A Comparison of Health Technology Adoption in Four Countries

(Japan, Korea, the UK, and the US)

by

Myung Hun Kim

A thesis submitted to
Health Services Management Centre
Of the University of Birmingham
for the degree of
DOCTOR OF PHILOSOPHY

Health Services Management Centre
The University of Birmingham
May 2008

Abstract

This research empirically examines and compares the adoption of health technologies through case studies. The health technologies under review are assisted reproductive technologies, cochlear implants, haematopoietic stem cell transplantations, caesarean section deliveries, Gamma knife units and kidney transplants in four countries: Japan, Korea, the UK and the US.

The interactions between the micro factors of health technologies and the macro environment in the adoption of health technologies are examined on the basis of a literature review and analysis of data. The micro factors were evaluated in terms of economic, clinical and technical aspects. In assessing the macro factors, payment systems and regulations related to the selected health technologies were taken into account. To examine the micro factors, the results of health technology assessments in earlier studies were reviewed. In order to explore the macro factors, historical changes in the payment systems affecting the selected health technologies and legal regulations, including legislation, directives, guidelines and court orders related to the technologies, were investigated. The adoption level of health technologies was evaluated in time-series and cross-sectional terms, measuring the trend of technology adoption and comparing the experience of the four countries under review. This research suggests clustering health technologies into "welfare oriented technology" and "private benefit oriented technology" by considering the economic incentives of adopters, individual desires of consumers and public concern over the technology. Private benefit oriented technologies are those which adopters expect to increase income from the providers or which meet the personal desires of the consumers. For welfare oriented technology, the decision is dominated by the aims of public welfare. As the model predicted, the adoption of welfare oriented technologies was higher in the health systems under national planning, while that of private benefit oriented technologies was higher in the systems whose health provisions accept market conditions.

Acknowledgements

Foremost, my thesis would not have been possible had it not been for the support I received from the Chevening Scholarship committee of the United Kingdom and Commonwealth Office. I am very appreciative of their generous support throughout the duration of my stay in Britain. I am also forever indebted to the Severance Hospital, Yonsei University Medical Centre, for their unremitting support of my studies. I am honoured to have been the first recipient of funding for continuing education from the institute.

I would like to thank the many people to whom I owe a debt of gratitude for their help and support. I am especially grateful to Professor James Raftery for his constructive feedback and attentive comments, which were immensely beneficial to the development of my thesis. Without his enthusiastic support, it might not have been possible to reach this point. I am also grateful to Professor Chris Ham and Ms. Penelope Mullen at HSMC for their time and guidance.

I would like to express my special gratitude to Professor Kyung Sik Lee who was the Superintendent of Severance Hospital and sent me for doctorate study. Without his support, my challenge for doctoral degree could not be inspired. I also would like to express bottomless appreciation to Professor Bum Gu Cho who has been an everlasting spiritual prop for me and my wife. I am deeply indebted to my honoured seniors Mr Jong Gil Lee and Mrs Hyun Kyung Park who enoumosely encouraged me to venture doctorate study.

I would like to thank my dear friends, Professor Dong-won Han at Hanyang University and Jin-Young Moon at Seogang University for their helpful comments and continual encouragement. Finally, I would like to acknowledge the generosity of the academic institutes, organisations and researchers, especially Dr. A. Gratwhol at EBMT, for allowing me access to the information and resources necessary for my research. Despite everyone's total support in making this thesis possible, its errors and shortcomings, of course, remain my responsibility.

Lastly, I would like to thank my family and acknowledge their caring support, in particular, my wife, Jin-Hee, who has been my most devoted supporter, giving nothing but encouragement. I also wish to send my heartfelt thanks to my mother and parents-in-law, especially to my father-in-law, Mr. Sung-Duk Park, who had longed for my achievement,

and passed away during this endeavour. To my beloved sons, Sung-Min and Jun-Yup, who are my inspiration, I would like to express my gratitude for their patience.

Table of Contents

Part 3 Discussion and Conclusion

List of Table

List of Figures

List of Abbreviations

ACOG - American College of Obstetricians and Gynaecologists
AID – artificial insemination with donor semen
ALL - acute lymphoblastic leukaemia
AML - acute myelogenous leukaemia
AMT - Advanced Medical Technology
ART - assisted reproductive technology
ASRM - American Society for Reproductive Medicine
AVM - arteriovenous malformation
BBRA - Balanced-Budget Refinement Act
BIPA - Beneficiary Improvements and Protection Act
BMDW - Bone Marrow Donors Worldwide
BMT - bone marrow transplants
BODY - British Organ Donor Society
BTG - British Transplant Games
CAPD - continuous ambulatory peritoneal dialysis
CBTUS - Central Brain Tumour Registry of the United States
CC - conventional chemotherapy
CDC - Centres for Disease Control
CML - chronic-myelocytic-leukaemia
CON - certificate-of-need
CS - caesarean section
DHHS - Department of Health and Human Service
DoH – Department of Health
DPC - Diagnosis Procedure Combinations
DRG - diagnostic related group
EBMT - European Group for Blood and Bone Marrow Transplantation
EHI - Employee Health Insurance
ESRD - end-stage renal disease
FCSRCA - Fertilisation Clinic Success Rate and Certification Act
FDA - Food and Drug Agency
FFS - fee for services
GDP – Gross Domestic Product
GIFT - gamete intrafallopian transfer
GKF - GK Financing LLC
GVHD - graft-versus-host disease
HA - Health Authority
HCFA - Health Care Financing Administration
HDT/PCT - high-dose myeloblatic therapy and progenitor-cell transplants
HIRA - Health Insurance Review Agency
HMO - Health Maintenance Organisation
HSCT - haematopoietic stem cell transplantation
HT - health technology
HVDT - Health Visitor Distraction Test

IBMTR/ABMTR -International Bone Marrow Transplant Registry and the Autologous Blood and Marrow Transplant Registry
ICSI - Intracytoplasmic sperm injection
IUI - Intrauterine insemination
IVF-ET - in-vitro fertilisation embryo transfer
JMDP - Japanese Marrow Donor Programme
JMDRPC - Japan Marrow Donor Registry Promotion Conference
JNOS- Japan Network for Organ Sharing
JSOG - Japan Society of Obstetrics and Gynaecology
KMDP - Korean Marrow Donor Programme
KONOS - Korean Network for Organ Sharing)
LDP - Liberal Democratic Party
LOS - length of stay
MCO - Managed Care Organisation
NBMDR - National Bone Marrow Donor Registry
NGO - non-governmental organisation
NHS- National Health Service
NICE - National Institute for Clinical Excellence
NIH - National Health Insurance
NMDP - National Marrow Donor Program
NOTA - National Organ Transplant Act
NOTA - National Organ Transplant Act
NOTDI - National Organ and Tissue Donor Initiative
KOTDP - Organ Donation Action
OECD - Organisation of Economic Co-operation and Development
OPPS - Outpatient Prospective-Payment System
OPTN - Organ Procurement and Transplantation Network
OTIC - Organ Transplantation Information Centre
PBOT - private benefit-oriented technology
PBSCT - peripheral-blood-stem-cell transplants
PCT - Primary Care Trust
PFI - Private Finance Initiative
POS - Point-of-Service
PPO - preferred provider organisation
PPS - Prospective Payment System
PRO - Peer Review Organisation
QALY - quality adjusted life year gained
QoL - Quality of Life
RBRVS - Resource-based Relative-Value Scale
RERF - Radiation Effects Research Foundation
SEOPF - Southeast Organ Procurement Foundation
STAR - Search Tracking and Registry
TIME - Transplants in Mind
UKNTN - UK National Transplant Network
UKTSSA - United Kingdom Transplant Support Services
ULTRA - Unrelated Live Transplant Regulatory Authority

UNHS - Universal Hearing Screening
UNOS - United Network for Organ Sharing
VBAC - vaginal birth after caesarean section
WHO - World Health Organisation
WOT - welfare-oriented technology
WTP - willingness to pay
ZIFT - Zygote intrafallopian transfer

Part 1

Introduction

Chapter 1: Introduction

1.1 Research background

Recent decades have witnessed a significant improvement in the health status of people in most of Organisation of Economic Co-operation and Development (OECD) member countries, including the four countries considered in the present thesis; Japan, Korea, UK, and US. This improvement has been achieved largely by public health measures, health education, preventive activities, screening programmes and advances in medical treatment (Office of Health Economics: OHE 1994). Health care expenditure has also increased rapidly and the issue has become a primary concern of the health policies in almost all developed countries and even among developing countries. During the past three decades, health spending has almost doubled within OECD countries (OECD 1993; Anderson et al., 2000). Three factors have been mainly responsible for increasing health costs (Schwartz and Mendelson 1992): 1) demographic changes resulting in an increased number of elderly patients; 2) rising labour costs; and 3) advancements in health technology (HT) (Kalb 1990[1]; Newhouse, 1992; Gelijns and Rosenberg 1994; Fuchs 1996; Okunade and Murthy, 2002). While technological advances have significantly contributed to improving healthcare practices and enhancing health status, there have also been increasing questions about their long-term ethical, social and economic implications (Robert et al. 1999). Many developments, such as genetic treatments, assisted reproductive technologies and technologies used for sustaining or terminating life, raise serious and complex medical, ethical, legal, economic and social controversies (Perry and Thamer 1999).

Optimal and appropriate use of HTs has been a major concern in health policies and reimbursement strategies of third-party payers. Hence, most countries regulate HTs by law, by reimbursement plans, or by restrictions on services to be provided (Jonsson and Banta, 1999). HTs have been subject to heated disputes involving ethical integrity and equity regarding the allocation of health care resources. To guard ethical integrity, the use of HTs

[1] Kalb argues that medical technologies may be responsible for as much as 50% of health sector inflation, while Newhoue (1992) regards that health technology is responsible for perhaps as much as 75 % of the increase in health care spending.

has been regulated by law, directives or court orders. Third party payers limit coverage via various cost containment measures in pursuit of equitable use of financial resources.

The advent of new HTs has brought not only more input in health care but also concerns with cost-effectiveness. There has been intense interest in the determinants of the dissemination of HTs. Existing studies to date have been mainly case studies, predominantly of single topics. Comparative studies on international level are limited to some countries in Europe and/or in English only. To explore the determinants for health technology dissemination, it is essential to deal with several topics across diverse health systems.

The present research examines the adoption of 6 different HTs in four countries: Japan, Korea, the UK and the US. Little attention has been paid previously, specifically to Asian countries. In particular, Japan and Korea have been largely ignored, due perhaps to language barriers. Economic prosperity in Japan and Korea has, however, recently increased the attractiveness of comparative studies. These regions are in a unique position in the adoption of health technologies. In both countries, the funding for health care is financed via social insurance and health providers are paid through a fee for services (FFS). Hence, the choice of medical intervention is largely left to the discretion of the physician and/or user. In the UK, the resources for health services are largely financed by general taxes and provided by the national health services (NHS). Financial resources are allocated to the health authorities (HAs) based on the calculation of weighted capitation targets. The NHS as a single entity traditionally managed both the finance and delivery of health services. In the US, most health care is provided by the private sector. Health services are generally provided on an FFS basis. In tandem with the expansion of Managed Care Organisations (MCOs), health service provisions have been fundamentally transformed from fragmented care on the basis of retrospective fee payment to comprehensive care on pre-paid fixed fees. Due to differences in the financing, payment and delivery methods, the health systems of these four countries can be characterised as market oriented in Japan, Korea and the US and publicly controlled in the UK.

This research makes international comparison across diverse health systems. Cross-national comparisons are very rare, mainly due to the difficulties out of substantiating the multi-factorial influences on the adoption of health care technology. Collecting data of comparable quality for each country also presents a major barrier to comparative studies.

1.2 Key concepts

1.2.1 Health technology

In defining technology, concerns are generally focused on new and innovative aspects. In the literature, the terms "new technology", "technological innovation" and "innovation" are often interchangeable. The term 'new technology' commonly refers to a new device, process or system targeting limited processes or products.

While 'innovation' and 'technological innovation' imply the concept of ongoing development, new technology does not. An innovation could be an 'idea, practice, or material artefact' (Rogers and Shoemaker 1971) and this is true of the adoption of an internally generated or purchased device, system, policy, programme, process, product, or service is new to the adopting organisation (Damanpour 1991).

Gatignon and Robertson (1989) classify innovations as minor or major. According to them, minor innovations refer to discontinuous innovations while major innovations are continuous. There are some other characteristic aspects of innovation. Technological innovation is confined to products, services and production technology (Damanpour 1991; Damanpour and Evan 1984; Knight 1967) in contrast to 'administrative innovation' which concerns organisational structure and administrative processes (Damanpour and Evan 1984; Kimberly and Evanisko, 1981; Knight, 1967). Technological innovation covers not only individual technologies but also system-wide processes of ongoing technological development.

There have been three different perspectives in defining health technologies (HTs)'. First, in a narrow sense, HT is limited to a drug, machinery, piece of equipment or medical or surgical procedure of diagnosis and treatment (OTA 1982, 6; Stocking 1985, 5). Second, in an extended sense, HT can include the organisational and supportive systems in medical

care (OTA, 1982). Williams (1997) argues that there is no reason to exclude any technology related to health care delivery insofar as 'innovation,' 'different,' 'new' or 'improved' could be applied to it[2]. Finberg and Hiatt (1979) and Abel-Smith (1994) argued that artistic, scientific and technological skills need to be included in the conception of HT. In their view, HT required materials, procedures, equipment and skilled human resources for adoption in health care practice. Raftery and colleagues (2005) distinguished differences between the UK and the US in defining HT. A UK definition as described by DoH (1992):

"all methods used by health professionals to promote health, prevent and treat disease, and to improve rehabilitation and long term care";

and a US definition from OTA (1976):

"the set of techniques, drug, equipment and procedures used by health care professionals in delivering medical care to individuals and the systems within which such care is delivered".

Reflecting these major differences between the UK and the US, they suggested different levels from broad interventions (such as organisational structures) through to possible components in health practice (individual diagnostic tests, drugs, surgical procedures and other intervention).

The terms "health care technology" and "medical technology" have not been clearly distinguished. It may be useful to consider medical technologies are those directly applying to medical practice, while health care technologies encompass those supporting the overall processes of health care. Similarly, medical technology could be described in a narrow sense while health care technology could imply a broader view. Highly skilled

[2] Williams (1997) describes the concept of health technology as follows:
"any innovation in the practice of health care delivery, be it a different arrangement of beds (or patients) in a ward, a different division of labour among staff, a change in the location of treatment, a new surgical procedure, a new drug, a new piece of diagnostic or monitoring equipment, a new prosthetic device, or even improved heating or ventilating systems in a hospital" (pp.205-206).

professionals who have been specifically trained for certain medical procedures could accordingly be considered medical technologies.

The present research adopts "health care technology" because it implies an overall view of medical equipments, skills and procedures. To encompass the various characteristics of the technologies, this research prefers to adopt the concept of health care technology.

1.2.2 Micro versus macro factor

This section, based on a brief literature review, outlines micro and macro factors in the diffusion of HTs. Decisions tend to be restrained by socio-economic, cultural and political environments. Szczepura and Kankaanpää (1996) identified three determinants in technology adoption; actors in the process, the environment, and characteristics of the technology. Applied to health care, environmental characteristics encompass the method of compensation for health services, legal regulations surrounding the adoption health technologies and organisational characteristics of potential adopters.

First, the method for compensating health services primarily determines; 1) who decides to adopt, 2) who is responsible for the initial cost to adopt, 3) who decides to use and 4) who pays for the use.

Second, legal regulation, including laws and court decisions can directly control technology adoption in healthcare. Most countries regulate the adoption of new drugs, medical devices and equipment (Jonsson and Banta, 1999: 1293) in order to guard the safety and efficacy of their application. Court rulings can impact on the adoption and use of new technologies. Sometimes, a court order to pay for the use of certain technology may accelerate the diffusion of that technology (Ferguson et al., 1993) [3].

[3] Court decisions on the litigation of insurance coverage often occur where health plans are operated on a commercial basis. Courts rule against insurance carriers sued for reimbursement for unproven medical procedures when the insurance contract is interpreted in favour of the insured (Ferguson et al., 1993; Anderson et al., 1998). In the UK, about 20 cases a year are sent to the High Court in England and Wales to determine if medical procedures should be carried out even if a patient refuses or is unable to consent to such treatments (Oates, 2000: 1282). According to Oates (p. 1282), three types of cases have been brought for court decision: to save life; to allow that patient die peaceably; or yo enhance quality of life of the patient or to ensure improvement or prevent deterioration in his or her physical or mental health.

Third, actors in health care for technology adoptions are ordinarily health providers including physicians and health care organisations. There have been numerous attempts to trace the impetus of technology adoption from an organisational standpoint. Frambach and Schillewaert (2002) offer three concepts: organization size, organization structure and organizational innovativeness. Size is widely found to have positive relationship with innovation adoption. Those with larger size of organisations tend to have a greater impetus to adopt innovations in order to support and improve their performance. Smaller sized organizations are likely to be more flexible and more receptive towards innovative approaches (Nystrom et al., 2002; Mansfield, 1968). Damanpour (1991) argues that centralisation[4] has a negative relationship with innovation. Regarding the strategic posture of a firm, the organisations which pursue an innovation-orientation marketing strategy are more likely to support activities to promote innovation (Hurley and Hult 1998, Datar et al 1997).

Regarding the characteristics of the technology *per se*, the perceived benefits have been recognised as major factor for adoption (Robinson 1990, Mansfield 1993). In healthcare, potential adopters consider if these are sufficiently favourable to recoup the initial costs within a suitable time (Davies, 1979). Following questions are major consideration in the decision for adoption (Rogers, 1995); whether new technologies are compatible with substitutes, possible to observe how to handle, possible to try, as well as relative advantages. Darley and Beniger (1981) proposed two more specific sub-dimensions for the relative advantages in Rogers' concept: capital cost of the innovation and perceived savings.

Many models have attempted to spell out the processes of technological diffusion, which are usually studied on the individual or organisational level, mainly derived from empirical studies. In the studies of HT dissemination, the primary concern has been to identify the factors influencing the spread of health technologies and then to discover the relations between these factors and the process of diffusion within given environments (Gomulka, 1990: 80). There have been several attempts to cluster, for example, external

[4] This variable reflects the locus of authority and decision making and is the extent to which decision-making autonomy is dispersed or concentrated in an organisation.

factors (Escarce 1996; Frambach and Schillewaert 2002); internal factors, or a mixture of both (Mahajan and Peterson 1985); and intrinsic and extrinsic elements (Schoonmaker 1998). Internal or intrinsic factors focus on the inherent values of a technology, while external or extrinsic factors concentrate on the circumstances related to the technology adoption.

Table 1-1. **Major sources for HT adoption**

Micro factors	Macro factors	Residual factors
1) Economic factors a. Budget for investment b. Budget for operation c. Financial incentives 2) Clinical factors a. Effectiveness b. Safety c. Morbidity 3) Economic and clinical factors a. Cost-effectiveness 4) Technical factors a. The need to acquire new skill to use the technology safely b. Planning and logistic[5]	1) Reimbursement systems 2) Public regulation 3) Market conditions 4) Patient demand a. Prevalence of disease	1) Traditions and culture 2) Attention from media 3) Role of industry 4) Information a. Conference and related activities[6] b. The possibility of organising studies to document[7] 5) Opinion leaders b. Innovative person who advocate for the technology

In healthcare, the forces encouraging or discouraging technology adoption are not clearly distinguished by simply juxtaposing internal with external influences or intrinsic with extrinsic. Poulsen and colleagues (1998) suggested 18 factors having significant influence on health care technology dissemination as follow; budget for investment, budget

[5] This concept refers that the necessary planning and logistics to use the technology, including the preparation of the operation, the composition of the personnel, the availability of instruments, the length of the operation, etc.

[6] Experience and information about the technology from scientific conferences, and: or related activities

[7] The possibility of organising studies, which is affected by problems like the presence of logistical problems, the availability of funding, the professional's interest in the study, the patient's attitude towards participating study, the ethical dilemma of study.

for operation, financial incentives, nature of technology[8], planning and logistics[9], expected extra benefit[10], scientific evidence[11], organizing studies[12], training, traditions and culture, opinion leaders, competition, conferences and related activities, role of the industry, attention from the Media, patient demand, public regulation.

These components are intertwined and interdependent. "Micro" versus "macro" categorisation may be more helpful in uncovering the features in a complementary way. As summarised in *Table 1-1*, we clustered the above diffusion factors suggested by Poulsen and colleagues into micro factors, macro factors and residual factors. Most of them are consistent with the factors recognised through brief literature reviews on the earlier part of this section.

Usefulness that comprises the advantages in micro factors becomes the primary source of adoption decision at practice level, while compensation for health services and the regulations surrounding the adoption of innovation drive choice at the macro level.

Table 1-2. **Relationship between micro and macro factor by method of finance**

Macro			**Micro**
Finance system	Payment system	Delivery system	Economic incentives of adopters
Social insurance	Retrospective	Fragmented	Profit
General tax	Budget allocation	Integrated	Cost saving
Private insurance	Mixed - Prospective - Capitation - Retrospective	Mixed - Integrated - Fragmented	Cost saving and/or Profit

Narrowing down to the mechanisms directly associated with health care provision, funding, compensation and the delivery of health care are essential at macro level. *Table 1-*

[8] The need to acquire new skills to use the technology safely

[9] The necessary planning and logistics to use the technology, including the preparation of the operation, the composition of the personnel, the availability of instruments, the length of the operation, etc.

[10] The initial expected value of the technology with respect to effectiveness includes cost-effectiveness, cost-advantages, safety, morbidity, and convalescence.

[11] The availability and quality of the published scientific evidence with respect to the safety, effectiveness and cost-effectiveness

[12] The possibility of organizing studies to document the effectiveness of the technology, which is affected by problems like the presence of logistical problems, the availability of funding, the professionals' interest in the study, the patients' attitude towards participating in a study, the ethical dilemma of a study.

2 summarises the relationship between micro and macro factors. Payment system and the delivery of health care are primarily stemmed from how the fund for health care is financed.

In the system where health services are provided under the national plan, funding is largely financed by general taxation in a social welfare programme. Health care costs are financed by budget allocations. Health providers at all levels of health care practices are required to collaborate each other and share responsibility for the outcome of care and the use of financial resources within given budget. They are not able to adopt expensive equipment or devices unless the responsible authority allots budget to purchase or authorises them. In adopting new health technologies, potential adopters tend to pursue cost-saving effects.

Social insurance programmes traditionally pay for health services on a FFS basis. Under this circumstance, health care is delivered in a fragmented way and the patient is largely free to choose health providers. Consequently, health care provision under social insurance is generally run by market mechanisms. The least level of responsibility for the outcome of health care is obliged to health providers. Providers under social insurance seek to increase the volume of care because retrospective fee schedule shifts the financial risks to the insurer. If health providers compete with each other, they may seek advanced technologies to take competitive advantages against other providers.

Health systems financed by private health plan depend on market mechanisms in both funding and paying health services. Under market conditions, two different structures can exist: 1) the insurer and health care provider are separated, in terms of both function and organisation; 2) insurance and health care provision is fused together, as implemented in various forms of Managed Care Organisations (MCOs). In the first system, the providers are generally compensated through a retrospective fee schedule, while in the second system the providers get compensation through prospective or pre-fixed fee schedules. The providers with a retrospective fee schedule pursue profit, while those with a prospective or fixed fee schedule pursue cost saving by acquiring proficiency from HT adoptions.

There have been many attempts to understand what leads to action for new technology adoption. The technology acceptance model suggests an interaction between micro and macro factors in the process of technology adoption, specifically between perceived

usefulness and perceived ease of use. Legris and colleagues (2003) employed this model to examine the mediating role of perceived usefulness and perceived ease of use in relating the system characteristics (external variables) to the probability of the system adopting the technology. The technology acceptance model suggests that an individual's perception of how easy or difficult it is to use a technology will influence the adopter's perceptions about the usefulness of the technology. Technology adoption is determined by individual intentions to use a technology. This is jointly determined by individual attitudes toward a technology and its perceived usefulness.

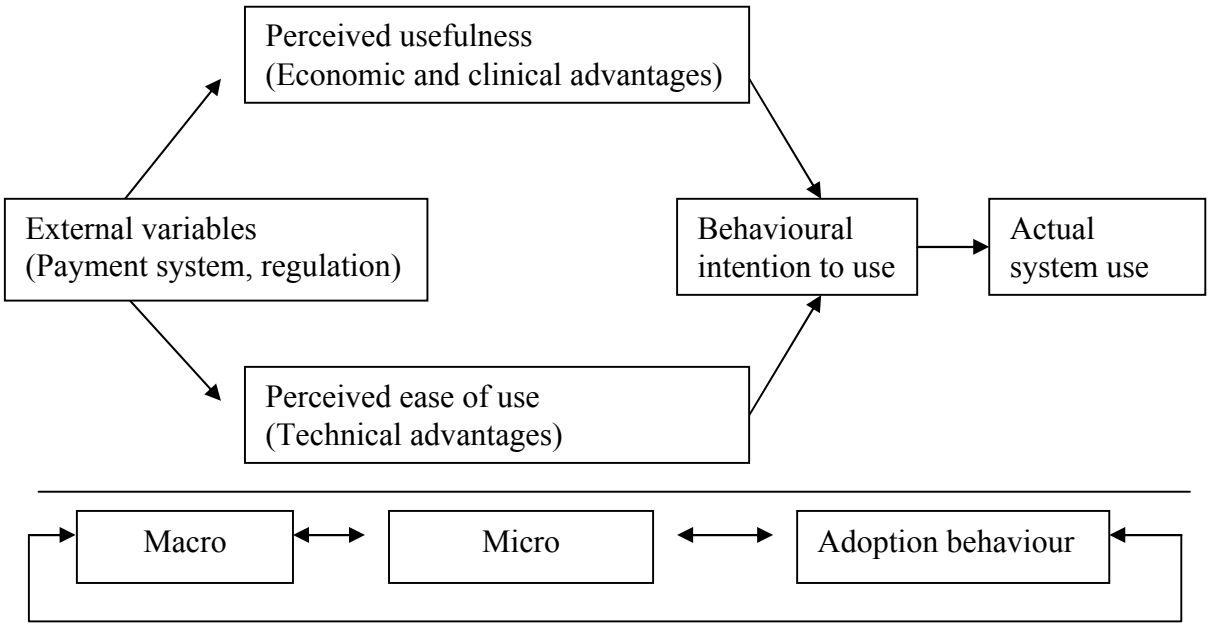


Figure 1-1. **Flow of technology acceptance (modified from Davies, 1989)**

The *Figure 1-1* shows that external variables affect perceived usefulness and perceived ease of use. In healthcare, perceived usefulness and perceived ease of use can press for adoption of a technology at practice level, while compensation and legal regulation set the policy context. As depicted in *Figure 1-1*, external variables in the technology acceptance model are equivalent to macro variables in the present research, while the components of perceived usefulness and perceived ease of use are comparable with micro variables. In the present research, perceived usefulness refers to effectiveness that is examined in terms of economic and clinical factors, and perceived ease of use is assessed in terms of technical factors.

The feedback between micro and macro effects guarantees the maintenance of the system's dynamics over time and produces some effect on self-organization (Mella, 2001). The feedback arises from necessitating factors - which act on the agents in the system and is maintained by the action of recombining factors - which act collectively.

1.2.3 Classification of health technologies

As well as classifying health systems, HTs can also usefully be classified. HTs have been so far clustered into procedures, devices, equipments, and pharmaceuticals. Other approaches have been scarcely attempted in classifying HTs. The present research employs 'welfare-oriented technologies (WOTs)' versus 'private benefit-oriented technologies (PBOTs)' categorised in terms of the major motivation for the adoption of HTs. The main forces comprise the purposes for adoption and the agents who decide to adopt, associated with the perceived utility of HTs.

Primarily, the worth of a HT on an adopter is determined by economic terms, that is, whether improves income or lessens the cost of health care. If potential adopters pursue profits, their main concerns for HT adoption likely be to do with revenue generation, while they may pursue cost reduction if they are responsible for finance.

The value of a HT also matters to the patient who might gain from use of the HT. This can be categorised into satisfying personal desire like cosmetic surgery or fulfilling public welfare need like a vaccination to prevent infectious diseases. *Figure 1-2* shows how 4 different groups of HTs can be linked to difference dimensions, specifically to the value of the HT comprising public versus private welfare and to economic incentives that include cost-effectiveness versus provider income.

1.3 Research questions and aims

Although there have been many attempts to recognised the determinants for health technology diffusion, lack of research for clarifying the interaction between micro and macro factors raises questions whether their findings are possible to generalise in other circumstances. As explicated in previous sections, both micro and macro factors have been

convincingly recognised to have significant influences on the diffusion of HTs, but the effort to explore the interaction between them has been scarce.

In this research, we have five objectives:

- To explore the role of micro factors in HT diffusions.
- To explore the role of macro factors in HT diffusions.
- To explore the interaction between micro and macro factors in HT diffusions.
- To recognise residuals in determining HT diffusions.
- To make recommendations as appropriate.

1.4 Conclusion

The present research explores major factors in the adoption of HTs. In previous research, HTs tended to be considered as an 'internal' or 'intrinsic' factor and the environment characterised as an 'external' or 'extrinsic' factor. The research reported here terms of the HT as a micro factor to be assessed in economic and clinical terms. The environment is termed a macro factor, and includes the payment system and regulation of HTs. Through case studies examining the adoption of 6 HTs in 4 countries, the current research attempts to explore the interaction between micro and macro factors in HT adoption. , This research classifies HTs into WOTs and PBOTs, based on the interaction between micro and macro factors.

Chapter 2: Research methods

The present study adopts a number of methods to answer the questions stated at the end of chapter 1. It undertakes a purposive review of the literature on health systems of selected countries and the selected HTs. It also considers a series of case studies in order to assess the role of micro factors on the level of HT adoptions. We thus assess evidence from studies that have previously examined each HT on clinical and economic terms.

The retrospective case studies of the adoption of HTs have time-series and cross section aspects. The case studies include interpretation of regulations in order to illustrate their influence on the adoption and use of selected technologies. These also include reviews of reimbursement schemes and their changes over time. Other residual factors are also taken into account, including the cultural and historical background related to each HT.

The review compares a set of 6 HTs in 4 countries in terms their relative advantages in economic and clinical terms. To review the evaluation of micro factors, we searched a range of international computerised database, including Centre for Reviews and Dissemination (CRD; DARE, NHS EED and the HTA database), MEDLINE (Ovid version for the period January 1966 to January 2004), EMBASE (Ovid version for the period between 1988 to January 2004). We scanned the title and abstracts of all references and retrieved all those that dealt with clinical outcomes and economic evaluations. Given the lack of empirical evidence on the determinants of HT adoption, retrospective case studies assessed the influence of compensation schemes for health services and regulations related to those technologies. We choose these particular case studies in order to ensure we included examples of HT adoption in the three broad areas – device, equipment and procedures.

Some HTs are currently experimental while some others are already being established. The sources of data for the case studies were from professional communities, companies, governmental organizations and individual specialists. Data was also collected from journals and formal and informal documents.

Each case study aims to present a comprehensive list of all sources concerning each of the six technologies being adopted in the four countries. In an exploratory study of this type, case studies are well suited for answering the questions of the how and why the level of adoption varies among the countries.

2.1 Selection of topics

The selected HTs are classified into three groups; medical procedures, devices and equipment. Medical procedures include assisted reproductive technologies (ARTs), kidney transplantation, caesarean section (CS) delivery and haematopoietic stem cell transplantations (HSCTs). Medical device includes cochlear implants. The Gamma Knife unit is selected as an example of medical equipment. Pharmaceuticals are excluded due to limitations on data availability. For Korea in particular and to some extent for Japan, no data were available to do similar studies of drugs. Even for the UK, the most integrated health system, data on drugs are available only for primary care, not for hospitals.

These HTs differed in terms of cost, as can be seen from their costs in the UK. The cost of caesarean section delivery is least among the selected topics. The mean cost for CS delivery in the UK was ranged from £1,004 to £1,406 (Henderson 2001). The cost for ARTs is not much expensive if conception is achieved at first time, but repeating treatment cycles (sometimes three or more times) imposes a serious financial burden. According to Lloyd and colleagues (2003), the cost per ongoing pregnancy was £10,781. Regarding IVF, "unstimulated-IUI plus IVF," and "stimulated IUI plus IVF" were £12,600, £13,100 and £15,100 per live birth-producing pregnancy respectively (Pashayan et al, 2006). The costs for HSCTs are varied, but are consistently on of the most expensive medical procedure with £13,427 for elective and £14,716 for non elective BMT respectively at reference costs 2000 of the NHS (NHS Executive, 2001). The indicative cost of kidney transplantation is £17,000 including induction therapy but excluding costs incurring supports from UK Transplant. In the NHS, the cost on maintaining a patient is £30,800 on average per year whereas a kidney transplant costs £20,000 in the first year and £5,000 a year per patient

thereafter for anti-rejection drugs. Accordingly, the patient has a functioning transplanted kidney gains cost benefit in subsequent years of £25,800 per annum (UK Transplant 2007).

Cochlear implant is a surgical procedure using an artificial device which is relatively expensive. Overall cost for cochlear implant is about £12,000 including £10,000 for the device.

To install Leksell Gamma knife unit, about £3 million of capital costs are required which includes £2 million to purchase the unit and £950k for site preparation and minor equipment. The costs using Gamma Knife unit are varied according to the indications for radiosurgery.

Both kidney and cochlear implantations improve the quality of life, though cochlear implant is not related with life extension. Discrepancy in coverage across the third-party payers implies that third-party payers have differing approaches to cochlear implantation. In Korea, for example, public insurance programmes began to cover cochlear implants from January 2005. Before the transformation to an insurance coverage approach, the Korean government had subsidised cochlear implantation to reduce the cost to patients. In the UK, the NHS funded cochlear implants since 1991. Many of private insurance policies like HMOs in the US still did not cover the cost, while Medicare provides coverage for cochlear implantation (Garber et al., 2002).

