supplementary Questions

What is the preparation of staff to undertake organ procurement using the legislation and procedures that you utilise?

Who provides this preparation for their role in organ donation and when does it take place?

Appendix XI: Codes of Respondents to Questionnaire and Direct Experience in Organ Donation

PORTUGAL Code	Post	BELGIUM Code	Post	Organ Donation & Relatives	NORWAY Code	Post	Organ Donation & Relatives	NORWAY Code	Post	Organ Donation & Relatives
P St. J		Bru			N St. O			N UN		
P.SJ 1	SITU Consultant	B.Bru 1	Head Nurse Recov	Yes / Yes	N.St. O 16	C. Med Intensivist	Yes / Yes	N.UN 1	Intensiv Neurosurg	No / Yes
P.SJ 2	Consult Paediatm. ITU	B.Bru 3	Nurse ITU	No / No	N.St. O 20	Intensivist	Yes / Yes	N.UNPOP 23	Gen Intensivist	Yes / Yes
P.SJ 3	Doctor	B.Bru 9	Nurse PITU	Yes / Yes	N.St. O 23	Intensivist	Yes / Yes	N.UNPOP 17	Nurse Neuro Post Op	Yes / Yes
P.SJ 4	Intensivist	B.Bru 11	Nurse ITU	Yes / Yes	N.St. O 24	Intensivist	No / No	N.UNPOP 12	Nurse Neuro Post Op	Yes / Yes
P.SJ 5	Nurse ITU	B.Bru 13	Nurse ITU	Yes / Yes	N.St. O 43	Intensivist	Yes / No	N.UNPOP 11	Nurse Neuro Post Op	Yes / Yes
P.SJ 8	Head Nurse	B.Bru 19	Nurse ITU	No / No	N.St. O 48	Neurologist	Yes / Yes	N.UNPOP 7	Nurse Neuro Post Op	Yes / Yes
P.SJ 9	Nurse ITU	B.Bru 21	Nurse ITU	Yes / Yes	N.St. O 58	Nurse ITU Recov	No / No	N.UNPOP 1	Nurse Intensivist	Yes / Yes
P.SJ 10	Head Nurse	B.Bru 25	Nurse ITU	No / No	N.St. O 61	Nurse ITU	No / No	N M		
P.SJ 12	Nurse ITU	B.Bru 28	Nurse ITU	Yes / Yes	N.St. O 62	Nurse ITU / Recov	Yes / No	N.M 22	Nurse Neuro / Gen ITU	Yes / Yes
P.SJ 14	Nurse ITU	B.Bru 29	Nurse ITU	No / No	N.St. O 65	Intensivist Recov	Yes / No	N.M 21	Intensivist	Yes / Yes
P.SJ 15	Nurse ITU	B.Bru 30	Head Nurse ITU	No / No	N.St. O 77	Intensivist	Yes / Yes	N.M 20	Nurse ITU	Yes / Yes
P.SJ 17	Licensed Nurse	B.Bru 32	Intensivist	No / No	N.St. O 78	Nurse ITU / Recov	Yes / No	N.M 18	Nurse ITU	Yes / No
P.SJ 18	Nurse ITU	B.Bru 33	Nurse ITU	Yes / Yes	N.St. O 84	Nurse ITU	Yes / No	N R		
P.SJ 103	Intensivist	B.Bru 34	Nurse ITU	Yes / Yes	N.St. O 87	Nurse ITU	No / No	N.R 4	Nurse ITU	Yes / Yes
P.SJ 106	Nurse	B.Bru 36	Intensivist	Yes / Yes	N.St. O 90	Nurse ITU	Yes / Yes	N.R 5	Nurse ITU	Yes / Yes
P.SJ 109	Nurse ITU	B.Bru 37	Trans Co-ord	No / No	N.St. O 97	Nurse ITU	Yes / Yes	N.R 36	Nurse ITU	Yes / Yes
P M										
P.M 66	Nurse ITU	B.Bru 38	Intensivist	Yes / Yes	N.St. O 112	ITU / Recov	Yes / Yes	N.R 38	Intensivist	Yes / Yes
P.M 62	Nurse ITU	B.Bru 48	Intensivist	No / No	N.St. O 120	Nurse ITU	Yes / Yes	N.R 43	Nurse ITU	Yes / Yes
P.M 61	Head Nurse ITU	B.Bru 49	Nurse ITU	No / No	N.St. O 135	Nurse ITU	Yes / Yes	N.R 91	Intensivist	Yes / Yes
P.M 64	Nurse ITU	B.Bru 50	Intensivist	No / No	N.St. O 140	Head Nurse ITU	Yes / Yes	N.R 98	Intensivist	Yes / Yes
P.M 70	Nurse ITU	B.Bru 51	Intensivist	Yes / Yes	N.St. O 124	Nurse ITU / Recov	Yes / Yes	N.R 115	Intensivist	Yes / Yes
P.M 72	Nurse ITU	B.Bru 101	Trans Co-ord	Yes / Yes	N T			N.R 123	Intensivist	No / No
P.M 68	Nurse ITU	B.Bru 102	Patient Co-ord	Yes / Yes	N.T 6	Consult Intensivist	Yes / Yes	N.R 124	Intensivist	Yes / Yes
P.M 67	Head Nurse ITU	B.Bru 103	Intensivist	No / No	N.T 2	Consult Intensivist	Yes / Yes	N.R 125	Consult Intensivist	Yes / Yes
P.M 60	Nurse ITU	B.Bru 104	Surgeon	Yes / No	N F			N.R 126	Transp Coordinator	Yes / Yes
P.M 69	Head Nurse ITU	B.Bru 105	Surgeon	No / No	N.F 25	Nurse ITU	Yes / Yes			
P.M 71	Nurse ITU	B.Bru 106	Surgeon	No / No						
P.M 89	Consultant Intensivist	B.Bru 107	Intensivist	Yes / Yes						
P.M 63	Nurse ITU	B.Bru 108	Intensivist	Yes / Yes						
P.M 90	Doctor	B.Bru 109	ER Physician	Yes / Yes						
P.M 123	Nurse ITU	B.Bru 110	Nurse ER	Yes / No						
		B Lev								
		B.Lev 1	Intensivist	Yes / Yes						
		B.Lev 5	Head Nurse ITU	Yes / Yes						
		B.Lev 9	Intensivist	Yes / Yes						
		B.Lev 11	Nurse ITU	Yes / No						
		B.Lev 12	Nurse ITU	Yes / No						
		B.Lev 13	Head Nurse Recovery	Yes / Yes						
		B.Lev 16	Consultant Intensivist	Yes / Yes						
		B.Lev 24	Consultant Intensivist	Yes / Yes						
		B.Lev 26	Intensivist	Yes / Yes						
		B.Lev 36	Intensivist	Yes / Yes						
		B.Lev 39	Intensivist	Yes / Yes						
		B.Lev 101	Transplant Co-ord	Yes / Yes						
		B.Lev 109	Social Nurse	Yes / Yes						