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Organ Donation in Japan: A Longitudinal Study of Quality of Life of Living Liver Donors

Etsuko Soeda

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ORGAN DONATION IN JAPAN:
A LONGITUDINAL STUDY OF QUALITY OF LIFE OF LIVING LIVER DONORS

A Dissertation

Submitted to the School of Nursing

Duquesne University

In partial fulfillment of the requirements for
the degree of Doctor of Philosophy

By

Etsuko Soeda

August 2010

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Etsuko Soeda

2010

ORGAN DONATION IN JAPAN:
A LONGITUDINAL STUDY OF QUALITY OF LIFE OF LIVING LIVER DONORS

By

Etsuko Soeda

Approved April 7, 2010

L. Kathleen Sekula
Associate Professor of Nursing
(Committee Chair)

Rick Zoucha
Associate Professor of Nursing
(Committee Member)

Ann Mitchell
Associate Professor of Nursing
(External Member)

Minoru Tanabe
Associate Professor of Medicine
(External Member)

Eileen zungolo
Dean, School of Nursing
Professor of Nursing

ABSTRACT

ORGAN DONATION IN JAPAN: A LONGITUDINAL STUDY OF QUALITY OF LIFE OF LIVING LIVER DONORS

By

Etsuko Soeda

August 2010

Dissertation supervised by L. Kathleen Sekula

Japan is a highly developed country with a gross national product second only to the United States. Yet in the field of organ transplantation involving organ donation from victims who died from trauma such as automobile accidents and brain hemorrhage, Japan is behind all western countries and many developing countries. Removing organs from deceased donors was prohibited in Japan until 1997.

Currently cadaveric organ donation remains minimal and, as a result, patients in need of heart transplantation must often pay for surgery performed abroad. One of the saddest sights on Japanese streets is a child standing on the street with a poster saying “Please donate money for a transplant in the US.”

Japanese surgeons are among the most skilled. In spite of the fact that there are almost no organ donations from deceased victims, surgeons have become extremely

successful in developing new techniques for organ donation from living donors. To operate surgically on a healthy person is unprecedented in medical practice and is contrary to the solemn advice of Hippocrates who said, “first do not harm (Gillon, 1985).”

The purpose of this dissertation was to longitudinally explore the quality of life (QOL) and health status of living donors after the donation.

The phase 1 study was done in 2002 which measured QOL of living liver donors (n=46) by utilizing a QOL tool, the Short Form 36 ® (SF-36®) and a researcher made questionnaire. This study showed that the majority of donors (69%) said they completely recuperated from the operation, while 32% said they did not. Moreover, living donors scored lower on the SF-36® than their controls when measured within a year after their surgery, and donors who were more than two years post-surgery had higher scores meaning their health status and QOL was better than those within a year after surgery.

For this phase 2 study, the same living donors were invited to participate, including those donors whose recipient died, because the death of the recipient must clearly represent a significant emotional trauma to the donor. The same QOL tool, SF-36®, and the researcher made questionnaire were used in this phase 2 study, and the change in their QOL and health status over seven years were examined.

There were no donor deaths in the donor population, though nine donors were admitted to a hospital for a variety of reasons. The majority of donors (61.9%) said they had completely recuperated from the operation, while 12 donors (33.3%) said they still had some symptoms. The donors who scored lower on the SF-36® from the phase 1 study scored higher for this phase 2 study. However, many still have minor complications

and some lost their income or changed their job after this surgery. Also, donors whose recipient died after the surgery showed a lower QOL score even after many years.

The significance of this study indicates that most living liver donors see themselves as having recuperated well, though some still had long-term problems.

DEDICATION

For my parents,
Tomoyasu and Mitsue Soeda

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First of all, I am deeply grateful to Kathleen Sekula who was the most supportive Chair. I am also very grateful to Dr. Minoru Tanabe, Dr Rick Zoucha, and Dr. Ann Mitchell, my committee members, for their valuable input in preparing this dissertation. I would also like to acknowledge and thank Sir Roy Calne for his language support and guidance throughout this process.

Fortunately, I had many mentors who kindly supported my career development in the field of transplantation: Prof. Masaki Kitajima, Prof. Yasuhide Morikawa, Prof. Motohide Shimazu, Prof. Go Wakabayashi, Dr. Ken Hoshino, and Dr. Yasushi Fuchimoto, who started our transplant program at the Keio University Hospital in 1995. Especially, Dr. Ken Hoshino was the one who introduced a new career as a transplant coordinator at that time. In Japan, education for nurses was based on Diploma courses and there was a need to acquire special skills and knowledge. We were working hard day and night to treat sick patient who have been fighting with their disease from the time when there was no transplant in Japan.

Colleagues and patients always encouraged me to explore the needs of organ transplantation and transplant coordinators profession in Japan. I would like to thank all donors and recipients, because they are the real fighters.

I owe a special thanks to my parents who have always provided love and support through all my academic efforts both in the US and Japan.

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CHAPTER 1

INTRODUCTION

Japan is a highly developed country with a gross national product second only to the United States. Yet in the field of organ transplantation involving organ donation from victims who died from trauma such as automobile accidents and brain hemorrhage, Japan is behind all western countries and many developing countries. Removing organs from deceased donors was prohibited in Japan until 1997.

Currently cadaveric organ donation remains minimal and, as a result, patients in need of heart transplantation specifically must often pay for surgery performed abroad. One of the saddest sights on Japanese streets is a child standing on the street with a poster saying “Please donate money for a transplant in the US.”

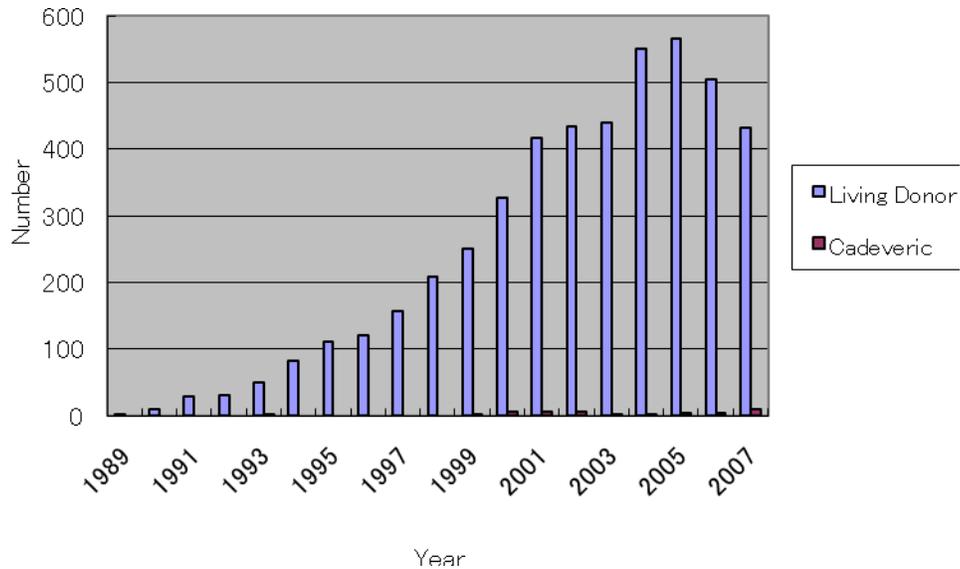
Japanese surgeons are among the most skilled. In spite of the fact that there are almost no organ donations from deceased victims, surgeons have become extremely successful in developing new techniques for organ donation from living donors. To operate surgically on a healthy person is unprecedented in medical practice and is contrary to the solemn advice of Hippocrates who said, “first do not harm (Gillon, 1985).” The purpose of this dissertation is to explore the quality of life (QOL) and the status of health of living donors after the donation.

1.1 Background

In Japan, living donor liver transplantation (LDLT) has provided a partial solution to the severe lack of cadaveric organ donors for the replacement of livers in patients with end-stage cirrhosis, fulminant disease, and congenital disorders of metabolism. In view of the extreme shortage of organs from deceased donors, Japanese surgeons have developed new surgical techniques and pre- and post- operative patient management so that now, LDLT can be used in some adult to adult as well as adult to child cases.

Nagasue and colleagues (1992) were the first to report a successful living donor liver transplantation in Japan in 1989. Prior to this report, children such as those who suffered from congenital biliary atresia were beyond the reach of organ transplantation. In 1993, a group of surgeons performed the first successful adult to adult LDLT using a left-lobe graft (Hashikura et al., 1994). In 1996, surgeons performed LDLT using a right-lobe graft successfully to overcome the barrier of graft-size mismatching for adult recipients (Lo et al., 1997). Consequently, Japanese society began to recognize liver transplantation as a life saving procedure and the demand for LDLT increased. In 2004, Japanese National Insurance began to cover medical expenses for LDLT and since that time the number of patients who request liver transplantation has continued to increase. To date, 4,292 LDLT (Figure 1) are reported from the Japanese Liver Transplantation Society (The Japanese Liver Transplantation Society, 2006b).

Figure 1. Number of Liver Transplantation in Japan



However, there are clear safety issues for living donors. According to Umeshita (2003) the post-operative morbidity for LDLT donors is about 12%, while operative mortality is zero. However, one donor death was reported from Kyoto University shortly after the Umeshita report (Akabayashi, Slingsby, & Fujita, 2004). In 2006, one donor in Gunma University Hospital became a paraplegic because of heparin over-dosage (Kiyosawa, 2007). These mortality and morbidity rates are relatively low in comparison with those of European and American countries.

From the nurse coordinator's perspective, there are many troublesome anecdotal notes recorded in reference to nurses and doctors who care for these patients. For instance, a nurse reported to a coordinator that a 20 year old female living donor was crying alone in her bed unable to sleep thinking of her donor operation, although she had gone through the regular consent process and consented to the surgery. Consequently, she

underwent the donating operation, because she had a strong wish to save her father. After the operation, she expressed her mixed feelings by explaining her family's sad story. She said that she lost her elder brother who had completed suicide two years ago. Since his suicide, her father, who was a policeman began to regret the way he had treated his son and started to drink heavily, which accelerated his liver damage. This is why she wanted to save her father by donation. For this young girl, it took a while to express her reasons for wishing to donate. Some young physicians report that it is very hard for them to attend a living donor surgery because surgeons have to put a scalpel on the healthy skin. Even when the donor operation is performed with minimum risk, the indications of transplantation are clear, the living donor gives voluntary informed consent, and the living donor has the right to change his/her mind even after signing the consent, the idea of living donor liver transplant is still considered to be unnatural by many.

In the near future, the new Organ Transplant Bill will be revised to be a less restrictive one by the Congress of the Japanese government, but it will take a long time to take effect in Japan (Table 1). In the meantime, patients who need a liver transplant have to depend on living donors in Japan. Therefore, there is a need to determine the quality of life (QOL) of living donors and to assess how they recuperate after organ donation.

Table 1. The Original Organ Transplant Bill vs. the Revised Organ Transplant Bill

	<i>Original organ transplant bill</i>	<i>Revised organ transplant bill</i>
Concept of death	Three basic signs of death: <ul style="list-style-type: none"> • non heart beating • non breathing • dilation of pupils 	Three basic signs of death Brain death
Brain death	If s/he shows her/his will to donate on the donor card, brain death will be considered as a death.	Brain death will be considered as a death.
Requirement for organ donation	<ul style="list-style-type: none"> • Older than 15 yr. • Has a written consent by the donor • Need to have a family consent 	<ul style="list-style-type: none"> • No restriction of the age. • Consent by the donor family is enough for organ donation.

Living donor kidney transplantation, as an altruistic charitable gift between members of a family, is generally accepted by Japanese society and health care professionals. In 2006, 1,136 kidney transplantations were performed in Japan and 939 (82.6%) were from living donors (Ota, 2007). Isotani (2002) reports medical complications such as pneumothorax, deep venous thrombosis, and wound pain, but reports that these complications are treatable and the patients' QOL is the same as or better than in the general population. In a study which compared the QOL of living liver donors and living kidney donors (Rudow et al., 2005) it was reported that both groups reported favorable outcomes, however living kidney donors had less concern for risk of death, bleeding, altered appearance, and infection. That is because laparoscopic removal of a kidney is becoming more easily available for living kidney donors. However, the

ethics of this have been recently challenged by Scheper-Hughes (2007), Director of the university-based “Organ Watch” in the prestigious “American Journal of Transplantation.” She has written on the “Tyranny of the Gift.” She points out that the marketing of tissues and organs with commercial organ sales is usually condemned as unethical, but many of the objections raised are also relevant to the so called “altruistic donation within a family.” She discusses selected cases and points out that female donors tend to have more pressure put upon them by family members to sacrifice a kidney than males (Scheper-Hughes, 2007). However, an editorial comment was published that was critical of Scheper-Hughes’ selection of the worst cases to support her condemnation of living donor surgeries in transplant cases (Kaplan & Williams, 2007).

If there is much higher donor morbidity and mortality in kidney living donor transplantation, there is a valid concern that there will be a decrease in the number of donors. Therefore, the QOL of living liver donors must be evaluated to determine the validity of reports. Transplant coordinators must have a thorough understanding of QOL in order to support potential living liver donors based upon that knowledge.

1.2 Significance of the Study

Living donors are healthy people who volunteer to undergo a major operation to save a loved one. This is a unique situation and it is important to assess how they recuperate after surgery longitudinally, over time. Investigation of QOL issues will help the transplant team become aware of the resources needed to improve living donors QOL. This information may help transplant teams to better understand what interventions might help enhance QOL for living donors. Further, by understanding what is relevant to the living donors, appropriate information, counseling, and anticipatory guidance can be

provided when potential living donors make the decision to donate. The transplant team should provide ethically-congruent total care for transplant recipients, living donors, and their families. This may help the Japanese public to understand the real benefit of organ transplantation and to increase understanding of organ donation in general and the need to accept brain death donation (as defined in the Revised Organ Transplant Bill).

1.3 Research Questions

1. What is the self-perceived quality of life (as measured by the SF-36®) in a sample of living donors seven years post surgery?
2. Does the self-perception of QOL (as measured by the SF-36®) in the study sample of living donors change over a 7 year period?
3. Does the self-perception of QOL in the study sample of living donors differ when compared with norms established for the general Japanese population?
4. Do the living donors in this sample who had a lower QOL score improve over a 7 year period?
5. Have the living donors in this sample received any medical treatment over the last 7 years because of organ donation?