Public authorities and/or third-party payers often control HTs with small volumes but requiring high costs hence bring about dispute on inequitable use of financial resources. HSCTs and Gamma knife units provide examples.

In deciding whether or not to adopt HTs, the incentives towards adoption vary by remuneration method, health provider and patient. Based on the result of economic evaluation and public regulation, public authorities support some technologies while controlling others. Public authorities support those HTs confirmed to relieve the disability of patient. Sometimes public support takes the form of subsidy and support for organisations to promote the adoption of HTs. For example, most governments support organ donation and allocation activities through specific organisation, such as JNOS (Japan Network for Organ Sharing) in Japan, KONOS (Korean Network for Organ Sharing) in

Korea, UKTSSA (United Kingdom Transplant Support Services) in the UK, UNOS (United Network for Organ Sharing) in US. Public support for aids for the deaf is also widespread. In the UK for example, Newborn Hearing Screening, previously known as Universal Hearing Screening (UNHS), is provided to identify deafness through neonatal screening. In the US, UNHS is currently mandatory in 32 states and it is assumed to reduce the median age of identification of hearing impairment from 12 to 18 months to 6 months or less (Keren et al, 2002).

Since third party payers are required fair allocation of limited financial resources, they seek to control the HTs for conditions not regarded as diseases, such as ARTs for infertility and caesarean section delivery without medical indication. Third-party payers are also reluctant to provide high cost technologies with low volumes, such as Gamma Knife radiosurgery. ARTs represent a unique case. In general, they have not been covered by health insurance programmes until recently. In pursuit of birth promotion, some countries such as Japan and Korea commenced subsidy while expanding insurance coverage for ARTs. On the contrary, public supports for ARTs are being limited in the UK and US. The NHS of the UK does not have guideline on the provision of infertility treatment, and individual health authorities have the right for coverage decision. About 25% of total ART cost in England is funded by the NHS (NICE, 2005). In the US, most health insurance programmes do not provide coverage for ARTs, and thus about 85% of total ARTs cost is paid by patient from their pocket money (Collins et al, 1995). These brief reviews disclose that public supports including the expansion of insurance coverage on ARTs are getting increased in pursuit of population growth. It refers that the concern for infertility treatment is moving from the matter of personal desire to have baby to public concern to promote population growth.

2.2 Selection of countries

2.2.1 Major health indicators of selected countries

The major indicators related to healthcare such as the level of health expenditure and the ratio between public and private funding indicate the characteristics of a health system.

Table 2-1 shows the income per capita of the selected countries with the highest in the US followed by the UK, Japan and Korea. In terms of GDP (Gross Domestic Product) at PPP (Purchasing Power Parity), the US is about double of Korea, and Japan and the UK are in the middle between them.

Table 2-1. **Income level of each country (GDP at PPP)**

Income	Japan	Korea	UK	US
GDP(at Purchasing Power Parity) $ per capita (2005)	32,649	23,926	35,051	43,444

Data source: International Monetary Fund, 2006

Table 2-2 provides demographic data for each country. The total population of the US is about 5 times bigger than in the UK. The size of the UK is about 20 % bigger than that of Korea, and about half that of Japan. In terms of infant mortality rates, all four countries have a similar level, with lowest level in Japan. The total fertility ratio per woman is the lowest in Japan with 0.6, and highest in the US with 2 children.

Table 2-2. **Demographics by each country**

Demographic indicators		Japan	Korea	UK	US
Life expectancy at birth	M	79	75	77	75
	F	86	82	81	80
Infant mortality rate (per 1,000 live births)		3	5	5	4
Total fertility ratio (per woman)		0.6	1.2	1.7	2
Population total (thousand)		128,085	47,817	59,668	298,213

Data source: World Health Organisation (WHO), World Health Statistics 2006

Table 2-3 shows the health spending of each country. In terms of total expenditure relative to GDP, health spending is very high in the US and low in Korea. In terms of per capita expenditure, Americans 'consume' about 8 times more money than Koreans. As illustrated on *Table 2-2*, the life expectancy at birth is quite similar between two countries. There are huge differences among 4 countries in public funding levels. The majority of health spending comes from public finance in the UK, while the proportion is less than half of total spending in the US. The highest level of 'out-of-pocket' money in private

expenditure is in Korea, indicating that consumerist behaviour might be strong. While health systems in Japan and Korea are similar, the amount of private finance as a proportion of total health expenditure is much higher in Korea than in Japan. This is a consequence of higher co-payments and the fact that more items are excluded from insurance coverage in Korea. Although private spending is high in the US, health service consumers are largely controlled in part by prepaid health insurance programmes.

Table 2-3. **Health expenditure by country (2004)**

Health expenditure indicators	**Japan**	**Korea**	**UK**	**US**
Total health expenditure (% of GDP)	7.8	5.5	8.1	15.4
Per capita total expenditure on health at average exchange rate (US$) (2004)	2823.2	776	2899.7	6096.2
General government expenditure on heath (% of total)	81.3	52.6	86.3	44.7
Private expenditure on health (% of total)	18.7	47.4	13.7	55.3
Out-of-pocket money expenditure on health (% of total private expenditure)	94.9	80.4	91.8	23.8
Private prepaid plan expenditure on health (% of total private expenditure)	1.9	7.1	8.2	66.4
Percentage of out-of-pocket money of total private expenditure on health	17.74	38.10	12.57	13.16
Percentage of prepaid plan of total private expenditure on health	0.35	3.36	1.12	36.71

Data source: WHO, World Health Statistics 2006

In terms of workforce and infrastructure, as illustrated in *Table 2-4*, Japan and Korea differ from the UK and the US in having a much higher hospital bed ratio, whilst having much lower physician ratio. The extent of public versus private involvement also differs significantly. The fraction of public beds of the total is the highest in the UK at 96% and at its lowest in Korea at 18.5%. Private sector involvement is the highest in Korea at 86%, followed by Japan and the US with 67 % and 35% respectively, and then the UK, with only 5%.

Table 2-4. **Comparisons for Hospitals beds**

	Japan	Korea	UK	US
Hospital beds (per 1,000 population)[a]	129 (2001)	86 (2001)	39 (2004)	33 (2003)
Physician (per 1,000 population)[a]	1.98 (2002)	1.57 (2002)	2.56 (2000)	2.3 (1997)
Public beds (% of total bed)[b]	35.8	18.5	96	33.2
Private sector[b]	67	86	5	35

Data source: a. WHO, World Health Statistics 2006
b. OECD, OECD Health Statistics 2001.

2.2.2 Health system of selected countries

2.2.2.1. Japan

The health system in Japan comprises a mixture of private health care providers and public funding. The fund for health services is financed by social insurance from the contributions of the insured and their employers. Total health spending accounted for 7.9 % of GDP in Japan in 2002 (OECD, OECD Health Data 2005). Private providers dominate the health service. The Ministry of Labour, Health and Welfare determines insurance premiums for government-managed health insurance programmes at a fixed proportion to the payroll. There is no price competition among insurers, and the insured are not allowed to switch insurers. The amount of government subsidy also varies among the insurance plans

Both ambulatory and inpatient services are paid for on a FFS basis. Private physicians and hospitals work under the same fee schedule, which sets fees essentially in the same way for both.

Health providers compete with each other to attract customers. Patients are free to go any physician or hospital. There is no obliged collaboration among health providers, therefore health care services are delivered in a fragmented way.

Expenditure has been maintained at a lower level than any other industrialised country. Major mechanisms to control health spending are as follows (Ikegami, 1991);

- A uniform fee schedule controlled by central government
- A ceiling for the public expenditure
- Inspection of medical fee claims

First, the regulated fee schedule that is applied evenly across the country has been the most significant measure in terms of controlling health expenditure. In the past, health services were compensated by contracts between the insurers and medical association, with costs reimbursed by per capita per annum. The system was transformed in 1943 to the current 'point system[13]'. The point based payment system has been a primary method of controlling health expenditure (OECD, 1995). Service volume has been greater in Japan than in other countries. In 1997, the average length of stay in an acute hospital was 32.9 days in 2001, which is much higher than other three countries: 11 days in Korea; 6.9 days in the UK; and 5.8 days in the US (OECD, OECD Health Data 2003). To tackle the problem, a trial of a fixed fee system has recently been carried out in Japan. In 2003, a lump-sum payment system based on Diagnosis Procedure Combinations (DPC) was introduced to 82 specific function hospitals in Japan. While the US DRG/PPS system is a "per case payment" system, the DPC based payment system adopts a "per day payment." By applying a fixed fee system, it is generally believed that the Japanese system provides an incentive to shorten the average length of stay (LOS) (Hideo, 2003).

Second, the Japanese government began to contain overall public expenditure in the early 1980s, which pursued to retain it below 45 % of GDP. In relation to health expenditure, the main concern was focused on limiting the increase in the fee schedule. Health care costs became an obvious target due to rapid increase that gone up 6 % from 4 % during 1970s. Consequently, the pace was significantly slowed down during 1980s

Third, the Medical Fee Payment Fund of Social Insurance inspects the medical fees claimed by health care providers. The medical fee inspection programme primarily aims to detect any error and also examines the appropriate provision of health services. As a result,

[13] Each item of medical practice has its point as set by the government. The providers are paid according to the points they provided. The unit price of the point is negotiated between the government and medical professional groups.

the medical fee inspection programme ensures health care providers are aware of their costs of care (National Federation of Health Insurance Societies, Japan, 1997).

Other measures to control health care costs include co-payment and classification of hospitals by their function. The co-payment rate varies from 10 % to 30 % of total costs incurred in accordance with the insurance plan[14]. To improve quality of care and efficiency in health care delivery, the Medical Service Law of 1992 categorised hospitals into three types according to their functional level: 'acute care hospitals' which provide advanced medical care; 'chronic care hospitals with recuperation beds' which accommodate long-term patients; and other ordinary general hospitals. By an amendment of Medical Service Law in 1993, people who are consulted at acute care hospitals (including teaching hospitals) without a referral letter have to pay extra fees.

2.2.2.2. Korea

The health care system in Korea is characterised by a mixture of public funding and private provision. Total health spending accounted for 5.6% of GDP in Korea (OECD, OECD Health Data 205). Since 1989, the statutory insurance system has covered the entire population, except for less than 5% of people who are unable to pay premiums and automatically become Medical Aid beneficiaries subsidised by the central government.

Like Japan, insurers implement a traditional insurance function. Health services are delivered in a completely fragmented way. Insurance programme compensates health services on an FFS basis.

The approaches to control health care expenditure have principally relied on the following measures;

- price control
- excluding services from the insurance coverage
- co-payment
- controlling the use of expensive HTs

[14] The employees' insurance programmes reimburse 90 % of total cost for the insured, and 80 % of inpatient services and 70 % of outpatient services for the dependent. The insurers of national insurance programmes reimburse 70 % of total cost both for the insured and their dependants. The insurers of retired employees reimburse 80 % of total cost for the insured, and 80 % of inpatient services and 70 % of outpatient services for their dependants.

The government strictly controls fee schedules with the system determining the fee level[15]. The medical fee is also subjected to a national retailer price plan. As a corollary, the medical fee has been kept in line with retailer price.

Health care in Korea is highly commercialised. Market mechanism prevails health industry due to high proportion of private providers who seek profits (76.8 % of total providers as of 1994) (Yang, 1996), free access of patients to the providers and large portion of out-of-pocket payments at the point of consumption. Although the fee system is uniformly applied to all providers, there are two sources spurring price competition[16]. The large proportion of out-of-pocket money at the point of consumption leads to price competition among providers.

2.2.2.3. UK

Health services are largely provided by public funding in the UK. The National Health Service (NHS) was created in 1948 as a publicly financed and centralised system providing free universal access to health care. In the aftermath of World War II, the Labour government created the NHS as called for by the Beveridge Report of 1942. The NHS provides the majority of healthcare from general practitioners to hospitals, long-term healthcare, dentistry and ophthalmology. Private health care has continued parallel to the NHS, paid for largely by private insurance, but it is used only by a small fraction of the population, and generally as a top-up to NHS services. Many NHS services are free at the point of delivery, paid for by general taxation; in 2007 the NHS budget was 21.1% of the national budget (HM Treasury, Budget 2007).

---

[15] It requires the following four steps. First, the government conducts research on the profitability of health care providers for the next year by projecting increases in health care costs. This serves as a yardstick to determine the level of fee increases next year. According to the Price Stabilisation and the Fair Trade Act, fee increases should be approved by the Economic Planning Bureau that controls overall national economic policies. Then, the Ministry of Health and Welfare finally enters negotiations with the medical community to arrange the items of medical services covered by insurance and fee rates for each item of service.

[16] First, many services are not covered by insurance. Second, patients pay a high rate of co-payment ranging from 20 % to 55 % of total costs. Although the co-payment rate is the same for all providers, patients differently perceive the costs of providers from one to another, because patients are liable for co-payment of uncovered services completely out of their pocket at the end of each visit. A large proportion of co-payment and payment for uncovered items is paid for out of the pockets of patients, making them more sensitive to the cost of providers.

To improve efficiency in providing health services, Margaret Thatcher's Conservative government launched reforms in 1991. As a major principle, a market system was introduced into the NHS. Certain GPs became "fund holders" and were able to purchase care for their patients. Health authorities were required to purchase the rest of health services from NHS hospitals. Thus purchasing and providing were split for the first time in the NHS.

Health reforms under the Labour government that came to power in 1997 have encouraged outsourcing of medical services and support to the private sector. Under the Private Finance Initiative (PFI), an increasing number of hospitals have been built by private sector consortia; hospitals may have both medical services and non-medical services (such as catering) provided under long-term contracts with the private sector.

In 2000, the Blair government introduced the National Health Services Plan, the largest program of investment and reform since 1948. The plan envisages increasing health care spending to 9.4% of GDP by 2008 (HM Treasury, Spending Review 2002). In the reforms, health authorities and all NHS regional offices have been dismantled since 2002. The responsibilities are being shifted to primary care trusts (PCTs), which provide 90% of the first contact with patients. Health Authorities have transformed from being purchasers to having a more strategic role in determining the overall health needs of their areas; assessing priorities, promoting public health, and monitoring the quality and effectiveness of both commissioners and providers of health care.

As of the end of 2006, 152 primary care trusts control about 80% of the total NHS budget and have control over all local services. These PCTs are able to purchase care from public, private, voluntary and not-for-profit health care providers. Hospitals, or NHS foundation trusts, operate on a not-for-profit basis and are able to borrow money for investment, recruit their own staff. As part of the new NHS framework, the system relies on the advice of a newly established organization—the National Institute for Clinical Excellence (NICE)—which provides the NHS with guidance on current best practices and cost effectiveness related to medicines, medical equipment, clinical procedures, and the management of specific conditions.

2.2.2.4. US

Health care in the United States is provided by many separate legal entities. The US spends more on health care than any other nation in the world. Current estimates put US healthcare spending at approximately 15% of GDP. Around 84% of citizens have health insurance, either through their employer (60%), purchased individually (9%), or provided by government programs (27%; there is some overlap in these figures) (US Census Bureau, 2005). The federal government does not guarantee universal health care to all its citizens, but Medicare programmes provide for the elderly, disabled, children, and the poor, and federal law ensures public access to emergency services regardless of ability to pay. Medicaid programmes financed by state government provide for the poor aside from Medicare benefits. Americans without health insurance coverage, currently about 16% of the population, or 46 million people, are expected to pay privately for medical services. Health insurance is expensive, and medical bills are overwhelmingly the most common reason for personal bankruptcy in the United States (Himmelstein et al., 2005).

Roemer (1991) characterises the US health care system as possessing three major features. First, the US spends a great deal of money on health care services. Second, as a federated nation, it governs health care systems in a highly decentralised manner at the federal, state, and local level. Third, as a free market economy, it incorporates very permissive *laissez-fair* concepts throughout its health care system. The federated political system and free market structure have particularly significant implications for health care systems. The free market structure has minimised public involvement, and thereby, vitalised the participation of private entities in financing and providing health care services.

The Medicare programme implemented the hospital prospective payment system, based on the DRG (Diagnostic Related Group) system, in October 1983. Two mechanisms are embedded within the PPS (Prospective Payment System) in order to curtail cost increases in health care services. First, by giving financial incentives to hospitals, the programme expects them to improve efficiency in providing inpatient services by means of reducing the lengths of stays and the quantity and cost of services provided during hospital stays. Second, the introduction of Peer Review Organisations (PROs) has also encouraged

doctors and hospitals to reduce hospital costs (Prospective Payment Assessment Commission, 1994)[17].

As a measure to control health care costs in the private sector, various kinds of managed care organisations (MCOs) have been developed including Health Maintenance Organisations (HMOs)[18], preferred provider organisation (PPO), and point-of-service (POS)[19].

2.2.3 Classification of health system for the selected countries

The present research deals with four countries: Japan, Korea, the UK and the US. These four countries are unique in that they have different systems of finance and compensation for health services. Details on the health systems, along with their incentives for HT adoption, are described below sections.

Table 2-5 offers a broad schema describing the key characteristics of the health systems of each country in terms of financing and delivery system; by clustering both according to the balance between public and private sector involvement. In a similar vein, Propper and

[17] Cost control was one of the major objectives of the PROs Cost and utilisation objectives of PROs; this included reductions in admissions for procedures that could be safely on an outpatient basis, reductions in inappropriate admissions and use of unnecessary ancillary services, and elimination of inappropriate cardiac pacemaker implantations or re-implantations (Davis et al., 1991).

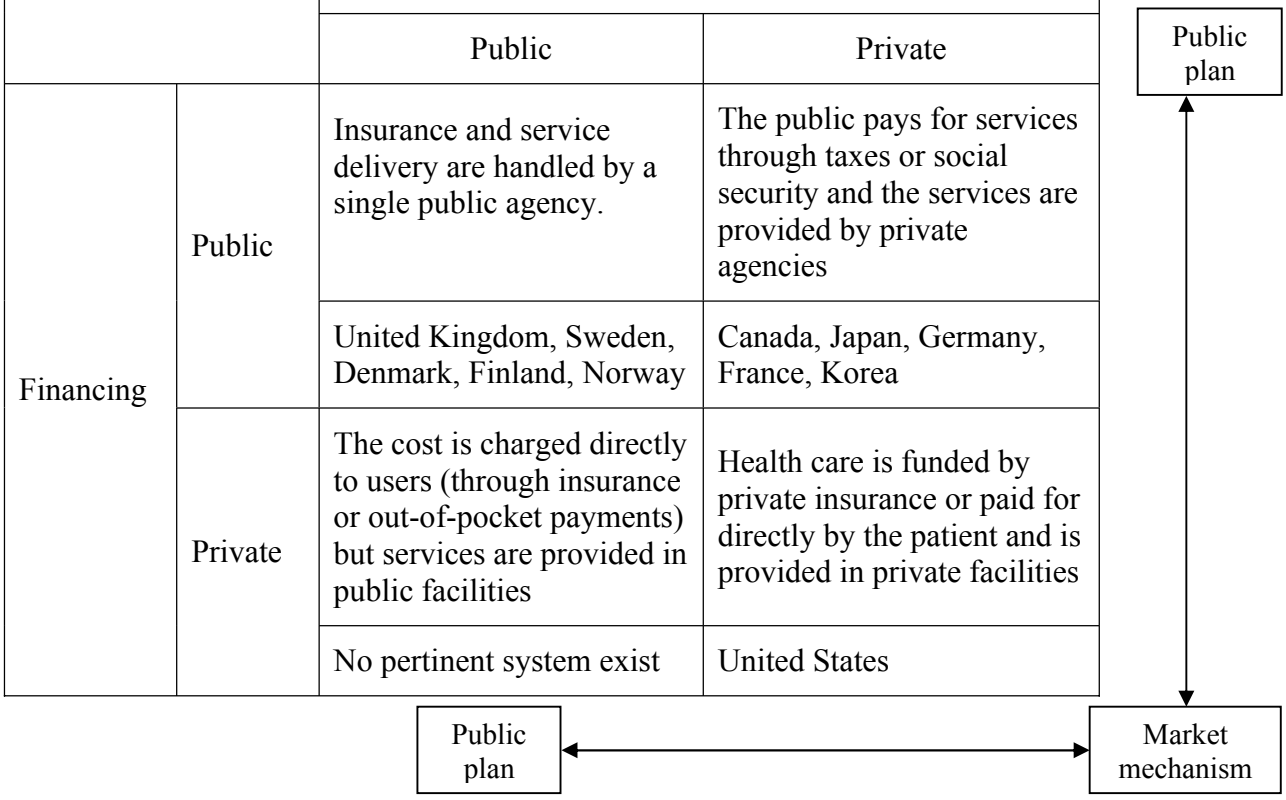
[18] The HMO assumes the financial risk for provision of services on a prospective basis and, therefore, integrates the functions of insurance and the provision of medical services (Enthoven, 1978).

[19] There are five commonly recognised models in HMOs (Kongstvedt, 1993), which are staff, group, network, IPA, and direct contract. PPO is a form of managed care through which employer health benefit plans and health insurance carriers contract to purchase health care services for covered members from a selected group of participating providers. Most PPOs contract directly with hospitals, physicians, and other diagnostic facilities. Providers are selected to participate on the basis of their cost efficiency, community reputation, and scope of services. PPOs reimburse the participating providers in full for covered services, except the amounts assigned to patients as coinsurance or deductibles, at a discounted price schedule, which compensates the providers with a competitive cost advantage relative to cost-based payment systems. Providers participating in PPO are reimbursed on FFS basis and totally free to see other insurers' patients. Members in PPOs have the choice of using either in or out of network physicians and hospitals. To control the utilisation and cost of health care services, many PPOs implement utilisation management programmes. There are two types of POS plans (Kongstvedt, 1993): capitated and primary care POSs and open-access POS HMOs. Under capitated POS, primary care physicians are reimbursed through capitation payments or other performance-based reimbursement methods. The primary care physician acts as a gatekeeper for referral and institutional medical services. The members are not fully covered for services rendered that either are not authorised by the primary care physician or are delivered by the providers who are not participating in the POS plan.
The members enrolled in an open-access POS can choose HMO benefits or indemnity-style benefits for each instance of care. The indemnity coverage available under POS options from HMOs typically incorporates high deductibles and coinsurance to encourage members to use HMO services instead of out-of-plan services.

Green (1999) classify health systems into four types: mainly public provision, public finance; mixed provision, public finance; mixed provision, mixed finance; and mainly private provision, private finance. Health systems are continually engaged in a dynamic process of reform in response to changing needs, new policy directions, and medical developments (Blanchette, 1997).

Table 2-5. **Health systems by public-private sector intervention (Modified from Blanchette, 1997)**

		Delivery	
		Public	Private
Financing	Public	Insurance and service delivery are handled by a single public agency.	The public pays for services through taxes or social security and the services are provided by private agencies
		United Kingdom, Sweden, Denmark, Finland, Norway	Canada, Japan, Germany, France, Korea
	Private	The cost is charged directly to users (through insurance or out-of-pocket payments) but services are provided in public facilities	Health care is funded by private insurance or paid for directly by the patient and is provided in private facilities
		No pertinent system exist	United States



As Deber and colleagues (1998) point out, *"virtually every country employs some combination of financing and delivery models, relying on various public-private combinations in various sectors of the health system or for various groups of the nation's population (p. 439)."* In this vein, it is quite difficult to place a health system into a static classification. Traditionally, the NHS was financed via public intervention and the provision of health services controlled by public organisations. Constant reforms, from

internal market transformation through to the reforms of the current Labour government, have moved the NHS towards a market-based model.

In summary, the health systems of selected countries are characterised as follows; 1) the UK health system represents a public planning in both finance and delivery aspects, 2) those of Japan and Korea are categorised into public planning in finance but market mechanisms in delivery, 3) the system in the US is recognised as using a market mechanism in both terms of finance and delivery. Since health services in both Japan and Korea are compensated on a FFS basis while being provided in a fragmented way, a market mechanism is being promoted in health care provision.

2.2.4 Health systems and health technology adoption

Table 2-6 provides an overview of the health systems of the four countries. The health systems of Japan and Korea are similar. Finance comes from social insurance; health providers are compensated by a FFS system; and health services are provided in a fragmented way. Health care providers exploit HTs in order to increase income. Since financial risks are transferred to third party payers, health care providers and users are not conscious of the costs of using health services. By introducing DRG based payment system for some items, health care reforms have been partly attempted by adopting pre-fixed fee payment systems in both Japan and Korea.

Table 2-6. **Major components of healthcare system in selected countries**

Country	Finance	Payment	Delivery
Japan	Social insurance	Retrospective reimbursement	Fragmented
Korea	Social insurance	Retrospective reimbursement	Fragmented
UK	Tax-funded	Budget allocation	Coordinated
US	Private insurance Tax-funded	Internal compensation Contract Retrospective reimbursement	Integrated Coordinated Fragmented

As the ownership of health care facilities predominately lies within the private sector, market oriented mechanisms are dominant in health services in both Japan and Korea, even though healthcare funds are mostly financed by social insurance schemes. Regarding the adoption of health technologies, these systems have the following characteristics:

- Healthcare providers are largely free to choose medical treatments without taking financial risks
- Most health services are covered by health insurance – as long as the intervention is medically required and costs are not unjustifiably high
- The decision for the adoption of HT is in the hands of health care providers
- Health providers finance capital cost is in their own decision

In the UK, financial resources for HT adoption were allocated by Department of Health to Health Authorities (HAs) on the basis of weighted capitation targets. Traditionally, the NHS managed both the finance and delivery of health services as a single entity. To improve efficiency in providing health services as well as responsiveness to local needs, a series of reforms have been introduced since 1989 with the aim of breaking down the traditionally bureaucratic public sector state monopoly

The New Labour's White Paper; 'The New NHS: modern, dependable', favoured partnerships of collaborative networks among entities involved in health service provision. As Hunter (2000) notes, "*unrelenting performance management is the hallmark of Government's managerial style* (p.71)", the New Labour Government stressed the 'management of the NHS' delivery on waiting list targets and on financial targets.

In the traditional NHS, the physicians had no need to be cost conscious. The health care reforms in recent years have led health care providers to be more cautious in terms of resource use. Regarding health technology adoption, the NHS is characterised by:

- Healthcare providers choosing medical treatments in consultation with patients. As the services are provided within given financial resources to HAs, patients must wait until financial resources are available for them
- HAs restrict the HTs to be available on the basis of priority of local needs and evidence of effectiveness

- Global budget systems limit the availability of money to purchase expensive equipment (Rosen and Mays, 1998: 106)

In the US, most health care is provided in the private sector. State and local public hospitals account for 22% of the total 6,265 hospitals and contain 157,000 beds. Among them, 17% of all hospitals (and 14% of all hospital beds) are owned by the federal government (Tradewell, 1998)[20]. The number of public hospitals has been shrinking constantly, and declined 23% from 1975 to 1995. Notwithstanding the dominance of the public sector in terms of provision, sources of finance are more mixed. In 1998, the private sector accounted for 55.3% of total healthcare spending (OECD, OECD Health Data 2000). In terms of population covered under the age of 65 in 1999, private health plans accounted for 72.3%, and public insurance programmes for 12.3% (Custer and Ketsche, 2000). The remaining 17.4% of the population was without insurance coverage. Public insurance programmes through Medicare and Medicaid cover 23.4% of the total population, including the people over the age of 65.

The majority of health care providers in the US appear to pursue financial gain either by increasing income or decreasing costs. Traditionally, health services were remunerated on an FFS basis, and critics pointed to a tendency towards overspending due by supplier-induced demand (Ham and colleague, 1990: 71). In an attempt to control health care spending, the US Congress passed the Health Maintenance Organisations (HMOs) Act in 1973 encouraging the formation of managed care organisations (MCOs). The introduction of HMOs has brought about a fundamental transformation away from the traditional indemnity plan in terms of both delivery and reimbursement system. There was a move from FFS-based fragmented services to the provision of comprehensive care for a flat prepaid fee. In 2001, about 62.3% of the total population were joined in some form of managed care plan (Managed Care On-Line™, 2002) covering 177.9 million people.

By ensuring comprehensive care within given fees, financial risk is transmitted to healthcare providers in the managed care arrangement of the US. MCOs thus endeavour to control healthcare costs by avoiding hospitalisation and the use of expensive medical and

[20] Privatising public hospitals: strategic options in an era of industry-wide consolidation, Reason Public Policy Institute, Policy Study No. 242, http://www.rppi.org/ps242.html retrieved on 5 January 2002.

surgical procedures in favour of less-expensive options; including outpatient, home, or nursing home care (Balder, 1996; 22-27). The front line option is to prevent hospitalisation if possible, and keep good quality care at the primary care level.

The DRG based reimbursement system introduced in October 1983 for the Medicare beneficiaries is also designed to avoid excessive stays in hospital and gives the hospital a financial incentive to discharge patients as early as possible. Hospitals are paid on the basis of two fixed "standardised payment amounts" per discharge of Medicare beneficiary; these are the operating amount and capital amount.

General incentives inherent in DRG can be summarised as 1) to reduce the cost of each inpatient case stay and 2) to increase the number of inpatient admissions (OTA, 1983). Under the current US DRG system, new technology is often underpaid (Princeton Reimbursement Group, 2002). As the cost per patient stay can be reduced by using fewer interventions, including technological services and labours, the resulting incentive may favour in specialisation among hospitals for services encouraging capital intensive technologies in fewer institutions (OTA, 1983).

Competition among healthcare providers creates incentives to equip with state-of-art technologies and staffing by dominant figures. Technologies that are cost-saving to hospitals will tend to be encouraged in a fixed or flat fee reimbursement scheme. This is commonly applied to DRG systems and the services provided by MCOs. By contrast, in indemnity plans, where the fees are compensated for on an FFS basis, technologies that may contribute to increasing revenues are encouraged.

Competition among healthcare providers creates incentives to equip with state-of-art technologies and staffing by dominant figures. Technologies that are cost-saving to hospitals will tend to be encouraged in a fixed or flat fee reimbursement scheme. This is commonly applied to DRG systems and the services provided by MCOs. By contrast, in indemnity plans, where the fees are compensated for on an FFS basis, technologies that may contribute to increasing revenues are encouraged.

In summary, the reasons for potential adopters to adopt a new technology vary according to the health system. *Table 2-7* describes relationships among major agents in each country in adopting new technology on comparative aspects. It implies that the incentive for technology adoption may vary widely depending on the health care system

Table 2-7. **Relations among major agents in adopting new technology**

	Japan	**Korea**	**UK (NHS)**	**US**
Decision maker for technology adoption	Individual hospital and physician		DoH, HA, Individual hospital and physician	Individual health care organisation, hospital or physician
Finance for technology adoption	Individual hospital or physician		DoH, HA, Individual hospital	Individual health care organisation, hospital or physician
Decision maker for technology use	Individual hospital or physician		HA, Individual hospital	Individual health care organisation, hospital or physician
Who gets profits produced by adopting new technology	Individual hospital or physician		N/A	Individual health care organisation, hospital or physician
Who gets benefits of cost reduction created by new technology	Patients, social insurance		Nation	Patients, private insurance, public insurance
Major incentive to adopt net technology	Profit maximisation		Cost reduction	Profit maximisation, Cost reduction

2.3 Analysis of data

Micro factors will be assessed in terms of economic and clinical effectiveness which are commonly evaluated in terms of cost-effectiveness or overall costs for use. As a method to "*describe or predict the differential costs and benefits of two or more alternative interventions* (Ruttens, 1996: 216)," economic evaluation or health care technology

assessment has been a major tool to address the role of micro factors playing in the adoption of health care technologies. In tandem with a constant rise of health costs, which are often associated with new technologies, there have been growing requirements to demonstrate the benefit versus cost of new technologies[21].

Economic evaluations have been employed as an aid to the development of treatment guidelines, decisions within health care organisations, the introduction of new health care technologies, and reimbursement and pricing decisions (Johannesson, 1995). The primary role of economic evaluation in health care is to "*help decision-making by considering the output of competing interventions in relation to the resources they require* (Kernick, 1998:1663)." Economic evaluation provides a basis for decisions about approval of new technology.

In cost-benefit analysis, there are two main approaches to assign monetary value to life and health (Drummond et al, 1995; Klose, 1999). The first measures market valuations, which take into account human capital and friction costs enumerating either the value of a person's life or the indirect cost of disease with reference to a person's contribution to the gross domestic product as measured by wage rates[22]. The second approach assesses "willingness to pay (WTP)" for a technology and its effects based on individuals' preferences. WTP is calculated from data on trade-offs between the effect to be evaluated and a monetary amount from which WTP measures can be derived. WTP and quality adjusted life year gained (QALY) are two preference-based measures of health-related outcome. QALY attempts to measure the outcome of a disease in terms of different combinations of duration and quality of life. The WTP approach directly asks respondents what amount they are willing to pay to give up permanently their previous state as valuing a specific health and time profile.

---

[21] In Australia, economic evaluation is a requirement for public sector funding of new drugs (Raftery, 1998). Based on economic evaluation, the Australian Pharmaceutical Benefits Advisory Committee decides whether drug products should covered by public subsidy (Hailey, 1997). Palmer and colleagues (1999) argue that full costs and benefits of all health care problems and all alternative interventions should be assessed to determine whether a change in the mix of intervention would increase efficiency. In the US, the Food and Drug Administration Modernisation Act of 1997 requires pharmaceutical manufactures to support economic claims about their products in pursuit of improving health care economic information exchange while protecting consumers from misleading claims (Neumann et al., 2000).

[22] This approach was widely criticised because of its inconsistency with the basic rationale of the economic calculus used in cost-benefit analysis, as it requires measures based on individuals' preferences.

In assessing economic advantages, the current research depends on the results of economic evaluations located for each HT, considered in terms of overall costs, patients' share, cost per life year gained, or costs per QALYs. Economic information for each topic is summarised in *Table 2-8*.