CHAPTER 2

REVIEW OF THE LITERATURE

2.1 Introduction

The first part of this chapter explains the theoretical framework which guided this research. The second part defines quality of life (QOL) as it was utilized throughout this study.

2.2 Theoretical Framework

The practice of all health care professionals is, at its very core, ethical in its *raison d’etra*. Regardless of whether it is day-to-day decisions, or dilemmas that require prolonged thought and analysis, it is important that those in health care take seriously the discipline of bioethics (ethics for the health professions). Health care has changed dramatically over the past decades due to the development of new technology, and can be seen in the examples of the dilemmas related to organ transplantation, genetic engineering, surrogate mothers, and euthanasia. New bioethical problems occur more frequently and do not have easy answers. The dilemma of whether it is ethical to take organs from a living donor for the sake of another is a valid question. The answer is not a simple “yes” or “no”, but it requires serious consideration of moral values. Therefore, to guide this study the author has chosen the theory of Symphonology (Husted & Husted, 2008). Symphonology is a bioethical theory that is concerned with agreements within “a set of standards of behavior, preconditions necessary to agreement and professional interactions in the health care setting.” (p. xvii).

No research studies were found by this researcher which used this theory previously in the Japanese population. This theory has just been published in Japanese (Husted & Husted, 2009). However, the situation in which Japanese patients make decisions about their health care is similar to that in the US. Whenever patients meet with their physicians, nurses attend in order to assure that patients understand all information they are given. In cases involving transplant recipients and donors, interviews with psychiatrists are mandatory. Both recipients and donors receive all information (full disclosure) from their physicians and nurses before making decisions, are given the right to make their decisions based on their own judgment, and to withdraw consent at any time. Since this is what would be required by the theory of Symphonology, this researcher believes the use of this theory for Japanese subjects is culturally applicable and ethically germane.

“Symphonia” is a Greek word meaning “agreement.” Thus, Symphonology is the study and exploration of agreement in the health care setting, the agreement that exists between patients (both recipient and donor) and health care professionals. A symphonological bioethical outlook is formed from the rational nature of health care providers and patients and the nature and purposes of the health care setting. For interaction between rational agents to be possible, there must be an agreement between them, formulating the terms of their interaction. Husted & Husted’s bioethical theory is derived from this agreement. The Symphonological bioethical theory is a practice-based approach to ethical decision making and it gives a firm foundation for the patient’s trust with the health care professional/patient agreement (Husted & Husted, 2008).

Agreement is a shared state of awareness, a meeting of the minds, on the basis of which interaction occurs while the agent is one who initiates action or one who is capable of taking an internally generated action (Husted & Husted, 2008). Here, a shared state of awareness includes recipient and donor in which the health care professionals allow them to act as their own agents. The agreement is usually an implied agreement, not spoken, but generally understood. There are six bioethical standards that are preconditions to the agreement, namely, autonomy, freedom, self-assertion, objectivity, beneficence, and fidelity (Husted & Husted, 1995). The conditions of each of these standards as preconditions of any agreement must be met with both donor and recipient before it is morally acceptable to consider going ahead with the surgery. The following, as defined by Husted and Husted:

1. "Autonomy" as uniqueness. A person's right to be what he or she is and to be dealt with according to that uniqueness. A right to take individual action. A donor has the right to make the decision to donate based on his or her own individual uniqueness.
2. "Freedom" as self-directedness. An agent's capacity and consequent right to take independent actions based on the agent's own evaluation of a situation. A donor must be free to make the decision to donate based on his/her own evaluation and life-plans.
3. "Self assertion" as self-ownership and control. The right of an individual to be free of undesired or undesirable interaction; the right to control one's time and effort; the right to initiate one's own actions. A donor must be willing to donate, without any coercion or undue interference from others.

4. “Objectivity” as a willingness to know something as it is apart from emotion or personal prejudice. The living organ donor must be medically and psychologically suitable to make the decisions to donate – able to evaluate the facts of the situation for self. Furthermore, a donor must be fully informed of the risks and benefits for self as a donor and have the right of refusal at anytime.
5. “Beneficence” as a person’s action based on the intention to do no harm (Hippocrates) and do good. A donor should be fully informed of the risks and benefits for self, free of pressure or feelings of guilt brought on by others. The donor must be able to weigh that which is deemed beneficial or harmful to self.
6. “Fidelity” as a patient’s faithfulness to his/her values. A donor has the right to be faithful to his or her own life and make this decision based on his or her own life-plans.

Although each donor decides after thorough consideration of both the risks and benefits of live organ donation, there will always be fear of surgery, pain, complications, and death. Potential donors may find it difficult to express fears and to find a compassionate individual to whom they can express their worries and mixed feelings. Moreover, feelings will change from time-to-time depending on the context. For instance, a donor might feel happy when her/his recipient survives and recovers from the operation, but will feel sad when her/his recipient dies after the operation. In addition, there may be severe feelings of guilt if the person decides not to be a donor and the person cannot find another donor and dies. Therefore, these donors need to be continually assessed and supported by the transplant team.

Because the living donors were healthy before being a donor or having surgery, they will expect a full recovery from the surgery and a good QOL, similar to, or the same as, before surgery. A living donor's life experience affects how s/he will use her/his own uniqueness (autonomy) in making decisions about being a living donor and in his/her perception of QOL.

As with every decision, each donor makes in the process of donor evaluation, the context is of central importance. What is and is not appropriate is influenced by the context. For example, whether we wear a light or heavy coat will depend on the weather, namely the context. In organ donation the context is more complex, the donor must have time to assess the situation to make an informed decision that includes self and the recipient.

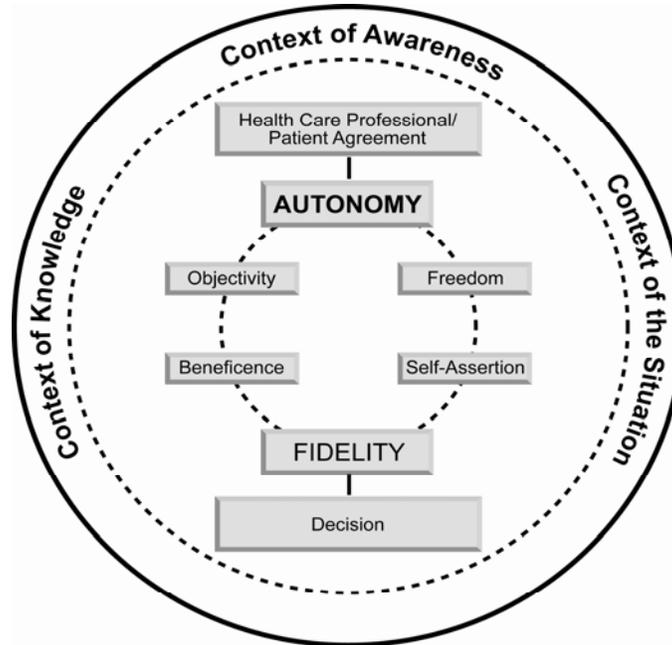
There are three elements of the context. First is the context of the situation. The context of the situation are those aspects that are found in the situation and necessary to understanding the important relevant factors which enable one to act effectively within the situation. Second is the context of one's knowledge. It is the person's preexisting knowledge that one brings to each and every situation. A donor must have complete and accurate knowledge of the facts involved in being a donor. Third is the context of awareness. It is our awareness of the situation and our own body of knowledge that enables us to act and to understand all aspects of a complex interaction (Husted & Husted, 2008). The nurse needs to make sure that the donor and recipient have ongoing information as the situation unfolds so that their context of knowledge is accurate and complete and can be used to make decisions within the given context. Without this they are not aware of the pertinent aspects from which they must make decisions.

For LDLT, the context of the situation will involve progress of the recipient's liver damage, relationship to the recipient, the motivation of living donation, and the emotional status of the donor. Especially, in the case of acute onset of the liver damage, such as fulminant hepatic failure, the donor has to make a decision within a few hours to save the recipient's life. On the other hand, in the case of the late onset of liver damage, such as viral hepatitis B and C, the donor has a time to make a decision after completion of the medical treatments. The context of knowledge will be preexisting knowledge relevant to the situation of the recipient and donor. The donor will use his awareness of the situation and the aspects of his or her body of knowledge to prioritize the relevant aspects in the situation. The context of awareness bridges this gap between knowledge and situation so that the best decision can be made for this person at this point in time.

These three elements are interwoven and brought to bear on the care and decisions that need to be made for and with any donor. In this way, the standards are contextually applied and each application of them is unique for each donor (Figure 1).

Application of the Husted & Husted's Symphonological Bioethical Decision Making Model to LDLT can help donors, recipients, and the transplant team to establish strategies to help them experience a better QOL after organ donation.

Figure 2. Husted's Symphonological Bioethical Decision Making Model II.(Husted & Husted, 2008)



2.3 History of Liver Transplantation in Japan

A history of transplantation in Japan

There are two periods in the history of organ transplant in Japan. One is the period before the passage of the Organ Transplantation Bill and the other is the period after the passage of the bill in 1997.

Before the passage of the Organ Transplantation Bill (~1997)

The history of organ transplantation in Japan began with a kidney transplant in 1956 performed at Niigata University (Amemiya, 1999). It was only two years after the first clinically successful kidney transplantation between identical twins performed at the Peter Brent Brigham Hospital in the US in 1954 (Harrison, Merrill, & Murray, 1956). In 1964, the second kidney transplant was performed at Tokyo University and the first liver

transplant was performed at Chiba University. It was a year after the first clinically successful liver transplantation by Starzl at Colorado University Hospital in 1963.

While patients started to recognize transplantation as a real hope to survive, surgeons were struggling to find a way to overcome rejection. In 1959, 6-Mercaptopurine was reported as an immunosuppressive agent by Schwartz and Damashek shown to prolong survival of renal allografts by Calne (1960). In 1961, Calne reported Azathioprine as an effective immunosuppressive agent with fewer side effects (Calne, Alexandre, & Murray, 1962). In 1963, it was used clinically by Murray and his team. The discovery of new immunosuppressive agents especially Cyclosporin, transformed organ transplantation to a confident medical procedure (Calne, 2007).

There was an optimistic assumption for Japanese surgeons that they could start organ transplant programs using those drugs. However, the first trial of heart transplant stopped those developments in Japan.

In 1967, the first heart transplant from a cadaveric donor in the world was performed in the Republic of South Africa. The next year, Wada, one of the heart transplant surgeons who was trained in the United States returned to Japan and performed the first heart transplant from a cadaveric donor in Japan. The recipient lived for 83 days after the transplant. Right after the transplant, Wada was a hero as a successful heart transplant surgeon, but he was accused of being a murderer after the recipient's death and the transplant was then seen as an illegal human experimentation. After this incident, the subject of organ transplantation and brain death became controversial and emotionally charged for Japanese people (Kaai, Hirano, & Koguro, 1998).

While the development of transplantation in Japan ceased, Starzl performed the first successful liver transplantation (Starzl, Marchioro, Porter, & Brettschneider, 1967) and Calne performed the first successful liver transplantation in Europe (Calne, 1968), and both these groups established the principles of transplantation procedure. Moreover, in 1978 Calne introduced the new immunosuppressive drug, cyclosporine, for kidney transplantation and that drug made organ transplantation a more successful procedure (Calne et al., 1978). In 1983, the use of cyclosporine had become more common and organ transplantation was accepted worldwide as a life saving procedure (Sayegh & Carpenter, 2004)

In 1985, the Japanese Ministry of Health and Welfare established an ad hoc committee on brain death, and the committee developed national criteria for brain death which was called Takeuchi criteria (Takeuchi et al., 1987). In 1987, the Japanese Medical Association acknowledged that brain death was equivalent to death of the human being. In 1992, the Prime Minister's Special Committee on Brain Death and Transplantation visited some transplant institutes in both the United States and European countries and presented the final report saying that brain death is death of the human being and that a donor's prior intention to be an organ donor is necessary for organ removal (Saegusa, 1999). However, the report of that committee also stated objections concerning the idea of brain death (The Japanese Transplant Network, 2004).

After the 1992 report was submitted, many years of discussions about organ transplantation and brain death ensued. No transplant was performed to save patients with end stage organ failure. There were many changes in the government and frequent

dissolutions of parliament did not provide enough time for discussion of the organ transplant bill to advance.

In the meantime, the first live-donor liver transplant (LDLT) was performed in a pediatric patient who suffered from biliary atresia in Brazil in 1988 (Raia S, 1989). However, the patient did not survive. The first successful case was performed by Russell Strong in Australia (Strong et al., 1990). The same year, the first LDLT was performed in Japan. Right after the transplant, the surgeon, Nagasue, was accused of performing surgery on a normal healthy mother, a live donor. However, he became a hero when the child recovered after the surgery and the mother was well. After this success, LDLT was acknowledged as a realistic hope for patients with end stage liver disease in Japan for whom previously the only alternative was death.

After the passage of the Organ Transplant Bill (1997)

In 1997, the Organ Transplant Bill was passed and brain death was acknowledged as equivalent to human death. In 1999, 31 years after the first heart transplant performed by Wada in 1968, the first brain-dead donor was procured. It was like daybreak after the long dark days and years in the history of organ transplant in Japan. However, the new law has proven to be difficult to implement, because of many restrictions. The Congress is therefore currently reviewing the law to facilitate organ donation.

According to the Japan Organ Transplant Network, from 1997 to 2007, 250 patients received organ transplantation from 65 brain-dead donors in Japan. The number of brain-dead donors is still small but the number of saved patients is significant. The average length of waiting time for kidney transplant patients is 5,276 days; for heart 665

days, for lung 656 days, and for liver 572 days. This is a long period of time compared to western countries (Network, 2008).

Therefore, there are more organ transplantations from living donors than deceased donors in Japan. To date, more than 4,000 LDLTs have been performed in Japan and the advances of surgical techniques and medical management of recipients expanded the indications for transplantation (The Japanese Liver Transplantation Society, 2006a).

2.4 The Role of the Transplant Coordinator in Japan

In countries where organ transplant is recognized as a valuable surgical treatment, the role of the transplant coordinator is clear and plays an important part in every organ transplantation program. To become a transplant coordinator, nurses must acquire basic knowledge about transplantation and must have special training in caring for both the donor and the recipient.

The traditional role of the nurse since the time of Florence Nightingale is to comfort the sick. In LDLT, the nurse/coordinator has to comfort the healthy donor suddenly plunged into a strange environment and who is often frightened and in pain. The hallmark of good nursing is to make sure the patient is clean, has food and drink, and to explain the nature of the illness, the treatment and the prognosis (Marriner-Tomey, 1994). Thus the role involves the nurse acting as advocate for the patient who frequently is unable to appreciate the best option for her/his management and the well-being of their family. The nurse should liaise with doctors and others involved in the care of LDLT donors.

Living organ transplantation offers a new dimension in healthcare which has slowly become recognized and has evolved into a new area of practice for clinicians. For

the first time in medicine, in the case of living donors, healthy people are subject to surgical assault, the consequences of which inevitably involve pain and discomfort. There may be the possibility of serious morbidity (i.e., leakage of visceral contents, failure of wounds to heal) and there is always the risk of mortality. The risk of mortality is low in kidney donation, less than one in a thousand, but is significantly higher in liver grafting especially in transplantation of half of a liver between adults where there is the danger of serious morbidity of around 12% for the donor, due to bile leak, infection, and liver insufficiency, among others (Umeshita et al., 2003).

A living donor may be perfectly willing to take the risk. However, there are more considerations than just the individual in question. These may include the family of the donor and whether the donor is responsible for the care of children, financially and/or emotionally. Most living donor transplant programs will not accept an under-age donor giving a kidney or part of a liver to a parent, yet some centers accept child-to-parent grafts as a routine procedure in Japan. The coordinator is clearly aware of these matters and is closely involved with the families of both the donor and the recipient. It is impossible to avoid the whole question of donation and receipt of the organ. Some members of the family may feel pressured to be a donor and feel guilty if they refuse, but if they accept and they suffer disability or die, their families may feel extremely resentful.

The question of payment to the donor is an important matter, which may not be obvious to the doctors and nurses or even the coordinator. Thus, for example there may be monetary coercion involved in the negotiations with potential donors. Those involved with obtaining a donor for the recipient may offer financial help in the purchase of a house or relief from debt. The coordinator or health care providers rarely know about

these coercive practices. The various ramifications of generosity, guilt, recrimination, general worry, and concern are an unnatural burden to inflict on a healthy person but it is a consequence of the success or failure of transplantation. There are matters that are hard to bear for the care givers of the patients involved who are the potential donors. As has been stated there is a tendency of over enthusiasm about live donation on the part of the recipient as well as the doctors and the institution where the operation will be performed. Therefore, the international transplantation community have debated the ethical concerns of organ donation and Abecassis published a consensus statement on the live organ donation which a transplant team must follow (Abecassis et al., 2000). This is consistent with Husted's bioethical theory. Table 2 outlines the consensus statement on live organ donors on the statement.

Table 2. Consensus Statement on Live Organ Donors

Premise	<ul style="list-style-type: none"> • Organ donor should be competent, willing to donate, free from coercion, medically and psychosocially suitable, fully informed of the risks and benefits as a donor, and fully informed of the risks, benefits, and alternative treatment available to the recipient.
Informed consent	<ul style="list-style-type: none"> • Understanding - Donors must understand accurate information regarding risks and benefits to themselves. • Disclosure - Description of the evaluation, the surgical procedure, and the recuperative period. • Anticipated short- and long- term follow-up care. • Alternative donation procedures, even if only available at other transplant centers • Potential surgical complications for the donor, citing the reports of donor deaths (even if never experienced at that transplant center) • Medical uncertainties, including the potential for long-term donor complications • Any expenses to be borne by the donor • Potential impact of donation on the ability of the donor to obtain health and life insurance • Information regarding specific risks and benefits to the potential recipient • Expected outcome of transplantation for the recipient • Any alternative treatments (other than organ replacement) available to the recipient • Transplant center-specific statistics of donor and recipient outcomes • Voluntary nature - Transplant center must ensure that the decision to donate is voluntary • Documentation - The usual informed consent and the documentation of the disclosure process are needed.
Medical suitability	<ul style="list-style-type: none"> • Potential living organ donor should be healthy adults (aged 18 years and older) • Selection of the potential donor is based on an algorithm of suitability that includes radiological imaging of the liver (to assess the following intrahepatic anatomy: hepatic artery, portal vein, hepatic veins, and bile ducts), liver volumetric data, and the presence or absence of steatosis • Heart, lung, and kidney tests
Psychosocial suitability	<ul style="list-style-type: none"> • Evaluate psychological, emotional, and social stability • Evaluate the competence of the donor to give informed consent • Evaluate and discuss the possibility of coercion of the potential donor.

Final statement –

The transplant team, donor advocate, and the potential donor and recipient pair are the responsible parties who should determine if the benefits of the planned donation outweigh the risks. The risks of a complication to the liver kidney donor are not the same as the risks for being a live donor of a liver, lung, intestine, or pancreas. These highly specialized donor procedures should only be performed at centers with the necessary management resources and only by surgeons with appropriate expertise. There must be agreement among the potential donor, recipient, and physicians for living organ transplantation to proceed. Transplant physicians must have decision-making autonomy that prevents undue pressure on the medical team to perform a procedure that they do not believe is medically indicated. While the autonomy of the potential donor must be respected, so also must the medical decision making of the transplant team be respected. Therefore, the team should never feel obligated to perform a transplant from a living donor if it believes that it will do more harm than good.

Nevertheless it must be accepted that the donor may be motivated by truly altruistic feelings and it is questionable whether medical and nursing observations should interfere with such wishes. Altruism is a genuine emotion, but it is incumbent upon the medical and nursing staff to make all the facts known to the various parties. Donors who agree to a major and potentially dangerous procedure should be made aware of, and should be told in careful and simple language, about the possibility that all their efforts might be in vain if the graft is rejected. To circumnavigate these issues is difficult and an emotionally draining role of the transplant coordinator. In the situation of living donor transplantation, the transplant coordinator will take a role as an advocate for a living donor and a counselor for a recipient and her/his family.

The difficulty of accepting the concept of brain death

Most Japanese are Buddhists and the essential teachings of Buddhism are different from other religions. Buddhism involves the teachings of the Buddha, just as Christianity involves the teachings of Jesus Christ and Islam involves the teachings of Mohammed. Yet, there is one major characteristic that is unique to Buddhism, and this is

that those who embrace Buddhism can also become Buddhas (Takada, 2006). In Christianity, Judaism, and Islam, believers are encouraged to learn the teachings of the founder and to devote themselves to a unique, absolute deity, but human beings cannot become a deity. However, in Buddhism, by learning the teachings of the Buddha, and awakening to the truth concerning the universe and human beings, anyone is said to be able to become a Buddha. Hence, it can be said that ultimately Buddhism is everyone's attempt to become such a Buddha (Takada, 2006). To become such a Buddha, traditional Japanese believe that a complete body is needed. For example, there may be patients who ask to keep bones of the amputated leg.

There are a number of similarities between Buddhism and Christianity (Takada, 2006). First, Buddha and Christ are the respective founders of Buddhism and Christianity. They both devoted their lives to the propagation of their respective truths and to saving people. Moreover, the Buddha has two aspects: that of a human, and that of one who has attained enlightenment. This is also true of Christ, who has a human aspect and a divine aspect as the savior Christ. The teachings of both continue to give encouragement and support to many people around the world.

The difference between the two lies in their teachings (Takada, 2006). In contrast to Christ, who preached devotion to God as an absolute being, the Buddha denied the very notion that an absolute existed. It also seems that there was a difference in how the two propagated their teachings. In contrast to Jesus who commanded that when the disciples went forth as missionaries they should go in groups of two or more, the Buddha told his disciples to go alone. It appears that during the time of the Buddha there was relative peace, whereas in the time of Jesus, Israel was under the control of Rome and

there were many violent uprisings and dangers. The deaths of the two were also quite different. Christ was arrested and crucified, but the Buddha lived to be eighty years old and was said to have been mourned at death by every living entity (Takada, 2006). For Japanese, the presence of the family at the death is very important and most people still believe that the cessation of the heart beat is the real death; therefore this difference may be another reason why the Japanese have difficulty in accepting brain death.

Deceased Organ Donation in Japan

For the reasons outlined above, the number of organs transplanted from dead donors in Japan is extremely low. Ten donors were identified in the whole of Japan in 2007. In contrast the head of the liver transplantation program in Valencia, the third largest city in Spain, often receives offers of 8 donors in one week (J. Mir, personal communication, May 7, 2007). In the past 20 years, more than 2,500 kidneys and 2,100 livers have been transplanted in Valencia, all from deceased donors. The overall Spanish transplantation activity and results are excellent (Matesanz & Miranda, 2002).

By attempting to understand the Spanish success in obtaining organs from deceased donors, perhaps some of their practices could be adopted in Japan.

1. Organ donation coordinators are employed in all Spanish hospitals. Most are experienced medical doctors, whose responsibility is to identify potential donors in their hospitals. They are trained to interview the relatives sympathetically and they liaise with intensive care staff and arrange for the diagnosis of brain death by suitably qualified neurological experts (Matesanz, 2003).
2. Spanish law provides for an “Opt-out” framework. In other words, all people in Spain are considered to be a potential donor, unless they opt-out in advance.

Organs can be removed from brain dead patients, provided they have not registered as not willing to donate organs after death for transplantation. If the wishes of the deceased are not known, the relatives will be asked if they know of the deceased opinion on organ donation. An “Opt-in” law requires explicit permission from the next of kin in each case even if the donor had carried a “willing to donate organ after death” card. An “Opt-out” law facilitates organ donation as a good and charitable act and enables the coordinator to work without opposition from and lack of cooperation by nursing and medical staff, which often occurs with “Opt-in” laws (Matesanz, 1998).

3. Sufficient intensive care beds and operation room space are available to take care of the potential donors, so that organ failure can be prevented and organ removal instigated promptly by an experienced surgical and nursing team (Matesanz, 2003).
4. The government is seen by the people to be sympathetic to organ donation and the media are encouraged to explain to the public the benefits of organ transplantation and its ethical justification (Matesanz & Miranda, 2002).
5. Government funds are provided to pay the donor family a grant towards the funeral expenses (Manyalich, 2007).
6. The doctors, nurses and all health care workers involved in the organ donation are paid properly for extra hours worked, especially during the night and over holiday periods (Manyalich, 2007).

Naturally, Spain is proud of the success of their deceased organ donation program. The average number of donors per year is 40 patients per million in the

population, compared to only 20 patients per million in the UK and 0.08 patients per million in Japan. This cannot be attributed just to the higher rate of road traffic accidents in Spain compared to that in the UK and Japan, but also to a much greater resolve of the government to provide financial and physical resources to minimize the number of potential donors whose organs are not used for transplantation. It is clear that for Japan to improve its deceased organ donation record, much work will have to be undertaken to convince central government, the public and healthcare professionals that the effort would be worthwhile in providing the gift of life for many doomed patients and avoiding the shame of sending patients abroad for treatment that could and should be available in Japan.

An Asian example of responses to the “Opt-out” law was recently outlined by Vathsala (2007) from Singapore, where following the passing of the new law, the donor rate increased 10-fold reaching 10 donors per million per year, the highest rate of deceased organ donors reported by any Asian country. All people in Singapore are considered to be a potential donor, unless they opt-out in advance and this law facilitated organ donation as a good and charitable act.

The media

As might be expected the media in Japan have been fascinated with the story of transplantation and they take advantage of the many opportunities to portray human anguish, guilt, pain and suffering, and ethical considerations. There have been many programs, articles, and books written about organ donation and one recent Japanese TV production has raised important questions in the form of a Japanese soap opera.

In Japan, many people are informed about current issues through soap operas. In one example, the central character was a man in his 40s with end-stage hepatitis C although he appeared rather fit on the TV. The question of live organ donation was raised since the chances of getting a cadaveric liver in Japan are so low. The patient's brother was identified as a possible donor and he was anxious to give half his liver despite the dangers explained to him by the coordinator. But his wife opposed organ donation pointing out that her husband was the bread-winner and should consider the welfare of his family. Nevertheless the brother persisted in his wish to be an organ donor and he was worked up for this procedure. He was summoned to the hospital for a scan and was involved in a road traffic accident on the way to the hospital. He ended up in the intensive care ward "brain dead". His wife was furious with his brother for initiating the organ donation process and blamed him as being the cause of her husband's death and she refused permission for his liver to be used as a cadaveric brain-dead donor.

Both the wife and the daughter were evaluated but were not appropriate donors. The soap opera was typical in that it highlighted many issues that can occur in such a situation. The ending showed the wife being wheeled into the operating room next to her husband after being reevaluated and accepted as a donor.

While one must keep in mind that this was simply a soap opera , it served to outline some of the major issues in live organ donation and also address the issue of the poor record of cadaveric organ donation in Japan, which means that Japanese patients requiring an organ that cannot be given by live donation, e.g. a heart, or multiple organ donation for a child, have to beg in the streets for sufficient money to travel to America, Australia, or Europe and have the operation done there, which seems a sad reflection on

the state of organ donation in Japan. The implication of this media portrayal of organ transplantation may be seen as an effort to emphasize that this vital and scarce form of treatment should be regarded by the nation as something that should be available to its citizens. This TV program may be seen as an attempt to influence the attitudes of the Japanese population regarding cadaveric organ donation and acceptance of the procedure as a necessity.

An “opting-out” system whereby organ donation from brain-dead victims would be regarded as standard procedure unless objections had been made by the relatives has been helpful in certain European countries (Table 3), reducing the anguish of decision making at the time when brain-death is diagnosed (The Nippon Hoso Kyokai, Jan. 28, 2009). The use of living donors needs to be carefully scrutinized to avoid the abuses of payment, coercion, and excessive enthusiasm to find a donor. These ethical matters will be of increasing importance in the foreseeable future as the results of transplantation continue to improve.