Table 2-8. **Economic evaluation for selected HTs**

	Economic evaluation	Comparable approaches
ARTs	Cost per cycle Cost per live birth	
caesarean section delivery	Cost per procedure	Vaginal delivery,
HSCTs	Cost per procedure	Chemotherapy
Kidney transplantation	Costs per QALY, Cost per procedure	Home dialysis, Hospital dialysis
Cochlear implant	Costs per QALY, Cost per procedure	Other hearing support materials
Gamma Knife Radiosurgery	Costs per QALY, Cost per procedure Cost for installation	Open skull surgery

The clinical and economic advantage varies according to the reason for which each technology is adopted, such as success rate, the effect on improving quality of life (QoL), prolongation of life, restoring function, preventing disability and avoiding mortality and morbidity. The present study depends on the information found in the literature regarding the clinical effectiveness of each HT. For the ARTs, clinical effectiveness is often assessed in terms of success rate per cycle and the outcomes of ART procedures are compared to each other. No specific way has been found of showing the clinical effectiveness of caesarean section delivery. Compared to vaginal delivery, adverse effects including maternal death rate and complications have been common indicators in assessing effectiveness. As for HSCTs and organ transplantations, clinical effectiveness has been assessed in terms of survival rate following the transplantation and comparisons of QoL between the periods of pre- and post-transplantation.

Technical advantage denotes the dominance in technical terms of using a particular technology, which described in terms of ease of use on theoretical contemplation. On the patient's side, technical advantage implies comfort, less pain and a shorter time spent on diagnosis and treatment. For medical professionals, technical advantage would include operational convenience and lower time demands.

As it is not possible to assess technical advantage in quantitative terms, it is considered a residual factor and is assessed by listing the reasons, other than clinical and economic rationales, why patients or health care professionals may prefer a particular technology.

The diffusion of HT is a matter of 'speed' and 'level'. Speed refers to how the technology has spread over the defined area within a limited time period. The level of diffusion concerns the supply of the technology compared with the need for the technology. It is, however, difficult to find a method by which to assess the speed of innovation and level of diffusion. Major difficulties lie in uncovering the process and timing of adoption (Sloan et al., 1986). As all countries experience different circumstances with regard to the use of the technologies, the adoption level of health care technology cannot simply be recognised by the current adoption.

Theoretical frameworks assessing the dissemination of new technologies fall into three groups (Feder and Uy, 1985): time-series studies; cross-sectional studies; and panel-data studies.

Time-series studies attempt to model the pattern of adoption as a logistic function over time. Accordingly, these studies measure technology diffusion in terms of adoption by time. For example, these approaches assess the percentage of firms employing a new technology at each date, or the percentage of products produced by using the technology. As time-series studies analyse technology adoption in certain regions at a certain time points, these approaches make it possible to investigate the effect of regional characteristics on adoption.

Cross-sectional studies assess technology diffusion by taking a snapshot of a firm's technology in use at certain point in time. These studies aim to measure the impact of a firm's characteristics on adoption decisions. Recognising that technology is likely to be

unevenly diffused through the regions, population or firms, these studies can provide insight into the characteristics of firms associated with acquiring the technology.

Panel-data studies analyse in parallel details of the characteristics of industry and firms in order to understand the adoption choices made at each point in time.

The present research assesses the diffusion of health care technology in both time-series and cross-sectional terms, measuring the trend of technology adoption with comparisons of four countries. The level of HT diffusion is assessed by comparing the number treated with per million population (pmp). The data for the adoption of each HT has been collected from various sources, as which summarised on *Table 2-9*, below.

Table 2-9. **Data sources for HT adoptions**

HTs	Japan	Korea	UK	US
ART	JSOG	KSOG	HFEA	ASRM
caesarean section delivery	MHLW	NHIC	DOH	CDC, NCHS
HSCT	JSHCT	HSCT Nurse Association	BSBMT	IBMTR/ ABMTR,
Cochlear implantation	ACITA	Local agents	D. Marshall	A.Q. Summerfield
Gamma Knife	Manufacture JGMSA	Manufacture	Manufacture	Manufacture
Kidney transplantation	JOTN	KONOS	UKTSSA	UNOS

Note:

a. JSOG- Japan Society of Obstetrics and Gynaecology
b. JGMSA- Japan Gamma Knife Support Association
c. KSOG- Korean Society of Obstetrics and Gynaecology
d. HFEA- Human Fertilisation and Embryology Authority
e. ASRM- American Society for Reconstructive Microsurgery
f. MHLW- Ministry of Health, Labour and Welfare.
g. NHIC- National Health Insurance Corporation
h. DOH- Department of Health
i. BSBMT- British Society of Blood and Marrow Transplantation
j. IBMTR/ABMTR- International Bone Marrow Transplant Registry and the Autologous Blood and Marrow Transplant Registry
k. ACITA- Association of Cochlear Implant Transmitted Audition
l. JOTN- Japan Organ Transplant Network
m. KONOS-Korean Network for Organ Sharing
n. UKTSSA-United Kingdom Transplant Support Service Authority
o. UNOS- United Network for Organ Sharing

Part 2

Case studies

Chapter 3: Assisted Reproductive Technology

3.1. Introduction

Infertility is the condition in which one year of unprotected intercourse does not result in pregnancy. It is currently estimated that about 60-80 million couples around the world suffer from infertility (WHO 1995). Thirty-five % of these cases are attributed to female factors, 35% to male factors, and 15% to multiple factors. For the remaining 15% of the cases, the cause is unknown (Solursh et al. 1997).

Medical and scientific advances in ARTs have made various options for conceiving a baby, or various medical interventions, available, including ovulatory induction using fertility drugs, artificial insemination by way of partner or donor sperm, surgical procedures, medical management, and in-vitro fertilisation embryo transfer (IVF-ET).

Taking fertility drugs is the most common option for infertility treatment. The term *ARTs*, though, usually refers to the more advanced treatments IVF-ET and gamete intrafallopian transfer (GIFT) (Ryan 1996). There is a wide range of ARTs that can be employed in infertility cases, depending on the cause of infertility. IVF-ET is the first ART procedure ever developed, and it remains the most commonly performed procedure. It is a procedure that involves retrieving a woman's eggs and a man's sperm, then placing both of them on a laboratory dish to increase the chances of fertilisation. If fertilisation takes place, the eggs are once again placed in the woman's uterus several days after the retrieval, and it is hoped that implantation and embryo development will occur therein, as in a normal pregnancy. The first IVF-ET baby, Louise Brown, was born in the UK Since then, the number of IVF-ET treatments performed each year has increased, and the success rate of the procedure has improved significantly.

Zygote intrafallopian transfer (ZIFT)[23] has the advantage of allowing fertilisation to be confirmed, and has demonstrated a higher success rate than IVF-ET when used in appropriate cases. Like IVF-ET, ZIFT involves ovarian stimulation, monitoring, and egg retrieval, followed by sperm processing and fertilization in the laboratory. Another slight

[23] With ZIFT, the fertilised egg that is placed inside the woman's uterus is allowed to divide only up to the two-cell stage and not up to the four- or eight-cell stage, as with the conventional IVF-ET. This fertilised egg at the two-cell stage is called a *zygote*.

difference between IVF-ET and ZIFT (besides the stage at which the embryo is transferred to the uterus) is the place where the embryo is implanted in the woman's body. In ZIFT, the zygotes are placed directly into the fallopian tube. Therefore, a criterion for performing ZIFT is that the female partner must have at least one open and functioning fallopian tube.[24]

Gamete intrafallopian transfer (GIFT) was developed in 1984 as a variation of IVF-ET. GIFT is not very different from IVF-ET. The main difference between the two is that in GIFT, fertilisation is naturally achieved within the female partner's body and not in the laboratory. In GIFT, eggs are retrieved from the woman's ovary through ovarian stimulation, and then the sperm and eggs are placed directly into the woman's fallopian tubes to induce fertilisation.

Intracytoplasmic sperm injection (ICSI) was developed to treat couples who have a very poor probability of achieving fertilisation due to the male partner's extremely low number of viable sperms. In ICSI, sperms are injected directly into the centre of the egg using a microscopic pipette.

Intrauterine insemination (IUI) is the simplest and least costly ART. It involves giving the woman fertility drugs in the hope that these will help her produce more eggs. Then, sperms are injected directly into the uterus.

There are two types of surrogacy that are also possible options for infertile couples: genetic and gestational surrogacy. In genetic surrogacy, a surrogate is artificially inseminated with the husband's sperm. As such, the newborn is genetically related to both the husband and the surrogate. In gestational surrogacy, the woman produces eggs, but for some reason, she is unable to achieve pregnancy or carry pregnancy to term. In this case, the embryo and sperm of the couple who are trying to conceive a baby are placed in the surrogate's uterus through IVF-ET. The surrogate thus simply provides the host uterus, but the newborn is genetically related to the couple and not to the surrogate.

Table 3-1 summarises the regulation and reimbursement policies in relation to ARTs in some OECD countries. As shown in the table, there are huge variations among countries

[24] One disadvantage of ZIFT is that the zygote is placed inside the woman's uterus using a laparoscope, which necessarily involves surgical incision. In IVF-ET, there is no need for any incision as the fertilized eggs are transferred to the uterus through the vagina. Although laparoscopy is a minor surgical procedure, it nevertheless makes ZIFT more complex, risky, and costly than IVF-ET.

in terms of their ARTs regulation and reimbursement policies. As ARTs involve the use of unnatural processes to aid human reproduction, their development has generated more controversy among religious groups, bio-ethicists, and the general public than any other medical procedure has (Jones and Cohen 2001). The controversy surrounding ARTs have spurred deliberations on the ethical, legal, religious, and public-policy aspects of such technologies, which have resulted in the establishment of guidelines and/or legal regulations in relation to them. These guidelines and regulations take into account various medical perspectives and social circumstances, including cultural traditions. Some negative reactions to ARTs stem from the delivery of non-genetically-linked newborns, the occurrence of chromosome abnormalities, and the practice of gender selection through sperm sorting.

Table 3-1. **Regulation and reimbursement policy for ARTs**

Country	Situation
Australia	Australia's Reproductive-Technology Accreditation Committee (RTAC) ensures a high standard of care. Australia is the only country in the world that provides unlimited government reimbursement for infertility treatments, with no restriction on the lifetime use of IVF-ET treatments.
Austria	An ARTs-related law was passed in 1991. From January to June of 2000, approximately 70% of all IVF-ET treatments (including medication) for women aged <40 and for men aged <50 and with tubal dysfunction or male infertility were publicly funded.
Canada	There is no legal regulation of the use of ARTs. All IVF-ET treatments are privately funded, except in the province of Ontario, where only up to three cycles in a lifetime are publicly funded, and only for women with completely occluded fallopian tubes.
France	If the infertility treatment is carried out in a public hospital, the costs are fully covered by public funds, but only up to six artificial inseminations and four IVF-ET treatment cycles.
Germany	The Embryo Protection Act of 1990 prohibits several ART procedures. Only up to 14 inseminations, two GIFTs, and four IVF-ET cycles are covered by public funding. No health insurance company reimburses ICSI.
Netherlands	Public funding covers only up to three IVF-ET cycles. Most private insurance companies also pay for three IVF-ET cycles, but they charge a co-payment. Commercial surrogacy is prohibited.
Norway	Legislation controls infertility treatment, limiting it to heterosexual couples. Public funding is available only when the treatment is performed in a public hospital.

Data Sources: Hughes and Giacomini (2001)

3.2. Micro Factor Evaluation

3.2.1. Economic Factors

An estimation of cost effectiveness can be obtained by comparing the cost of a medical intervention with the probability of having a baby through it. Accordingly, the cost effectiveness of ARTs has been evaluated by assessing their overall cost and comparing this to their success rates.

The costs of different ARTs vary greatly according to the protocols applied, which depend mainly on the number of embryos that are transferred in IVF-ET (Silva et al. 1997).[25] For instance, the standard IVF-ET protocols that transfer two or three embryos are less cost-effective than those that transfer only one embryo (Wølner-Hanssen and Rydhstroem 1998).

Table 3-2. **Cost effectiveness of infertility treatments (results in the UK): Average cost per case based on 1991/92 prices**

Treatment	Average Success Rate (%)	Average Cost per Maternity (£)			Total Cost (£)
		Infertility Services	Maternity Services	Hospital Sector	
Drug Therapy					
Amenorrhoea	17	235	2,924	271	3,430
Oligomenorrhoea	8	5,000	2,925	575	8,500
Endometriosis	8	750	2,925	575	4,250
Tubal Surgery	20	13,175	2,220	230	15,625
IVF-ET	12	19,500	2,608	383	22,491
Artificial Insemination[26]	5	2,800	2,260	920	5,980

Source: Ryan and Donaldson (1996)

Although transferring only one embryo may require more treatment, lower multiple-pregnancy rates lead to greater cost effectiveness. *Table 3-2* provides a summary of the average maternity care cost related to ARTs in Scotland as an example; it consists of the cost of the actual treatment and the expenses incurred through maternity and neonatal care,

[25] They found that they could reduce the costs to less than half by modifying the protocols. In their practices, the overall costs were reduced from US$7,000-US$11,000 to US$3409 for every cycle that was initiated, while keeping the pregnancy rates at a level beyond the national average (30% vs. 18.6%).

[26] Artificial insemination is generally chosen before electing for IVF-ET. IVF-ET is performed if the insemination procedures fail to achieve pregnancy in spite of repeated attempts. Artificial insemination includes IUI, IVI (intravaginal insemination), and AID (artificial insemination by a donor).

including the hospital sector, for the treatment of complications. *Table 3-3* shows that therapy using amenorrhoea achieves a higher success rate at lower costs, while IVF-ET appears to be less cost-effective than tubal surgery and drug therapy using amenorrhoea.

Table 3-3. **Cost effectiveness of infertility treatments (1992)**

Procedure	Number of Procedures	Live-Birth Rate (%)	Multiple-Birth Rate (%)	Cost per Delivery (US$)
IUI	103	5.8	0.0	8,674
CC-IUI[a]	188	6.3	8.3	7,808
hMG-IUI	80	17.5	21.0	10,282
IVF-ET	81	22.2	44.0	43,138
Tubal Surgery	24	12.5	0.0	76,232
Donor Oocytes ART	34	32.3	18.0	35,062

Source: Van Voohis et al. (1997)
Note: a. clomiphene cirate and IUI

As shown in *Table 3-3*, in the study by Van Voorhis et al. (1997), intrauterine inseminations (IUI), clomiphene citrate and IUI (CC-IUI), and gonodotropin stimulation and IUI (hMG-IUI) were less effective than the other ARTs when evaluated in terms of their live-birth rate per cycle. Due to the lower costs of such procedures, however, IUI, CC-IUI, and hMG-IUI proved to be more cost-effective than the ART procedures. Tubal surgery through laparotomy performed in cases involving tubal problems was less cost-effective than IVF-ET. ICSI achieved significant cost savings as well as higher pregnancy rates compared to donor insemination, which is a compatible option if the characteristics of the semen are poor (Granberg et al. 1996).

"Willingness to pay" for the procedure has also been used as a yardstick in assessing the benefits of ARTs in economic terms, as data on ART purchases are generally unavailable (Neumann 1997). As summarised in *Table 3-4*, the general population of the UK involved in WTP evaluations was willing to pay 29% of their payroll income for a 50% chance of having a child (Dalton and Lilford 1989). Neuman and Johannesson (1994) reported that the survey respondents were willing to pay £9,273 on average for IVF-ET if they were infertile, and that the procedure had a 10% probability of successful conception.

Table 3-4. **Willingness to pay for ARTs**

Research	WTP	Expected Chances
Dalton and Lilford (1989)	29% of the total payroll income	50%
Neuman and Johannesson (1994)	£9,273	10%

In conclusion, artificial-insemination technology appears to be more cost-effective than IVF-ET, GIFT, and ZIFT. Drug treatments are also generally more cost-effective than IVF-ET, but the latter is more cost-effective than tubal surgery. It is difficult to conclude that any particular procedure is more cost-effective than any particular one, as each measure is applied to a specific condition of infertility.

3.2.2. Clinical Factors

Since ARTs seek to enable infertile couples to conceive and have a child, the clinical effectiveness of ARTs is commonly assessed in terms of pregnancy and live-birth rates per treatment cycle. At IVF-ET centres worldwide, the probability of sustained pregnancy through IVF-ET is one chance in four to six (Davis 1998). As Ryan (1996) noted, the important matter to consider in deciding whether to provide ARTs is not the cost of the procedure but the outcome of the investment to be made.

In assessing the benefits of ARTs, several factors have been used as major parameters, such as the success rates of the procedures, their side effects, and their psychosocial impacts. The success rates of the procedures in terms of conception are widely varied around the world, and even across individual centres within the country.[27]

The results of each procedure in terms of the live-birth rate per cycle are also varied, as shown in *Table 3-5*. In general, IUI, ICSI, donor oocytes, and the transfer of cryopreserved embryos appear to have higher success rates compared to IVF-ET, GIFT, and ZIFT in

[27] In July 1996, the Human Fertilisation and Embryology Authority (HFEA) of the UK issued a report regarding the 25,730 IVF-ET treatments performed across the UK An overall average live-birth rate of 14.5% was found, within a range of 4.9% at the lowest centre to 23.7% at the highest, as estimated in 95% confidence intervals, for an adjusted live-birth rate (Marshall and Spiegelhalter 1998).

terms of pregnancy rates and live-birth rates. The recent development of ICSI shows high pregnancy rates in cases where the man has severe sperm defects. The indication to apply ICSI was limited to male-factor infertility

Table 3-5. **Results of ARTs**

Birth		Organisations Reported		Country	Year[a]	PR [b] (%)	LB[c] (%)
IVF[d]	Fresh	HFEA	Stimulated	UK	1995	19.2	15.7
			Unstimulated	UK	1995	3.2	1.7
		JSOB		Japan	1997	22.3	15.7
		KAOB		Korea	1996	29.6	18.8
	Frozen	HFEA		UK	1995	14.7	11.7
		JSOB		Japan	1997	16.6	10.6
		ASRT/SART Registry		US+Ca	1995	23.7	19.3
GIFT		ASRT/SART Registry		US+Ca	1995		27.0 per retrieval
		JSOB		Japan	1997	30.4 per transfer	10.6 per cycle
		KAOB		Korea	1996	33.4 per cycle	2.0 per transfer
ZIFT		ASRT/SART Registry		US+Ca	1995	32.2 per ET	30.5 per transfer
		JSOB		Japan	1997	27.5 per ET	20.0 per transfer
IUI		ASRT/SART Registry		US+Ca	1995	31.5 per cycle	22.5 per cycle
ICSI		ASRT/SART Registry		US+Ca	1995	31.3 per ET	25.4 per ET
		KAOB		Korea	1996	26.4 per cycle	15.0 per cycle
Donor Oocytes		ASRT/SART Registry		US+Ca	1995	43.3 per ET	36.0 per transfer
Transfer of Cryopreserved Embryos		ASRT/SART Registry		US+Ca	1995	19.4 (20.7)	15.2 (16.8)

Data Sources: 1) Japan Society for Obstetrics and Gynaecology (1998)
2) HFEA, 1997 Annual Report
3) Society for Assisted Reproductive Technology and American Society for Reproductive Medicine (2002)
4) Korean Association of Obstetricians and Gynaecology (1999)

Note: a. year of data collection
b. pregnancy rate
c. live-birth rate
d. units of success rates in both PR and LR, represented “per cycle”

The application of the technique has been expanded to include cases where the use of conventional IVFs has failed, where there is ejaculatory dysfunction and immunological infertility problems, and where the woman has undergone chemo/radiation therapy due to cancer (Ola et al. 2001). Fishel et al. (2000) found significantly higher fertilization and

pregnancy rates with ICSI among those who have tried conventional IVF-ETs without success. The most significant advantage of ICSI over donor insemination would be having a baby with the same genetic make-up as the father.

While the use of ARTs may improve the chances of pregnancy, these techniques have some critical deficiencies. ARTs evince a higher probability of multiple births[28] when more than one embryo is transferred into the uterus to increase the chances of successfully implanting an embryo. Considering the fact that triplets and higher-order multiple-birth offspring are about six times more likely to die in their first year compared to singletons (Interim Licensing Authority for Human In-Vitro Fertilisation and Embryology[29] 1991), and entail about ten times higher costs per delivery, as determined by Goldfarb et al. (1996), it is better to avoid multiple births.[30] In 1995, throughout the UK (HFEA 1997), over a quarter (28.8%) of the pregnancies achieved through IVF-ET yielded twins, triplets, or higher-order multiple-birth offspring. According to the SART (Society for Assisted Reproductive Technology) Registry data, 37% of all the ART births in the US were multiple births (twins or higher-order multiple births) (CDC 1997).[31]

There is also a complex set of secondary issues, such as the birth of neonatal infants and short- and long-term maternal complications. The risks to the lives of the women and their offspring are also generally considered in assessing the advantages of ARTs. According to the precedent researches, pregnancies achieved by IVF-ET tend to be more complicated than those achieved normally. According to Serour and colleagues (Serour et

[28] Since the early 1970s, the frequency of triplet and higher-order multiple gestations among white mothers in the US increased by almost 200% (Wilcox et al. 1996). According to Wilcox and colleagues, the number of triplets or higher-order multiple births in the US increased from 29.2 pmp in 1972-1974 to 85.0 pmp in 1990-1991. The use of ARTs is responsible for approximately 38% of this increase, and the additional 30% increase was caused by the increase in the cases of child bearing among older women. The remaining third of this increase is associated with the use of ovulation-stimulating drugs.

[29] The Interim Licensing Authority for Human In-Vitro Fertilisation and Embryology (ILA) was replaced by a statutory body, the Human Fertilisation and Embryology Authority, on August 1, 1991.

[30] To reduce the cases of multiple births, two measures have been applied: limiting the number of embryos transferred, and selectively removing the conceptus (or concepti). As the latter choice raises a number of medical, ethical, legal, and psychosocial issues (Donner et al. 1990), the former choice is preferred by practitioners. The elective transfer of two embryos appears to be effective in reducing multiple births without impairing pregnancy rates (Fujii et al. 1998, Devreker et al. 1999).

[31] Multiple births in the general population of the US amount to less than 3% (CDC 1999).

al. 1998), the overall rate of complications was 8.3% among those having conception in 3500 ART cycles.

The psychosocial burden involved when one elects to undergo ARTs is another of its negative side effects (Boivin et al. 1998). As women must go to great lengths to achieve a biological pregnancy, including years of diagnosis and assisted reproductive interventions, they endure a great deal of psychological distress as well as socio-economic disadvantages. As pointed out, couples entering an IVF-ET programme are generally psychologically well adjusted (Newton et al. 1990, Edelmann et al. 1994), which can be taken to mean that only psychologically well-adjusted couples seek medical help in their efforts to conceive a baby (Eugster and Vingerhoets 1999). In general, the distress that accompanies a failed treatment is greater among women than among men (Newton et al. 1990, Collins et al. 1992, Slade et al. 1997).

3.2.3. Technical Factors

Since there is no alternative to ARTs when it comes to helping an infertile couple conceive of a child, their technical evaluation is limited. A comparison of ARTs confers relative advantages to some procedures. In the past two decades, IVF-ET and GIFT have been preferred as infertility treatments. The major advantage of IVF-ET and ICSI is that they can be applied on an outpatient basis (Kutoba et al. 1999), which would entail lower costs, reduce the patient's psychological stress, involve simpler procedures and preparations for treatment, would not require admission, would require fewer medical staff, and would improve the communication between the doctors and the patient (Kutoba et al. 1999). These advantages have also facilitated surrogacy in IVF-ET infertility treatment.

3.3. Macro Factor Evaluation

3.3.1. Japan

The field of assisted reproductive medicine has a long history in Japan, with the artificial-insemination technique having been first applied in 1982, but no legal regulation

on ARTs exists therein. The medical communities[32] played as the major guards against the misuse of such technologies in the country. In October 1983, the Japan Society of Obstetrics and Gynaecology (JSOG) issued its first set of guidelines, entitled *Opinion on In-Vitro Fertilisation and Embryo Transfer*. The guidelines approved of the procedure for married couples (Article 3).[33] In April 1988, the society issued another set of guidelines, entitled *Opinion on Frozen Storages and Implantation of the Human Embryo and Ova*.[34] The guidelines restricted the freezing of fertilised ova for storage, and rejected the use of frozen storage for methods involving embryo donation or surrogacy. The society has also issued opinions on such topics as micro-fertilisation in 1992, artificial insemination with donor semen (AID) in 1997, and pre-implantation genetic diagnosis in 1998. The society approved of egg donation on February 17, 2000 (Mainichi Daily News, February 17, 2000).

The Ad Hoc Committee on ART of the Ministry of Health Labour and Welfare approved AID and egg donation on December 2000, but to married couples only. The committee also supports embryo transfer fertilised by donor sperm and donor eggs. Under the guidelines, both sperm and egg donation can be done only three times, and the age of the donor is restricted to below 55 for sperm donation and below 35 for egg donation.

In many cases, infertile couples had to go overseas, to countries where both egg donation and surrogacy were allowed. Although JSOG allows egg donation, a recent survey carried out by the Latest-Technology Assessment Committee of the Science and Welfare Evaluation Committee (Mainichi Daily News, May 6, 1999) revealed that majority of the Japanese people see both surrogacy and sperm or egg donation negatively from the point of view of a third person.[35] As such, doctors performing procedures using a third person's egg (Mainichi Daily Newspaper, June 22, 1998), or for unmarried couples (Mainichi Daily Newspaper, August 30, 1998), were expelled from JSOG. Since procedures involving surrogacy and technologies using a third person's sperm or eggs are not deemed publicly

[32] The societies include the Japan Society of Obstetrics and Gynaecology, the Japan Society of Fertilisation and Implantation, and the Japan Society of Fertility and Sterility.
[33] Japan Society of Obstetrics and Gynaecology (1984).
[34] Japan Society of Obstetrics and Gynaecology (1988).
[35] 70.1% of the public answered that it is unacceptable even if the spouse agrees to undertake the procedure. Only 3.1% of the respondents accepted gestation using sperm or eggs donated by a third person or surrogate mother.

acceptable, many couples in Japan who want to undertake these modalities generally go abroad, often to the US. In fact, several American agencies recruit clients in Japan and make arrangements for infertility treatments in the US. The services match the couples with surrogate candidates, reflecting the preference of the couples. From 1993 to 1998, 114 Japanese children were born in America by way of surrogate mothers or a third person's eggs or sperm (Mainichi Daily News, January 7, 1998).[36] Moreover, since 1991, more than 10 Japanese babies have reportedly been born to surrogate mothers in the US (The Japanese Times, May 22, 2001). Some couples go to Korea, especially for surrogacy, where the cost is much lower than that in the US. An infertility clinic in Seoul performed five cases of surrogacy for Japanese couples in 1992-1993, and received over 10 inquires from Japan (Joongang Daily Newspaper, November 22, 1993). The Minister of Health, Labour, and Welfare, Mr. Chikara, announced at a House of Council Budget Committee session: "A panel compiled a recommendation last year that surrogate birth should be banned because it is by no means desirable." The Japanese government seeks legislation banning surrogate childbirths (The Japanese Times, May 22, 2001).

Public health insurance programmes do not cover the costs of ARTs. The reason behind the exclusion of ARTs from insurance coverage is that infertility is not regarded in Japan as a disease requiring medical treatment. Due to the continued lowering of the birth rate (1.38 per couple in 1999 and 1.25 in 2005), the Japanese government set off the so-called "Angel Plan" to promote childbirth by making the relief of the child-rearing burdens of parents a high priority. The first phase of the plan's implementation, however, from 1995 to 1999, was unsuccessful. The Japanese government thus set off "New Angel Plan," which was implemented from 2000 to 2004. In accordance with the plan, the Ministry of Health, Labour, and Welfare (Policy Bulletin 96, April 1, 2004) encouraged infertile couples to avail of ARTs by shouldering its costs up to ¥100k (equivalent to £417 as of May 2007) from one to five years.[37]

[36] Among 114 children, 34 were born from surrogate mothers commissioned by 25 couples. Sixty-four children were conceived and born with donated eggs, which had been implanted into infertile women's wombs. The remaining 16 children were conceived with a donor sperm.

[37] The fund for subsidy is raised by the central and local governments, each shouldering 50% of the fund. The total subsidy paid by the central government in 2004 was ¥88m (£3.6m).

In summary, IVF-ET is not regulated by the law in Japan. In many cases, patients go abroad to undergo treatments that are not approved by JSOG. Moreover, public health insurance programmes do not cover ARTs, but there is a growing consensus among policymakers to extend the insurance coverage so as to include IVF-ET.

3.3.2. Korea

The first successful VIF in Korea was performed in 1985 at Seoul National University Hospital. In 2002, about 100 clinics in the country were offering infertility treatments, carrying out a total of about one thousand cycles of infertility treatment.

There is no relevant legal regulation regarding the use of ARTs in Korea. As such, the decision to use human fertilisation technologies lies in the obstetricians. No particular control is applied to donor insemination, sperm or egg donation, and even to surrogate arrangements. In addition, obstetricians are not required to register the number of ARTs treatments they have performed; hence, it is impossible to monitor and track the ARTs procedures conducted by physicians and undergone by clients. Furthermore, the Bioethics and Biosafety Act of 2004 was adopted, which aims to control researches that make use of stem cells and the primordial genetic material. Under the law, scientists are allowed to conduct embryonic-stem-cell research, but only for the purpose of curing 18 particular diseases, including diabetes, Alzheimer's disease, AIDS, and cerebral palsy. Article 13 of the law prohibits commercial dealing in gametes and creating a human embryo for reasons other than conception.

Health insurance does not cover any procedure related to infertility treatments.[38] Even diagnostic tests for infertility are not covered (Official Notice on Health Insurance Coverage No. 1492-8112, MOHW 1994). The insurance programme covers complications stemming from infertility procedures and natural delivery procedures (Official Notice on Health Insurance Coverage No. 65720-404, MOHW 1993). Due to the continued lowering

[38] One cycle of IVF-ET costs about £1,600-£2,200. The exclusion of infertility treatments from insurance coverage (since infertility is not regarded in Korea as a disease requiring active medical treatment) discourages infertile couples from undergoing such treatments.

of the birth rate in Korea, the Ministry of Health and Welfare of Korea introduced a benefit programme in March 2006, which subsidises infertile couples, giving them two-time payments of up to about £1,086 (equivalent to ₩2 million as of May 2007) each for infertility treatment. Couples whose combined incomes are lower than 130% of the income of an average wage earner in an urban area (£2,277, or ₩4.19 million), in the case of a two-member household, are candidates for the subsidy.

3.3.3. UK

In the UK, the government set up the Committee of Inquiry into Human Fertilisation and Embryology in 1982 (chaired by D. M. Warnock) to review the ethical and legal questions arising from the use of ARTs (Brahams 1990). The committee published a report in 1984, entitled *Human Fertilisation and Embryology: a Framework for Legislation*. The central point raised in the report was that "reproductive medicine should be regulated, and the status of children born as a result of the new and various forms of assisted conception should be clarified" (Brazier 1992). The report led to the enactment of the Human Fertilisation and Embryology Act of 1990 (Dickens and Cook 1999). Essentially, the act was created in response to the public concern over the emerging technology stemming from the birth of the first IVF-ET baby, Louise Brown, in the UK in 1978 (Doyle 1999). The act mandates all clinics to secure licenses from the Human Fertilisation and Embryology Authority (HFEA) to be able to carry out the following activities (HFEA 1996):[39]

- bringing about the creation of an embryo;

[39] Johnson (1998) categorises statutory regulation into two broad forms: flexible general prohibitions and inflexible specific prohibitions. According to him, flexible general prohibitions include activities that are permitted (given a special license). Scientists or doctors are not obliged to conduct these activities, and they should thus apply for a license in HFEA if they wish to do so. Flexible general prohibitions, which are prohibited unless a license is granted, include the following activities (p. 1774): (1) bringing about the creation of an embryo by initiating the process of fertilisation (for treatment and research); (2) keeping or using an embryo (for treatment or research); (3) placing a spermatozoa or an embryo in a woman's uterus; (4) storing gametes for use in research involving the creation of an embryo; (5) using donated spermatozoa or eggs in the course of providing a woman with infertility treatment services; and (6) mixing human gametes with the live gametes of an animal.

Inflexible specific prohibitions refer to those activities that are simply not acceptable to venture into under any circumstance, including the following (p. 1773): (1) placing non-human gametes or embryos in a woman's uterus; (2) keeping an embryo alive in vitro after the appearance of the primitive streak, which is taken to have appeared not later than 14 days after the mixing of the gametes; (3) replacing the nucleus of an embryo's cell with a nucleus taken from the cell of any other person or embryo, or the subsequent development of an embryo.

- keeping and using an embryo;
- storing gametes;
- using donated sperms or eggs in the course of providing a woman with infertility treatment services; and
- mixing human gametes with the live gametes of any animal.

The Human Fertilisation and Embryology Act of 1990 also makes it a criminal offence for any person, under any circumstance, to place in a woman's uterus:

- a live embryo other than a human embryo; or
- any live gamete other than a human gamete.

The Code of Practice translates the requirements of the Act (Deech 1999), including those that relate to such matters as staff and facilities, standards of clinical practices, record-keeping, screening, counselling, and the welfare of the child, or the child's guidance. The HFEA (2001) Guidelines cite requirements in relation to the following:

- the number of pre-embryos to be transferred;[40]
- the development state of the pre-embryo at the time of transfer;
- the day of the embryo's transfer;
- the age of the female partner;[41]
- the ovarian reserve, as expressed, for example, by the three-day follicle stimulating hormone level and the unidentified but inherent variability among programs;
- the development of new knowledge regarding the implantation window;
- and the difference between the implantation rates of fresh and cryopreserved materials.

HFEA can revoke the license of a scientist or doctor if he or she violates any of the guidelines promulgated by the Code of Practice. The 1985 Surrogacy Arrangements Act legalised surrogacy in the UK, except when the arrangements between the infertile woman

[40] The fifth edition of the Code of Practice limits the number of embryos that may be transferred to a single cycle to three (HFEA Annual Report 1998).

[41] Eggs should not be taken from female donors beyond 35 years of age, unless there are exceptional reasons for doing so. As for sperm donors, HFEA recommends an age limit of 45. This paternal age, however, is currently under review.

and the surrogate mother are made for commercial purposes. This legal stance on the issue of surrogacy is clearly based on the following two principles (Brazier et al. 1997):

- surrogacy must not be commercialised; and
- surrogacy arrangements should not be enforced.