Table 3. Methods to Obtain Informed Consent for Organ Donation

Written consent by a donor is needed (Opt-in)	Japan
Agreement by a donor or his/her family is needed (Opt-in)	US, Germany, England, Australia, Holland, Canada, Denmark, Korea.
Without denial of organ donation, all potential donors can donate (Opt-out)	Austria, Belgium, France, Spain, Italy.

Problems in Living Donation

There is a reluctance to discuss the mortality of adult-to-adult liver transplant and worldwide no precise data are available. However it is probably in the region of 1 to 2 %, although experienced and skilled centers report less than half this number. Five donors

have themselves been in need of a liver transplant as a result of donating half of the liver and only one of these five donors was rescued (Ringe et al., 2008). Unfortunately some transplants are done by inexperienced surgeons or by skilled itinerant surgeons in environments which do not have appropriate infrastructure for pre- and post- operative care. Sometimes the fate of the donor is not known to the surgeons who have operated, for example when a patient develops delayed infection, or pulmonary embolism after the surgeon has flown home.

There is little doubt in the minds of most citizens that donation of a kidney or a quarter of a liver to a close family member can be justified, providing the operation is performed by skilled surgeons in institutions with an appropriate infrastructure. This was highlighted in the first identical twin transplant between minors, where the Massachusetts Supreme Court ruled that the operation should proceed; otherwise the potential donor would be denied the opportunity to help a twin and would feel guilty subsequently when the sick twin died. For parent-to-child or adult-to-adult kidney transplantation, again the procedure is acceptable provided there is a good chance of success and the recipient is not suffering from some serious co-morbid disease, e.g. cancer or heart failure. For liver transplantation the situation is less easy to explain, especially if an adult-to-adult transplantation is proposed; and even more so, if the recipient suffers from hepatitis C or cancer which may recur in the graft and the hepatitis C virus may well lead to progressive liver failure.

The limitations of the value of data from questionnaire-alone studies are well known. The change in perception over a period of time was illustrated in the following personal case study. A 5 year old child needed a liver transplant. For medical reasons the

parents were not suitable as donors and the siblings were too young to be donors. A large extended family was aware of the child's predicament and an unmarried female second cousin volunteered to be a donor. She was very positive despite frequent discussions with doctors and coordinators explaining risks, she was determined to try to save the life of her second cousin.

The operation went well. Eighteen months later, the recipient was fully recovered and had normal liver function, but I was distressed to receive a letter from the donor's father who was angry and stated that his daughter's quality of life had been severely impaired as a result of organ donation. In addition to the pain and worry of the operation, she suffered severe hiccups whenever she ate and was frightened to go out and socialize. The letter went on to say that although the recipient had greatly benefited from the operation, the donor's life and his daughter's malaise forced him to conclude that, from the point of view of his own close family, the liver transplant had been a failure.

It is possible that the perception of the donor may change, for the better or worse, over the next few years depending upon symptoms and the long-term outcome of the recipient.

2.5 Definition of Quality of Life

In Japan, the most universal definition of QOL is based on that of the World Health Organization which is "A state of complete physical, mental, and social well-being not merely the absence of disease"(WHO, 1997). There are many definitions of QOL in the medical and nursing literature. For instance, Calman views QOL and "the gap between the patient's expectations and achievements"(Calman, 1984). Therefore, the smaller the gap, the higher the QOL is projected. Testa and Simonson described QOL as

"the physical, psychological, and social domains of health, seen as distinct areas that are influenced by a person's experiences, beliefs, expectations, and perceptions" (Testa & Simonson, 1996). Schipper and colleagues defined QOL as "the functional effect of an illness and its consequent therapy upon a patient as perceived by the patient" (Schipper, 1983). Their depiction includes a description of 4 dimensions of QOL: physical and occupational function, psychological state, social interaction, and somatic sensation.

2.6 QOL studies in Living Donors

The method of living liver donation was first developed as a life saving procedure available for children by providing living liver donations from their parents. In recent years, a remarkable increase in adult living donor liver transplantation is recorded. More adults now receive living donor transplants in Japan than children (The Japanese Liver Transplantation Society, 2005).

Research studies focusing on living donors began to increase after the numbers of living donor transplantation started to increase around 2000. In 2001, Trotter reported the result of a survey of living donors to determine the effect of right hepatic lobe donation on quality of life using the SF-36®. Major complications occurred in 16 % of patients, and minor complications in another 16% of patients. Seventy five percent of patients answered that they recovered fully at a mean time of 3.4 months (Trotter et al., 2001). Beaver and colleagues (2001) studied living donors using a questionnaire and the SF-12®. They reported complications requiring readmission in 22% of their respondents with a mean recovery time of 3 months. They then reported no significant change in the SF-12® scores. Kim-Schluger (2002) also measured QOL of living donors using the SF-36® and found that donors whose recipients had major complications scored significantly

lower on the mental health scale than those with recipients without major complications. Walter (2002) studied patients from a psychosomatic perspective and found that 26 % of donors showed high scores for tiredness, fatigue, and limb pain following donation. However, post-operative complications appeared to have no influence on these psychosomatic outcomes.

An explanation for the percentage of complications being slightly higher in the Walter study versus the Trotter study may be due to the use by Walter of a broader definition of complications. Walter used a broader Clavein classification of complications which has been used for QOL after liver resection and liver donation (Erim, 2006).

While research describes the difficulties of living donor liver transplantation in Japan, little is known about quality of life and other outcomes after living donor liver transplants in Japan. A phase 1 study was undertaken to measure quality of life and health status in living donors in Japan immediately after, and up to 6 years after the surgery. Living donors were excluded from the phase 1 study if the recipient had died (Beavers et al., 2001). This introduced a bias that will be addressed in the definitive study.

2.7 Phase 1 Study: QOL Research in 2002

In 2002, QOL was studied in a sample of living donors after surgery (Soeda, 2004). The purpose of the phase 1 study was to describe the QOL perceived by living liver donors and their physical, social, and emotional recovery after having donated an organ. By assessing their perception of their QOL and evaluation of their physical, social, and emotional recovery after an organ donating operation, it was projected that transplant teams will be better able to help patients improve their QOL

Research Questions

The research questions addressed in this phase 1 study were as follows:

1. What is the self perception of quality of life of the living donor as measured by the SF-36® QOL assessment tool?
2. Does this perception differ from the perceptions of QOL when compared with the data of the healthy control group, a group of healthy people in Japan who were given a general population survey of Japanese version of SF-36®?

Operational Definitions

Living donor. An individual who donated a portion of her/his liver for the purpose of LDLT in Keio University Hospital. The living donor had been within 6th degree of relationship and 3rd degree of unrelated relatives to their recipients (The Japanese Liver Transplantation Society, 2004). All living donors gave voluntary informed consent after meeting with surgeons and a psychologist.

Living donor liver transplantation (LDLT). An operative procedure that a portion of liver was transplanted to a recipient who was in a life-threatening condition with end-stage liver cirrhosis, fulminant disease, or congenital disorders of metabolism (Tanaka & Yamada, 2005)

Short Form 36 ® (SF-36®). A quality of life assessment tool which was licensed by the Medical Outcomes Trust (MOT), Health Assessment Lab (HAL), and QualityMetric Incorporated. Its Japanese version was introduced via iHope, International in Japan. The SF-36® was designed for use in clinical practice and research, health

policy evaluations, and general population surveys. The SF-36® includes multi-item scale that assessed eight health concepts: 1) limitation in physical activities because of health problems; 2) limitations in social activities because of physical or emotional problems; 3) limitations in usual role activities because of physical health problems; 4) bodily pain; 5) general mental health (psychological distress and well-being); 6) limitations in usual role activities because of emotional problems; 7) vitality (energy and fatigue); and 8) general health perceptions (Fukuhara et al., 2002; Fukuhara & Suzukamo, 2004).

Quality of Life. “A state of complete physical, mental, and social well-being not merely the absence of disease”(WHO, 1997). For this study QOL was measured by Japanese version of SF-36®.

Healthy Control Group. A group of healthy people in Japan who were given a general population survey of Japanese version of SF-36®.

Assumptions

- 2.7.1.1 The self report of QOL by competent patients and healthy individuals was valid.
- 2.7.1.2 Valid QOL data were required for the development of appropriate nursing interventions and for the ethical decision making for living donor candidates.

Limitations

1. The subjects consisted of patients who were being followed at one of the metropolitan university hospitals in Tokyo, Japan. Because there was a limited number of LDLT, the number of cases in the convenience

sample was small. Therefore the result of this study must be interpreted with statistical caution.

2. The control group was a Japanese Norm Group reported from the group who developed the Japanese version of SF-36®.
3. Unless there were a 100% response rate, there was the potential of non-respondent bias.
4. The condition of their recipients tended to bias the result of their perception of QOL.

Methodology

Procedure. The donor evaluation protocol followed at Keio University Hospital was approved by their ethics committee in 1995. Potential donors were between 20 and 60 years old within 6th degree related or 3rd degree unrelated to the recipient. A transplant surgeon first described the evaluation process, surgery, postoperative care, and possible complications, including death. A review of the program and the literature regarding the morbidity and mortality associated with living donation was discussed with potential donors during an initial meeting concerning living donation. Most patients and potential donors requested further information after this meeting. They wanted to know more about the possibility of death.

A donor surgeon then conducted a stepwise assessment of medical and psychological suitability. Potential coercion by the medical team or family members and inappropriate motivation by guilt or unrealistic expectations were explored. A psychiatrist assessed stress and family support as well as the competency of the donor to give informed consent. The possibility of death or serious medical complications

occurring in either the donor or recipient and the possibility that the operation may not be completed if counter indications were found prior to the surgery.

A transplant team met weekly to review each potential donor/recipient pair. An independent committee not connected with the transplant team, such as pediatrician and hepatologist, also met regarding each case. This independent committee then conducted an additional stepwise assessment of medical and psychosocial suitability. Potential coercion by the medical team or family members and inappropriate motivation by guilt or unrealistic expectations were again explored.

After the independent committee reviewed and approved each case, the committee's decision was discussed with both the recipient and donor. Then, both recipient and donor signed informed consent forms. At this time, the transplant team made sure that their decision was kept confidential but both recipient and donor understood that they could change their minds before surgery.

Sample. Between April 1st 1995 and December 31st 2001, 46 living donors were enrolled in the study. Six donors whose recipient died after the transplantation were excluded from the study.

Survey Methods. The chief of both adult and pediatric transplant teams called each transplant recipient to explain the purpose of the phase 1 study. The donor was most often a parent, sibling, or child therefore doctors asked the recipients to explain the research to their donors. Other donors were contacted by the research team. All recipients understood the reason and purpose of this research and they agreed to explain to their donor who then agreed to participate. Verbal consent was given to the transplant surgeon, the researcher did not ask for written informed consent. Then, questionnaires were sent by mail post-

operatively and consisted of 30-questions written by the transplant team (appendix A) and a standard SF-36® questionnaire (appendix B). The questionnaires assessed the self-perceptions of the donors' health after the donation, social support during the donating process, and the donor's thoughts about organ donation in general.

Because there was a question regarding their sexual relationship and for other reasons of confidentiality, the researcher explained in the letter that donors did not need to write their names on the questionnaire. The letter explained that the mailed questionnaires would be returned to a person who was not part of the transplant team. However, the researcher provided a place to write their names on the questionnaire if they wished and most of the donors included their name. All questionnaires were mailed back with researcher-provided envelopes which had different identifying stamps by which the research team was able to identify each participant. The researcher was able to match the questionnaire with each donor.

The SF-36® questionnaire is a validated survey that measures general health-related quality of life. It measures eight domains of physical and mental function. Numerical scores assigned to each category are used to generate composite scores: physical components score (PCS) and mental components score (MCS). The general population of the Japanese has average PCS and MCS scores of 50 with a standard deviation of 10.

Results. The letters (appendix C) and the questionnaires were sent to 46 living donors post-surgery. Forty one donors (average years after the surgery 2.4 years, median 1 year) responded by mailing the questionnaires back to the researcher for a response rate of 89.1%. All respondents were Japanese, approximately half were male (n=20) and half

female (n=21). Mean donor age was 38.7 years (range 22-65 years). More than half of the donors worked full-time or part-time prior to surgery (n= 25, 61.0%). Twenty two donors were parents of pediatric patients and 19 were spouses or siblings of adult patients.

There were no deaths in the donor population. Major complications were seen in 7 patients for a total complication rate of 17.0%. Complications included bile leak (n=5) and paralytic ileus (n=2) (Table 4). These complications were treated without any invasive procedure within 1 year postoperatively.

Table 4. Major Complications

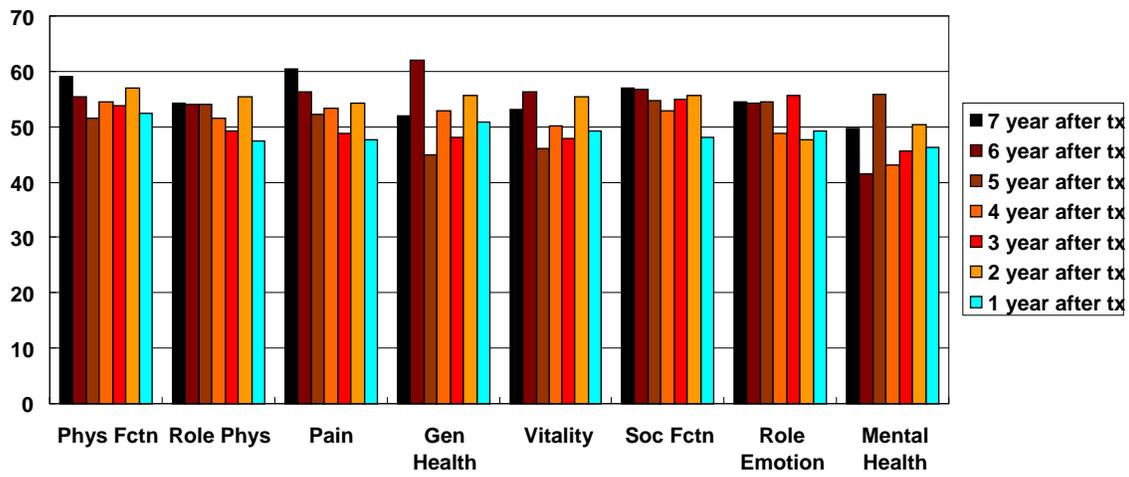
Graft (n)	<i>Right (12)</i>	<i>Left (24)</i>	<i>Left Lateral (20)</i>
Biliary leakage	1	3	1
Bowel Obstruction	0	0	2
Delay GI passage	0	3	3

The majority of donors (69.0%) said they completely recuperated from the operation, while 32% said they did not. Interestingly, 5.0% said they felt better than before the operation, because they had stopped drinking alcohol and smoking in order to be a suitable donor. The majority of donors (76.0) complained of some minor complication such as abdominal discomfort, numbness, and/or fatigue, although no donors had any limitation to their activities of daily living. On average, donors reported that they felt fully recovered 17.3 (\pm 11.4) weeks after the operation, and they returned to work after 8.1 (\pm 7.8) weeks. Half the donors (53.0 %) suffered from adverse financial affects due to the LDLX, 50% of whom were unable to have a paid vacation.