Regarding NHS funding for infertility services, the central government does not have guidelines regarding what health authorities should offer couples who are seeking infertility treatment. NHS funding for the investigation of fertility problems is generally available, but there is a wide variation regarding, and often limited access to, treatments using ARTs (National Collaborating Centre for Women's and Children's Health 2004). In Scotland, up to three IVF-ET cycles are publicly funded. Elsewhere, individual health authorities are accorded the right to determine whether funding should be provided to a particular ART treatment. Accepting the recommendation of NICE (National Institute of Clinical Excellence) Guidelines of 2004 (NICE, 2004), British government provides at least one free IVF cycle for women between the ages of 23 and 39 from April 2005 (BBC News, NHS to offer one free IVF cycle, 25 Feb. 2004). The NICE guidelines suggest that couples should be offered NHS funding for up to three cycles of IVF when the chances of success are more than 10%.

Table 3-6. **The use of eligibility criteria for funding by HAs (%)**

Eligibility Criteria	Ovulation Induction	Insemination	Tubal Surgery	IVF/ICSI/GIFT
Yes	29	33	26	64
No	53	43	50	4
Not funded	9	15	15	23
Not known	9	9	9	9

Data Sources: DoH, Survey of NHS Infertility Services (1997-1998)

As summarised in *Table 3-6*, there are huge variations among HAs in terms of the funding policies for infertility treatment. Many HAs provide ovulation induction, insemination, and tubal surgery without any criterion for funding, while IVF, ICSI, and

GIFT are strictly controlled by HAs. The 23 HAs that responded to the survey that was conducted in this study do not provide IVF-ET, ICSI, and GIFT. About 94% of those among them that provide infertility services limit the coverage based on certain criteria. The eligibility criteria include the following (DoH, Survey of NHS Infertility Services 1997-1998):

- the maximum and minimum ages of both the man and the woman;
- the maximum number of the couple's previous children;
- the maximum number of children from a previous relationship, and the minimum length of the relationship;
- the minimum length of residence in the HA; and
- the maximum number of previous cycles other than those that meet the above criteria.

A report on the provision of infertility services in the UK (Kennelly and Riesel 1997) revealed that most health authorities (76%) have a formal statement of policy on purchasing infertility services. The formalisation of policies on infertility services among health authorities has remarkably increased by 21% from 1993. The policies set limits on who can receive NHS funding. The College of Health data (Kennelly and Riesel 1999) show that the number of NHS-funded IVF treatments is falling: from 12.7 cycles funded per 100,000 in 1997 to 10.8 cycles in 1998.

While most tests and investigations are carried out by NHS, around 80% of the IVF-ET treatments are carried out privately (NHS Direct 2001).[42] Since many health authorities regard ART interventions as required for social rather than biological reasons, and as they believe that such interventions are resorted to for the treatment of childlessness and not of infertility, most health authorities provide limited funding for tubal surgery (Evans 1995). The most common restrictive policy is that pertaining to the maximum age at which a

[42] NHS Direct. Available at: http://www.healthcareguide.nhsdirect.nhs.uk/info/advice/subfertility.stm. Accessed November 24, 2001. According to Brinsden (1994), 95% of couples requiring advanced fertility care pay for such care themselves.

woman can be given funding for such purpose.[43] Based on the results of previous surveys, Kennelly and Riesel (1997) concluded that:

- the number of IVF-ET treatments funded by NHS has rapidly increased;
- the number of authorities who have adopted formal policies on infertility treatment is increasing; and
- while many authorities are using similar protocols for assessing a couple's eligibility for infertility treatment funding by HAs, the details are greatly varied.

The payment arrangements for infertility treatments vary according to the characteristics of the treatments. While most health authorities provide ovulation induction and tubal surgery based on a block gynaecology contract, in-vitro fertilisation is largely provided based on a specific fertility contract. The number of treatments paid for by health authorities has increased. While there is an increasing trend in the proportion of authorities paying for over 50 treatments (11% in 1994, 20% in 1995, 22% in 1996, and 26% in 1997), the number of authorities that are paying for less than 50 treatments has declined. NHS funded the infertility treatments of only 12.7 persons out of 100,000 in 1997, which represents an increase from the 9.3 persons out of 100,000 whose infertility treatments were funded in 1996. Furthermore, spending on ARTs varies among health authorities, ranging from zero to £500,000. According to the results of a survey that was conducted of NHS infertility services (HFEA, Survey of NHS Infertility Services 1997-98), a large proportion of the HA respondents did not have detailed data on the amount of their spending for infertility services, or data on such separate from their general gynaecology budget.

In the absence of instructions from their parent donors, unclaimed embryos must be destroyed within five years after their creation (HFE Act 1990). In 1996, about 3,300 cryopreserved embryos belonging to about 900 couples who had lost touch with the infertility clinics where such embryos were extracted from them, and who could not be reached, were destroyed upon orders of the government. To prevent the endless, expensive

[43] According to Kennell and Riesel (1997), as of 1996, a vast majority of districts specify minimum and maximum ages for women undergoing infertility treatment (35 and 40 years old, respectively), with a median age of 38. As for men, 20 districts also set minimum and maximum ages for undergoing infertility treatment (45 and 60 years old, respectively).

storage of abandoned embryos, the embryos can be stored on a limited basis for an additional five years (maximum), with the consent of both donors (Foster 1998).[44]

3.3.4. US

In the US, the Fertilisation Clinic Success Rate and Certification Act (FCSRCA)[45] was introduced on the federal level in 1992 to prevent false or inflated success claims by individual clinics (CDC 1999). As the ART market expanded, there were growing concerns on whether the providers of ART services were exaggerating the success rates of the ARTs procedures they performed, thus misleading consumers as regards the inflated success rates of clinical pregnancy and live births. According to the Ethics Committee of the American Fertility Society (1994), the Federal Trade Commission charged several infertility clinics with inflating their success rates. To address this issue, FCSRCA requires clinics conducting IVF-ET procedures to report the exact number of procedures they carried out, and the number of the live births they facilitated.[46]

At the state level, some states are involved in the legal regulation of ART practices for specific techniques. The legal issues related to reproduction involving donors and surrogates vary across the nation. First, as regards donor sperms, over 30 states clarify the legal responsibilities of the donors, which exclude their rearing role, and charge the consenting father with all the duties and rights related to the rearing of the resulting offspring. Second, as regards donor eggs, only three states (Oklahoma, Texas, and Florida) have legislation addressing the rights and duties related to the rearing of children born through treatments involving egg donations. Third, only the state of Texas has enacted legislation addressing the rights and duties related to the rearing of the offspring resulting from a treatment involving a donor pre-embryo. Fourth, as regards surrogacy[47], the state

[44] The additional storage period is allowed after the donor reaches the age of fifty-five.

[45] FCSRCA was promulgated to provide the public with reliable information concerning the effectiveness of infertility services and to ensure the high quality of such services by providing for the certification of embryo laboratories (p. 39374).

[46] FCSRCA was first published in 1997 in three volumes, grouped according to the geographic regions of the US: western, eastern, and central (Meikle et al. 1999).

[47] It is estimated that there have been over 6,400 surrogate births in the United States. Of these, there are less than 30 documented cases in which the surrogates attempted to renege on the contract and retain custody and control of the child.

law regulates the legality of surrogacy, looking into whether surrogacy contracts are legal and/or enforceable, and whether there is any amount of money that is part of the contract.[48] In seven states (New York, Michigan, Massachusetts, Utah, Arizona, New Mexico, and Washington), all forms of surrogacy, paid or not paid, are against the law. With varying degrees of state intervention, seven states (Florida, Arkansas, Tennessee, Virginia, Ohio, New Hampshire, and Nevada) recognise surrogacy and allow its practice. In four states (Louisiana, Nebraska, North Dakota, and Indiana), surrogacy contracts are not enforceable but are allowed. California is the only state that has a "case law" regarding surrogacy.[49] A recent court decision in California has fostered a legal climate for surrogacy and egg donation agreements that have already been favourable in California. In the case of Buzzanca[50], the court made a ruling on whether a married couple that was now divorced were the parents of a baby conceived through surrogacy involving an anonymous donor sperm and egg.[51]

The legal issues on embryos deal with the locus and scope of control over embryos created in the course of the use of ARTs. The US does not have a national policy regarding abandoned embryos. Moreover, the state intervention into the storage and disposition of embryos is marginal. Thus, gamete providers are largely left alone when it comes to deciding on whether their embryos will be transferred, cryopreserved, donated, or discarded. Based on their own guidelines, fertility clinics usually have a written agreement addressing the intention of their couple clients with regard to their leftover embryos (Foster 1998).

---

[48] The surrogacy law in the US is summarised from http://www.surrogacy.com/legals/map.html (the American Surrogacy Centre, Inc.), accessed February 14, 2002.

[49] In the state of California, a "case law" from the courts is recognised as constituting the law.

[50] An infertile married couple, Johnson Buzzanca and his wife Luanne, had entered into a surrogacy contract, and Jaycee was conceived as a result of the implantation of an anonymous embryo donation into the gestational surrogate. About one month before Jaycee was born, John petitioned for the dissolution of their marriage. While Luanne claimed that she was the lawful mother of Jaycee, John denied his parenthood of Jaycee. The surrogate also disclaimed being Jaycee's legal mother. Based on the Uniform Parentage Act, to be a child's legal parent, one must either be genetically related to the child or must have given birth to him or her. Jaycee thus became a "parentless" child owing to the surrogacy arrangement. Finally, the California Court of Appeals ruled in March 1998 that John Buzzanca and Luanne Buzzanca are the legal father and mother of Jaycee.

[51] The information is summarised from *Surrogacy and Egg Donation Law in California* (Pinkerton T. M.), the American Surrogacy Center, Inc. Available at: http://www.surrogacy.com/legals/article/calaw.html, accessed January 16, 2002.

Only three states (Louisiana, Minnesota, and Illinois) have established a legal basis for banning the disposal of pre-embryos.

The American Society for Reproductive Medicine's Ethical Committee also plays a significant role in the application of human reproductive technologies.[52] First, as for the disposition of abandoned embryos, the Ethics Committee maintains that it is ethically acceptable for a programme to consider embryos to have been abandoned if more than five years have passed since the contact was entered into with the couple (The Ethics Committee of the American Society of Reproductive Medicine 1997).

Although IVF is an effective treatment for infertility, most health plans do not provide coverage for the technology. Accordingly, most couples seeking fertility treatment pay for the treatment themselves. American Society for Reproductive Medicine (ASRM) estimates that about 30 to 40% of IVF services were partially covered in 1993 by insurance (Collins et al. 1995). Although 14 states in the US have mandated insurers to provide some form of infertility care, only six states out of the 14 oblige insurers to cover infertility treatment. There are also various limits on the conditions in which such treatments are payable (ASRM 1999a). For example, although Arkansas requires all insurers providing maternity benefits to cover the cost of IVF-ET, the state exempts HMOs from doing so. Maryland also excludes HMOs from the insurance coverage law. In Illinois, where the mandate offers comprehensive infertility services, a significant number of patients are excluded from

[52] The ethical considerations for ARTs cover the American Society for Reproductive Medicine's position on several aspects of reproductive medicine, including (The Ethics Committee of the American Fertility Society 1994):

- the constitutional aspects of proactive liberty;
- the American law and ARTs;
- the moral right to reproduce, and its limitations;
- the commercialisation of ARTs;
- the moral and legal status of the pre-embryo;
- the procedures of ARTs;
- the use of gametes;
- the cryopreservation of oocytes and pre-embryos;
- the use of micro techniques such as microinjection, assisted hatching, blastomere separation, and zona drilling;
- pre-implantation genetic diagnosis;
- surrogate and gestational host mothers;
- research on pre-embryos; and
- HIV testing and reproductive medicine.

coverage (Gleicher 1998).[53] In 1997, 22% of large firms whose employees are enrolled in an HMO covered IVF-ET, an increase of 19% from the year before (Murray 1998).[54] According to the Alan Gumacher Institute (1993, quoted from Neumann 1997, 1217-8), 14% of large plans and 16% of preferred provider organisations offer IVF-ET coverage. Insurance companies and health plans have been reluctant to cover infertility services in the US due to a lack of consensus on such services (Robertson and Schneyer 1997).[55] ARTs were also excluded in the Clinton National Health Security Plan (Baker and Paterson 1995).

So far, the adoption of ARTs has been driven by market principles associated with commercialism among the providers, the demand for such by infertile couples, and the high number of surrogate mothers available. According to Blank and Merrick (1995), some private clinics use aggressive marketing techniques, and certain firms have been accused of inflating their success rates. To attract patients seeking infertility treatment, several clinics have begun offering eligible patients the option of paying on a "shared-risk," "warranty," or "outcome" basis (Wozencraft 1996, quoted from Robertson and Schneyer 1997).[56] Robertson and Schneyer (1997) regard the use of a shared-risk payment plan as a doctor–provided form of risk-of-failure insurance. The programme is being adopted solely as a

[53] Government employees are excluded from the coverage, while patients under Medicare coverage, as well as the employees of small companies, self-insured companies, and churches, are covered.

[54] Research that has examined whether the infertility services can be developed in a managed-care plan in a way in which the cost is lowered while providing quality services support the increase of infertility services without increasing costs by managing structured programmes (Douglas et al. 1996, Arnold 1997, Blackwell et al. 1998). This implies that if an appropriate model is developed, then ART adoption will be remarkably increased in the US This is presumed from the fact that the number of cycles per capita in Canada and in France, where IVF-ET is covered by national insurance programmes, is three and five times higher, respectively, than that in the US (Collins et al. 1994). Even in the US, the adoption of IVF-ET per capita is twice as high in those states where insurance coverage is mandated for IVF-ET than in those states where the insurance does not cover the service (Sahni 1994).

[55] Tabbush and Gambone (1998) argue that health plans hesitate as those insured have privately held information about whether they will need the covered benefits for ARTs; thus, adverse selection occurs. Due to the information asymmetry between the insurer and the insured, some health plans that have extended their coverage to include infertility services have experienced poor economic outcomes. Robertson and Schneyer maintain that because IVF-ET is expensive, elective, often unsuccessful, and of no interest to most consumers, insurers and managed-care plans remain reluctant to cover the services and, in some cases, have withdrawn coverage after they provided such.

[56] Under a shared-risk arrangement, the clinics charge the patients a fee that is initially higher than the fee that they charge other ordinary IVF-ET patients. If the procedure is successful, they keep the entire fee. If no pregnancy occurs, they refund 90-100% of the fee (The ASRM Ethics Committee. 2002)

marketing tool for patients. Murray (1997) enumerates the effects of a shared-risk plan, which he describes as a "money-back guarantee," in the following:

IVF-ET money-back guarantees may also be very successful marketing ploys as it seems likely that many infertile couples will consider IVF-ET but will not actually pursue it. For some, the anticipated cost may be a major hurdle. Warranty programmes may be a great way to tempt people to make that enormous emotional leap from thinking about IVF-ET to committing themselves to try it (p. 293).

In the US, therapeutic donor insemination is also largely commercially oriented (Baker and Paterson 1995). Infertile couples purchase gametes from commercial sperm banks that operate nationally and that ship the donor sperms to across the country (Baker and Paterson 1995).

Legislation concerning surrogacy may also facilitate infertility treatment. Although surrogacy laws have been proposed many times in many states, most of these proposals die in the congressional committees.57 From 1997 to 1999, a surrogacy bill was proposed 18 times in 13 states (Organisation of Parents Through Surrogates, Inc. 2002). The bill was eventually passed only in Wyoming, Indiana, New Jersey, and California, and it is only in New Jersey that paid surrogacy is a crime.

The newly developed technology ICSI was approved by the Practice Committee of the American Society for Reproductive Medicine (formerly the American Fertility Society) on October 24, 1994, and by the Board of Directors of the American Society for Reproductive Medicine on November 5, 1994 (Practice Statement Committee, ASRM, 2002).

3.4. The Adoption of ARTs

3.4.1. Japan

Table 3-7 shows the number of ART cycles in Japan. As of 2004, there were 627 registered ART centres in Japan (Japan Society of Obstetrics and Gynaecology 2005). The accumulative total of babies from 1986 to 2004 who were conceived via ARTs was 135,575. In 2004, 18,168 babies were born through the use of ARTs, and 30% of these

[57] The proposed bill was circumscribed in Illinois, Connecticut, Texas, Indiana, New Jersey, and Minnesota, and the law was enacted in Wyoming, Oklahoma, Pennsylvania, New Jersey, and California.

(5,538 babies) were gestated through ICSI (the number of babies gestated through ICSI has increased rapidly). In 2004, 129 babies were born through AID, which represented a decrease from 188 in 1998.

JSOG has been collecting data on ARTs treatments since 1986. The Ethics Committee of JOSG on Practices and Researches began to collect such data from all registered ART centres in 1993. In 1999, JSOG established the Registration and Inspection Committee as a subcommittee of the Ethics Committee on Practices and Research. The committee is responsible for collecting and reporting assisted-human-reproduction activities in Japan.

Table 3-7. **The number of infertility treatment cycles conducted in Japan**

	IVF-ET	ICSI	GIFT	ZIFT	AID
1992	16,521 (12,297)	963 (610)	658 (628)	225 (207)	
1993	20,732 (15,174)	2,608 (1,785)	1,101 (991)	141 (103)	
1994	25,523 (17,231)	5,510 (3,804)	869 (782)	142 (138)	
1995	27,763 (19,020)	9,536 (6,672)	533 (168)	318 (305)	
1996	29,854 (20,764)	13,438 (8,626)	370 (343)	277 (220)	
1997	31,764 (25,672)	16,621 (11,517)	401 (365)	178 (155)	
1998	42,068 (29,465)	18,657 (12,823)	503 (452)	490 (380)	
1999	46,586 (31,468)	23,015 (15,849)	286 (280)	132 (119)	3,497 (1,711)
2000	4,2623 (30,576)	26,712 (17,185)	179 (122)	176 (139)	5,699 (1,570)
2001	45,498 (33,056)	30,369 (19,979)	104 (91)	102 (78)	5,838 (1,350)
2002	50,655 (36,617)	34,824 (22,900)	96 (95)	76 (67)	3,649 (2,521)
2003	62,514 (41,828)	38,871 (25,675)	157 (119)	88 (75)	4,374 (1,176)
2004	71,502 (48,742)	44,698 (29,582)	100 (76)	39 (37)	3,994 (1,498)

Data Sources: Japan Society of Obstetrics and Gynaecology (1994, 1995, 1996, 1997, 1998, 1999, 2000, 2001a, 2001b, 2003, 2005)
Note: The number in brackets refers to the number of patients treated.

A number of factors have manifested a significant effect on the adoption of ARTs in Japan. First, in the absence of any legal control, the by-laws of the professional community have played a significant role in approving the adoption of new technologies. Second, the professional community prohibits the adoption of technologies that may conflict with the

rights of the offspring, such as egg donation and surrogacy. Lastly, the public health insurance programmes do not cover ARTs and thus have had no influence on the latter's adoption.

3.4.2. Korea

Over 10,000 infertile couples seek ARTs every year in Korea. As the success rate of ARTs procedures has improved, the couples who avail of these techniques are becoming more active in undertaking the treatment. As of 2006, there were 92 centres registered in the Korean Medical Association as carrying out ARTs (Korean Society of Obstetrics and Gynaecology 2006).

Following the first successful live birth from IVF-ET, a private infertility medical centre became enthusiastically involved in infertility treatment. The centre[58], which is well known throughout the world as a leading infertility clinic, possesses most of the historical records in Korea relating to the adoption of ARTs. The centre had the first successful cases of GIFT (1986), ZIFT (1988), and ICSI (1994), and even a successful surrogate case (ko 1995).[59]

Although ARTs are regarded as well-established procedures, many infertile couples also seek various other methods, including religious, traditional, and folk remedies, while undergoing medical treatment for infertility. Some couples undergo ARTs alongside Oriental medicine, including acupuncture and herbal medicine, whose infertility treatments are primarily focused on body temperature as well as the fertilisation tract, especially in the uterus.[60]

---

[58] The clinic, previously a specialised clinic for obstetrics, became a general hospital under the name CHA Hospital.

[59] The detailed history of the adoption of ARTs is as follows (Ko 1995):

- Oct. 1985 - first IVF-ET baby born in Seoul National University Hospital
- June 1986 - first baby from a frozen sperm born in Korean University Hospital
- Sep. 1986 - first baby from a frozen sperm born in a private clinic (CHA Hospital)
- Nov. 1988 - first baby from a frozen embryo born in a private clinic (Je-il Hospital)
- Dec. 1988 - oocyte in CHA Hospital
- Nov. 1988 - first successful surrogate case reported in the annual meeting of the Korea Society of Obstetrics and Gynaecology
- March 1990 - first IVF-ET procedure using natural ovulation conducted
- Feb. 1994 - the first ICSI conducted in CHA Hospital

[60] Specialists in Oriental medicine believe that a fertilised embryo is not conceived in the uterus if the body temperature of a woman is lower than normal. To treat infertility, therefore, herbal medicine, acupuncture,

As shown in *Table 3-8*, the preferred ART in Korea has been shifting from IVF-ET towards the newly emerged ICSI.

Table 3-8. **The number of treatment cycles in Korea**

	IVF-ET	ICSI	GIFT	ZIFT
1992	5,852		198	295
1993	6,536		330	180
1994[a]	856	175	110	236
1996	6,527	1,603	51	
2001[c]	7,740	4,987	63	
2002[d]	9,292	6,704	2	9
2003[e]	8,192	7,488	4	3

Data Source: Assisted-Reproductive-Technology Committee, Korean Association of Obstetricians and Gynaecologists (1997-2006)

Note: a. The data represent only the cases reported by 63 out of 87 registered infertility centres.
b. The data represent only the cases reported by 35 out of 92 registered infertility centres.
c. The data represent only the cases reported by 56 out of 90 registered infertility centres.
d. The data represent only the cases reported by 73 out of 92 registered infertility centres.
e. The data represent only the cases reported by 48 out of 91 registered infertility centres.

Cultural factors are thought to be responsible for the rapid diffusion of ARTs in Korea. The single most significant factor spurring ART has been the desire to have a son (rather than a daughter. The first son succeeds the family group as the head of family. He is called 'seed sibling' of the family group and succeed the bloodlines, and hence, carrying on the family lineage. He is obliged to have the sacrifice rites for ancestors up to three generations at least, as anniversary memorial ceremonies bestowing respect on them. The rituals are also performed on traditional holiday including New Year's day and thanks giving day. Although current civil law confers equal distribution of family fortune among siblings, most family wealth is traditionally inherited to the first son.. Although three countries in Asia, that include China, Japan and Korea, have similar tradition based on Confucianism and respect a rank within a family, a status of men in a family is different among these

---

and other measures are administered to the patients. The success rate of infertility treatments in Oriental medicine is around 45% on average. Fertilisation occurred in some cases where the couple had been diagnosed in Western medicine as incapable of achieving fertilisation due to reasons such as blocked fallopian tubes (Seoul Broadcasting System 1994).

countries. In Korea, the first son is regarded as a lineal decent of family who has to tend his filial piety to his parents and obliged to live together with his parents to take care of them. In contrast, China and Japan have a patriarchal system that regards a man as the leader of the extended family who share a common life in China or as a leader who controls family members and all of family members should be subordinated to him in Japan.

In this respect, failure to give birth to a son, and the consequent discontinuation of the bloodline, is regarded as the most serious impiety against one's ancestors in Korea. As only a son can inherit the family name, sons have been strongly preferred in Korea.[61] It has thus been a generally accepted practice for men who are unable to foster a son with their licit wives to have a "breeding concubine."[62] This tradition continues today in the form of surrogacy. Since official data on surrogacy are not available, it is difficult to identify the number of real cases. When infertile couples choose the surrogacy option, they first try to find a surrogate mother among their sisters and relatives on either side of the family (Chang 1999: personal communication).[63] Traditionally, infertile couples chose surrogate mothers from among their sisters and relatives, but they increasingly tend to seek surrogate mothers from among Korean Chinese residents in Korea as this entails lower costs. Of late, however, infertile couples tend to seek surrogate mothers through international marriage-matching agencies, which generally find partners in China or among Korean-Chinese residents who are illegally residing in Korea.[64] According to a former nurse of a leading infertility centre, of the five to seven surrogate cases performed in the centre, about two to three cases involved Korean-Chinese surrogate mothers from China or Korea (Jung et al. 2000). At present, over 100 surrogate cases are performed in Korea every year (Im 2001).

[61] The current sex ratio in Korea explicitly represents the tradition, with the male-to-female ratio at birth being 112.8 on average for the past 10 years, and 110.2 in 1998 (Korean Statistical Office, Summary of Vital Statistics).

[62] The term literally means a "seed receiver" in Korean.

[63] K. W. Chang was a biologist in the infertility clinic in Severance Hospital, Yonsei University Medical Centre.

[64] The author obtained the information from a leading private infertility clinic, and then contacted a private marriage-matching agency to inquire if the agency can find a surrogate mother. The chief executive officer of the agency said that they can make arrangements for a surrogate mother.

According to a survey carried out by Joongang Daily Newspaper, Korean people generally do not accept surrogate childbirth.[65] It may thus be hard to legitimately regularise surrogate childbirth in Korea in the foreseeable future. However, as the Korean Medical Association declared in its Code of Conduct on November 15, 2001, surrogate childbirth is authorised unless it is commercially oriented; as such, surrogacy cases in Korea are expected to increase.

According to a staff member of a private infertility centre (data obtained via personal communication), the fee for surrogate services is determined through negotiations between the couple and the surrogate mother. The couple commonly makes an up-front payment of about £17,000 and gives the surrogate mother a monthly compensation of £1,200 to cover the income that will be lost by the latter during gestation. The couple also covers all the other medical costs that will be incurred throughout the process. All infertility clinics carrying out infertility treatments through surrogacy are very reluctant to release detailed information regarding their practices.[66] *Table 3-9* reveals the surrogacy practices in the period 1992-1993.

Table 3-9. **Characteristics of the surrogate mother**

	1992	**1993**
Number of surrogate mothers	14	7
Age of surrogate mother (average)	36.1	33.9

Data Sources: Assisted-Reproductive-Technology Committee, Korean Association of Obstetricians and Gynaecologists (1997)

The realities pertaining to the spread of ARTs in Korea may be summarised as follows:

- there have been no specific guidelines from either the professional community or public authorities;

[65] Sixty % of the survey respondents want surrogate childbirth banned, and 29% accept it unless the surrogate arrangements are commercial. Only 9% accept surrogate childbirth even when done for commercial purposes (Hong 2001).

[66] Infertile couples, especially the women, feel a sense of shame over their condition. As such, most infertility clinics have a side gate so as to provide couples with a discreet access to the clinic. Infertility in women has been traditionally regarded as a critical physical defect, and used to be a major motivation for men to expel their wives from their families.

- since public insurance programmes do not provide benefits for infertility treatments, providers are encouraged to offer ARTs while infertile couples are discouraged from availing of such technologies due to the cost burdens involved; and
- cultural factors have been a significant impetus for infertile couples seeking ARTs.

3.4.3. UK

The first live-born IVF-ET pregnancy in the world took place in the UK in 1978. According to the HFEA data (HFEA 2007), over 114,858 babies were born by means of ARTs from 1991 to 2004. During the period, over 700,000 treatment cycles were carried out and undergone by 480,000 patients.

One in seven couples have trouble conceiving, and about 43,700 couples seek fertility treatment each year from the 75 clinics around UK- some NHS, but mostly private (Burridge, 2001). The number of patients in the UK undergoes IVF-ET treatment increase every year, and the number of patients seeking treatment that was 33,713 in 2006 as increased by 455% from 1991 (HFEA, HFEA Register data 1991-2006). Up to 8,000 infertile women and 600 surrogates may seek surrogacy arrangements (van den Akker 1999). According to van den Akker (1999), two agencies deal with partial surrogacy, and only six of the clinics that have an HFEA license for infertility services have experience in IVF-ET surrogacy.

As depicted in *Table 3-10*, the use of the IVF-ET treatment has steadily increased in the UK while the use of DI has rapidly decreased. Micromanipulation, which includes ICSI and SUZI, was introduced in 1992. With higher live births in micromanipulation (22.4% compared to 19.3% in conventional IVF-ET and 10.3% in DI), there has been a steady increase in the number of treatment cycles using it. At present, micromanipulation represents 44% of all ARTs procedures conducted in the UK. The number of treatment cycles using conventional IVF increased in the early 1990s, but has either remained steady or only slightly decreased since that time. In 2004, 10,880 babies were born through ARTs, and 4,587 (42%) of these were conceived through micromanipulation including ICSI and SUZI.

Table 3-10. **The number of cycles applied**

	IVF-ET[a]	ICSI & SUZI[b]	DI[c]
1991	6,609 (6,146)	33 (32)	9,303 (4,301)
1992	18,201 (12,959)	128 (120)	26,078 (7,642)
1993	21,239 (16,137)	578 (504)	24,230 (7,634)
1994	23,517 (18,304)	1,284 (1,120)	21,484 (7,257)
1995	25,414 (19,895)	3,822 (3,351)	18,001 (6,296)
1996	27,203 (20,914)	6,176 (5,393)	14,913 (5,583)
1997	25,033 (19,734)	8,917 (7,680)	13,305 (5,106)
1998	23,551 (18,619)	11,906 (9,656)	11,579 (4,496)
1999	22,237 (18,528)	12,077 (10,198)	10,207 (4,224)
2000	22,722 (18,191)	12,728 (10,464)	8,354 (3,575)
2001	22,344 (17,951)	13,858 (11,401)	7,580 (3,181)
2002	22,479 (17,818)	14,921 (12,077)	7,323 (3,143)
2003	21,889 (17,516)	15,521 (12,587)	7,322 (3,113)
2004	23,283 (18,461)	16,698 (13,463)	6,888 (2,951)
2005	23,704 (19,119)	17,523 (14,390)	5,839 (2,639)
2006	22,076 (17,964)	19,506 (15,938)	4,001 (2,054)

Data Sources: HFEA. A long-term analysis of the 1991-2006 HFEA Register Data.
Note: a. IVF-ET includes micromanipulation but excludes frozen-embryo replacements.
b. micromanipulation only, without IVF
c. The DI and GIFT data use donor gametes both for stimulated and unstimulated donor insemination treatment cycles.
d. The numbers within the parenthesis refer to the numbers of patients who underwent the procedure.

The UK is uniquely positioned in the field of ARTs in several aspects, namely:

- the first successful IVF-ET was performed in England;
- the first surrogate mother was an English woman; and
- the UK established the first public authority to control and monitor the application of ARTs.

3.4.4. US

ARTs have been used in the US since 1981 to help women achieve pregnancy (Perone 1994). It is estimated that over 6.1 million people in the US suffer from infertility (ASRM, Patient's Fact Sheet, 2002) Acording to Centres for Disease Control (CDC) (2000), 48,391 babies were born in 1998 as a result of ARTs undertaken in 390 ART clinics.

Table 3-11. **The major ART procedures used in the US (1985-2001)**

	IVF-ET		GIFT	ZIFT
	Fresh	Frozen		
1985	2,389	289/105[c]	56	-
1986	2,864	824/319[c]	466	-
1987	7,561	490	1,968	-
1989	13,445	2,124	1,694	-
1990	14,150	3,290	3,692	1,081
1991	24,671	-	5,452	2,104
1992	29,404	-	5,767	1,993
1993	31,718	-	4,992	1,792
1994	39,390	-	4,214	962
1995	36,035[a]	5,052[b]	3,741	1,078
1996	30,598	14,049	2,878	1,200
1997	33,032	18,312	1,943	1,104
1998	35,333	23,604	1,293	1,054
1999	63,639		838	945
2000	73,406		549	763
2001	79,042		340	661

Data Sources: Society for Assisted Reproduction, The American Society for Reproductive Medicine (1988-2007)

Note: a. standard IVF-ET
b. standard IVF-ET+ICSI
c. number of patients

As shown in *Table 3-11*, in most of these cases, the ART that was employed was IVF-ET, and fresh embryos developed from the women's own eggs were used. The number of ART centres in the US tripled in the past decade since the mid-1980s. The number of IVF-ET cycles increased more than 10 times in the same period. The combination of high cost and limited insurance coverage is regarded as the primary obstacle in availing of infertility treatment in the US (Gleicher 1998).[67]

In recent years, the proportion of IVF-ET procedures with ICSI has rapidly increased because the chances of fertilization when performing IVF-ET in combination with ICSI has

[67] According to Neumann et al. (1994), in the US, the cost incurred per successful delivery with IVF-ET increased from US$66,667 for the first cycle to US$114,286 by the sixth cycle, on average. However, for couples in which the woman is 40 years old or above, and where there is a diagnosis of male-factor fertility, the cost rises from US$160,000 for the first cycle to US$800,000 for the sixth. Griffin and Panak (1998) found that the cost of live delivery with ARTs in 1993 was US$59,484 on average: US$69,448 for IVF-ET; US$49,469 for GIFT; and US$15,500 for cryopreservation.

also increased. In 1995, about 11% of the fresh, non-donor ART cycles performed used ICSI, most often to overcome problems with sperm function or motility. The rate increased by approximately 30% in 1996, then increased to approximately 40% of the ART cycles performed in 1998 (CDC 2000). As shown in *Table 3-10*, the increase in the percentage of IVF-ET procedures where fresh embryos were used represents the increased cycles adopted in combination with ICSI. According to the annual reports on ART, the procedures using ICSI showed higher live-birth rates than the non-ICSI group. The increases in the adoption of ICSI are regarded as related to the improved success rate of live births, even though the risk of congenital malformation exists in children born from ICSI (Wennerholm et al. 2000, Causio et al. 1999).

In the US, both the regulation and policy changes in insurance coverage impacted the spread of ARTs. From 1985, state laws were enacted in some states, particularly those in which the insurance coverage includes infertility treatment, at the outset in Maryland. Owing to the passage of legislation in many states from 1987, as shown in *Table 3-11*, the number of ART cycles performed significantly increased after 1987.