The majority of donors said they were willing to donate their organs should they become brain dead and 34% had already signed a donor card. Concerning their decision to donate, all donors signed informed consent forms twice, before starting the donor evaluation and before the donor operation, ten donors (24.4%) said they felt pressure to be a donor by the medical staff and thirteen (31.7%) said they felt pressure to be a donor by their recipient or family members. They reported that when they thought back on the situation, only 5% said they would have preferred the recipient to have had a brain dead donor, while 76% said they had never thought of the matter. Overall, 88% the donors were satisfied with the donation, 12.0% were not sure whether they were satisfied or not, but none said they were dissatisfied.

Figure 2 shows the mean values for the SF-36® numerical scores comparable to the Japanese general population. The mean scores of donors who were surveyed within a year after the surgery scored lower than those of donors followed for longer periods and the general Japanese population. Also, the scores of mental health of most donors were lower than the Japanese general population. Interestingly, scores on some areas of the SF-36® were higher than the Japanese general population, such as “general health” 6 years after.

Figure 3. Result of cross-sectional SF-36® score



2.8 Summary of Research Gaps

The phase 1 study demonstrated that living donors in Japan scored lower on the SF-36® than their controls when measured within a year after their surgery. Donors who were more than two years post surgery had higher scores meaning their health status and QOL was better than those within a year after surgery. Because Japan is a country which depends mainly on living donor transplantation, it is important to study the outcome measures for living donors after surgery. No research has been conducted longitudinally post-surgery. As the demand of living donor transplantation increases, there is a great need for QOL and health status studies in this population. The purpose of this dissertation research is to look at the longer term effects of living donor transplantation on quality of life and health status.

CHAPTER 3

METHODOLOGY

3.1 Introduction

The methodology chapter explains the design of the study, the setting, and the sample. Also included is a description of the data collection instruments. The procedure for data collection, protection of human subjects, and the data analysis can also be found in this chapter.

3.2 Design of the Study

This investigation is a non-experimental longitudinal, descriptive study to determine the health-related quality of life of living donors in Japan. Quality of life was measured using the SF-36® (appendix B). Detailed information regarding each living donor was measured by a researcher designed questionnaire for phase 2 (appendix C). The data obtained from living donors was compared to the profile of the general Japanese population. Then, the aggregate data at time 2 (phase 2) was compared to the aggregate data at time 1 (phase 1) study.

3.3 Setting

The site for this study was a teaching hospital which has a living liver transplantation program in Tokyo, Japan. In this organization, the management of medical care involves all major departments and specialty areas, and the continuation of a medical and nursing education program. A commitment to thorough medical management is emphasized by the identification of the hospital as a specific center of

excellence, especially as an organ transplant center. With highly trained specialists, advanced equipment, research, graduate resident and inter/national fellowship programs, and nurses and physician practice and involvement these organizations have continued to deliver a high quality of care to all. The coordinator is closely involved in all aspects of the procedures for organ transplantation from the initial assessment of donor and recipient and their families through the operations and the early and late follow up.

3.4 Sample

Living donors of the phase 1 study [n=41] were invited to participate in this second study. Since the death of the recipient clearly represents a significant emotional trauma to the donor, in this study living donors whose recipient died were also invited to participate [n=6]. Therefore, the total number who were invited to participate in this study was 52 [n=52]. The participation of these subjects was strictly on a voluntary basis.

3.5 Data Collection Instrument

Two instruments were used to collect data for this study, the SF-36® and the researcher designed questionnaire for phase 2.

The SF-36® was developed to survey health status in the Medical Outcomes Study in the United States (Fukuhara & Suzukamo, 2004). The test was developed in an attempt “to develop a general health survey that is comprehensive and psychometrically sound, yet short enough to be practical for use in large-scale studies of patients in practice settings” (Fukuhara & Suzuka, 2001). The SF-36® includes one multi-item scale that assesses eight health concepts: (1) limitation of physical activities (physical functioning) due to health problems (i.e., effects on daily activities such as pulling a table, lifting

groceries, climbing stairs, walking a couple of blocks); (2) limitation of social activities (social functioning) due to physical or emotional problems (i.e., effects on social activities such as visiting friends and relatives); (3) limitation of usual role activities due to physical health problems (i.e., effects of physical health issues on working hours or daily activities); (4) bodily pain, namely, assessment of pain severity and how pain affects ability to work; (5) general mental health in terms of psychological distress and well-being (i.e., levels of anger, sadness, happiness); (6) limitation of usual role activities due to emotional problems (i.e., effects of emotional issues, such as depression or anxiety, on work or daily activities); (7) vitality (i.e., questions about the subject's assessment of his/her levels of energy, tiredness); and (8) general health perceptions (how the subject feels about his/her own health).

The SF-36® was developed by Ware and Sherhorne in 1992 and was adapted for the Japanese population by Fukuhara and Suzuka (2001; Fukuhara & Suzukamo, 2004). This tool had become one of the most popular QOL evaluation tools in Japan.

The researcher developed questionnaire for phase 2 includes 17 questions about general information, physical recovery, social activity, and thoughts about their decision making in regards to living donor liver transplantation (Appendix C). The purpose of the use of a questionnaire was to elicit the responses from living donors in regards to their experience of live organ donation. Using the researcher developed questionnaire provided the opportunity for study subjects to express additional information about their physical recovery, social activity after live donation, and thoughts about living donation in addition to the items of the SF-36®.

3.6 Procedure for Data Collection

The researcher mailed a letter to living donors to inform them about the study ahead of time. Two weeks later, the researcher mailed informed consent forms and two questionnaires, SF-36® and researcher made questionnaire, with a self-addressed stamped envelope for return.

3.7 Procedure for Protection of Human Subjects

The researcher obtained Institutional Review Board (IRB) approval from both Duquesne University and Keio University. Ethical considerations, such as the privacy, dignity, and comfort of the living donors were addressed at all times during the study. The living donors were informed of their rights and asked to read the consent form. All questions were answered by the researcher. The study subjects were advised that they were free to withdraw from the study at any time. The benefits of the study, such as improving the care for living donors, were explained to the living donors. In addition, there are no known risks for participating in the study. All study data are stored in the researcher's locked drawer under supervision of the university. Data will be properly destroyed at the completion of the study and dissemination of the results.

3.8 Procedure for Data Analysis

The data were analyzed using the Statistical Package for Social Sciences, version 14.0 J. (SPSS, Chicago, IL). For descriptive analysis, data are expressed as mean values, median, and standard deviation. A comparison with the phase 1 study for the SF-36® was conducted through t-test. For all tests, a significance level of $p < 0.05$ was set.

CHAPTER 4

RESULTS

4.1 Introduction

The purpose of this study was to collect data which would describe the QOL of the living donors who participated in the phase one study in 2001. The total sample of this study consisted of 36 living donors. There were 52 eligible participants for this study. Of those participants, three questionnaires were returned “undeliverable,” making the possible participants 49, thus making the response rate of 36 participants, 73.5% of potential participants.

4.2 Description of the Sample

Thirty six donors (years after the surgery average 10.1 years, median 11 years) responded to the researcher’s request to participate in the study. All respondents were Japanese, approximately half were male (n=15) and half female (n=21). Mean donor age was 50.2 years (range 34-74 years). More than half of the donors worked full-time or part-time prior to surgery (n= 25, 69.4%) and a similar proportion of the donors are currently working full-time or part-time (n=28, 77.7%). Twenty three donors were parents of pediatric patients and 13 were spouses or siblings of adult patients. The recipients from five donors (13.9 %) died after the surgery. Of these five cases, three recipients died within three months and two recipients died several years after the surgery.

Table 5. Description of the sample (Phase 1 and Phase 2)

	<i>Phase 1 (n=41)</i>		<i>Phase 2 (n=36)</i>	
Mean age	38.7 years (range 22-65 year old)		50.2 years (range 34-74 year old)	
Mean years after the surgery	2.4 years		10.1 years	
Sex	male	20	male	15
	female	21	female	21
Relationship to a recipient	parent	22	parent	23
	souse/siblings	19	souse/siblings	13
Ethnicity	Japanese	41	Japanese	36

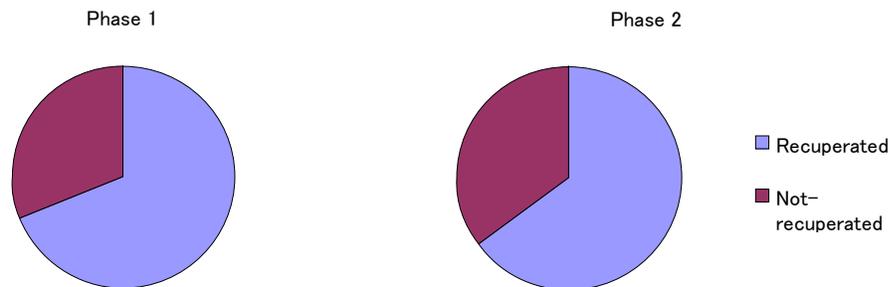
4.3 Results

The Researcher Designed Questionnaire for The Phase 2

About health conditions. The majority of donors (61.1%) said they completely recuperated from the operation, while 12 donors (33.3%) said they still had symptoms (Figure 4). Interestingly, two donors said they felt better than before the operation. These two donors did not report feeling better than before the surgery when asked in the phase 1 study. Especially, one donor had a difficult time and her QOL score was lower than the Japanese general population after the surgery in the phase 1 study, but she answered that she reported feeling better than before in the phase 2. Also, she answered open-ended question, “How do you feel better than before”, as “I started running in order to recover from the donor surgery, and I have got back my strength to complete 100 km (=62.5 miles) marathon. The average period for donors to feel that they recovered from the

operation was 11.5 (± 14.5) months, complaining of some limitation of daily activity for an average of 11.7 months (± 11.4). Thirty six percent of donors felt they recuperated quicker than they expected, 33.3% said they recuperated as they expected, and 30.6 % said they recovered more slowly than they expected.

Figure 4. Post-operative recuperation



Of the 12 donors who said they had not recuperated well, eight said they recuperated more than 75% of their wellness, two 50~75%, and one 25~50%. The one who answered that she recuperated 25~50% did not state the reason why she felt that way, but she was the one who developed breast cancer after donor surgery. Those two who answered that they recuperated 50~75% stated their reasons as “Fatigue” and “Diarrhea.” One said that he had been having diarrhea after every meal without exception. The eight donors who recuperated more than 75% stated their reason as, “Scar”, “Fatigue”, “Psychiatric disorder”, and “Abdominal hernia.”

When they were asked whether they had any limitation when doing physical activities, such as playing golf, swimming, business trip, working for long time, and traveling, 32 donors (88.9%) answered that they used to have some limitation but no limitation now, and the average length they had limitations was 11.7 (± 14.5) months after the surgery. Four (11.1%) donors answered that they still had some limitations. Of

those 4 donors, two said that they had limitation when they went swimming. Because they had a big scar on their abdomen, they still hesitate to go to public pools and the sea. One donor said that he had a limitation because he had back pain. The other one did not answer the question.

In terms of minor complications, more than half of the donors (n=20, 55.6%) suffered from pain for the average length of 7.5 months and 2 of them still had pain. One was 10 years after and the other was 12 years after the surgery. More than half the donors (n=24, 66.7%) complained of abdominal discomfort for the average length of 3.8 months and 12 donors still had abdominal discomfort. The longest time after the surgery was a man 13 years after the surgery and the average time post surgery for most patients was 8 years. Many donors (n=23, 63.9%) still had scar numbness for the average length of 10.4 months. Eleven donors (30.6%) lost their appetite for the average length of 7.2 months, but only one donor, a female donor who suffered breast cancer with chemo therapy still lost her appetite. Fourteen donors (39.9%) complained of distended stomach after meal for the average length of 8.0 months and 9 donors still complained of this. Fourteen donors (39.9%) had fatigue for the average length of 12 months and 7 still had fatigue. Only 5 donors (13.9 %) had diarrhea and four donors still had diarrhea. Two donors had constipation and one of those two donors also had diarrhea. Five donors (13.9 %) had back pain and four donors still had back pain. Seven donors (19.4%) had sleeping difficulty for the average length of 15 months and one donor still had it. Of these seven donors four were the donors who lost their recipient. Four donors reported their other symptoms as “Oily meal sits heavy on the stomach”, “When I go for annual health check, a doctor always says that the shape of my stomach is strange”, “I cannot sleep on my side

and I only can sleep on my back”, and “My right abdominal muscle get cramps in the winter.” In particular, the lady who said her abdominal muscle got cramped was the lady who participated in the 100km marathon.

Table 6. Minor Complications

	<i>Phase 1 (n=41)</i>	<i>Phase 2 (n=36)</i>	
	<i>Had the symptom</i>	<i>Had the symptom</i>	<i>Still have the symptom</i>
Scar pain	24	20	2
Abdominal discomfort	31	24	12
Scar numbness	29	23	23
Loss of appetite	16	11	1
Distended stomach after meal	23	14	9
Easy to get tired	2	5	5
Diarrhea	3	2	2
Constipation	4	5	1
Back pain	4	7	1
Difficulty sleeping			

On the other hand, the majority of donors (n=31, 86.1%) answered that they felt their health condition was the same as others in their general population. Then, five donors (13.9%) answered that they felt their health condition was not the same as others in their general population. Of these five donors, two donors stated the reason that related to the donor surgery, was “fatigue” and “abdominal pain with distention.” Another two donors stated the reason that did not relate to the donor surgery, was “overweight” and

“chemotherapy for breast cancer.” One donor stated both reasons “fatigue” and “sprain of cervical and lumbar vertebrae by automobile accident.” Of these five donors two donors lost their recipients after the transplant.