FCSRCA of 1992 regularised surrogacy contracts. The law on surrogacy, however, has customarily been determined at the state level, with little federal intervention. While some states have established laws permitting surrogacy, and some have passed laws outlawing surrogacy, the majority of states have yet to address the issue. In these states, lawyers representing families opting for surrogacy have, out of necessity, taken innovative approaches. According to Weltman (1996), about 5,000 cases legally contracted for surrogate births in the past 15 years.

In summary, the following factors have significantly affected the adoption of ARTs in the US:

- insurance coverage mandated by state laws beginning in 1985, which spurred ART adoption starting from the late 1990s; and
- FCSRCA of 1992, which made infertility clinics cautious about the success rate of ARTs, and hence restrained the adoption of the procedures without pertinent indications.

3.5. Conclusion

Since it is impossible to evaluate micro factors in terms of cost-effectiveness, unit cost for each procedure was assessed. The unit cost for IVF-ET in Japan, Korea and the UK are broadly similar. The cost in HMOs of the US is similar to the other three countries, and the costs in other health plans of the US were much higher, by up to five times. The cost for surrogacy was especially high in the US. The costs of ARTs are also varied among the procedures, with highest in ICSI followed by IVF-ET. Although the cost is high when undertake ICSI, success rate in terms of both pregnancy and live birth rate is also higher in ICSI compared to IVF-ET.

Table 3-11 summarises the regulation and finance on ARTs in four countries. No legal regulation has been enacted other than the UK where ART practices have been regularised by the Surrogacy Arrangement Act 1985 and the Human Fertilisation and Embryology Act 1990 defines the legal status of a surrogacy contract including the child's legal mother as the woman carrying it regardless of whether mother and child are genetically related (Brinsden et al 2000, 925). The UK also regulates the number of embryos that can be implanted.

In Japan, the Japan Society of Obstetricians and Gynaecologists guidelines constitute official approvals to regularise the practice of ART. With strong conformity of its members, any infertile couple seeking a procedure that JSOG members do not support should have gone abroad.

In Korea, no legal regulation has been enforced either by public authorities or by the professional community. The adoption and use of ARTs is fully in the hands of obstetricians and infertile couples. Accordingly, the use of any technology assisting reproduction simply depends on the ethical stance of individuals and their income levels.

Both in Japan and Korea, cultural traditions focusing on genetic linkages contributed in impeding technology adoption especially technologies requiring a third person donor such as AID, egg donation and surrogacy.

In the UK, the relatively higher level of ART is plausibly a result of legal regulations providing approval of practice unless it breaches the code of practice. In addition, the UK's leading role in the development of ART where the first IVF-ET was successfully achieved may have contributed to its relative popularity.

Table 3-12. **Summaries of regulation and reimbursement policy on ARTs**

		IVF-ET	DI	Egg donation	Surrogacy
Regulation	Japan	1983 by JSOG self-regulation	1997 by JSOG self-regulation	1999 by JSOG self-regulation	Not being supported and consensus has not yet been grown
	Korea	No regulation but consensus grown to accept in the public	No regulation and consensus has not yet been grown to accept in the public.	No regulation and consensus has not yet been grown to accept in the public.	No regulation and consensus has not yet been grown to accept in the public.
	UK	The Human Fertilisation and Embryology Act 1990:			The Surrogacy Arrangement Act 1985
	US	No federal legislation governing ARTs.			The Fertilisation Clinic Success Rate and Certification Act 1992 supports surrogacy contract
		The Fertilisation Clinic Success Rate and Certification Act 1992 requires reporting success rates.			
Financing policy	Japan	Not covered by public insurance programme			
	Korea	Not covered by public insurance programme			
	UK	Reimbursement complicated: in Scotland, up to three IVF-ET cycles publicly funded. Elsewhere, individual authorities may choose no to provide coverage and the majority infertile couples fund privately.			
	US	Insurance coverage policy is varied according to individual state. Thirteen states have mandates for infertility treatment coverage. Most infertile couples fund privately.			

* Note: The information for the UK and the US is partly quoted from Hughes (2001)

Left under market mechanisms in the UK, significantly high costs have been enough to limit adoption of these procedures.

In the US, there is no legal limit even on embryo storage, and decisions about this issue have been left to individual clinics. In pursuit of fair trade, the Fertilisation Clinic Success Rate and Certification Act (FCSRCA)[68] of 1992 obliges ART clinics to release correct data on success rate.

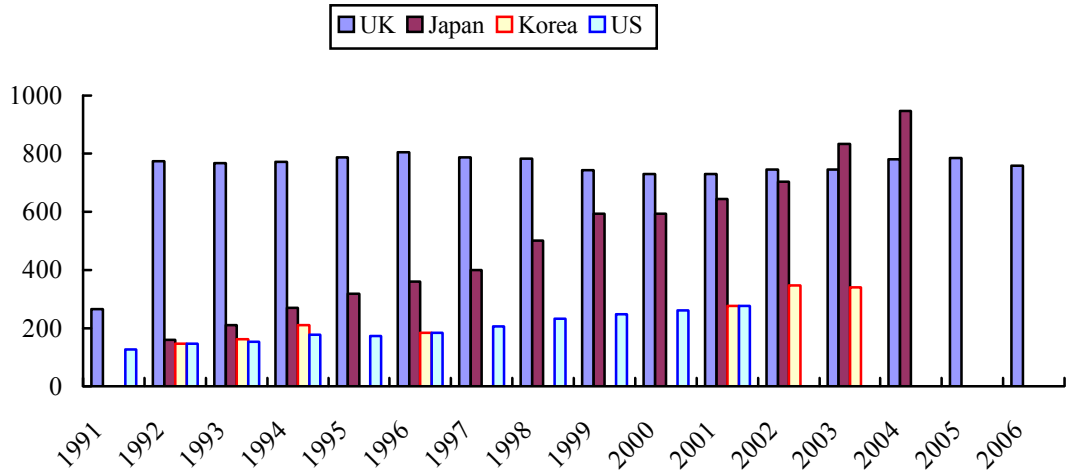


Figure 3-1. **Total ART cycles pmp, four countries, 1991-2006**

Note: the data in all four countries include ICSI

The use of ARTs by country over time as *Figure3-1* shows increases in all countries except the UK. The increase is striking for Japan. Following the introduction of ICSI in 1992, its adoption rapidly spread while other technologies have been circumscribed. The adoption of ICSI has been much faster in Korea and Japan compared to the other two countries.

While the number of IVF-ET cycles including ICSI is high in Japan, in terms of cumulative total, overall usage of ARTs is distinctively higher in the UK. On the contrary, both IVF-ET cycles and overall ART usage are much lower in the US compared to the other case study countries. Also, both levels of IVF-ET cycles and overall ART usage were

[68] FCSRCA was intended to provide the public with comparable information concerning the effectiveness of infertility services and to assure the quality of such services by providing for the certification of embryo laboratories (p. 39374).

quite similar between Japan and Korea in the past, but adoption levels in Japan have been taken up rapidly which is mainly attributed to public funding.

Donor insemination is very high in the UK, accounting for over half of total ARTs until 1993. Since then, DI has been fallen while micromanipulation including ICSI and SUZI increased rapidly. Although there is no comparable information on donor insemination in Japan and Korea, it is highly unlikely that there would be much donor inseminations in these countries. In Japan, DI was prohibited by the JSOG until 1997. In Korea, DI is limited by the importance attached to “blood lines.” The proportion of donor insemination is also much lower in the US at around 10 % of ARTs.

Chapter 4: Caesarean-Section Delivery

4.1 Introduction

Caesarean section refers to a major surgical procedure in which a baby is removed from the uterus by making an incision into the abdomen, and then into the uterus. This procedure is used as an alternative to vaginal delivery, and can be indicated in certain conditions. Caesarean section birth rates are rising worldwide, and many factors have been cited for this phenomenon. WHO (1985) considers a caesarean section ratio of 10% as being reasonable. However, many parts of the world far exceed this level. Caesarean section delivery is a global epidemic, with Korea having the highest rates (43% in 1999). In the UK, the caesarean section ratio averaged 12.8% from 1980 to October 1999, ranging from 10 to 17.4% (Savage 2000).[69] In the US, the rate of caesarean section increased from 5% in 1970 to 16% in 1978, and then peaked at 24.7% in 1985. The US Department of Health and Human Services set targets in 1991 to reduce the overall caesarean section ratio to 15%, and the primary rate to 12%, by 2000 (Healthy People 2000).

Caesarean section deliveries are typically performed because (1) the mother has already undergone caesarean section during a previous delivery, and the doctor believes that a "repeat" is necessary to avoid rupturing the uterus; or (2) the woman experiences complications during pregnancy. Caesarean section also reduces the risk of rare neurological disorders like cerebral palsy. In many cases, caesarean section is required to save the life of the baby or mother. According to an NICE guideline (2004), the clinical indications for planned CS, which should be scheduled before the onset of labour, are as follows:

- breech presentation;
- multiple pregnancy;
- preterm birth;
- undersized foetus (too small for its gestational age);
- placenta previa;

[69] In Scotland, the caesarean section ratio rose from 9% in 1976 to 16% in 1995 (The Scottish Office 1997).

- cephalopelvic disproportion;
- HIV-positive mother; and
- primary genital herpes simplex virus (HSV) infection occurring in the third trimester of pregnancy.

As caesarean section delivery requires more resources than vaginal delivery and is partly a matter of choice, electing caesarean section for non-medical reasons seems to draw controversy.[70] Caesarean section ratios are attributed to many complex factors in both medical and non-medical reasons. Advancements in technologies used in the delivery of babies have cultivated a philosophy of medical education and practice to regard pregnancy and birth as situations requiring medical intervention. Cultural pressure fostering caesarean section births comes from superstitious beliefs, especially in Korea, that the fate of a person is predetermined by the moment of birth. Caesarean section births are also guided in tandem with judicial circumstances, including court orders and usual practices seeking to avoid malpractice claims. Caesarean section cases forced by judicial order have been particularly evident in the UK and US. Furthermore, there have been some cases in which doctors were threatened with malpractice if they did not opt for a CS. In addition, caesarean section delivery is fostered by both the obstetricians and women giving birth. On the part of the obstetricians, the motive is personal benefit insofar as surgical procedures generally guarantee higher income than non-surgical procedures. On the part of the women giving birth, a caesarean section birth is often the preferred means of delivery since it will allow them to schedule delivery at their own convenience, and since it can allow them to avoid the pain usually experienced during labour or any physical changes following birth.[71] Many women also choose caesarean section delivery to avoid prenatal damage.[72]

[70] Gabay and Wolfe (1994) estimated that over one-half of the caesarean sections performed in 1987 were unnecessary and resulted in 1.1 million extra hospital days in the US and a cost of over US$1 billion.

[71] According to Jackson and Irvine (1998), 38% of the elective caesarean section deliveries that had been performed in District General Hospital in Watford, England were performed on account of maternal request. Of all the births in the hospital, 18.8% were delivered by CS, 9.1% of which were elective CSs and 9.7% emergency CSs. In the Radcliffe Hospital of the UK, the proportion of CSs performed by maternal request has increased from 1% in 1986 to 30% in 1996 (MacKenzie 1999).

[72] Al-Mufti et al. (1997) found in their survey that 17% of obstetricians would choose an elective caesarean section in the absence of any clinical indication, mainly out of fear of perinatal damage.

The selection of caesarean section is also closely related to the schemes involving the payment of the cost of delivery.[73] Women with private insurance policies are more likely to choose instrumentally assisted deliveries, including CSs, than those covered by public insurance programmes (Stafford 1990, Stephenson 1992, Fisher et al. 1995, Roberts et al. 2000, King 2000, Murray 2000).

Some other demographic and socio-economic elements appear to influence caesarean section ratios. In the US, caesarean section delivery is more likely to be chosen by married mothers and white mothers (Gruber and Owings 1996) since the choice of delivery via caesarean section is closely related to socio-economic status, including access to insurance coverage. Generally, the likelihood of a caesarean section delivery rises with maternal age (Sizer et al. 2000, Gruber and Owings 1996, Braveman et al. 1995): as the maternal age increases, the spontaneous vaginal-delivery rates fall while the instrumental-delivery rates, elective and emergency caesarean section ratios, labour induction rates, and epidural rates rise. Braveman and colleagues (1995) also found that insurance, maternal age[74], education, prenatal care initiation, hospital teaching status, ownership, and region are significant predictors of caesarean section delivery.[75]

4.2. Micro Factor Evaluation

4.2.1. Economic Factors

The economic evidence is focused around the cost of CS compared to vaginal birth. Compared with home births, caesarean section birth costs are much higher. Caesarean section deliveries, as well as natural deliveries, have not been evaluated adequately (Petrou et al. 2001). As summarised in *Table 4-1*, the costs cited in published studies and in the NHS reference costs widely vary for each mode of delivery.

[73] Cai et al. (1998) found that the expansion of insurance coverage, in a system where the physicians were compensated on a fee-for-service basis, was mainly responsible for the increase of caesarean section ratios in Minhang District, Shanghai, China.

[74] In the UK, Sizer and colleagues. (2000) found that as the maternal age increases, the spontaneous vaginal delivery rates fall, and the instrumental-delivery rates, elective and emergency caesarean section ratios, labour induction rates, and epidural rates rise.

[75] Gregory and colleagues (1999) found that the Medicaid-insured women who delivered their babies in private non-teaching hospitals had an overall caesarean section delivery rate that was 2 to 2.5 times that of similar women who delivered at public hospitals (24.5% vs. 9%).

Table 4-1. **Range of costs cited in published studies and in the NHS reference costs (£)**

	Range of Costs		NHS Reference Costs including postnatal stay[a]
	Excluding Postnatal Stay	Including Postnatal Stay	
Spontaneous vaginal delivery	341-886	629-1,350	520-889
Instrumental vaginal delivery	606-968	242-1,794	921-1,416
CS	1,004-1,486	1,238-3,551	1,449-2,122

Data Sources: Henderson et al., (2001)
Note: a Inter-quartile range of uncomplicated non-elective cases quoted from

The caesarean section delivery cost variations are closely related to the length of stay (LOS) after the delivery. As shown in *Table 4-2*, the LOS following caesarean section delivery in the US is about double that following vaginal delivery, mainly due to the maternal complications that occur during and after delivery.

Table 4-2. **LOS by type of delivery: 1980-1998**

Type of Delivery	1980	1985	1990	1995	1998
C-Section	6.5	5.2	4.5	3.6	3.7
Vaginal Delivery	3.2	2.7	2.3	1.7	2.1
All Deliveries	3.8	3.3	2.8	2.1	2.5

Data Sources: CDC, Vital and Health Statistics, National Hospital Discharge Survey: 1998 Annual Summary

Although caesarean section delivery is much more costly compared to vaginal delivery, it has been proven to be a cost-effective approach in situations where the mother and/or baby experiences distress, or to preventing infectious diseases. Elective caesarean section deliveries appear to be a cost-effective intervention when they prevent the vertical transmission of HIV among women receiving various antiretroviral therapy regimens, who refrain from breastfeeding (Halpern et al. 2000).[76] As vaginal delivery has been demonstrated to increase the risk of causing cervical cancer to recur among women who are

[76] It should be considered that, although elective caesarean section remained cost-effective, results were sensitive to variations in vertical transmission rates and to paediatric HIV treatment costs in their study. The International Perinatal HIV Group (1999) found that elective caesarean section reduces the risk of transmission of HIV from mother to child independently of the effects of vertical transmission.

afflicted with the disease, caesarean section deliveries are recommended for pregnant women with cervical cancer (Sood et al. 2000).

4.2.2. Clinical Factors

In general, caesarean section deliveries offer some benefits, such as the following:

- they can save the lives of newborns and their mothers, or prevent the potential complications that may arise from a delayed vaginal birth;
- the pain of labour may be minimized or avoided; and
- it is possible to time the delivery.

Although elective caesarean section cannot prevent all risks associated with childbirth, by avoiding labour and prolonged pregnancy, mothers can avoid such problems as unexpected intrauterine death[77], permanent brain damage due to labour[78], and the risk that the baby would weigh >1,500 gat birth.[79]

Being a major surgery, caesarean section delivery, however, entails many risks. Hall (1994) reported that elective lower-segment caesarean section is associated with a much higher risk of maternal death. The rate of mortality after caesarean section delivery is 4.5 times greater than after vaginal delivery (Schuitemaker et al, 1997). Although some deaths following caesarean section delivery are related to maternal illness rather than to the surgery (NIH 1980), many of such deaths are caused by infections. The higher risk of maternal death in caesarean section delivery is also associated with the use of general anaesthesia, which is not required in vaginal delivery. On the other hand, individual medical conditions such as heart problems may increase the risk of death in vaginal delivery compared to caesarean section delivery.

[77] This problem occurs in about 1 in 600 pregnancies (Hiller et al. 1998).
[78] It is estimated that one in 1,750 labours result in hypoxic ischaemic encephalopathy, whereas intrapartum events account for about 10% of all babies with cerebral palsy (Nelson and Ellenberg 1986).
[79] Death at birth occurs in about one in 1,500 cases in the UK (Confidential enquiry into stillbirths and deaths in infancy 4th report 1997).

The surgery that is performed in caesarean section delivery increases the risk of maternal death, hysterectomy, haemorrhage, surgical injury to the other organs, infection[80], blood clots, and re-hospitalisation due to complications (Lydon-Rochelle et al. 2000, Schuitemaker et al. 1997, van Ham et al. 1997). According to Hillan (1995), only 9.5% of the respondents in their study who underwent caesarean section delivery did not experience any postoperative problem.

Furthermore, potential long-term complications may arise from the scar tissue adhesions resulting from caesarean section delivery, such as pelvic pain, bowel problems, and pain during sexual intercourse. Scar tissues also make subsequent CSs more difficult to perform, increasing the risk of injury to other organs and the risk of chronic problems from adhesions. In addition, scar tissue, which stimulates the incidence of placenta previa and placenta accreta, increases dramatically with each successive caesarean section (Ananth et al. 1997, Asakura and Myers 1995, Hemminki and Merilainen 1996).

4.2.3. Technical Factors

Caesarean section delivery is beneficial to a mother's psychological state. Those who have undergone an emergency caesarean section retrospectively report having had minimal psychological distress, having hardly perceived the risk of incurring a serious injury during delivery, and having had significantly greater satisfaction with pain relief (Maclean et al. 2000). Psychologically adverse effects have also been reported, however, including: (1) more symptoms of post-traumatic stress (Ryding et al. 1998)[81]; (2) more reports of psychosomatic symptoms during the first year after delivery (Garel et al. 1988); and (3)

[80] According to Henderson and Love (1995), the overall infection rates for women who delivered through primary and secondary caesarean section in a Canadian community teaching hospital were 42.1% and 46.1%, respectively.

[81] The study compares the psychological reactions of women after emergency caesarean section (EmCS), elective caesarean section (ElCS), instrumental vaginal delivery (IVD), and normal vaginal delivery (NVD), assessing the longitudinal change of post-traumatic stress from a few days postpartum to one month postpartum. The Emcaesarean section group reported the most negative delivery experience at both times, followed by the IVD group. At a few days postpartum, the Emcaesarean section group experienced greater general mental distress than the NVD group did, but less than that experienced by the Elcaesarean section and IVD groups. At one month postpartum, the Emcaesarean section group showed more symptoms of post-traumatic stress than did the Elcaesarean section and NVD groups, but not when compared to the IVD group. An unplanned instrumental delivery (Emcaesarean section or IVD), therefore, should be regarded as a pointer with respect to possible post-traumatic stress.

deterioration in mood and a diminution of self-esteem (Fisher et al. 1997).[82] In general, women who have undergone unplanned caesarean section deliveries are likely to show less adaptive responses and more ineffective responses than those who have undergone planned caesarean section deliveries (Reichert et al. 1993, Ryding et al. 1998).

4.3. Macro Factor Evaluation

4.3.1. Japan

In Japan, no legal regulation exists to control caesarean section deliveries. The health insurance programmes in the country exclude normal delivery in their coverage plans because they do not regard normal delivery as a medical treatment.

Compensation schemes do not confer any benefit on obstetricians for caesarean section delivery. While a single normal delivery in Japan costs about £760, the fee for caesarean section delivery during working hours is only about £470, and £820 during non-working hours. In the case of first-time delivery, mothers who undergo normal delivery stay in the hospital for about eight days after birth (for additional normal deliveries, mothers stay in the hospital for seven days after birth). On the other hand, mothers who undergo caesarean section delivery stay in the hospital for about 11 days. Considering the longer hospital stay after caesarean section delivery, and the comparatively lower fees involved, obstetricians and hospitals prefer normal delivery.

In summary, the health insurance policy in Japan, which does not cover normal delivery, is unique, and the cost of normal delivery is much higher than that of caesarean section delivery.

4.3.2. Korea

Like Japan, there is no legal regulation controlling caesarean section delivery in Korea. The fee differences between normal and caesarean section deliveries in the country,

[82] They found that significant adverse psychological effects were associated with the mode of delivery. Women who had undergone spontaneous vaginal deliveries were most likely to experience a marked improvement in mood and an elevation of self-esteem across the late-pregnancy to the early-postpartum interval. In contrast, women who had undergone caesarean section deliveries were significantly more likely to experience deterioration in mood and a diminution of self-esteem.

however, may encourage obstetricians to choose caesarean section deliveries. According to the National Health Insurance Corporation (2000), the average length of stay for vaginal delivery in the year 2000 was 2.9 days, and 7.2 days for caesarean section delivery. The cost of caesarean section delivery then, therefore, was 2.6 times higher than that of vaginal delivery. In 1999, the average cost of caesarean section delivery in Korea was £532, while that of vaginal delivery was £205. In 1991, the fees for vaginal and caesarean section deliveries were £58 and £206, respectively. The data indicate that although the gap between the fees for vaginal and caesarean section deliveries narrowed in the 1990s, the rate of caesarean section deliveries continued to increase. It has been strongly assumed in Korea that the higher fee for caesarean section delivery on account of the longer hospital stay required by it and the use of expensive items, including high-priced antibiotics, during the conduct of the procedure is mainly due to the preference of both physicians and hospitals for caesarean section delivery.

Table 4-3. **Fees by deliveries and payment systems, 1999**

Payment			Teaching Hospital	General Hospital	Hospital	Clinic	Average
On FFS	Vaginal Delivery	Average LOS(day)	3.5	3.2	3.1	2.5	2.9
		Average Cost	£229.37	£215.77	£172.89	£149.18	£176.56
	caesarean section Delivery	Average LOS(day)	8.2	7.6	7.6	6.6	7.2
		Average Cost	£557.12	£528.02	£445.41	£400.75	£457.99
On DRG[83]	Vaginal Delivery	Severity 0	£285.35	£271.61	£243.98	£221.65	-
		Severity 1	£369.58	£352.98	£319.67	£291.82	-
		Severity 2	£567.78	£543.70	£495.33	£455.18	-
	caesarean section Delivery	Severity 0	£576.11	£551.08	£500.58	£457.78	-
		Severity 1	£608.57	£583.27	£532.25	£487.64	-
		Severity 2	£621.25	£595.31	£543.12	£497.72	-

Data Sources: The Ministry of Health and Welfare, 1999 DRG Guidelines.

In Korea, the choice between FFS and DRG is discretionary and is in the hands of the providers. As shown in *Table 4-3*, although the gap between the fees of vaginal and

[83] The DRG system was partly introduced in February 1997 as a three-year demonstration project. The items covered by the DRG scheme expanded each year, and more hospitals eventually accepted it. At the time the system was launched, only 54 hospitals, mostly public organisations managed by the central or regional governments, participated in the scheme.

caesarean section deliveries has significantly narrowed under the DRG scheme, it is still unlikely that the rate will decline if measures related to cost reimbursement will be implemented. Rather, obstetricians and hospitals prefer caesarean section delivery under the DRG programme since this scheme is more financially beneficial to the providers. The financial advantage is much greater for caesarean section delivery when its fee is paid by DRG than by FFS. In the flux of fierce opposition against the DRG system led by the Korean Medical Association, the Korean Society of Obstetrics and Gynaecology also proclaimed opposition against the DRG system in September 2003. Consequently, majority of the members of the Korean Medical Association hesitated from employing the DRG system. Although they acquired compensation based on FFS, the fee was still much higher in caesarean section delivery (£104.40) than in natural delivery (£81.26).[84]

The recent data on the comparison of the fees of normal and caesarean section births, as shown in *Table 4-4*, suggest that all types of providers offering delivery services may still prefer caesarean section delivery. To reduce the caesarean section ratio, the Ministry of Health and Welfare set off a series of measures in the year 2000. The first action was the public disclosure of the caesarean section ratios of individual centres providing childbirth services, unveiled by the National Health Insurance Corporation. The great variation among obstetrics clinics and hospitals provoked public fury. In December 2004, the Ministry of Health and Welfare organised the Ad Hoc Committee for the Decrease of caesarean section Deliveries. The committee marked as its target the reduction of the caesarean section delivery rate to 20% by the year 2010. Towards this end, the committee set forth the plan of developing standard protocols as regards caesarean section indications and of continuing to publicise the caesarean section ratios of individual clinics. Since then, the National Health Insurance Corporation has been publicising the caesarean section ratios of individual clinics, indicating the likelihood that their patients will undergo caesarean section delivery as high, moderate, and low, with the clinics strictly adhering to the protocol. The second action was a fee policy for delivery. In 2007, the Ministry of Health and Welfare drastically raised the

[84] The fee refers only to the delivery, and excludes the accompanying fees, such as the physician's fee and the meals.

natural-delivery fee to £154.11, which is much higher than the caesarean section delivery of £131.03 based on FFS.

Table 4-4. **Fees by deliveries and payment systems, 2005**

	Fees (Average)		LOS (Per Day)	
	Normal Delivery	caesarean section Delivery	Normal Delivery	caesarean section Delivery
Total	£304.28	£515.90	3.2	7.0
Special hospital	£396.21	£644.31	3.5	7.9
General hospital	£345.26	£612.02	3.3	7.5
Hospital	£311.60	£517.56	3.3	7.1
Clinic	£279.95	£460.99	3.1	6.7

Data Sources: The Ministry of Health and Welfare, Brief Report on caesarean section Rates, July 26, 2006

As seen in *Table 4-5*, the actual fee was much higher when paid through the DRG system. Although the fee for the delivery itself is lower at present in the FFS system for caesarean section delivery, the overall fees are still much higher in caesarean section delivery.

Table 4-5. **Fee differences between the DRG group and the FFS group (£)**

Fees	1999			2000		
	Vaginal Birth	Caesarean Birth	Differences	Vaginal Birth	Caesarean Birth	Differences
DRG	206.19	499.30	293.11	208.66	500.37	291.71
FFS	207.19	433.71	267.68	184.68	451.59	266.91
Differences	40.15	65.58		23.98	48.77	

Data Sources: Ko et al. (2000)

In summary, the average cost of caesarean section delivery was more than two times higher than that of normal delivery in 1999, which was four times higher in 1991. Although the Ministry of Health and Welfare introduced the DRG scheme for caesarean section delivery in 2003 to reduce the gap between caesarean section delivery and normal delivery, the compensation for childbirth is still higher in caesarean section delivery. In 2004, HIRA started to disclose to the public the caesarean section ratios of individual centres; the centres with high rates were then condemned as moral hazards. In addition, the public

disclosure of the caesarean section ratios hints the probability of choosing caesarean birth in each centre.

4.3.3. UK

The much higher rates of caesarean section delivery in the UK compared with the WHO recommendation have raised some questions. The Royal College of Obstetricians and Gynaecologists, on behalf of the Department of Health, carried out a comprehensive nationwide study on caesarean section births in 2001 to determine why these differences exist, and to determine the best way of addressing the inequality. The results of the study became the basis for the development of clinical guidelines for caesarean section delivery and of the National Service Framework for Children guidelines. The results of the study carried out by the National Audit in response to concerns over the variation in the caesarean section ratios across the country also support the development of the guidelines.

So far, no legal regulation of caesarean section delivery exists in the UK. Due to the higher caesarean section ratios and the accompanying cost burden on the society, caesarean section ratios have been a sensitive issue on the part of the public and among policymakers. In the UK, each 1% increase in the caesarean section ratio results in an increase of £5 million in costs to the NHS (Drife 1997). According to *Reference Cost 2000* (DoH 2000), the national average cost of non-elective caesarean section admission is £738, with an inter-quartile range of £505 to £874. The national average cost of caesarean section delivery is £1,738, with additional costs coming primarily from the use of the facility and the longer stay in the hospital.[85]

The women's choice stance in the UK is well epitomised in the practice guidelines established by the Ethics Committee of the Royal College of Obstetricians and Gynaecologists, as quoted in the immediately preceding section. Maternal choice is now a major factor stimulating caesarean section delivery. According to Eftekhar and Steer (2000),

[85] The costs included herein relate to the delivery episode itself, and no costs are incurred in health terms for a healthy baby. If a baby requires health care for a medical condition, then the baby becomes an admitted patient in its own right. The costs of the child's treatment are shown vis-à-vis the relevant treatment categories (e.g., special-care baby unit, cardiac surgery, etc.), as necessary.

maternal request accounted for 14% of the caesarean section deliveries carried out in Chelsea and Westminster Hospital in 1999. The vast majority of requests were prompted by the woman's fear of foetal and neonatal injuries potentially occurring during delivery and pregnancy, followed by infertility (Tranquilli 2001). In addition, maternal requests for caesarean section are more likely for those who have already undergone one (Tranquilli 2001, Quinlivan et al. 1999, Jackson and Irvine 1998, Geary et al. 1997), or for those who have experienced an obstetric complication during pregnancy, such as breech presentation (Tranquilli 2001, Quinlivan et al. 1999, Jackson and Irvine 1998). The experience of a difficult birth was also a factor in maternal requests (Churchill 1997, Turnbull et al., 1999). *Changing Childbirth Report* (DoH 1993) outlined guidelines for choosing the mode of delivery, the kind of professional healthcare providers, the place of delivery, and the degree of intervention. The Audit Commission Report (1997) further stated that maternity services needed to become more women-centred.

The Human Rights Act of 1998, which came into force on October 2, 2000, states that women have the right to opt for caesarean section delivery, with the involvement of a senior consultant. Article 2 of the Act ensures that "everyone's right to life is protected by law." The passage and implementation of this Act is regarded as a way of holding the medical staff accountable for taking adequate and appropriate steps to protect or preserve a life, in addition to preventing any harm from befalling a patient (Gillman 2000). Elective caesarean section is also supported by specialists in the obstetric community. There has been a consensus to confirm a patient's right to autonomy, which should be respected as long as the woman is fully informed (Paterson-Brown 1998, Amu et al. 1998).

In addition, European decisions and the legal commentary on Article 2 raise the right of a patient to demand for the involvement of senior staff members and the right of a woman to choose how her baby will be delivered. The medical-staff members are required to take note of, and to respect, a woman's preference for how she wishes her baby to be delivered. Article 3 prohibits inhumane or degrading treatment or punishment. Article 8 states that everyone's right to privacy, family, home, and correspondence must be upheld and respected. A person's privacy includes a person's physical and psychological integrity. Accordingly, the Act urges obstetricians to undertake caesarean section delivery even when

a woman chooses it out of fear of pain or fear that an accident would occur during labour. In practice, obstetricians report that the woman's desire to deliver by way of caesarean section influences the final decision as to the method of delivery.[86]

The caesarean section ratio is also influenced by the human resources in NHS. According to the Royal College of Midwives, more women are being forced to undergo caesarean section delivery because of the shortage of midwives (*The Times*, November 7, 2000).[87] In 1997-98, about 30% of all deliveries were conducted by hospital doctors, and 70% by midwives. At present, more deliveries are being handled by doctors. The overall balance between the two professions has steadily changed over the years. During the period 1989-90, about 24% of all deliveries were conducted by doctors, and the remaining 76% by midwives. As virtually all spontaneous deliveries then were conducted by midwives, the shift partly accounts for the increasing proportion of caesarean section deliveries.[88]

Savage and Francome (1993) explored the reasons for the rise in the caesarean section ratio in Britain by conducting a nationwide survey.[89] Out of the total of 623 responses, the major reasons given by the obstetrician respondents for caesarean section deliveries were as follows:

- litigation (125/20.06%);
- heightens safety (52/8.34%);

---

[86] According to a survey conducted by Al-Mufti et al. (1996), 31% of female obstetricians are likely to prescribe an elective caesarean section delivery even in the case of first-time pregnancy or delivery and a likely uncomplicated one. This implies a potential demand for caesarean section delivery.

[87] This was discussed by midwives, obstetricians, and members of the National Childbirth Trust at a conference jointly organised by the Royal College of Obstetricians and Gynaecologists, the Royal College of Midwives, and the National Childbirth Trust. It was conceded in this conference that there is an important link between the lack of continuous support by midwives during labour and the rising incidence of medical intervention, including CS, in childbirth. In the US, Blanchette (1995) compared the caesarean section delivery rates of a group cared for by certified nurse-midwives (CNMs) in a public facility and of a low-risk group cared for by physicians in a private setting. They found that the caesarean section birth rate in the group cared for by CNMs (13.1%) was about half of that in the group cared for by physicians (26.4%).

[88] Recently, midwives have been deserting NHS in droves. While some 90,000 are registered, only about 32,000 are practising in the health service. According to the Royal College of Midwives, this can cause anxiety and contribute to an ever-rising rate of CSs and other avoidable interventions that are more dangerous than natural birth (Bennett 2001). More midwives enter private practice as it brings better income and greater freedom. To resume one-to-one, continuous care with a midwife during labour, the British government plans to invest £100 million cash (*Guardian*, May 2, 2001). This may make it possible to recruit an extra 2,000 midwives and to modernise maternity units.

[89] Consultants were asked an open-ended question. All but nine of the 232 consultants in England and Wales responded, and four of the 74 in Scotland. Over 50 different reasons were given by the consultants.

- allows foetal monitoring (49/7.86%);
- effective in reducing perinatal mortality (37/5.93%);
- increases the expectation of the parents (34/5.45%);
- addresses breech presentation (34/5.45%); and
- allows better monitoring (32/5.13%).

The reason most frequently mentioned by the obstetricians was malpractice litigation, followed by staffing problems and misinterpretation of the foetal condition.

In summary, the Human Rights Act of 1998, which respects maternal choice of delivery, and the dearth of midwives in NHS, have been regarded as the major factors influencing the choice of the kind of delivery in the UK

4.3.4. US

Various attempts have been made to curb the caesarean section delivery rate in the US, such as the issuance and implementation of legal regulations, public policies, guidelines for practices, and reimbursement policies of insurers by various authorities at both the national and state level.

At the federal level, the Newborns' and Mothers' Health Protection Act (NMHPA) of 1996[90] mandated that the coverage for hospital stays on account of childbirth generally cannot be less than 48 hours for normal deliveries or 96 hours for caesarean section births (Federal Register 1998, Vol. 63).[91] After the enactment of the law, the average charges of

[90] Maryland passed the first maternal-length-of-stay legislation in 1995. The law was passed in Illinois in July 1996. In the fall of 1996, President Clinton signed the Newborns' and Mothers' Health Protection Act, which supplements the state laws by covering those receiving care in a state without legislation, those who are insured by a company headquartered in another state, and those working for a self-insured employer (Raube and Merrell 1999).

[91] The Newborns' and Mothers' Health Protection Act of 1996 (NMHPA) was enacted on September 26, 1996 to provide mothers and their newborn children with protection during the critical days immediately following birth. To ensure that mothers and newborns would receive adequate care, the law establishes a minimum hospital stay in connection with childbirth. The law applies to group health plans, health insurance issuers (e.g., insurance companies, HMOs) that offer insurance in connection with group health plans, and health insurance issuers who sell coverage in the individual market. For group health plans and health insurance issuers in the group market, the law is effective for the plan years beginning on or after January 1, 1998. For the individual market, the law applies to health insurance coverage on or after January

delivery increased, but more for vaginal delivery than for caesarean section delivery (Udom and Betley 1998).[92]

At the state level, a law imposing practice guidelines on obstetricians for caesarean section births was implemented in Florida in 1992. The law also required hospitals to establish peer review boards that would evaluate the caesarean section deliveries performed in such hospitals. For the monitoring of the law's implementation, hospitals are required to report each caesarean section case to a state agency. The impact of the law in reducing the caesarean section birth rates was greater in terms of reducing the primary cases of CSs than in terms of reducing the repeat cases, especially in the first quarter of 1993 (Studnicki et al. 1997).[93]

Various public authorities have also participated. The concern regarding caesarean section deliveries was focused on repeat deliveries. The actions towards vaginal birth after caesarean section (VBAC) began in the late 1980s.[94] When the National Institute of Health introduced the NIH Consensus Development Programme in 1980, national guidelines for the use of caesarean section were also introduced (NIH 1981). The dictum "Once a Caesarean, always a Caesarean" began changing gradually starting in the early 1980s. In 1981, when the vaginal birth after caesarean section rate was only 3%, the National Institute of Health began to encourage trials or labour. In an effort to follow the national

---

1, 1998. The interim rules for the individual market apply to health insurance coverage offered, sold, issued, or renewed in effect, or operated in the individual market on or after January 1, 1999.

[92] In Maryland, the average charge for vaginal delivery increased by 10% while that for caesarean section increased by 6.7%.

[93] In their research, significant decreases in the number of repeat CSs were found in groups representing 72.6% of the population, while significant decreases in primary CSs were found in groups representing only 36.5% of the births without a prior CS. Reductions in the number of repeat CSs were achieved both among Medicaid beneficiaries and among those privately insured, whereas reductions in the number of primary CSs were found almost exclusively among commercially insured mothers, where the existing rates are the highest.

[94] About 65 to 88% of women are able to deliver vaginally after having had a caesarean section delivery (Flamm et al. 1988). Many studies (Flamm et al. 1994, Cowan et al. 1994) reported that the risk of the rupture of the previous uterine incision and of a potential catastrophic occurrence for both the mother and the baby was quite uncommon in a trial of labour in a woman with a single prior low-transverse caesarean section delivery. There have also been controversial reports that warn of maternal and neonatal complications, such as those associated with prior caesarean section delivery. McMahon et al. (1996) conceded that the rate of maternal morbidity associated with a previous caesarean section delivery is higher than the rate of maternal morbidity associated with a repeat caesarean section delivery (Sachs et al. 1999).

guidelines, regulations have been implemented by various authorities at both the national and state level. In October 1988, the American College of Obstetricians and Gynaecologists (ACOG) issued a physician practice guideline stating that a prior caesarean section would no longer justify the performance of a repeat caesarean section.

In 1990, the target caesarean section ratios were proclaimed in the objectives of "Healthy People 2000." To prevent disease and promote better health, the US Department of Health and Human Services developed a set of objectives, contained in the "Healthy People 2000" programme, as part of the decade-long effort in 1990. The objectives were set to reduce the overall caesarean section birth rate to below 15 per 100 deliveries by the year 2000 (Healthy People 2000)[95], and to reduce the financial burden and risks of maternal death as well as the morbidity and perinatal morbidity associated with caesarean section delivery.

Recently, ACOG released a document to help hospitals and physicians review and reduce their caesarean section birth rates where appropriate, compared with evidence-based goals set by an expert working group addressing the Health People 2010 objectives of the US Department of Health and Human Services (ACOG News Release, August 9, 2000).

ACOG's efforts to reduce the number of repeat caesarean sections in the US have been going on for more than a decade. In October 1988, ACOG issued a physician practice guideline stating that a prior caesarean section no longer justifies the performance of a repeat caesarean section. ACOG also recommends that the cervix should be dilated by 4 centimetres or more before a diagnosis of failure to progress is made.[96]

As the choice of caesarean section delivery is a sensitive concern for payers, the latter have made various attempts to curb the caesarean section ratios. Historically, the financial incentives to opt for a caesarean section delivery have been greatest among those who have a private insurance plan, and less among those who have a public health insurance plan. Needless to say, those who have no insurance plan had the least financial incentives to opt for a caesarean section delivery. Patients with private or HMO insurance plans are nearly

[95] The primary caesarean section delivery rate and the repeat delivery rate targets were 12 and 65 per 100 deliveries, respectively. According to Wolfe (1994), the optimum national caesarean section ratio should be nearer 12%.

[96] According to Gilford and Morton, out of one million caesarean section deliveries performed in the US each year, about 294,000 are done because of lack of progress in labour.

seven times more likely to have a repeat caesarean section delivery as an elective procedure compared to those with Medicaid or self-pay plans (Hanley et al. 1996). As such, women with Medicaid coverage are more likely to undergo a vaginal delivery than women with private insurance plans are (Wagner and Matts 1999).

To moderate the differentials between the physician fees for caesarean section and vaginal births, many private insurers and state Medicaid plans have attempted to equalise the physician fees for caesarean section and vaginal deliveries. Gruber et al. (1999) suggest that reducing the physician's fee for caesarean section delivery can cause reductions in the caesarean section ratio. They argue that the fee effect is sufficiently large to explain over one-half, and up to three-quarters, of the differentials between the caesarean section delivery rates of private and public health insurance coverage. There are evidences (Darby 1992, Keeler and Fok 1996)[97], however, that lowering the fee differentials will have only a marginal effect in terms of reducing the caesarean section ratios. Under Medicare, the 1993 RBRVS (Resource-based Relative-Value Scale) scheme compensated vaginal deliveries more than it did caesarean section deliveries based on the physicians' workloads by the product of time. The scheme put the vaginal delivery cost at a slightly higher level than that of caesarean section delivery (Keeler and Brodie 1993).

Due to lower reimbursements, many private practitioners refuse to perform caesarean section procedures on women with public health insurance policies or with no insurance policies.[98] As a result, those women who are unable to receive care from private practitioners often end up going to public hospitals.

For HMOs, caesarean section ratios are similar to the rates of private insurance plans, which usually pay obstetricians on a fee-for-service basis. In HMOs where the salaries of obstetricians are fixed, no particular financial incentives for caesarean section delivery are

[97] Keeler and Fok (1996) studied the impact of an insurance reform under California Blue Cross that equalised the physician's fees for vaginal and caesarean section delivery, causing a relative 21% decline in the physicians' fee for caesarean section delivery. They found only a modest 0.7% reduction in the caesarean section ratios, perhaps because the physician's fee is only a small fraction of the total cost of caesarean section delivery. A large part of the cost comes from the two extra hospital days that caesarean section delivery requires on average. Gruber et al. (1999) argue that the findings of Keeler and Fok do not necessarily have predictive power on the effects of Medicaid fee changes because there has been a positive relationship between physician's fees and treatment intensity, as underpinned by Yip (1998).

[98] Medicaid reimbursements vary widely from state to state, and are typically only half or less than half of the fees paid by commercial insurers (Alan Guttmacher Institute 1987).

presented, and thus, the caesarean section ratio is much lower. Some studies (Weinstein and Trussell 1998, Oleske et al. 1998) also support the view that the expansion of managed-care organisations in the healthcare industry has no meaningful impact on the caesarean section ratios.

In summary, the efforts to curb the rate of caesarean section deliveries from the early 1980s have been persuasive. NIH introduced a national guideline for caesarean section in 1981, which was set to promote vaginal birth after caesarean section. The professional community joined the public in 1988 in the campaign for vaginal birth after caesarean section. Further forceful action was then taken by the federal government, which set as a target the reduction of the nationwide caesarean section ratio to below 15% in the Healthy People 2000 project. The actions of third-party payers were also forceful, cutting down the physician's fee for caesarean section delivery, thereby minimizing the fee differences between natural delivery and caesarean section delivery.

4.4. The Adoption of caesarean section delivery

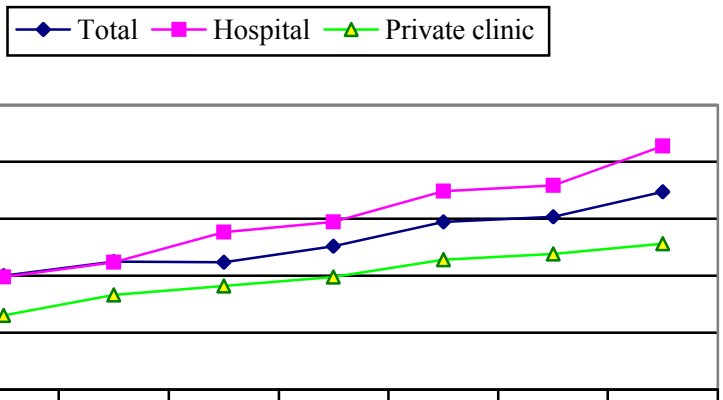
4.4.1. Japan

In Japan, the caesarean section ratios have been kept at a much lower level compared to most other countries, but the number of caesarean section cases is increasing. The rate doubled between 1984 and 1999 and rapidly increased from the late 1990s, as shown in *Figure 4-1*. The Ministry of Labour, Health, and Welfare attributes the recent increases of the caesarean section ratios to the increase in the mother's age at the birth of her first baby.[99] As reported in the media, malpractice litigations often prod obstetricians to choose caesarean section delivery.

[99] **Table F-4-1. Mother's age at the birth of her first child**

1965	1975	1985	1989	1995	1999	2000
25.7	35.7	26.7	27.0	27.5	27.9	28.0

Data sources: Ministry of Health, Labour, and Welfare, Japanese Government 2000 Vital Health Statistics.



	1984	1990	1993	1995	1996	1999	2002	2005
Total	7.3	10	11.23	11.2	12.56	14.7	15.18	17.36
Hospital	8.2	9.9	11.2	13.8	14.7	17.4	17.9	21.4
Private clinic	6.1	6.5	8.3	9.1	9.9	11.4	11.9	12.8

Figure 4-1. **Caesarean section ratios in Japan (% of total birth rates on September each year).**

Data sources: Ministry of Health and Welfare. (2008). Survey on health care organisation and the brief summary on hospital report.

In the past the obstetricians was very reluctant to choose caesarean section delivery mainly because of fee compensation. The obstetricians prefer normal delivery because it is not covered by public health insurance plans and are therefore free from outward monitoring. Since most private providers try to avoid caesarean section births, women who may need a caesarean section birth end up going to public hospitals. This results in lower caesarean section birth rates in private hospitals and birth clinics than in public hospitals.

As depicted in *Figure 4-1*, caesarean section deliveries have been increasing. The following reasons behind the increase have been pinpointed (Asahi Newspaper, 10 July 2006):

- The shortage of obstetricians encourages them to choose caesarean section delivery to save the time in labour[100]. The obstetricians have decreased fear of malpractice litigation. Clinics and hospitals prefer CS delivery to reduce pressure on obstetricians and to reduce the risk of a malpractice suit.

[100] Japan Society of Obstetrics and Gynaecology and Japan Association of Obstricians and Gynaecologists submitted a petition in November 2005 to the Ministry of Health, Labour and Welfare complainting shortage of obstetricians and requiring fee increase for their practices including childbirth.

- Increasing malpractice litigation, as much that the cases related to obstetrics occupy 10% of total high court cases
- other factors including increasing maternity age and changing attitudes of women towards pain and safety.

4.4.2. Korea

The caesarean section ratio in Korea is the highest in the world. At its peak, the rate was over four times higher than the WHO guideline. As shown in *Figure 4-2*, the caesarean section ratio in Korea has risen from 6% in 1985 to 13.3% in 1990, and it continued to rise to 21.3% in 1995, and then to 43% in 1999. The caesarean section ratios in Korea have declined since 1999 mainly due to the public's efforts to curb the rates by assessing, with the assistance of the Health Insurance Review Agency (HIRA), whether the choice of caesarean section delivery is justified by their clinical condition. The caesarean section ratio of each hospital or clinic is also publicly announced. As such, women can foresee the probability of their choosing caesarean section delivery. Hospitals and obstetricians become cautious in choosing caesarean section delivery because they know that their practices will be inspected by HIRA and that they will be publicly blamed if their rate turns out higher than that of the others.

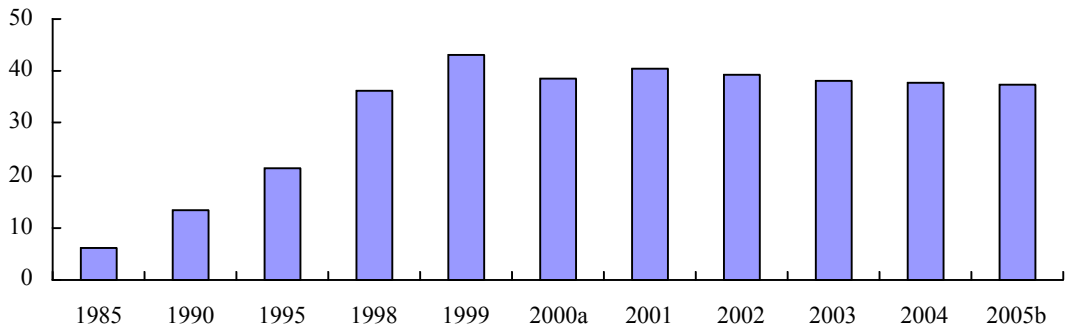


Figure 4-2. **Caesarean birth rate trends in Korea. (1985-2005)**

Data sources : 1) The National Health Insurance Corporation (2002)
2) The Ministry of Health and Welfare (2006a), caesarean section delivery rate for the recent five years (the data were released on August 28, 2006 upon the request of Hyo-Seok Kim, a member of the National Assembly)

Note: a. The date includes only six months (from July to December).
b. The date includes only six months (from January to June).

The Ministry of Health and Welfare (2006b) came up with the following list of the major factors promoting the choice of caesarean section delivery:

- delayed maternity – the average maternal age at the time of giving birth in 2005 was 30.1 years old, and those aged above 35 were 12.1% (advanced age at the time of giving birth often causes complications, including gestosis and placenta previa; as such, caesarean section delivery is often the mode of delivery chosen by pregnant women with advanced ages);
- defensive practice to avoid malpractice litigation;
- increasing vaginal birth after caesarean section due to the rise in the caesarean section ratio for the delivery of the first baby;
- higher fee for caesarean section delivery than for natural delivery (£311 for virginal delivery versus £528 for caesarean section delivery); and
- misconception regarding caesarean section delivery (caesarean section delivery is preferred so that the time of delivery can be chosen to ensure the good fortune of the baby, to maintain the shape of the mother's body after delivery, and to avoid pain while giving birth).

Among the aforementioned factors promoting the choice of caesarean section delivery, Magnier (2001) pinpointed that the highest caesarean section ratio is fuelled by the belief that such delivery is safer, can help one avoid legal conflicts, and makes it possible to ensure the good fortune of the baby by selecting the time of its birth.

Many commentators suggest that the judicial precedent set in malpractice suits, which have generally ruled in favour of cases in which caesarean section delivery was carried out during childbirth, has been the most significant factor in driving up the number of caesarean section deliveries. Consequently, obstetricians often recommend undertaking caesarean section delivery even though the risks of childbirth are marginal. In a survey by WomenLink, 80% of women who have experienced caesarean section childbirth claimed that their obstetricians guided their choices (Yeonhap News, July 8, 2000).[101] As underscored by the Ministry of Health and Welfare, and as mentioned in an earlier chapter,

[101] Of the remaining 20%, 15.6% of the women decided by themselves to have a caesarean section delivery, while the other 4.6% were persuaded by family members to do so.

the belief that one's destiny is predetermined by the "Four Pillars" (the year, month, day, and hour of one's birth) motivates mothers to deliver a child through caesarean section. When mothers are recommended or have decided to undergo caesarean section delivery, it is common for them to schedule the date and time of their childbirth in consultation with a fortune teller.

The caesarean section ratios do not significantly differ according to the type of organisation, with only slightly higher rates in teaching hospitals. The rates were widely varied among health providers in the year 2000, ranging from 11.8% at the lowest to 84.8% at the highest (National Health Insurance Cooperation 2000). Even among the teaching hospitals, the rates were varied, ranging from 24.2% to 61.2%. Kim et al. (1992) found that education and household income levels were major predictors of the variance of caesarean section ratios. They disclosed that the rates were higher among those who had higher education and higher income.

Caesarean section delivery rates escalated until 1999, and then began to decline from 2000. Ko et al. (2001) proved that the disclosure of the nationwide caesarean section ratio by the National Health Insurance Corporation was the primary factor that led to the reduction of the caesarean section ratio after 2000. In 2000, the caesarean section delivery rate dropped by 38.6%; after 2000, it decreased by 10.2%.

As shown in *Table 4-6*, the caesarean section delivery rates were higher in the groups that used the DRG scheme than in those that used the FFS scheme. The caesarean section ratio in the DRG group was about 4% higher than that in the FFS group. This indicates that a change in the reimbursement policy from the FFS to the DRG scheme would promote caesarean section deliveries (Lee and Yu 1999). The influence of the DRG system on the caesarean section ratio increase is limited, whereas the compensation from an insurance programme is at the discretion of the health providers (whether they would get their remuneration based on FFS or DRG). As of August 2006, 19.2% of the total of 1,862

obstetrician clinics got their compensation based on the DRG system (Health Insurance Review Aagency-HIRA, 2006)[102].

Table 4-6. **Differences between the caesarean section ratios of the DRG and FFS groups**

	1999			2000			
	Total Births	**Caesarean Births**	**Caesarean Rate**	**Total Births**	**Caesarean Births**	**Caesarean Rate**	**Increase**
DRG	55,334	25,048	45.3	24,937	9,727	39.0	-6.3
FFS	44,684	18,473	41.3	13,144	4,582	34.9	-6.5

Data sources: Ko et al. (2000)

Note*:* The data are limited to the cases obtained from the clinics and hospitals that have over 100 cases where the compensation was claimed based on the DRG scheme.

4.4.3. UK

The largest and most comprehensive study on caesarean section childbirths conducted in the UK has revealed that one in five deliveries is a caesarean section delivery (Thomas and Paranjothy, 2001). According to the study, the caesarean section ratios in England and Wales increased from 1% in 1946 to 2.6% in 1958, then to 4.8% in 1970. The rate doubled in the 1970s, increasing from 4% in 1970 to 9% in 1980. It then slowed down in the 1980s and reached 12% in 1990. However, once again, the rates rose to almost double during the 1990s.

At present, more than half of the caesarean section births in the UK are emergency operations. In 2003-04, about 9.6% of the deliveries in England were elective CSs, and 13.1 % were emergency CSs (Department of Health, NHS Maternity Statistics: 2003-04).

As estimated, the cases in which the mother or foetus, or both, were in danger of dying unless surgical intervention was performed accounted for about 5.8 to 8.5% of all births in England in 1993 (Francome et al. 1993). In line with the worldwide consensus, the professional community in the UK believes that a 10% caesarean section ratio, or less, is an adequate measure (Savage 2000).

[102] The data was calculated from the list joined in DRG based payment system released by Health Insurance Review & Assessment Service (HIRA) on website: http://www.hira.or.kr/common/dummy.jsp?pgmid=HIRAF010105000000 accessed 7 October 2006.

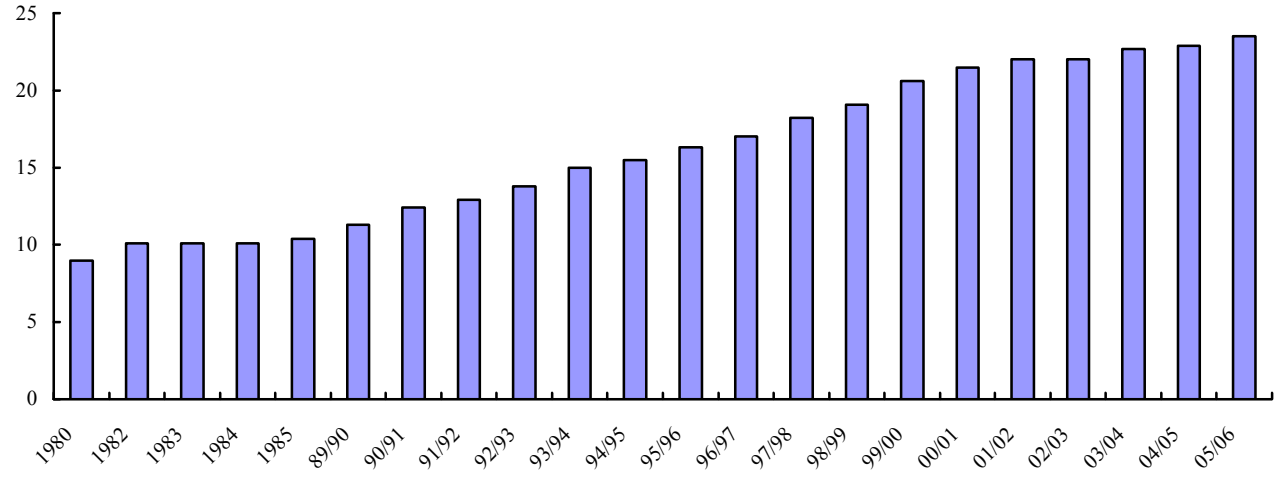


Figure 4-3. **Caesarean section delivery ratios (1980-2005/06)**

Data Sources: DoH (2005). NHS Maternity Statistics, England: 2003-2004

As seen in *Figure 4-3*, the caesarean section ratio in the UK continues to increase. There have been much controversy, however, surrounding UK's unreasonably high caesarean section ratio, and several factors contributing to such have been pinpointed.

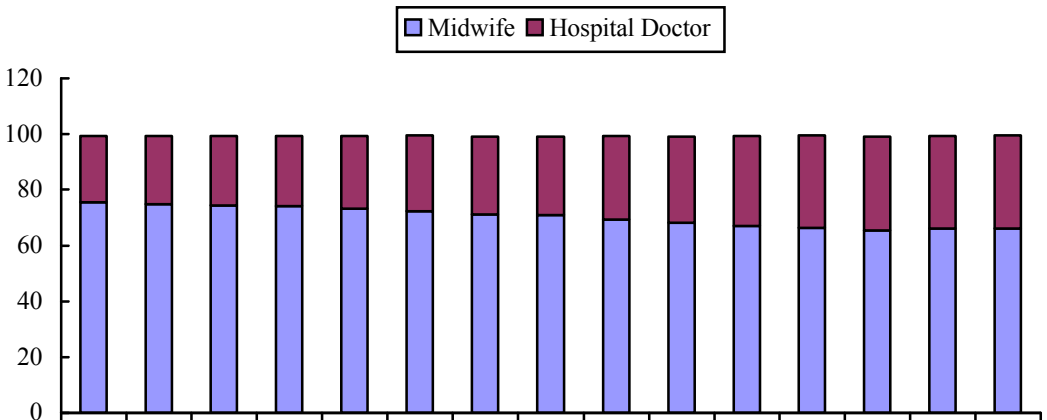
First, majority of the obstetricians in England and Wales are now prepared to agree to maternal requests for caesarean section delivery in the absence of the obstetric necessity for such (Cotzias et al. 2001).[103] Some of the most common reasons offered for this are patient pressure (89%), fear of litigation (35%), and the practice of evidence-based medicine (32%). Such change in the obstetricians' attitude towards maternal requests for caesarean section delivery is a significant shift. In the 1980s, if the obstetricians were asked how they would respond to a maternal request for caesarean section delivery in an uncomplicated pregnancy, the majority indicated that they would refuse (Johnson et al. 1986, Hall 1987). The Changing Childbirth policy in the UK recommends giving way to maternal choice in obstetric decision-making (DoH 1993). The Changing Childbirth policy apparently changed the people's attitudes and encouraged the acceptance of woman-centred care (*Guardian*, September 27, 2000*).* Although the British government tries to control unnecessary choice of caesarean section delivery by steering through NICE guidelines

[103] In the research, 69% of the respondent obstetricians responded that they would agree to an elective pre-labour caesarean section delivery maternal request

.

issued in 2004 that maternal request alone can not be the indication, it has not yet been successful to control it.

Second, the shortage of midwives has forced women to go to hospitals for delivery, and consequently contributed to increasing the number of caesarean section deliveries in the UK As the Royal College of Midwives argues, the shortage of midwives is also a major factor in spurring hospital births, and therefore, in increasing caesarean section deliveries. *Figure 4-4* shows the decreasing proportion of midwives involved in overall deliveries that dropped from 75.6% in 1989-90 to 66.1% in 2003-04 periods.



	89/90	90/91	91/92	92/93	93/94	95/95	95/96	96/97	97/98	98/99	99/00	00/01	01/02	02/03	03/04
Hospital Doctor	23.7	24.5	25.1	25.3	26.1	27.2	28.1	28.4	30	31.1	32.5	33.3	33.8	33.3	33.5
Midwife	75.6	74.8	74.3	74	73.3	72.3	71.1	70.8	69.4	68.1	66.9	66.2	65.4	66.1	66.1

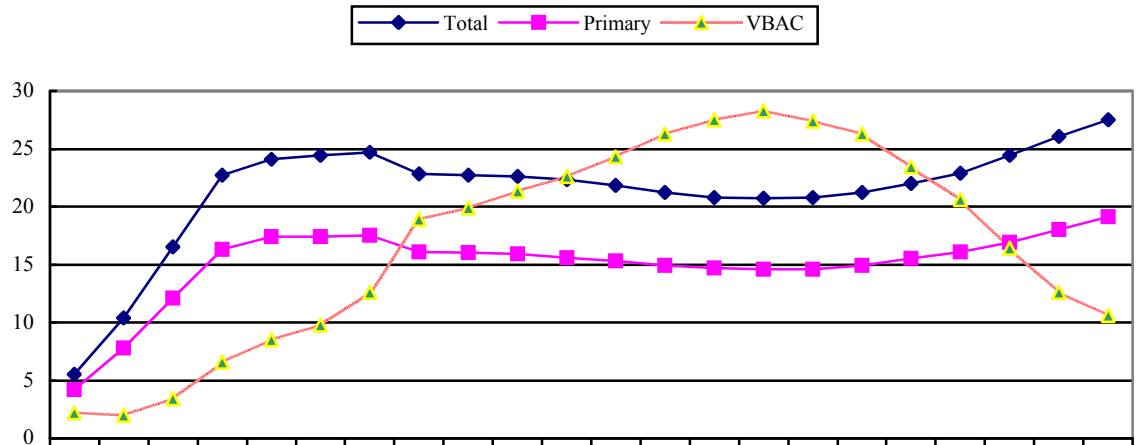
Figure 4-4. **Persons conducting deliveries**

Data Sources: DoH (2005). NHS Maternity Statistics, England: 2003-2004

4.4.4. US

The rate of caesarean section deliveries in the US has rapidly increased since 1965, peaking in 1988. In the subsequent years, the rate levelled off until 1996. According to Young (1997), few insurance companies, hospitals, and physicians were interested in reducing the caesarean section ratio, and many refused to admit that unnecessary caesarean section childbirths were being performed throughout the 1980s. Since recently, there are

signs that the caesarean section ratio is again increasing, though still low. Nearly 7% of the primary CSs and 40% of the repeat CSs in the US in 1998 may have been unnecessarily performed (Koroukian et al. 1998).



	70	75	80	85	86	87	88	89	90	91	92	93	94	95	96	97	98	99	00	01	02	03
Total	5.5	10.4	16.5	22.7	24.1	24.4	24.7	22.8	22.7	22.6	22.3	21.8	21.2	20.8	20.7	20.8	21.2	22	22.9	24.4	26.1	27.5
Primary	4.2	7.8	12.1	16.3	17.4	17.4	17.5	16.1	16	15.9	15.6	15.3	14.9	14.7	14.6	14.6	14.9	15.5	16.1	16.9	18	19.1
VBAC	2.2	2	3.4	6.6	8.5	9.8	12.6	18.9	19.9	21.3	22.6	24.3	26.3	27.5	28.3	27.4	26.3	23.4	20.6	16.4	12.6	10.6

Figure 4-5. **Total, primary CS, and VBAC ratios in the United States, 1970–9.**

Data source*:* 1) CDC (2005)) Trend in caesarean rates for first births and repeat caesarean rates for low-risk women: United State, 1990-2003. National Vital Statistics Reports, Vol. 54(4), p.82.
2) National Center for Health Statistics (NCHS). (2001). National Vital Statistics Reports. Vol. 49(1) 17 April
3) (CDC) (2005) Trend in caesarean rates for first births and repeat caesarean rates for low-risk women: United State, 1990-2003. National Vital Statistics Reports, Vol. 54(4), p.82.

Note: 1) *Total rate* refers to the percentage of all live births by caesarean section delivery.
2) *Primary rate* refers to the number of primary caesarean section deliveries per 100 live births to women who have not had a previous caesarean section delivery.
3*) VBAC* refers to the number of vaginal births after a previous caesarean section delivery per 100 live births to women with a previous caesarean section delivery.

Figure 4-5 shows the most dramatic change in 1989, the first full year after the ACOG guidelines were introduced. In 1989, the vaginal birth after caesarean section (VBAC) ratio increased remarkably while the rate of primary caesarean section births decreased. Since then, VBAC ratio continued to increase until 1996. Santerre (1996) argues that the ACOG guidelines may have influenced the practice of VBAC in the US. The decrease in the caesarean section ratio starting from 1989 has been attributed to an increase in VBAC. As the ratios of caesarean section deliveries and VBAC are inversely related to each other, the

overall caesarean section ratio has been falling as VBAC ratio has been increasing. The US Department of Health and Human Services attributes the increase in the total caesarean section ratio since 1996 to the rise in the number of primary caesarean section deliveries and the decline in VBAC rate (DHHS, HHS News, 8 August 2000).[104] The participation of women in VBAC is associated with various socio-economic factors. According to King and Lahiri (1994), the likelihood of receiving a VBAC increases with maternal education and the level of care provided by the hospital.[105] The probability is higher among women who are participating in HMOs than among women who are receiving care at public hospitals. The vaginal birth after caesarean section rate varies according to the source of payment. According to Oleske et al. (1998), Medicaid appeared to have a significantly higher rate of vaginal birth after caesarean section, while the total and primary caesarean section delivery rates were much lower than those with Medicaid and private managed-care plans. Customers and customer groups such as the Public Citizen Health Research Group were the main bodies who publicly criticised the high rate of caesarean section births.

There are also various changes in childbirth practices that have happened simultaneously with technological advances in obstetrics. The percentage of mothers receiving electronic foetal monitoring, ultrasound, and induction and labour stimulation has increased. The practice whose frequency has increased the most, nearly doubling, was induction. For those with induced deliveries, the increase in the number of caesarean section deliveries was greater than that for those with natural births due to failure to progress (Seyb et al. 1999, Sheldon et al. 1996, Maslow and Sweeny 2000, Alexander et al.

[104] The total caesarean section ratio has gone up 4% from 1998 to 1999, and the rise is primarily attributed to the increase in the number of primary caesarean section deliveries. Another factor that contributed to the rise in the total caesarean section ratio was the marked decline in the rate of VBAC, which fell to 11% in 1999 and rose to 17% in 1996. Recent research has shown that the diverging trends in the caesarean section and VBAC rates after 1996 may be the result of the increased risk of experiencing major maternal morbidity related to attempting VBAC (McMahon et al. 1996). The major increase in maternal morbidity in the VBAC group is mainly attributed to the infectious complications and injury to the pelvic organs (Boe et al. 1998, Judith et al. 2001). The main risk of VBAC is uterine rupture, which happens in about 1% of the cases (Flamm et al. 1994). In the case of uterus rupture, there can be catastrophic medical and medico-legal consequences (Scott 1991). Flamm (1998) states that the rising rates in repeat caesarean section deliveries in the US may be associated with the controversy surrounding the recent VBAC consent.

[105] The odds are higher in hospitals with intensive-care facilities than in those with intermediate neonatal-care facilities.