There were no deaths in the donor population, although nine donors were admitted to hospital. Each donor was admitted for a different reason and everybody was treated (Table 6). Five donors required clinical visits after the main donor surgery (Table 6).

Table 7. Admissions and Clinical Visits after the Donor Surgery

<i>Reasons for admission</i>		<i>Years after the surgery</i>	<i>N</i>
1	Autoimmune Hepatitis	12	1
2,3	Plastic surgery of the scar	0,1	2
4	Illus	0	1
5	Lumber Hernia	8	1
6,7	Breast Cancer	4,4	2
8	Testicle Cancer and LFTs↑	5	1
9	Thyroid Gland Cancer	1	1
<i>Reasons for clinical visit</i>		<i>Years after the surgery (n)</i>	<i>N</i>
1	Jaundice and Gastric Ulcer	4	1
2	High serum cholesterol	3	1
3	Panic Syndrome	0	1
4	Abdominal Pain	0	1
5	Diabetes	5	1

Four donors developed cancer, but there were no cases of liver cancer. One donor was admitted to the hospital to treat liver disease and one donor had a clinical visit for an

elevated serum bilirubin. Two donors underwent plastic surgery in order to improve the appearance of their abdominal scars. One donor had a psychiatric disorder immediately after surgery. He reported that he had a panic disorder after he returned to his work, because he had to be absent from work for a month and had a hard time catching up in his job. He said that he had this for several months.

Social Life after the Surgery. Before the surgery, half of the donors (n=18, 50.0%) were working full-time, seven (19.4%) part-time, nine (25%) were house wives, one was a student, one marked *other*. After the surgery, about half of the donors (n=19, 52.8%) were working full-time, nine (25%) part-time, six (16.7%) were house wives, no student, and two marked *other*.

Sixteen donors (44.4%) changed their social activity. There were five donors who used to work full-time, then one retired because of his age, one resigned because of mothering, and three changed to part-time. Of these three donors who gave up working full-time, all were donors who lost their recipients. One lost her baby from fulminant hepatitis and she had a hard time, then she gave up working full-time. One lost her husband several years after the transplant and she developed breast cancer after that, then she gave up working full-time. The last one lost her husband soon after the transplant and there is no further information about this donor. On the other hand, there were six donors who started working full-time. These six donors' recipients recovered well after the transplant and the donor started working because: four donors were relieved from the burden of care giving, one donor had to work after divorce, and one donor graduated from school.

In terms of return to their social activity, the majority (n=26, 72.2 %) said that the hospitalization did not effect their life in the long term. Two donors said that they changed their working place and four changed their job itself. Of these 6 donors, four said that they lost their income for several years and could not do house keeping for several years. One donor quit his job completely and one donor reported that he could not work overtime and he went to his bed immediately after his work. Two donors said that the siblings of their recipient were infants, “I made him/her lonesome during my donor operation” and that still affects them. One donor said that he lost income for a several months and the other donor said that she could not do housekeeping for a several months.

Thoughts about Organ Donation. Concerning their reflections on organ transplantation, the majority of donors (n=32, 88.9%) were satisfied that s/he was a live-donor, but one was not satisfied and three found it hard to say *yes* or *no*. Also, the majority of donors (n=24, 66.7%) did not wish that there would have been a cadaveric donor at the time of transplantation. However, twelve (33.3%) donors said either *wished strongly* or a *little*, that a cadaveric donor was available at the time so that they would not have been called upon to donate their liver. When asked “if you were back to the same situation, would you be willing to be a donor again?” the majority of donors (n=25, 69.4%) answered *yes*, six donors (13.9%) *no* and for five donors, it was hard to say *yes* or *no*.

The majority of donors (n=25, 69.4%) said that their mental activities are better and two said they are worse. Of these two, one donor lost her baby girl after the surgery and the other donor worked under stress. All donors reported that they maintain a *good* or the *same relationship* with their recipients, while two donors said that they had *worse*

relationship with others. Almost all donors had good or the same relationship with other family members, relatives and friends, but only two donors said their relationship got worse and there were no further information about it. No donors reported having difficulties in their sexual life and one donor gave birth to a baby after the surgery. There was only one donor who had a baby after the surgery.

Concerning organ donation, the majority of donors (n=24, 66.7%) thought that the number of deceased organ donor transplant operations should be increased. Twenty seven donors (75.0%) said that they will be “willing to be a donor” but less than half donors (n=15, 41%) had signed a donor card. When they were asked, “If your family member should become brain dead and asked you to donate an organ, would you be willing to donate an organ?”, twenty donors (55.6 %) said “yes,” two said “no,” and there were many donors (n=14, 38.8%) who said “*hard to say yes or no.*”

SF-36®

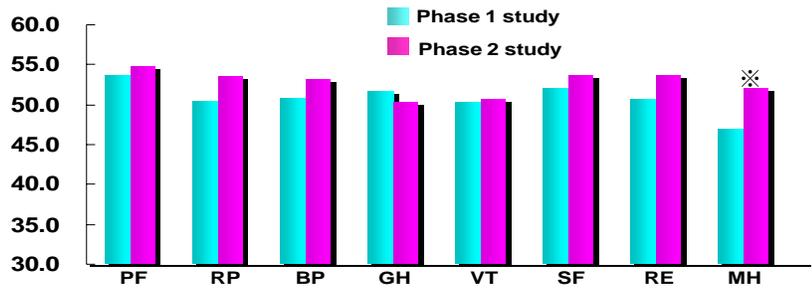
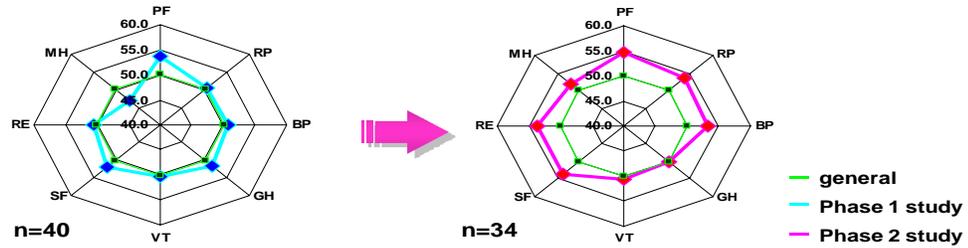
All subjects. Figure 5 shows the change of SF-36® score of all subjects comparable to the Japanese general population from the phase 1 to phase 2. All eight subscales, physical functioning, role emotion, role physics, bodily pain, general health, vitality, social functioning, mental health, were better than the Japanese general population, and there was a significant improvement of mental health. Only the phase 2 score of general health was slightly lower than the phase 1 study but the changes in scores were not significant. Only mental health went up ($p<0.05$).

Focused group. For the phase 1 study, the donors who were within a year after the surgery scored lower than those of donors followed up for longer periods and lower than the Japanese general population. For the phase 2 study, those who scored lower were

focused to measure changes over seven years. Figure 6 shows that those focused patients scores improved significantly over the seven year period.

Figure 5. SF-36® scores (Phase 1 vs. Phase 2)

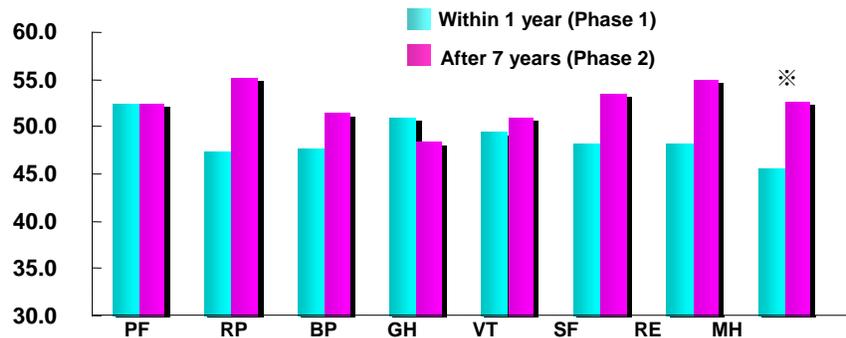
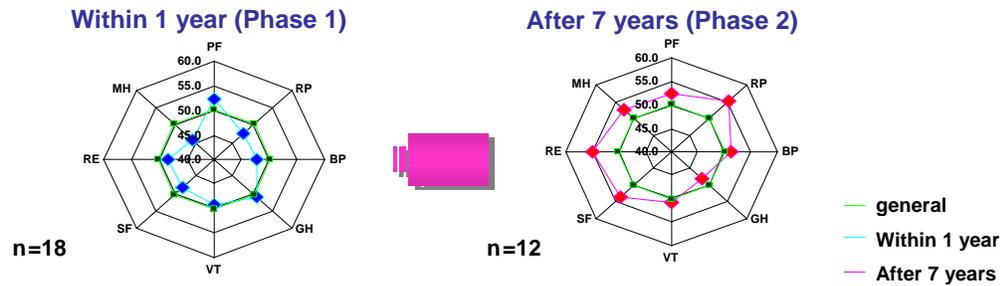
Phase 1 vs Phase 2 (All subjects)



※Significant <0.05

Figure 6. SF-36® (Focused Group)

Focused group



※Significant <0.05

For this phase 2 study, five donors whose recipient died responded. Of these five donors, there were two donors who showed low scores, one who suffered recurrent breast cancer and the one who still cannot come to terms with the loss of her child and these lowered the average scores of the phase 2 study.

Anecdotal Note

There were four donors whose recipients died of which three returned their questionnaires adding a note to the researcher.

The first donor was the mother who lost her baby after the surgery. Her baby girl was sent to this transplant hospital on Christmas day because of fulminant hepatitis, but she recuperated well without receiving a transplant that time. Several months later, she became unconscious again and underwent a transplant. She did not wake up after the

transplant and remained in a vegetative state until she died 6 months later. Meantime, her father started having a relationship with a teacher of kindergarten where this girl used to go. From this mother's point of view, she became a donor, had to take on many new roles and cope with a difficult relationship with her husband. She had a hard time after the surgery. She added a comment to the questionnaire saying that she had no regrets of being a living donor to save her baby; but that she had been experiencing fatigue especially around the anniversary of the donor operation day. She called this an "anniversary syndrome." She divorced her husband, started new job, and a network for sick children. She also published a book based on her transplant story.

The second donor was a wife of a patient who underwent a transplant because of Hepatitis B. When she answered the phase 1 questionnaire, her husband was still alive. She added a comment saying that, "My husband said that he does not need me anymore, because I already gave a portion of my liver. Even if this was a joke, I was hurt." However, she answered that she was satisfied with living organ donation. During the next seven years, she lost her husband from lung cancer and she also developed breast cancer. She added a comment regarding her physical condition and said it was nice to hear from the transplant team. She answered that she was dissatisfied with living organ donation and she would not be a donor again if she were in the same situation.

The third donor was a daughter of a patient (her mother) who underwent a transplant because of fulminant hepatitis. She was in her 20s at that time. Because the onset of fulminant hepatitis was acute and sudden without any medical history, this lady had to make a decision in a short period of time. Unfortunately, her mother died within several days after the transplant. The person who became the angriest was the husband of

the patient who died who was also the father of this donor. He showed his anger to the transplant team and told the transplant doctors to “carry his wife’s coffin to his car.” For this phase 2 study, she wrote about her current life, “Me and my father are doing fine. My first child is now a high school student and the second one is a junior high school student. I remember that they were very small when I faced the donor operation. Without support from my family, I think I would not have been able to donate at that time. After many years, there were updates on the news about living organ transplants. When I heard about donors’ death, I often thought that it could have happened to me. Then, I think I was very selfish at that time, because I was only thinking about myself. One to two years after the surgery I still had pain and discomfort in my back, but I am doing very well now. I think I have to live my own life well because my mother taught me so. Thank you very much for your support.”

4.4 Discussion

Quality of life

This is the first, long-term, quantitative study of living liver donors in Japan. The year of 2000 to 2001 was the time that the main target of living donor liver transplantation shifted from the pediatric to the adult patients. In the phase 1 study which was completed in 2002, the donors within a year after surgery showed low scores on the SF-36® and this may reflect that many donors had a difficult time after the operation because of lack of full understanding and preparations. The shift to adult-to-adult transplantation required a different preparation from the adult-to-pediatric program. Overall, all donors showed improvement seven years after surgery and most feel they were the same when compared to others in the population who were not donors.

Compared to previous QOL research regarding living liver donors, major complications occurred in 17.0% (n=7) of the donors which was nearly the same with Trotter's research (2001) that reported 16%. While Trotter (2001) reported that 75% of donors answered that they recovered fully at a mean time of 3.4 months for this phase 1 study, 69.0 % of donors answered that they fully recovered at a mean time of 2.4 years, and for the phase 2 study, 61.0 % of donors answered that they fully recovered at a mean time of 10.1 years. The main symptoms that these donors had were fatigue, scar numbness, and abdominal discomfort, but those symptoms lessened over the years. However, gastrointestinal symptoms such as diarrhea and constipation did not improve. It is hard to distinguish whether or not the gastrointestinal symptoms were related to the

surgery or to other factors (prior history, age, etc), but these donors reported experiencing these problems.

Beaver and colleagues (2001) reported that there were no significant low QOL scores in their donors but that there were 22% of the donors who were readmitted to the hospital to treat complications. There was less readmission to treat complications for this study. Only two donors had plastic surgery related to the scar and one donor developed autoimmune hepatitis. Beaver and colleagues (2001) also reported that the mean recovery time was 15 weeks and this phase 1 study showed 17.3 weeks, and phase 2 as 11.5 weeks. The mean recovery time was about the same as in previous research.