2001, Sims et al. 2001).[106] Especially, labour induction is highly likely to result in repeat caesarean section deliveries with women who have not previously experienced a vaginal delivery (McNally and Turner 1999, Yeast et al. 1999).[107]

Figure 4-5 also shows the rapid y decrease in VBAC since 1998 that has been fallen from 28.3% at the peak in 1996 to 10.6% in 2003. Pinette and colleagues (2004) showed that the drastic drop could be attributed to the revised guideline of ACOG on VBAC in October 1998 and July 1999. The revised guideline requires the presence of a surgeon, anaesthesiologist and operating personnel through out the labour for patients with prior caesarean section. According to them, the critical reasons for the decline in VBAC were patients refusing VBAC after counselling and inability to meet ACOG guidelines.

4.5. Conclusion

There are big variations in caesarean section ratios among those selected countries, with Korea at the highest. These can be attributed to the following differences between countries:

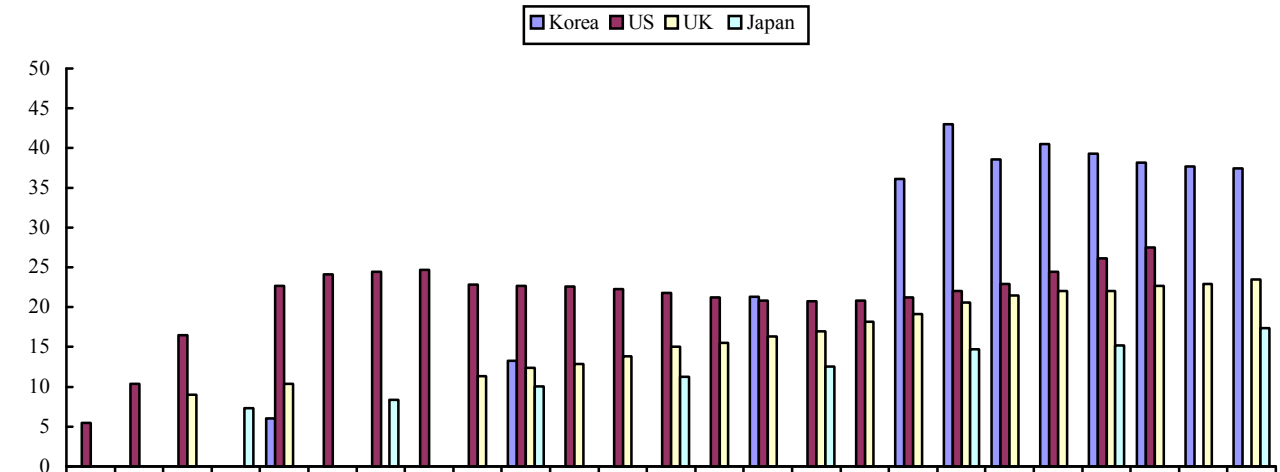
- payment scheme for covering birth costs
- Judicial rulings on labour procedures
- cultural influences

Figure 4-6 shows the change of caesarean section delivery ratio by countries and times. The ratio in Korea was lower than other three countries until the end of 1980s, which may be related with income. The most significant factor for the difference between Japan and Korea is insurance coverage. In the US, nation wide campaigns through "Health People" project were successful to keep control the adoption of caesarean section delivery by mainly promoting vaginal births after caesarean section delivery. In the UK, national policy to respect consumer's right that esteem maternal request in choosing caesarean birth has

[106] According to Alexander et al., the independent risk factors in the induced group for caesarean section delivery include nulliparity, undilated cervix prior to labour, and epidural analgesia. According to Maslow and Sweeny, elective induction placed nulloparas at a twofold higher risk for caesarean section delivery.

[107] In the research conducted by McNally and Turner, the repeat caesarean section ratio after the trial of induction course was 37.3%, while the caesarean section delivery rate was only 3.9% among women who had previously delivered vaginally.

been a significant influence for continuous increases since the early 1990s. The National Sentinel Caesarean Section Audit Report (RCOG, 2001) found that 3 % of women requested elective caesarean section delivery in the absence of any medical indications and these requests were agreed to in about 50 % of cases.



	70	75	80	84	85	86	87	88	89	90	91	92	93	94	95	96	97	98	99	00	01	02	03	04	05
Korea					6					13.3					21.3			36.1	43	38.6	40.5	39.3	38.2	37.7	37.5
US	5.5	10.4	16.5		22.7	24.1	24.4	24.7	22.8	22.7	22.6	22.3	21.8	21.2	20.8	20.7	20.8	21.2	22	22.9	24.4	26.1	27.5		
UK			9		10.4				11.3	12.4	12.9	13.8	15	15.5	16.3	17	18.2	19.1	20.6	21.5	22	22	22.7	22.9	23.5
Japan				7.3			8.4			10			11.2			12.6			14.7			15.2			17.4

Figure 4-6. **Changes in caesarean section ratios by countries and times (1970-2005)**

In 1999, when caesarean section ratio was at the peak in Korea, it was about three times higher that in Japan as summarized in *Table 4-7.*

Table 4-7. **Comparison of caesarean section delivery ratio to all births in 4 countries, 1999**

Nation	1999	2002
Japan	14.7	15.2
Korea	43	39.3
UK(England only)	20.4	22.
US	22	26.1

In Japan, health insurance programmes exclude normal births from their coverage plans. Vaginal deliveries are not classified as medical interventions, but caesarean section deliveries are covered. As a consequence, fees for normal deliveries are much higher than caesarean deliveries. That obstetricians do not prefer caesarean deliveries is confirmed by

the variations in caesarean delivery ratios, which are higher in public hospitals than in private practice. The unit cost for normal deliveries (£1,500~£2,500) is three times higher than costs for caesarean deliveries (£470~£820). Natural births are however preferred by obstetricians, as they are not monitored by the insurers. Accordingly, the much lower levels of caesarean section deliveries in Japan is largely a result of market forces, which pursue the private benefits of providers. In recent years, however, the caesarean section delivery ratio has rapidly increased due to the shortage of obstetrician and fears of malpractice litigation as weall changes in the attitudes of women giving birth to pain

In Korea, three major reasons led to it having the world's highest caesarean ratio. First, financial incentives provided higher compensation to obstetricians to encourage the use of caesarean deliveries. Second, the courts, which ruled against obstetricians for not performing caesarean section, have motivated obstetricians to perform caesarean section. Third, as caesarean section makes it possible to induce labour, many women prefer to have a caesarean section delivery in the hope of ensuring good fortune for their new born baby. Cultural beliefs stemmed from 'the Book of Changes' that is one of three major bibles of Confucianism guiding the way to avoid bad luck and encourage good luck require babies to be born at astrologically propitious dates and times. According the 'Book of Changes,' the fate of an individual is primarily determined by the time, date, month, and year of his/her birth.

Obstetricians also recommend caesarean deliveries to avoid malpractice litigations. According to an opinion poll by Consumer's Right, 59.9 % of obstetricians recommend caesarean delivery to avoid malpractice litigation (Women Newspaper, 24 Dec. 2004). To encourage normal births, social insurance programmes began to fully cover costs of normal births without any co-payments by the mother since 1 Jan. 2005. Kim and Ko (2002) found that the level of caesarean section delivery ratio is consistent by obstetricians and times. They assumed that the choice is not much related with clinical condition but about the habit of obstetricians.

In the UK, the caesarean section delivery ratio has continued to increase. As a result, public concern has prompted policy makers and healthcare professionals to address this increasing trend. The most dramatic changes in caesarean section ratios have been attributed to the increase in the proportion of elective caesarean section deliveries

performed during labour at the woman's request (MacKenzie, 1999)[108]. A survey (Paterson-Brown et al, 1998), identified that 31% of 85 London based female obstetricians with an uncomplicated singleton pregnancy at term would choose an elective caesarean section for themselves. This represents a changing view of women on choosing delivery methods[109]. It also means that the concept of a prophylactic caesarean section is becoming accepted since almost a third of female obstetricians would choose it for themselves. Another survey (Van Roosmalen, 1999) in the Netherlands found that only 8 out of 567 obstetricians (1.4%) would opt for caesarean section in an uncomplicated singleton pregnancy, indicated a big difference[110].

In the US, the caesarean birth ratio was among the highest in the world by the mid 1990s. The ratio varied according to the source of payers. Efforts to reduce the caesarean section ratio were instigated by the US government and the professional bodies. The NIH Consensus Development Programme formally commenced an initiative to reduce caesarean ratio in 1980. In tandem with the NIH programme, ACOG issued guidelines that recommend reducing primary caesarean and prompts vaginal births after caesarean. Especially, the ACOG guideline proclaimed in 1988 contributed to increasing VBAC ratios and thereby reduced caesarean section ratios until the VBAC ratio relapsed its control in 1996. Consequent ACOG guidelines issued 1998 and 1999 hastened the decrease of VBAC because it was difficult to meet the guidelines, leading to increased CS ratios.

[108] According to the MacKenzie, of 911 caesarean births performed during labour in 1976 and 1986 none were carried out at the woman's request while 6 % were done in 1996.

[109] 80 % of these doctors indicated fear of perineal damage as their main reason. Though a relatively lower proportion of Irish obstetricians compared to London based study, a consistent trend towards preferring caesarean birth if the obstetrician was female or younger (Gurgan et al., 2001).

[110] Mascarenhas and colleagues (1994) argued that the difference between caesarean section rates in Britain and the Netherlands is due that women's choice is denied in the Netherlands because the midwife decides when and to whom to refer the woman when problems arise, whereas in Britain women can opt for an elective caesarean section after discussion with their obstetrician.

Chapter 5: Haematopoietic-Stem-Cell Transplantation

5.1 Introduction

Haematopoietic-stem-cell transplantations refer to all types of high-dose myeloablatice therapy and progenitor-cell transplants (HDT/PCT), including and umbilical-stem-cell transplants (or cord blood transplants). Being applied in place of conventional chemotherapy (CC), HSCTs are rapidly developing as treatment options for patients who have soft-tissue cancer as well as haematopoietic and immunological disorders. During the past three decades, HSCT has evolved from an experimental treatment for a small group of diseases to a standard procedure for a wide range of blood and haematopoietic disorders and solid tumours. With an increasing understanding of the immune system, supportive care, and new pharmacologic agents, bone marrow transplants have now become a first-line treatment option for some haematopoietic disorders, and are currently being accepted as an established treatment option.

HSCTs are costly procedures, and most of the patients who are undergoing these procedures remain pancytopenic for three to four weeks, which may result in serious morbidity or even mortality (Hillner et al. 1992, Gulati and Bennett 1992, Dufoir et al. 1992, Welch and Larson 1989, Nemunaitis et al. 1991).

There are two different types of BMTs: autologous and allogeneic transplant (Lennard and Jackson 2000). Allogeneic transplants are for the following:

- severe aplastic anaemia;
- chronic myeloid leukaemia;
- acute myeloid leukaemia in first complete remission (patient < 50 years old);
- myelodysplasia (patient < 50 years old);
- acute lymphoblastic leukaemia in first complete remission (certain subtypes);
- severe congenital immunodeficiency;
- acute myeloid leukaemia and acute lymphoblastic leukaemia in second complete remission; and
- thalassaemia.

Autologous transplants, on the other hand, are for the following:

- acute lymphoblastic leukaemia (certain subtypes);
- Hodgkin's disease in second complete remission;
- non-Hodgkin's lymphoma in second complete remission;
- multiple myeloma; and
- solid tumours such as ovarian cancer.

In autologous transplants, the recipient becomes his or her own donor. The bone marrow is extracted from the patient prior to the transplant, and may be "purged" to remove lingering malignant materials. In allogeneic transplants[111], a donor provides the stem cells for transplantation to a recipient. The new bone marrow infused into the patient must match the HLA of the patient's own marrow as closely as possible. Allogeneic transplants are much more complex than autologous transplants, with more potential risk. For allogeneic BMTs, the patients must wait until a suitable donor is found; this is very time-consuming and often frustrating.[112] Recently, cord blood transplants have also become available. A cord blood transplant is performed when it is not suitable for the patient to undertake an autologous or allogeneic BMT. As cord blood can be extracted through a relatively simple and quick procedure after birth, it involves a much lower risk of the baby's acquiring the graft-versus-host disease (GVHD).

In terms of both the length of hospital stay and the average hospital charges, stem cell transplants are more advantageous than conventional BMTs.[113] Proponents of autologous peripheral-stem-cell transplants provide a more rapid haematopoietic reconstitution of the bone marrow after high-dose chemotherapy and/or radiotherapy regimens are conducted to treat various malignancies (OTA 1995).

---

[111] A case in which the donor is the identical twin of the patient is called *syngeneic BMT*.

[112] A major limitation to the use of hematopoietic-stem-cell-transplant therapy, however, is the limited availability of suitable donors. About 30% of patients who may benefit from transplantation therapy are still unable to find a 0-1 HLA antigen disparate donor, with a disproportionately larger number of unsuccessful searches in patients who are racial and ethnic minorities (Wagner 2002).

[113] According to the Ohio Bone Marrow Transplantation Consortium, the average length of hospital stay is 29 days, and the average hospital charges are US$94,220, in autologous peripheral-stem-cell transplantation, while the average length of hospital stay is 38 days, and the average hospital charges are US$127,692, in autologous bone marrow transplantation (OTA 1995).

The incidence of diseases that can be indications for HSCT varies according to age, sex, and region. As such, it may be difficult to compare whether a country has a higher HSCT rate than others. The incidence rates of most diseases are slightly higher in males than in females. The incidence rates of non-Hodgkin's lymphoma (NHL) widely vary across the globe and also between males and females.

Overall, the incidence rate of the disease is highest in the white group in the US, while the rate in Hiroshima, Japan, which was presumed to be high due to its atomic-bomb exposure during the Second World War, is much lower. Between the two BMT procedures, autologous BMT is more common. Some 5,000 autologous BMTs are performed each year in the US, outpacing allogeneic BMTs. In the UK, 61% of the total 2,738 cases in 2005 were autografts, and 39% were allografts (British Society of Dlood and Bone Marrow Transplantation, 2008). *Table 5-1* shows the rate of adoption of allogeneic BMT in some countries (Silberman et al. 1994). The circumstances of the adoption of allogeneic BMTs in the UK and in the US are quite similar. Access to allogeneic HSCTs varies from nation to nation; there was a twofold difference in rates between the country with the highest rate (France, 13.4 pmp) and that with the lowest rate (Germany, 5.6 pmp) among the 10 countries selected.

Table 5-1. **Annual rates of allogeneic BMT (in pmp, 1989-1991)**

Country	Transplants	Transplants per Year (pmp)
France	1,708	13.4
Sweden	168	9.0
Canada	576	8.9
Australia	369	8.8
UK	1,000	8.2
US	4,873	8.1
New Zealand	59	7.4
Netherlands	232	6.6
Germany	757	5.6

Data Sources: Silberman et al. (1994)

As shown in *Table 5-2*, HSCTs are being applied to a wide range of diseases to which these have not been indications in the past. The number of allogeneic transplants conducted

around the world is slightly higher than that of autologous transplants.[114] Allogeneic transplants prevail over autologous transplants for leukaemia patients, while the reverse is true in the case of Hodgkin's disease, non-Hodgkin's lymphoma, plasma cell disorder, and breast cancer patients.

Table 5-2. **Distribution of diseases and HSCTs in the CIBMTR database (2006)**

Disease	Allogeneic Transplants	Autologous Transplants
Acute lymphoblastic leukaemia	21,115	1,419
Acute myelogenous leukaemia	31,736	6,507
Chronic myelogenous leukaemia	23,915	694
Chronic lymphoblastic leukaemia	1,949	561
Hodgkin's disease	957	12,247
Non-Hodgkin's lymphoma	8,063	29,752
Plasma cell disorders	2,765	23,791
Breast cancer	162	23,045
Neuroblastoma	169	2,669
Ovarian cancer	21	1,666
Lung cancer	9	58
Sarcoma (soft-tissue, bone, and others)	54	221
Ewing sarcoma	59	798
Wilm tumour	6	716
Myelodysplastic syndromes	9,002	247
Other types of leukaemia	1,414	266
Modulloblastoma	4	138
Germ cell tumour	7	535
Brain tumours	5	517
Testicular cancer	9	1,026
Other malignancies	493	789
Autoimmune diseases	48	307
Severe aplitic anaemia	8,226	-
Inherited erythrocyte abnormalities	4,361	-
SCID and other immunodeficiencies	3,034	-
Inherited metabolism disorders	1,516	-
Histiocytic disorders	522	-
Other non-malignancies	327	-
Total	119,993	109,140

Data sources: CIBMTR Progress Report, January-December 2006
Note: The data are aggregated, as submitted by IBMTR centres worldwide.

[114] IBMTR (Centre for International Blood and Marrow Transplant Research) is composed of a network of more than 400 transplant centres in 47 countries worldwide. CIBMTR estimates that its database includes about 65% of all the allogeneic HSCTs done in North and South America, about 30% of all the allogeneic transplants done elsewhere, and about 60% of all the autologous HSCTs done in North and South America.

To facilitate BMTs, bone marrow donor registries have been established in most countries, and they cooperate to match patients with donors on an international level. Bone Marrow Donors Worldwide (BMDW) started in 1988 as an initiative of the Immunobiology Working Party of the European Group for Blood and Bone Marrow Transplantation (EBMT). Among the 3,858 allogeneic BMTs carried out in the EBMT member-countries in 1995, 20% (764 cases) were performed with volunteer bone marrow donors (Gratwohl et al. 1996).[115] In February 1989, the first edition was distributed, which contained the donor files of eight registries, totalling 155,000 volunteer bone marrow donors.[116] In December 1999, 54 registries from 35 countries participated in BMDW. The donors registered in BMDW numbered over six million. With nearly three million registered donors, the National Marrow Donor Program (NMDP) of the US presently has the largest bone marrow donor pool among the registries in BMDW.

5.2. Micro Factor Evaluation

5.2.1. Economic Factors

HSCT is selected when there is no other suitable alternative, and is therefore regarded as a last resort for the patients. It often leads to serious complications, however, and sometimes even death, and entails a high financial burden. Accordingly, HSCT has been performed sparingly or has been subjected to other cost containment measures. Therefore, its use requires a careful consideration of its potential benefits and harm to the patient and to the society as well.

BMT is one of the most expensive cancer treatments available at present. Johnson et al. (1998) found that high-dose chemotherapy combined with peripheral-blood-stem-cell transplantation (PBSCT) was one to two times more costly than conventional

[115] To make transplants available to a greater number of eligible patients, registries of volunteer bone marrow donors have been developed, which allows stem cell harvest from unrelated but matched donors. There are now over six million donors registered on national donor panels worldwide (Lennard and Jackson 2000).

[116] The pioneer registries were:
- Anthony Nolan Research Centre (United Kingdom);
- *France Greffe de Moelle* (France);
- National Marrow Donor Program (USA);
- Europdonor Foundation (Netherlands);
- German Registry of Bone Marrow Donors, Ulm (Germany);
- Italian Bone Marrow Donors (Austria); and
- Marrow Donor Program Belgium (Belgium).

chemotherapy in the treatment of acute leukaemia. According to their research, the use of BMT was found to cost approximately 1~1.7 times more than PBSCT.

Increasingly, autologous PBSCTs are preferred. Expecting advantages over BMT[117], physicians perform PBSCT for their patients under certain conditions.[118] The advent of the management of chemotherapy and transplants reduces the costs associated with autologous stem cell transplantation. Intensive high-dose chemotherapy supported by autologous stem cell treatment has become a common approach for NHL (Woronoff-Lemsi et al. 1997). According to a study conducted by Meisenberg et al. (1998)[119], high-dose chemotherapy combined with autologous stem cell rescue reduces the costs significantly, as the technique is increasingly being delivered in outpatient settings.

Compared with BMT, the length of stay post-reinfusion was significantly shorter in patients receiving PBSCT (Redaelli et al. 2004). As a result, the transplant admission costs were also lower in the PBPCT groups than in the BMT-alone group.[120] Through comprehensive meta-analysis, Johnson et al. (1998) also confirmed that the introduction of PBSCT in place of BMT would reduce HDT/PCT. Messori et al. (1999)[121] have found that BMT (even the second BMT) significantly prolongs survival, and thus has an acceptable cost effectiveness profile in comparison with conventional chemotherapy. As Johnson et al. (1998) argue, however, it is widely regarded that the cost effectiveness of HDT/PCT has yet to be conclusively determined.

In summary, the cost of PBSCT is lower than that of BMT, but the cost of BMT is higher than that of CC. Accordingly, PBSCT is regarded as better than BMT and CC, if

---

[117] Woronoff-Lemsi et al. (1997) found that the PBPCT group had relatively better clinical outcomes compared with the ABMT group. The average cost of the patients in the ABMT group was also higher than that in the PBPCT group.

[118] Primary among these advantages is that PBPCT typically engrafts faster than stem cells from the marrow do (Schmitz et al. 1996, Schultze 1997, Gradishar 1999).

[119] The average length of stay was reduced from 17.3 days to 8.2-2.7 days in the three different treatment settings. The mean costs were also reduced from US$39.7k to US$36.2-29.4k in the three treatment settings.

[120] The transplant admission cost of PBPC was 22,089 Canadian dollars, and 32,289 Canadian dollars in the bone marrow group.

[121] The study analysed 167 patients treated with a second BMT, who relapsed after their first allogeneic transplant for leukaemia, and 299 patients treated with conventional chemotherapy. Using an incremental cost of US$90,000 per patient, the cost effectiveness ratio of the second BMT in comparison with the CC was calculated to be US$52,215 discounted per discounted life-year gained.

only in terms of cost. The overall cost effectiveness of HDT/PCT, however, has yet to be proven.

Although it is unclear what the best option for patients is, better survival profiles are found among those who are undergoing both BMT and PBPCT treatments than among those undergoing only chemotherapy. Borgmann and colleagues (1995)[122] acknowledged that HLA-identical siblings resulted in a statistically greater likelihood of leukaemia-free survival than did chemotherapy in children with ALL. Burnett et al. (1998) found that the addition of autologous BMT to intensive chemotherapy substantially reduced the risk of relapse in all the risk groups, leading to an improvement in their long-term survival. On the contrary, in a study conducted by Varterasian et al. (1997), allogeneic BMT registered a slightly better survival rate for multiple myeloma than PBSCT did.[123]

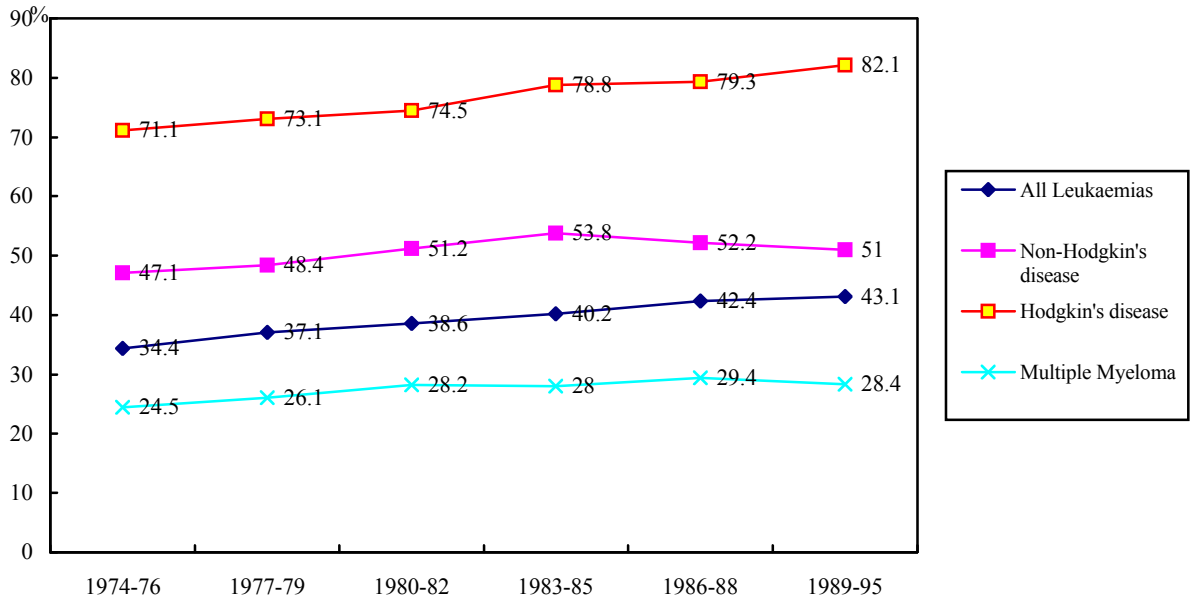


Figure 5-1. **All ages' survival rates (five-year)**

Data sources: National Cancer Institute (2000). SEER Cancer Statistics Review 1973-1996.

Some studies suggest conclusive results in terms of the cost effectiveness of BMT or PBSCT. Their true efficacy however in terms of prolonging the life of persons afflicted

[122] The study, which was carried out in Germany, compared the treatment results for children who underwent ABMT with those for children who underwent chemotherapy.

[123] The survival period of the BMT patients was 15 months, ranging from two to 84 months, and 11 months for the PBSCT patients, ranging from two to 84 months.

with the aforementioned diseases remains unproven. What is explicit is only that the PBSCT group also has a significantly faster haematopoietic reconstitution.[124]

Although no definitive evidence of it has been provided so far, the survival rates of patients with haematopoietic disorders have steadily improved, as shown in *Figure 5-1*.

5.2.2. Clinical Factors

The improved survival of patients has been bought about by logical and incremental drug randomization, better supportive care and the early incorporation of scientific advances into national trial (Will 2003)

The clinical advantages of HSCT are generally assessed in terms of the length of survival after the transplant and health-related QoL. Health-related QoL is commonly measured by comparing the ante- and post-transplant states. The complications of HSCT, such as the graft-versus-host disease (GVHD) and relapse, are also significantly considered in evaluating its clinical advantages.

Most studies that provide evidence of allogeneic or autologous BMT long-term survivors show an acceptable quality of life (QoL). Belec (1992) demonstrated that 92% of their autologous BMT patients perceived their QoL as acceptable. Molassiotis et al. (1995) identified the differences between patients with autologous BMT and those with allogeneic BMT. According to them, those patients who underwent an autologous transplant had

[124] According to Powles et al. (2000), the PBSCT group showed a median of 17.5 days for neutrophil recovery, and 20.5 days for platelet recovery, which were 23 days and 27 days, respectively, in the BMT group. According to Mary Horowitz, the head of the International Bone Marrow Transplant Registry Statistical Center in Milwaukee, more than 5,000 patients in the US so far have undergone transplants of donor peripheral blood stem cells. Based on the results of studies that investigated the results of stem cell transplants, it was found that patients who have undergone blood stem cell transplant begin producing white blood cells and platelets (white blood cells help blood clot) more quickly than did those who have undergone bone marrow transplant. As a result, the number of days in which patients are at risk of developing a life-threatening infection or uncontrolled bleeding is reduced. Blood-stem-cell-transplant patients also require fewer red-blood-cell and platelet transfusions [*Blood & Bone Marrow Transplant Newsletter* (1999), Issue 46, Vol. 10(2)].
A case-controlled analysis performed by Liberti et al. (1994) assessed the effect of the stem cell source on the autograft in a group of patients with malignant lymphoma that had been reported to the European Bone Marrow Transplant Group (EBMT). According to the results of the study, the progression-free survival was similar in the two types of transplants (38.5% PBSCT vs. 36.4% ABMT). The overall relapse and progression rate of the PBSCT patients was 51.2%, compared with 50.1% for the ABMT patients. The differences were not statistically significant. For both groups, the transplant-related mortality was 6%. It was concluded that in these closely matched groups, there is no difference in PFS between patients undergoing PBSCT and those undergoing ABMT. However, the patients who had been autografted with PBSC had a more rapid engraftment and a lower toxicity.

mainly psychological difficulties in their post-transplant life, whereas those patients who underwent an allogeneic transplant developed more physical problems.

There are also controversial results that show the improvement of QoL in autologous BMTs as being marginal.[125] Moreover, many question whether autologous BMT can lead to a superior QoL more than the incumbent chemotherapies can.[126]

Although most autologous BMT recipients show improved physical and psychosocial functions, research evidence indicates that about a quarter of such patients develop some degree of psychosocial morbidity.[127] Poorer sexual functioning, correlated with increased fatigue and decreased emotional functioning, was also identified (Wingard et al. 1992, Baker et al. 1994, Andrykowski et al. 1995, Molassiotis et al. 1995, Watson et al. 1999, Winer et al. 1999). The patients in the BMT group were also more prone to infertility than those in the CC group (Watson et al. 1999).[128]

Based on the meta-analysis of HDT/PCT, the micro-impetus on the dissemination of HSCT is summarised as follows:

- PBSCT has a relative advantage compared to BMT and CC in terms of cost;
- BMT is better than CC in terms of cost;
- HSCT's and CC's cost effectiveness in terms of prolongation of life has yet to be proven; and
- the relative advantage of HSCTs against CC in terms of QoL also has yet to be conclusively proven.

[125] Fannie and Martha (1996) found that there were only slight improvements in the patients' QoL after ABMT.

[126] No significant differences in QoL were found in the improvement between the ABMT and CHOP groups. The allogeneic BMT patients reported significantly poorer global QoL compared with that obtained after both ABMT and intensive-consolidation chemotherapy (Watson et al. 1999).

[127] Wolcott et al. (1986) found that 25% of the BMT patients in their study had significant emotional distress, physical dysfunction, low self-esteem, and less than optimal life satisfaction. However, the passage of time since the patients underwent BMT had no correlation to their psychosocial improvement (Molassiotis and Morris 1999).

[128] Twenty-seven % of the patients included in their study believed that they became infertile due to the treatment. The infertility rates by treatment type were 64% in the allogeneic BMT patients, 51% in the ABMT patients, and 10% in the CCT patients.

5.2.3. Technical Factors

A bone marrow transplant is a physically, emotionally, and psychologically taxing procedure for both the patient and his or her family. The patient should tolerate debilitating pain for several weeks. Some patients find the accompanying emotional and psychological stress more problematic than the physical discomfort. The psychological and emotional stress stems from several factors. Patients undergoing a transplant can feel isolated. The special precautions taken to guard against infection while the immune system is impaired can leave a patient feeling detached from the rest of the world, and cut off from normal human contact.

During the recuperation period, the patient feels very sick and weak. Complications like infection, bleeding, graft-versus-host disease, or liver disease can develop after a bone marrow transplant, which can cause the patient additional discomfort. A patient also feels pain, however, that is usually controllable by medication. In addition, mouth sores can develop, which can make eating and swallowing uncomfortable. Temporary mental confusion sometimes occurs, which can be quite frightening for the patient.

After being discharged from the hospital, a patient continues his or her recovery for two to four months. Patients usually cannot return to full-time work for up to six months after the transplant.

5.3. Macro Factor Evaluation

5.3.1. Japan

Major events in Japan related to HSCTs are as follows (Kono, 2004):

- 1981: insurance coverage for allogenic BMT
- 1991: JMDP (Japan Marrow Donor Programme) established
- 1994: insurance coverage for PBSCT
- 1998: insurance coverage for CBCT
- 2000: insurance coverage for allogenic PBSCT

As summarised above, insurance coverage has been also provided from the early stage of HSCT adoption and expanded in accordance with the advent of HSCTs.

Since the Japanese people regard the atomic bombings during the Second World War as a national disaster, the Japanese government shouldered all the medical costs of the treatment of physical problems associated with radiation exposure (Section 3, The Special Treaty Act for the Victims of the Atomic Bomb of 1994). The Radiation Effects Research Foundation (RERF) estimated that 87 of 176 leukaemia deaths among the 50,113 RERF Life-Span Study survivors were associated with significant exposure to radiation (Radiation Effects Research Foundation , 2007).

Activities for establishing assistance through legislation for the victims of the atomic bomb were begun in 1953 by the city councils of both Hiroshima and Nagasaki. They requested support for the disabilities caused by exposure to the bombs. The relief movements for the bombing victims began with the Assistance Act for the Bereaved Families of Those Who Died in the War of 1952 (.The Research Institute for Radiation Biology and Medicine, Hiroshima University, 2001) The Special Treaty Act for the Victims of the Atomic Bomb of 1968 provided comprehensive support for the victims, including medical care and financial support for livelihood. As the 50th anniversary of the bombing nears, the Act was revised in 1994 to increase the funding for the treatment of the victims. The Act of 1968 provided comprehensive medical care for patients with leukaemia, leukopenia, aplastic anaemia, liver diseases, dermatopathy, dysthyroid lung cancer, and cataracts. The Act of 1994 increased funding for medical services, health care, and livelihood for the victims.

The Ministry of Health and Welfare organised three research groups to promote BMT in 1990. Based on the recommendation of the research group, the Japanese government established the Japanese Marrow Donor Programme (JMDP)[129] in 1991.

The main role of JMDP is that of a bone marrow donor bank. It had 306,897 registered volunteer bone marrow donors at the end of March 2008 (JMDP, 2008). By that time, 24,690 patients were registered with JMDP as cumulative total and 2,412 patients were on the waiting list. Most patients registered with JMDP, however, have been matched with

[129] JMDP has a regional office in each municipality, and carries on an active campaign to recruit volunteer bone marrow donors throughout the country. Before JMDP emerged, the Japan Marrow Donor Registry Promotion Conference (JMDRPC) was launched in April with 13 registries. It is now composed of 48 registries across Japan. JMDRPC is mainly involved in recruiting volunteer bone marrow donor and advocating patients' benefits (Japan Marrow Donor Registry Promotion Conference 2001).

donors. In 1994, JMDP began to recruit bone marrow donors in collaboration with 100 public healthcare centres run by the government to provide primary healthcare services to the people. The number of volunteer bone marrow donors registered with JMDP has rapidly increased since the early 1990s. JMDP has also been actively involved in matching the bone marrow donors with the patients at the international level. JMDP keeps cooperative relationships with Korea, Taiwan, and the US by supplying these countries with bone marrow donors.

In Japan, health insurance programmes cover BMT, just like other ordinary medical treatments. All actual costs incurred for the donor-matching services are compensated from the health insurance plan where the patient is enrolled. The insurance also shoulders the transportation fees for one visitor during the time the patient is admitted in the hospital for a bone marrow donation. The costs reimbursed by the health insurance in 1999 for about one month of BMT treatment ranged from £24,000 to £30,000 (National Cancer Centre, Japanese government, Cancer Statistics in Japan -1999). The patient's share in the payment of the BMT cost during the first month following transplantation is about £1,530 when the patient stays in an ordinary bed.