From a transplant team's view, they work hard for donors to recover from the surgery first and discharge early without surgical complication. Moreover, in order to shorten the length of hospital stay and standardize care for donors, there are many transplant teams use clinical pathway for donor admission. However, from the finding of this study, there were many donors who still suffer symptoms such as scar pain, abdominal discomfort, scar numbness, loss of appetite, distended stomach after each meal, fatigue, diarrhea, constipation, back pain, and difficulty sleeping over seven years after the surgery. Therefore, long-term observation for these donors is necessary.

There were no data of previous health condition of those donors, because only healthy person could be a donor. Therefore, being healthy was a precondition of donor. However, minor pre-operative conditions such as easy to have diarrhea or tend to have "keloid" scar (cramped scar) are not take seriously and those condition will affect to how they perceive their QOL. Gathering all physical information about a donor will be a key

to help each donor to recuperate well after the donation. Therefore, thorough physical examination by coordinators or/and nurses is important.

There are only 31 transplant coordinators employed on transplant teams in Japan (Japanese Transplant Coordinators Organization), and majority of transplant teams do not employ a transplant coordinator. Because transplant surgery itself do not make a big benefit to Japanese hospital and many hospitals can't afford to employ one. However, this research findings showed that many donors have been suffering from symptoms over long time and those might be impacted to their perception of QOL. Therefore, each transplant team should have a transplant coordinator in order to follow up for a long time. Moreover, donors may have difficulty to talk to their doctors and it is much easier and safer for them to provide an easy access to their transplant coordinator.

Decision to donate

Concerning their decision to donate, all donors signed informed consent forms twice, before starting the donor evaluation and before the donor operation. Despite the many safe guards in place to ensure informed consent, many donors did not feel that they had a free choice in donating once they were identified as an acceptable donor. During their preparation in the phase 1 study, ten donors reported that they felt pressure from the medical staff and thirteen felt pressure to donate from their recipients or family members. However, in both studies, most donors (88%) were satisfied with their own decision making process.

Because all donors signed informed consent forms twice, theoretically they made their decision based on their autonomy which was one of the six bioethical standards related to Husted's theory. The only question which assessed their decision making was

“Are you now satisfied that you were a live-donor.” According to Husted’s theory, a patient makes decisions based upon a patient’s trust with the health care professional and patient agreement (Husted and Husted, 2008). Therefore, living donors need to be continually supported by the transplant team and the decisions reassessed throughout the process.

The findings showed improvement of QOL over seven years, but the majority (78%) were still suffering from symptoms. It would be important to inform this finding for future donor candidates with precise but sincere manners. Because giving up living donation will mean that there is no chance of getting organ transplant for the recipient. As a transplant coordinator, to support each donor’s decision making process by providing benefits and risks of live organ donation will be a key issue for the further development of living donor program as well as organ transplantation itself in Japan.

Organ transplantation in Japan

Despite their caveats in relation to living organ donation, the information obtained is of interest and was an attribute to the courage and generosity of the donor patients. Since cadaveric organ donation has played almost no part in liver transplantation in Japan, patients dying of liver disease and suitable for transplantation present to their families, friends and medical and nursing clinicians as tragic cases for whom a major sacrifice of living organ donation is the only possibility that can rescue them.

The generous response in so many cases has been a testimony of humanity but in each case a major stress was thrust upon the patient’s family that previously was unprecedented in medical practice. Those who came forward as potential donors may do so out of altruistic love, but a donor having been selected, the rest of the family members

inevitably have a sense of guilt feeling “perhaps it should have been me”. The medical and nursing staff has a key and difficult task of acting as advocates for the interests and wellbeing of the donors since they are aware of the mortal plight of the recipient.

The outcome in the short- and the long-term can be a dynamic source of stress for the donor and the rest of the family. Donor post-operative morbidity, sometimes serious and prolonged, was not uncommon and donor death is a tragedy of immense proportions that will stay as a lasting traumatic mental assault for the family and health care workers to bear.

Results from this study demonstrate an overall positive and optimistic outlook, but one cannot avoid the conclusion that there is a serious need for cadaveric organ donation to be established in Japan for those in need of kidney, liver and lung grafts and is an essential requirement for those dying of heart disease.

CHAPTER 5

SUMMARY AND RECOMMENDATIONS

5.1 Introduction

The work of this dissertation is summarized and the results indicate recommendations for future QOL studies of living liver donors.

5.2 Summary

In 2009, the Japanese Congress passed a new transplant law in 2010 which permits organ procurement from children and allows organ donation without written consent by a donor. Moreover, the most distinguished society in the field of transplantation called the Transplant Society will present their “Istanbul Declaration” (“Organ trafficking and transplant tourism and commercialism: the Declaration of Istanbul,” 2008) which stresses the need for organ self sufficiency for each country to the World Health Organization (WHO) and the WHO will recommend this declaration worldwide. This means Japan will have to stop sending patients abroad in order to receive organ transplants and we have to promote organ donation in Japan and develop our hospitals to increase organ donation.

From this study, most of the live liver donors recuperated well over the long-term, but many continue to have minor complications and some lost their income or changed their job after their surgery. Most donors were satisfied to have been a donor for their loved one, but some donors still have complicated feelings about the procedure. No donor developed liver cancer over the years of study, but some suffered from cancer elsewhere

which is similar in distribution to the general population. Because seven years had passed after the phase 1 study, some donors were in their seventies, but most answered that they feel as well as most people of their age group. It is difficult to measure the QOL, but this kind of answer suggests that living donation can be a good choice.

A surprising result is that many donors still have complications (although minor ones) seven years after their operation. Moreover, they discontinued seeing their doctors over the long term. The reasons for discontinuing follow up care must be examined. Future donors must be apprised of the possibility minor complications over the long term and must be encouraged to continue follow up care. Donors should be encouraged also to inform the transplant team of their minor complications following surgery.

To rescue patients with organ failure, new techniques such as artificial organs and regenerative medicine are being developed by many scientists worldwide. For instance, Yamanaka reported transforming skin cells to primitive cells similar to embryonic stem cells, called “induced pluripotent” stem cells (Yamanaka, 2007). This removes the ethical worries of working with embryonic stem cells. Also, in 2008 a collaborative group of English and Spanish workers reported a trachea transplantation which required both transplant and regenerative medical knowledge and techniques (Macchiarini et al., 2008). It is very difficult to make an artificial liver, because the liver has so many functions and a complicated anatomy. However, a portable artificial kidney in the development stage weights only 2 pounds (AWAK, 2009).

Japan is a country which is behind other developed countries in the field of organ transplantation. However, there is a hope that we will develop efficient transplant

programs combined with new technologies, and, if so, there will be a need for nurses to explain this developing medical practice to our patients.

5.3 Recommendations

The aim of this study was to investigate the QOL of live liver donors over the long-term. The study showed improvement of their QOL using one of the standardized questionnaires, SF-36®. Standardized surveys tend to lack both the specificity and the sensitivity necessary for capturing all of the particular QOL issues that some donors may have. Also, the technique of comparing the scores of donors versus the general population on such standardized questionnaires may be misleading as donors have already been selected for good health and psychological stability, an essential requirement for donation.

Future Research

For future research, the qualitative method of in-depth individual interviews will allow for the exploration of the complex and often sensitive issues involved in quality of life assessment. Issues such as relationship with their recipients, marital tension, financial difficulties, problems with other family members, and the donor's own sense of physical, social and emotional well-being, can be expressed in full as rapport is built during the course of an in-depth interview. All of the donors were determined to be in excellent health prior to donating.

To measure the impact of living donation for donors, a prospective study should be conducted with the purpose of following the participants closely over time.

Participants could be studied from the time they enter the transplant system and for years after the donation in a well designed study.

Limitations

This researcher has attempted to analyze the post-operative fate of living liver donors at one year and then beyond seven years. Of the donors operated on at the Keio University Hospital, all those eligible for this study were sent a voluntary questionnaire covering physical, social, and emotional recovery at one and seven years.

Problems related to retrospective analyses are well recognized, namely:

1. It is unusual to obtain 100% response rate to a questionnaire investigation. In this study, 46 donors were approached in the phase 1 study, 41 (89.1%) responded. In the phase 2 study, from 49 questionnaires sent 36 (73.4%) replied.
2. Risk of bias of poor outcome in non responders.

Having made the sacrifice of submitting to a major surgical procedure there may be reluctance on the part of the donor to admit their weakened health status. It will be important to query the donor regarding their feelings regarding their choice to be a donor with respect to the outcome of the recipient.

Also, this study was based on a single-center with a small sample size, thus limiting the general application of the results. Therefore, caution is necessary in applying the results to the general population of live donors.

APPENDIX A

Questionnaire for living-liver donors (Phase 1)

I. First, tell us about yourself.

1. Gender: male
 female
2. Age at the transplant 20s
 30s
 40s
 50s
 60s
3. Year of the operation: ____.
4. The recipient of your liver
 child
 parent
 sibling
 spouse

II. Tell us about your health condition

1. Compare your past health condition, how do you feel now?
 I feel my health condition is better than before the operation
→ answer 1) 2) then go to 2.
 I recuperated perfectly well. I feel the same as I did before the operation.
→ answer 2), then go to 2.
 I have not recuperated well completely. → answer 3), then go to 2.
- 1) How do you feel better than before? _____.
- 2) How long did it take to fully recuperate?
About ____ mo. _ week after the operation.

3) If you have not recuperated well, how much do you feel you recuperated so far.

- < 25%
- 25~50%
- 50~75%
- ↑75%

Why do you feel you have not recuperated well? What makes you feel in that way?

2. Today, do you have any limitation when doing physical activities, such as playing golf, swimming, business trip, working for long time, traveling?

- I have limitations →answer 1), then go 3.
- I do not have any limitation →answer 2), then go 3.

1) Please tell us about your limitation.

2) Today, you do not have any limitation, but how long did you have limitations after the operation. About ___mo. _week after the operation.

3. Before the operation, how long did you assume the length of full recuperation would take?

About ___mo. _week after the operation.

4. Did you recuperate as the same pace as you assumed?

- I recuperated faster than I assumed.
- I recuperated as the same pace that I assumed.
- I recuperated slower than I assumed.

5. Did you have any symptoms after the discharge? If yes, please note for how long you have had that symptom. Circle "Still have it" if you still have that symptom.

- Scar pain About ___mo. week after the operation / Still have it.
- Abdominal discomfort
About ___mo. week after the operation / Still have it.
- Scar numbness About ___mo. week after the operation / Still have it.

- () Loss of appetite About__mo. week after the operation / Still have it.
 - () Distended stomach after meal
About__mo. week after the operation / Still have it.
 - () Easy to get tired (weakness)
About__mo. week after the operation / Still have it.
 - () Diarrhea About__mo. week after the operation / Still have it.
 - () Constipation About__mo. week after the operation / Still have it.
 - () Back pain About__mo. week after the operation / Still have it.
 - () Difficulty sleeping
About__mo. week after the operation / Still have it.
 - () Other About__mo. week after the operation / Still have it.
6. Have you been diagnosed with any kind of disease after the discharge?
-

III. Tell us about your social life.

1. Please note any changes regarding your social activity, such as work, housekeeping, schooling.

1) What was your previous social life before the operation?

- () Working full-time
- () Working part-time
- () House wife
- () Student
- () Other

2) What is your social life after the operation

- () Working full-time
- () Working part-time
- () House wife
- () Student
- () Other

5. Did you go back to work as the same pace as you expected?

- It was faster than I expected
- It was the same as I expected
- It was slower than I expected

IV. Tell us about your financial and social support.

1. Did your income decline because of being a live donor?

- yes
- no

2. Did you take a leave from work as official paid absence?

- yes
- yes, but partially
- not at all

3. Did you use any financial support to pay for your hospital fee, surgical fee and any other expense relate to your operation?

- Your private life insurance
- Support from company where you work
- Public aid
- Support from other family members or relatives
- Other

V. Tell about your thought in regard to organ transplantation based on your experience.

1. Had you ever heard about living-donor liver transplantation before becoming involved?

- yes, I knew it very well
- yes, I have heard about it, but I did not know well.
- no, I have never heard about it.

2. How did you know about living-donor liver transplantation?
- books, newspapers
 - TV
 - friend, family members,
 - doctors, nurses
 - other
3. How did you decide to be a live-donor for your recipient?
- based on my knowledge from books, newspapers, TV
 - based on meeting with my friends, family members
 - based on meeting with my doctors
 - other
4. How much did you understand the explanations about live-liver donation before the operation?
- I was able to understand completely.
 - I was able to understand mostly.
 - I was able to understand about the half.
 - I was not able to understand well
 - I could not understand at all
5. After the operation, how was the pain?
- slightly painful
 - moderately painful
 - severely painful
 - very, very painful
6. Was the pain more painful than you expected?
- It was worse than I expected.
 - It was the same as I expected

It was the better than I expected

7. Was the length of hospitalization longer than you expected?

It was longer than I expected

It was the same as I expected

It was shorted than I expected

8. Tell us about any changes in following matters.

1) mental activities

better the same worse

2) relationship with recipient

better the same worse

3) relationship with other family members, relatives and friends

better the same worse

4) sexual activities

better the same worse

9. (For women only,) Did you get pregnant or have a baby?

yes

no

10. Tell us about your donation

1) Did you feel any pressure to be a donor by medical staff?

Felt pressure strongly

Felt pressure a little

Not at all

2) Did you feel any pressure to be a donor by your recipient or family members?

Felt pressure strongly

Felt pressure a little

Not at all

3) Did you wish that there would have been a cadaveric donor at the time of transplantation?

Wished strongly

Wished a little

Not at all

4) Are you now satisfied that you were a live-donor?

yes

no

hard to say yes or no

reason for the answer

5) Would you recommend to others to be a live-donor?

yes

no

hard to say yea or no

reason for the answer

11. Tell us about your thought of the transplant system.

1) Was there any missing service before the operation?

Information about operative procedure and test findings

Information about cost and paper works

Mental support

Other

2) Was there any missing service after the operation?

- Long-term care or medical follow-up
- Information about cost and paper work
- Emergent access when I feel sick
- Mental support
- Other

12. Tell us about your thought of transplantation

1) Do you think the number of cadaveric donor should be increased?

- yes
- no
- hard to say yes or no

2) If you become brain dead, will you be willing to be a donor again?

- yes
- no
- hard to say yes or no

Do you have a donor card? yes no

3) In Japan, there is a limitation to be a donor. (To be a donor, you have to be within the third degree biologically, or spouse.) What are your thoughts about this limitation?

- within the second degree and spouse is enough
(parent/child, grandparent, siblings)
- within the third degree and spouse is enough
(+cousin, aunt/uncle)
- beyond the limitation, but within the family group
- beyond the limitation, and outside of the family is okay
- other

13. Our national insurance will cover for liver transplant for children who are under age 15, but not for adults. Those adult patients who need a liver transplant have to pay by themselves, even s/he needs a new liver to live.

1) Have you ever heard about it?

I knew about it very well.

I have heard about it, but I don't know about it well.

I have never heard about it.

2) What do you think of this situation?

The national insurance should cover the transplant fee for all patients who need a new liver.

The national insurance should cover the transplant fee for more patients who need a new liver.

The national insurance should not change the rule

The national insurance should not cover any transplant at all.

14. Any general comment about the transplant.

15. Are you willing to share your experience with others who are thinking of future donation?

yes

no

hard to say yes or no

APPENDIX B

SF-36®v2 Health Questionnaire

This survey asks for your views about your health. This information will help you keep track of how you feel and how well you are able to do your usual activities.

Please answer every question. Since questions may look like others, but each one is different. Please take the time to read and answer each question carefully, and mark on the number that best describes your answer. Thank you for completing this survey.

1) In General, would you say your health is:

1. Excellent
2. Very good
3. Good
4. Fair
5. Poor

2) Compared to one year ago, how would you rate your health in general now?

1. Much better now than one year ago
2. Somewhat better now than one year ago
3. About the same as one year ago
4. Somewhat worse now than one year ago
5. Much worse now than one year ago

3) The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

- a. Vigorous Activities, such as running, lifting heavy objects, participating in strenuous sports
 1. Yes, limited a lot
 2. Yes, limited a little

3. No, not limited at all
- b. Moderate Activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf
 1. Yes, limited a lot
 2. Yes, limited a little
 3. No, not limited at all
- c. Lifting or carrying groceries
 1. Yes, limited a lot
 2. Yes, limited a little
 3. No, not limited at all
- d. Climbing several flights of stairs
 1. Yes, limited a lot
 2. Yes, limited a little
 3. No, not limited at all
- e. Climbing one flight of stairs
 1. Yes, limited a lot
 2. Yes, limited a little
 3. No, not limited at all
- f. Bending, kneeling, or stooping
 1. Yes, limited a lot
 2. Yes, limited a little
 3. No, not limited at all
- g. Walking more than a mile
 1. Yes, limited a lot
 2. Yes, limited a little
 3. No, not limited at all

h. Walking several hundred yards

1. Yes, limited a lot
2. Yes, limited a little
3. No, not limited at all

i. Walking one hundred yards

1. Yes, limited a lot
2. Yes, limited a little
3. No, not limited at all

j. Bathing or dressing yourself

1. Yes, limited a lot
2. Yes, limited a little
3. No, not limited at all

4) During the past 4 weeks, how much the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

a. Cut down on the amount of time you spent on work or other activities

1. All of the time
2. Most of the time
3. Some of the time
4. A little of the time
5. None of the time

b. Accomplished less than you would like

1. All of the time
2. Most of the time
3. Some of the time
4. A little of the time

5. None of the time
 - c. Were limited in the kind of work or other activities
 1. All of the time
 2. Most of the time
 3. Some of the time
 4. A little of the time
 5. None of the time
 - d. Had difficulty performing the work or other activities (for example, it took extra effort)
 1. All of the time
 2. Most of the time
 3. Some of the time
 4. A little of the time
 5. None of the time
- 5) During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?
- a. Cut down on the amount of time you spent on work or other activities
 1. All of the time
 2. Most of the time
 3. Some of the time
 4. A little of the time
 5. None of the time
 - b. Accomplished less than you would like
 1. All of the time
 2. Most of the time
 3. Some of the time
 4. A little of the time

5. None of the time
- c. Did work or activities less carefully than usual
 1. All of the time
 2. Most of the time
 3. Some of the time
 4. A little of the time
 5. None of the time
- 6) During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?
 1. Not at all
 2. Slightly
 3. Moderately
 4. Quite a bit
 5. Extremely
- 7) How much bodily pain have you had during the past 4 weeks?
 1. None
 2. Very Mild
 3. Mild
 4. Moderate
 5. Severe
 6. Very Severe
- 8) During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?
 1. None
 2. A little bit
 3. Moderately
 4. Quite a bit

5. Extremely

9) These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...

a. Did you feel full of life?

1. All of the time
2. Most of the time
3. Some of the time
4. A little of the time
5. None of the time

b. Have you been very nervous?

1. All of the time
2. Most of the time
3. Some of the time
4. A little of the time
5. None of the time

c. Have you felt so down in the dumps that nothing could cheer you up?

1. All of the time
2. Most of the time
3. Some of the time
4. A little of the time
5. None of the time

d. Have you felt calm and peaceful?

1. All of the time
2. Most of the time
3. Some of the time
4. A little of the time
5. None of the time

- e. Did you have a lot of energy?
 - 1. All of the time
 - 2. Most of the time
 - 3. Some of the time
 - 4. A little of the time
 - 5. None of the time

- f. Have you felt downhearted and depressed?
 - 1. All of the time
 - 2. Most of the time
 - 3. Some of the time
 - 4. A little of the time
 - 5. None of the time

- g. Did you feel worn out?
 - 1. All of the time
 - 2. Most of the time
 - 3. Some of the time
 - 4. A little of the time
 - 5. None of the time

- h. Have you been happy?
 - 1. All of the time
 - 2. Most of the time
 - 3. Some of the time
 - 4. A little of the time
 - 5. None of the time

- i. Did you feel tired?
 - 1. All of the time
 - 2. Most of the time
 - 3. Some of the time
 - 4. A little of the time
 - 5. None of the time

10) During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

- 1. All of the time
- 2. Most of the time
- 3. Some of the time
- 4. A little of the time
- 5. None of the time

11) How TRUE or FALSE is each of the following statements for you?

- a. I seem to get sick a little easier than other people
 - 1. Definitely true
 - 2. Mostly true
 - 3. Don't know
 - 4. Mostly false
 - 5. Definitely false

- b. I am as healthy as anybody I know
 - 1. Definitely true
 - 2. Mostly true
 - 3. Don't know
 - 4. Mostly false
 - 5. Definitely false

c. I expect my health to get worse

1. Definitely true
2. Mostly true
3. Don't know
4. Mostly false
5. Definitely false

d. My health is excellent

1. Definitely true
2. Mostly true
3. Don't know
4. Mostly false
5. Definitely false

APPENDIX C

Questionnaire for living-liver donors (Phase 2)

I. Tell us about yourself.

1. Gender male
 female
2. Age at the transplant 20s → Age (now) 20s
 30s 30s
 40s 40s
 50s 50s
 60s 60s
 70s
3. Year of the operation: _____.
4. The recipient of your liver: child
 parent
 sibling
 spouse

II. About your health condition

1. Compare your past health condition, how do you feel now?
 I feel my health condition is better than before the operation
→ answer 1) 2) then go to 2.
 I perfectly recuperated well as the same as health condition before the operation.
→ answer 2), then go to 2.
 I have not recuperated well completely. → answer 3), then go to 2.
- 1) How do you feel better than before?
_____.
- 2) How long did it take to fully recuperate?
About _____ year after the operation.
- 3) If you have not recuperated well, how much do you feel recuperate so far.
 ↓25%
 25~50%
 50~75%
 ↑75%

Why do you feel you have not recuperated well? What makes you feel in that way?
_____.

2. Today, do you have any limitation for doing physical activities, such as playing golf, swimming, business trip, working for long time, traveling?
 I have limitations →answer 1), then go 3.
 I do not have any limitation →answer 2), then go 3.
- 1) Please tell us about your limitation.
_____.

2) Today, you do not have any limitation, but how long did you have limitation after the operation.

About ___year after the operation.

3. Before the operation, how did you assume of the length of full recuperation would take?

About ___year after the operation.

4. Did you recuperate as the same pace as you assumed?

- I recuperated faster than I assumed.
- I recuperated as the same pace that I assumed.
- I recuperated slower than I assumed.

5. Did you have any symptoms after the discharge? If yes, please note for how long you have had that symptom. Circle "Still have it" if you still have that symptom.

- Scar pain About__year after the operation / Still have it.
- Abdominal discomfort About__year after the operation / Still have it.
- Scar numbness About__year after the operation / Still have it.
- Loss of appetite About__year after the operation / Still have it.
- Distended stomach after meal
About__year after the operation / Still have it.
- Easy to get tired (weakness)
About__year after the operation / Still have it.
- Diarrhea About__year after the operation / Still have it.
- Constipation About__year after the operation / Still have it.
- Back pain About__year after the operation / Still have it.
- Difficulty sleeping About__year after the operation / Still have it.
- Other _____ About__year after the operation / Still have it.

6. Do you feel your health condition is the same as people who are in your age group?

- Yes, I am the same as people who is in my age group.
- No → Why?

1) Reasons relate to donor operation (e.g. Scar pain)

2) Reasons which not relate to donor operation (e.g. Automobile accident)

7. Have you been diagnosed with any kind of illness after the discharge?

< Hospitalization>

Year(onset) Dx: _____ () still have it () treated

Year(onset) Dx: _____ () still have it () treated

Year(onset) Dx: _____ () still have it () treated

(Comment: _____)

< Clinic visit >

Year(onset) Dx: _____ () still have it () treated

Year(onset) Dx: _____ () still have it () treated

Year(onset) Dx: _____ () still have it () treated

(Comment: _____)

III. About your social life

1. Please note any changes regarding your social activity, such as work, housekeeping, schooling.

1) What was your previous social life before the operation?

- Working full-time
- Working part-time
- House wife
- Student
- Other

2) What is you social life after the operation

- Working full-time
- Working part-time
- House wife
- Student
- Other

2. You must been out of work, school, or housekeeping for a certain period of time when you were hospitalized for donation. Did that effect for your life for long term?

No

Yes → How did it effect? (Please check as many as you want.)

- I did not change my job, but I changed working place.
- I changed my job itself.
- I lost my income for several years.
- I lost my income continuously.
- I was absent from my school for long time.
- My grades at school had slipped.
- I could not do housekeeping for several years.
- I could not do housekeeping continuously.
- Others

IV. About your thought in regard to organ transplantation based on your experience.

1. Are you now satisfied that you were a live-donor?

- yes
- no
- hard to say yes or no

Reason for the answer _____.

APPENDIX D

Duquesne University Institutional Review Board
Protocol #09-84
Approval Date: 09/30/2009
Expiration Date: 09/30/2010



DUQUESNE UNIVERSITY

600 FORBES AVENUE
PITTSBURGH, PA 15282

Dear Sir/Madam

I am a PhD student at Duquesne University School of Nursing. As part of the requirements for graduation I am conducting a study looking at the quality of life of live donor patients. It has been seven years since we started a living liver transplant program at Keio University Hospital. To improve our clinical practice and patient care, I would like to ask you to participate in my research by completing the enclosed questionnaires. By returning the completed questionnaires, you are providing consent.

- It is your choice to decide whether to participate or not
- By responding to these questionnaires, we will assume that you agreed to participate
- If there is a difficult question to answer, you do not need to answer it.
- The data will be used for academic purposes and you will never be identified by your name.
- And your decision whether to be in the study will not affect your treatment in any way.

Keio University Hospital, Transplant Coordinator

Duquesne University School of Nursing, PhD

Etsuko Soeda, RN, MSN, CTC

APPENDIX E

Duquesne University Institutional Review Board
Protocol #09-84
Approval Date: 09/30/2009
Expiration Date: 09/30/2010



DUQUESNE UNIVERSITY

600 FORBES AVENUE
PITTSBURGH, PA 15282

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

TITLE: Organ Donation in Japan - A
Longitudinal Study of Quality of Life of
Living Donors

INVESTIGATOR: Etsuko Soeda, MSN, RN
35 Shinanomachi, Shinjuku-ku
Tokyo, Japan, 160 8285
+81-3-5363-2198

ADVISOR: L. Kathleen Sekula, PhD, APRN
Duquesne University, School
of Nursing
524Fisher Hall
Pittsburgh, PA 15282-
1760
+1-412-396-4865

SOURCE OF SUPPORT: This study is being performed as partial fulfillment of the requirements for the doctoral degree in nursing at Duquesne University. This study is supported by a grant from Keio Gijuku Academic Development Funds.

- PURPOSE:** The purpose of this study is to measure how Japanese living donor liver transplant donors doing well after seven years from the first study. You are being asked to fill out a questionnaire on quality of life. This will take approximately 15 minutes. These are the only requests that will be made of you.
- RISKS AND BENEFITS:** There are no risks greater than those encountered in everyday life.
- COMPENSATION:** There is no compensation by participate this study and participation in the project will require no monetary cost to you. A stamped envelope is provided for return of your response to the investigator.
- CONFIDENTIALITY:** Your name will never appear on any survey or research instruments. No identity will be made in the data analysis. All written materials and consent forms will be stored in a locked file in the researcher's office. Your response(s) will only appear in statistic data summaries. All materials will be destroyed at the completion of the research.
- RIGHT TO WITHDRAW:** You are under no obligation to participate in this study. You are free to withdraw your consent to participate at any time.

SUMMARY OF RESULTS:

A summary of the results of this research will be supplied to you, at no cost, upon request.

VOLUNTARY CONSENT:

I have read the above statements and understand what is being requested of me. I also understand that my participation is voluntary and that I am free to withdraw my consent at any time, for any reason.

On these terms, I certify that I am willing to participate in this research project. By continuing with the survey, I consent to participate in this research study.

I understand that should I have any further questions about my participation in this study, I may call Etsuko Soeda, the Principal Investigator (03-5363-2198), Dr. Kathleen Sekula, the Advisor (+1-412-396-4865), and Dr. Paul Richer, Chair of the Duquesne University Institutional Review Board (412-396-6326).

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