Two other policies also support the BMT activities in Japan. First, any donor who suffers an accidental injury in the course of a bone marrow donation is to be compensated under JMDP's accidental-insurance policy.[130] Second, Japan's public sector provides an official furlough for its employees when taking a leave of absence for bone marrow donation.

In summary, the public authorities in Japan have been very supportive of HSCTs due to the public consensus that most of the diseases afflicting its people were largely caused by the atomic bombings in the cities of Hiroshima and Nagasaki during the Second World War. To promote the welfare of the victims and their families, the government introduced welfare programmes to provide them with support. Moreover, the country's health plans

[130] The accident insurance policy covers the cost from the time the donor leaves his/her home to the time that the donor returns to his/her home. If the donor dies, the insurance company pays ¥100 million. If an incident happens to the donor that will require medical treatment, the insurance pays a ¥5,000 compensation per day for hospital admission for a maximum of 180 days, and also pays ¥3,000 per day for the medicines taken from the visiting outpatient dispensary.

have covered the cost of BMT at the early stage of its adoption, and JMDP has played an active role in promoting bone marrow donation among the people.

5.3.2. Korea

In Korea, the first successful allogenic BMT was performed in 1981. The first attempt to apply BMT for solid tumour was on 1990 that applied for breast cancer patient. Insurance coverage commenced in January 1992 for allogenic BMT and extended to autologous PBSCT in December 1997

In Korea, there are no specific regulations for BMT. The country's health insurance programmes limit their BMT coverage to the candidates approved by the Assessment Committee for HSCT. The guidelines for the assessment of the BMT candidates exclude patients who are over 40 years. To be approved, patients aged above 40 must meet the conditions below in each group of diseases:

- AML: in first remission;
- CML: in the chronic phase;
- ALL: in first remission (patients below 15 years old can be covered when in second complete remission); and
- aplastic anaemia: patients who have had transfusions less frequently and not beyond a year from the time of the diagnosis.

Health insurance in Korea started to cover autologous BMTs and PBPCTs beginning December 1, 1997.[131] Those patients who meet the following conditions are covered by the insurance for BMTs or PBPCTs:

- malignant lymphoma;
- ALL (acute lymphoblastic leukaemia): in first remission (in second remission for patients below 15 years old);
- AML (acute myelogenous leukemia);
- multiple myeloma;

[131] NFMI has so far not covered autologous BMT and PBPCT because these technologies are generally regarded as experimental.

- breast cancer; and
- others (cancer patients who can avail of chemotherapy can be candidates if the Assessment Committee for BMT approves of them).

The Assessment Committee for BMT approves more than 80% of all the applicants for insurance coverage.[132] As most physicians selectively apply their patients for insurance coverage for HSCT based on the guidelines[133], the acceptance rates by the Assessment Committee are high.

Charities have been active in supporting the amounts of the treatment interventions that patients must pay for themselves. The Korean Heart Foundation[134] and the Korea Welfare Foundation have been major charitable resources. Community Chest of Korea, a centralised charity fund established in 1999, raises about £268 million a year and allocates this amount for social-welfare programmes across the country. Since its establishment, the organisation has provided financial support amounting to approximately £1.07 million each year for children with cancer and haematopoietic diseases. While the Korean Heart Foundation and the Korea Welfare Foundation support HSCT costs for patients who have been approved for insurance coverage, the Korea Union Fund supports such costs regardless of the absence of approval by the insurer. In 1999, about 20% of all the patients who underwent HSCTs received financial support from charities.

To help patients find volunteer bone marrow donors, the Ministry of Health and Welfare established the Korean Marrow Donor Programme (KMDP) within the Korea Red Cross in 1994.

---

[132] Personal communication with the person in charge of HSCT in the National Health Insurance Cooperation.

[133] For those patients whose physicians recommend applying for health insurance to be able to avail of BMT, the hospitals claim to provide insurance benefits for BMT. In some cases, though, the claims are preceded by the requirement of the patients, although the physicians in charge believe that the committee will not accept the claim. As the hospitals in Korea compete against one another, the physicians generally cooperate with the patients and advocate the latter's requirements.

[134] The Korean Heart Foundation supports patients who are regarded as financially incapable of paying for BMT or PBSCT. The foundation supports up to ₩15 million (equivalent to £8,250 as of February 3, 2000) of the cost that is not covered by health insurance; the patients should pay for the remaining amount themselves. The Foundation also supports the costs of pre-BMT work-up and follow-up after transplantation. Since the patient's share of the cost of BMT or PBSCT ranges from ₩10 million to ₩20 million, the support given by the Korean Heart Foundation covers a large part of the total cost of the procedure for each patient.

In summary, no legal regulation regarding HSCT exists in Korea. As listed in the chronicles, health insurance programme began to cover allogeneic BMTs beginning in 1992, nine years after the first allogeneic BMT was performed in a human in Korea. The insurance plan extended the criteria for allogeneic BMTs to candidates with various diseases, as connoted in the chronicles. Beginning in December 1997, insurance coverage was given to autologous BMTs. From the beginning to the present, the public health insurance programme has had a limit on the coverage based on its own guidelines. Several charity programmes provide financial support for the patient's share, which is largely focused on children. KMDP plays key roles in expanding the country's marrow donor pool.

5.3.3. UK

In the UK, the first BMT was performed in 1973. A small number of BMTs had been carried out in other centres within and around London, but the major BMT activity was concentrated in four units in London: Royal Marsden Hospital, Hammersmith Hospital, Westminster Hospital and Westminster Children's Hospital, and Royal Free Hospital.

Under the NHS market reforms, commissioned bone marrow transplants were performed by individual health authorities in a fragmented manner. In pursuit of a more equitable use of resources, health authorities were required to use such resources for the benefit of the whole population; thus, priorities had to be set. The much-publicised case of Jaymee Bowen[135], popularised as "Child B," illustrates the dilemma regarding the allocation of limited resources (Ham and Pickard 1998). It has been widely reported as an example of explicit rationing in the market-reformed NHS.

In the flux of subsequent NHS reforms, the Regional Specialised Commissioning Group (RSCG) was established on April 1, 1999, and was given the responsibility of ensuring the effective working out of arrangements for specialised commissioning, including HSCTs. Planning is conducted on a subregional/network basis, and individual health authorities produce the services within the agreed plan. Bone marrow transplants are commissioned through a consortium. The current arrangements for specialised-services

[135] It concerned a young leukaemia sufferer who had been refused a second transplant by Cambridge Heath Authority in 1995. The child's father challenged this decision in the High Court, which ordered the Authority to reconsider its refusal. The decision was upheld by the Appeals Court.

commissioning are based on the national guidelines *(Guidelines on Commissioning Arrangements for Specialised Services)* published in April 2003. These guidelines amplified the advice given in *Shifting the Balance of Power: The Next Steps* issued in January 2002, which emphasised that Primary-Care Trusts (PCTs) are the primary commissioners of healthcare services for their local populations, and that they are expected to act collaboratively when commissioning specialised services.

Specialist hospitals carrying out blood and marrow transplantations are represented in the adult and/or paediatric BMT consortium. The centres providing paediatric BMTs that are members of the Paediatric BMT Consortium are:

- Great Ormond Street;
- St Mary's;
- United Bristol Healthcare Trust;
- The Royal Marsden;
- Barts and The London; and
- University College London Hospitals.

The Anthony Nolan Bone Marrow Trust, which plays a significant role in the promotion of BMT, was founded in 1974 as the first volunteer marrow donor registry. The Anthony Nolan Bone Marrow Register had a pool of 43,000 potential donors in 1982, and the number of its volunteers had increased to 345,000 as of the end of October 2001 (Anthony Nolan Trust, 2005 Staticslcal Data).

The National Blood Service established the British Bone Marrow Donor Registry (BBMR) in 2002. In 2002-2003, BBMR enrolled 42,634 new potential donors on its register. The BBMR has become the fastest-growing bone marrow register in the country, and is now the eighth largest of its kind in the world. BBMR's growth in the past three years, acquiring nearly 90,000 enrolments, enables the support of more transplants (National Blood Service, 2008). The bone marrow donor registries of the UK are linked to an international register of bone marrow donors worldwide (BMDW). For those patients who are hoping to receive a bone marrow transplant from a BBMR donor, the average waiting time from the beginning of the search to the receipt of the bone marrow is 133 days (House of Commons, 2007).

In an effort to provide cord blood for transplant purposes, the NHS Cord Blood Bank was set up in 1996 as a part of NHS.

In summary, traditional budget allocation has been transformed to purchasing by Has, and then to specialised commissioning for HSCTs. In tandem with the establishment of RSCG, HSCTs are commissioned through a consortium among HAs. Afterwards, PCTs become the primary commissioners for HSCTs, which act collectively.

5.3.4. US

The first BMT was performed by Dr. E. Donnal Thomas in the US. Since then, major advents in HSCTs have been achieved in the US, except the development of umbilical cord blood transplantation that was carried out in France in 1988. In tandem with scientific advancements, national policies to support HSCTs also have been institutionalised. In 1984, the US Congress passed the National Organ Transplant Act (NOTA). The Act contained guidelines for the evaluation of unrelated bone marrow transplants and of the feasibility of establishing a national donor registry. Its operations began in 1986. The name of the NBMDR was changed to NMDP following the establishment of a national registry based on the Organ Transplants Amendments Act of 1988. In the 1990s, the activities of NMDP rapidly expanded. In 1991, NMDP established the Office of Patient Advocacy, which was intended to help patients overcome the financial barriers in obtaining a transplant. In 1992, NMDP developed the Search Tracking and Registry (STAR), a computerized system that automatically manages all the steps of an unrelated stem cell or bone marrow transplant, to improve the speed and efficiency of searches. Since it began its operations, NMDP has recruited over 7 million potential bone marrow and blood stem cell donors amd nealy 70,000 cord blood units on NMDP Registry (NMDP, 2008). Nearly 334,000 new volunteers join NMDP Registy with about 33,000 net vet voluteers each month.

In the US, most HSCTs have been carried out through private funds. Medicare covers immunosuppressive drugs for an approved bone marrow transplant based on the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1993. The coverage was applied for 12 months in 1996. Then, it was extended gradually, and it currently covers 36 months. Medicare extended its coverage for autologous stem cell transplants, beginning

October 1, 2000, to include persons aged above 65 who have multiple myeloma (*Blood & Marrow Transplant Newsletter, 2000)*.

In the private sector, many health plans provided coverage for BMTs in the past decade as BMTs have become a more routinely treatment modality for solid tumour cancer. Many health plans now cover HDT/PCT. According to the General Accounting Office (GAO), the insurance coverage for HDT/PCT is rapidly growing, and at least seven states, including Virginia, mandated health plans to provide insurance coverage for patients with certain conditions (Davis 1996).

To achieve broader coverage from payers for established indications for blood and bone marrow transplants, the American Society for Blood and Marrow Transplantation (ASBMT) organized the "Managed-Care Initiative."[136] Moreover, as a part of the initiative, the development of evidence-based reviews and position statements on the effectiveness of autologous and allogeneic haematopoietic-stem-cell transplants for specific diseases was initiated (ASBMT 2000).

In summary, the overall landscape of the US insurance coverage for HSCTs is difficult to describe. Various health plans have different policies on HSCT coverage. As some states mandate health plans to cover HSCTs, lawsuits are also increasing against the coverage limits of insurance plans. Except for umbilical-cord blood transplants, many health plans increasingly expand coverage policies for HSCTs. The volunteer donor recruitment activities by NMDP have significantly contributed to improving donor availability.

5.4. The Adoption of HSCTs

5.4.1. Japan

Over 2,000 HSCTs are carried out yearly in Japan, and about half of these (46.9% in 1991-2002) involve allogeneic BMTs. Every year, around 6,000 new patients who might benefit from an HSCT emerge. In 1995, the annual mortality rate from leukaemia was 4.9 per 100, 000 persons (Ohno 1998). Leukaemia (including chronic myeloid leukaemia, acute

[136] The strategy of the Managed-Care Initiative is threefold (ASBMT 2001): (1) to bring together a coalition of stakeholders to address the issues of third-party reimbursement for blood and marrow transplantation; (2) to document, for specific diseases, the efficacy of blood and bone marrow transplantation; (3) to advocate on behalf of the BMT patients among those who decide or influence treatment reimbursement decisions.

leukaemia, Hodgkin's disease, and non-Hodgkin's lymphona), multiple myeloma, and aplastic anaemia, were responsible for 5.93% (5.49% in males versus 6.61% in females) of the total deaths in 1999 (National Cancer Centre, Cancer Statistics in Japan - 1999),

The number of HSCTs has rapidly increased since 1990, as shown in *Figure 5-2*. According to the results of the nationwide survey carried out by the Japan Society for Haematopoietic-Cell Transplantation (JSHCT)[137], transplants from unrelated donors have significantly increased since 1994. Autologous PBSCT takes the largest proportion of the total HSCTs, followed by allograft BMTs with unrelated donors. The number of allograft BMTs with siblings is decreasing, while the number of cord blood transplantations has been rapidly increasing since 2000. Since 1990, when the Ministry of Health and Welfare (currently MHLW) of the Japanese government began to support HSCT, the number of HSCT cases has rapidly increased.

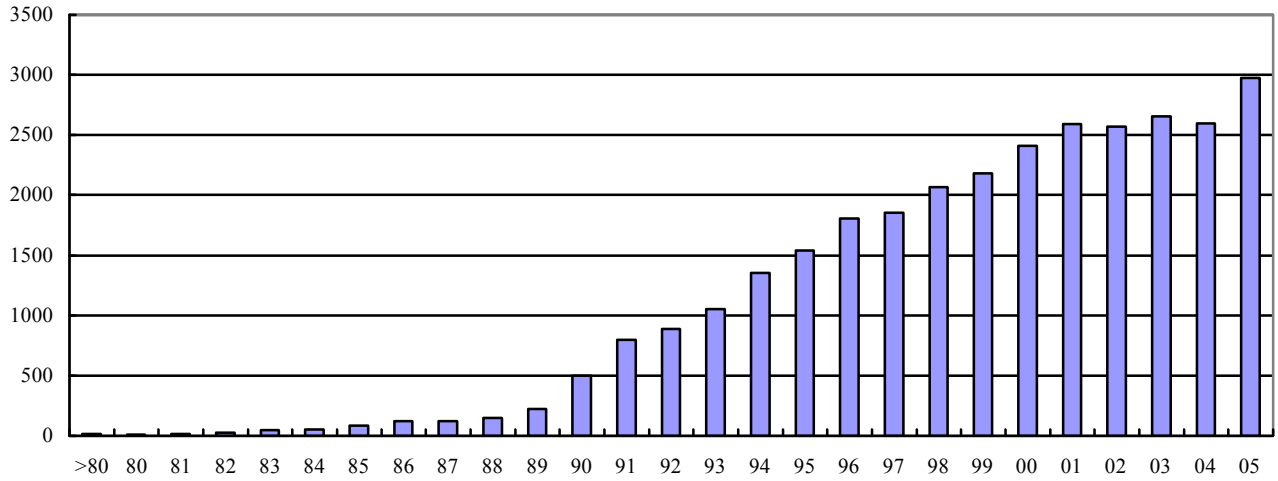


Figure 5-2. **Japan's transplant activity totals**

Data sources: 1) The Japan Society for Hematopoietic Cell Transplantation, Annual Report of Nationwide Survey 2003
2) The Japan Society for Hematopoietic Cell Transplantation, Annual Report of Nationwide

[137] The Bone Marrow Transplantation Committee of the Japan Society for Paediatric Haematology started nationwide surveys on stem cell transplants for child patients in 1983. The Japan Society for Hemaetopoietic-Cell Transplantation (formerly the Japan Society for Bone Marrow Transplantation) started the survey in 1993, separately from the survey for children. The first survey involved adult patients who underwent transplants between July 1990 and June 1993. From 1994 to 1997, the office of the society in Kanagawa Children's Medical Centre and the Aichi Cancer Centre Research Institute separately performed surveys for child patients and for adult patients, respectively. The medical centres that participated in the surveys were 112 paediatric departments, 124 internal-medicine departments, 1 surgery department, 6 gynaecology departments, 14 urology departments, and 14 other departments, or a total of 271 departments.

Survey 2006

JMDP has greatly contributed to the promotion of BMT in Japan. As listed in the chronicles, JMDP launched a donor-recruiting programme in January 1992, and the Japanese government introduced an official furlough for bone marrow donors in 1993. By virtue of public support for bone marrow donation, the number of BMTs from unrelated donors significantly increased. With the expansion of the marrow donor pool, the chances of matching patients with volunteer donors through JMDP increased. Of the total, the number of BMTs with unrelated donors increased from 2.1% in 1991 to 24.3% in 2002. By the end of 2002, 643 umbilical-cord blood transplants had been carried out in Japan. PBSCT has also been increasing since its inception in 1995.

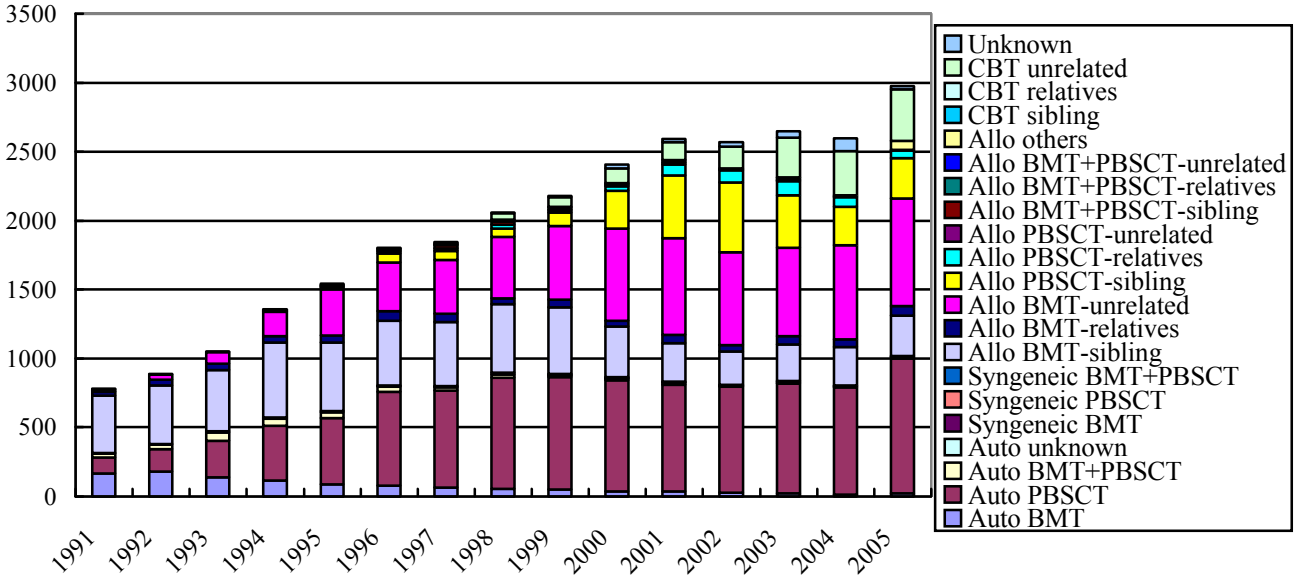


Figure 5-3. **HSCT activities in Japan (1991-2005)**

Data sources: Japan Society for Haematopoietic-Stem-Cell Transplantation, 2006 Annual Nationwide Survey Report.

In summary, HSCTs were carried out at 19.5 pmp in Japan in 2005. The public authorities have been very supportive, due to the consensus of that the incidence of leukaemia is closely related with the atomic bombings during the Second World War. With a strong national consensus that the bombings were a national disaster requiring public support for the victims, the Japanese people actively participated in marrow donations. The Japanese government has promoted the recruitment of marrow donors through JMDP, by

giving the latter financial support. Insurance programmes cover all sorts of HSCTs from the beginning of their adoption. As shown in *Figure 5-3*, the number of umbilical-cord blood transplants remarkably increased from 1998, when their insurance coverage was initiated.

5.4.2. Korea

Currently, about 700 BMTs are carried out each year in 28 BMT centres in Korea. Since 1981, when BMT was initially introduced, 3,820 cases have been performed by the end of August 2001 (Korean Haematopoietic-Stem-Cell Transplantation Nurse Association 2001). The incidence of leukaemia in Korea increased from 1,162 in 1987 to 1,696 in 1998, accounting for about 3.7% of the total cancer cases in 1987 and 2.6% in 1998 (Department of Disease Control 2000). While the incidence in terms of the total numbers increased, the proportion of total malignant cancers decreased. Haematopoietic diseases in children, including leukaemia and malignant lymphoma, accounted for 33.4% of the total cancer cases, making them the largest type of cancer among children.

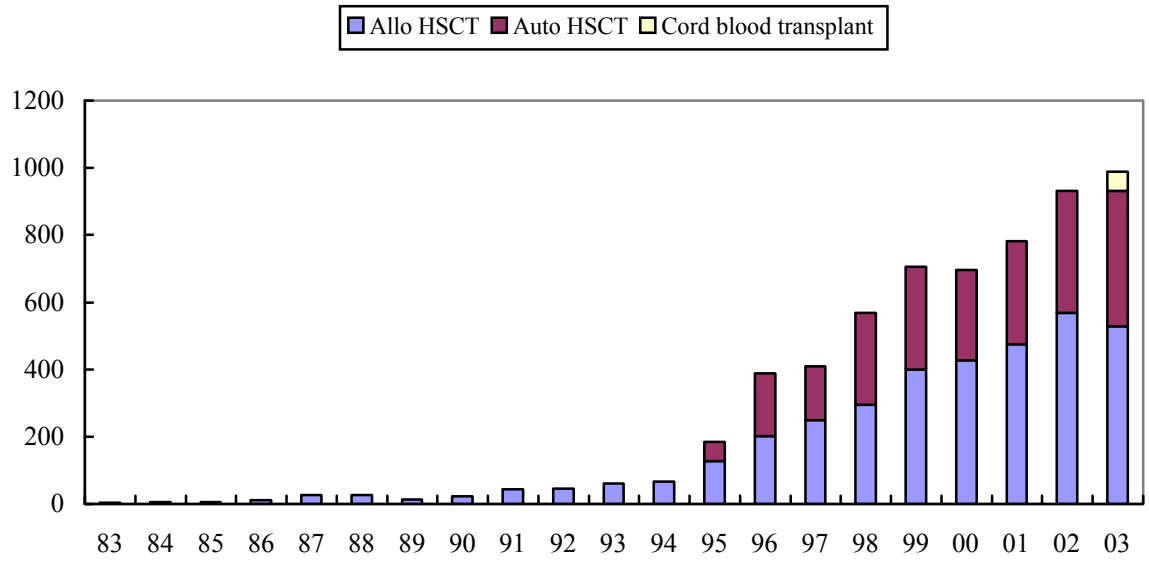


Figure 5-4. **BMTs in Korea (1983-2003)**

Data Sources: Korean HSCT Nurse Association (2003)

Note: 1) The data for allogeneic HSCT include autologous HSCT until 1994. The number of autologous HSCTs from 1990 to 1994 were 46, which was 19.1% of the total HSCTs.
2) The majority of autologous HSCTs are PBSCTs.

Recently, the number of PBSCTs has been increasing, accounting for 39.3% as of the end of August 2001. As shown in *Figure 5-4,* the number of HSCTs significantly increased in 1991, 1995, 1996, 1998, and 1999. The single most important factor spurring BMT activities in Korea was insurance coverage policy. Before insurance coverage was extended to include allogeneic BMTs, BMTs remained at less than 30 cases a year. Due to insurance coverage, the demand for BMTs has remarkably increased. Consequently, the number of centres performing BMTs also increased, as shown in *Figure 5-5*. Until 1989, only one medical centre was able to carry out BMTs. Since the early 1990s, many other centres have engaged in various bone marrow and stem cell transplants. In 1992, when health insurance programmes started to cover BMTs, five medical centres were joined together to carry out BMT. The increases in HSCTs in 1995, 1996, and 1998 were mainly due to the increase in the number of medical centres performing HSCTs. Particularly, the increased entrants in HSCT programmes and the expansion of insurance coverage to include autologous BMTs and PBPCTs in December 1997 are seen as the major causes of the recent increases.

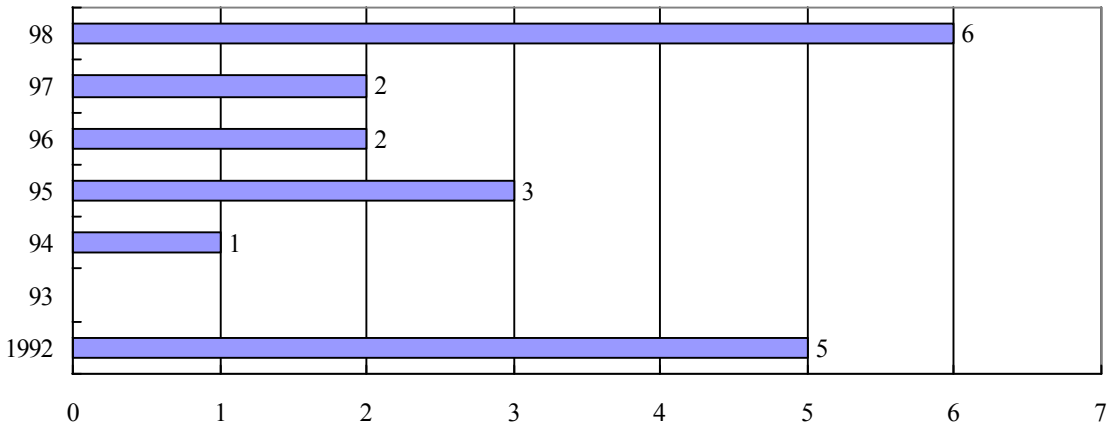


Figure 5-5. **New entrants involved in BMT each year (1992-1998)**

Data Sources: National Health Insurance Corporation (1999 : personal communication)

Competition within the hospital industry has played an important role to spur medical centres to join HSCT activities. New entrants owned by conglomerates like Samsung and

Hyundai have been major forces for the takeoff in 1993. Following the involvement of conglomerate-owned hospitals in haematology services, other teaching hospitals have also started to provide BMT.

The increased number of BMTs from unrelated volunteer donors has also contributed to the growth of BMTs during the latter half of the 1990s. As shown in *Figure 5-6,* BMTs from unrelated donors started in 1996 in Korea. The case "Sungduk Bauman"[138] gained considerable media attention and significantly promoted BMTs involving unrelated donors in 1996.

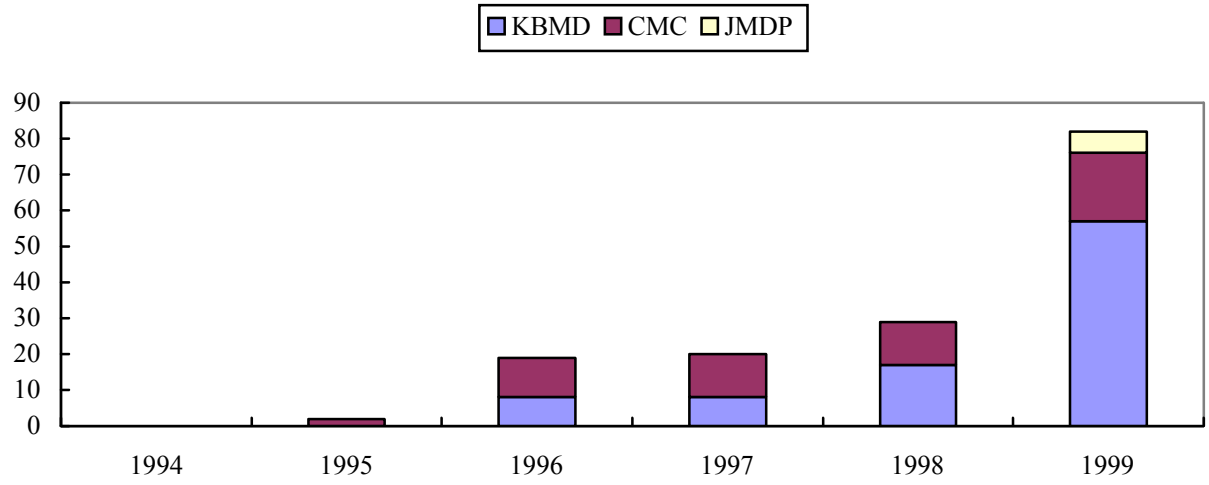


Figure 5-6. **BMTs from unrelated donors (1994-1999)**

Data sources: 1) The number of registered volunteer bone marrow donor was obtained from the Bone Marrow Team in the Research Centre for Blood Transfusion, Korea Red Cross (personal communication).
2) The number of BMTs from volunteer donors registered in KBMD was obtained from KBMD (personal communication).

In summary, four factors have been major influences for HSCT adoption. First, the changes in insurance coverage in 1992 encouraged the adoption of the procedure. Second, the competition among hospitals, which was propelled by the entrance of conglomerate-

[138] Sungduk Bauman was a second-generation Korean immigrant who settled in the US He was a member of the US Military Academy. He was required to undergo BMT due to leukaemia, and the US Military Academy actively campaigned to find a suitable bone marrow donor. The campaign gained considerable media attention, and its influence spread to Korea. Sungduk Bauman has found a volunteer donor in Korea and underwent BMT in July 1996 in the US

owned hospitals in the competition, promoted the adoption of HSCT, which they adopted as a marketing strategy to demonstrate their advanced technologies. Third, public actions spurred bone marrow donations, which began with the establishment of KMDP and which grew stronger in 1995, during the nationwide campaign to find a suitable donor for a Korean-American leukaemia patient living in the US. Fourth, charity funds also played a significant role. Even though public health insurance programmes cover BMT costs, the patient's share of the cost can be very high, ranging from £10 thousand to £27 thousand. In most cases, charity funds have supported almost the whole share of the eligible patient.

5.4.3. UK

The first BMT was performed in 1973 in the UK Over 2,000 HSCTs are currently carried out in the UK every year, and over 24,500 people in Britain are newly diagnosed with cancer of the blood, including leukaemia (Leukaemia Research 2007), as shown in *Table 5-3*. According to Leukaemia Research, 1,200 children are diagnosed with cancer every year in the UK, or one in 9,000. Among them, about 40% are diagnosed with blood cancers, the most common of which is acute leukaemia.

Table 5-3. **Annual incidence of blood-related cancer in the UK**

Diseases Diagnosed	Number of New Cases Each Year
ALL in children ALL in adults	450 200
AML in children AML in adults	50 1,950
CLL	2,750
CML	750
Total leukaemia	6,150
Hodgkin's lymphoma	1,400
Non-Hodgkin's lymphoma	8,450
Total lymphoma	9,850
Myeloma	3,300
Myelodysplasia	3,250
Myeloproliferative disorders	1,900
Aplastic anaemia	130
Total	24,500

Data sources: Leukaemia Research. 2007

As shown in *Figure 5-7,* the adoptions of HSCTs (both autografts and allografts) have been increasing since the 1990s. The increases have been bigger, though, with autografts than with allografts since 1993. Further increases were observed after the first umbilical-cord blood transplant at Great Ormond Street Hospital for Children in 1996.

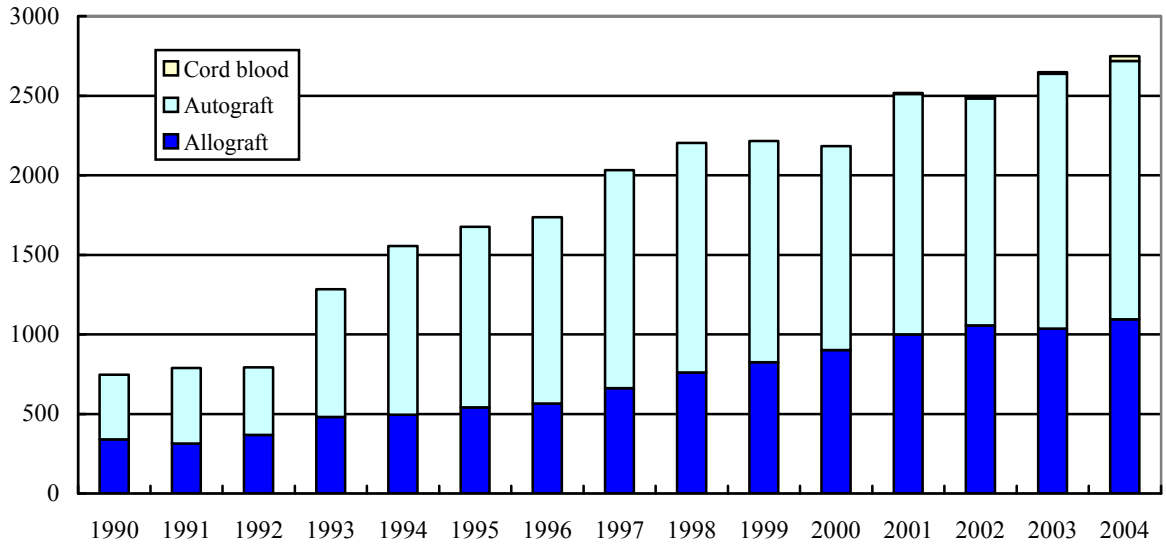


Figure 5-7. **HSCTs in the UK (1990-2004)**

Data sources: British Society of Blood and Marrow Transplantation (BSBMT)., 2007
Note*:* Data regarding cord transplantation from 2001 are available on the BSBMT database.

5.4.4. US

The first successful BMT in the US took place in 1968 at the University of Minnesota (National Marrow Donor Programme, 2001). In 1973, the first unrelated bone marrow transplant was performed in New York. Over 10,000 HSCTs are currently performed in the US each year. *Figure 5-8* shows that the adoption of auto PBSCT has been rapidly increasing since 1994 as much fractioned 58.8% of total in 2006, while that of auto BMT has been decreasing. Allograft PBSCT has also been increasing during the same periods.

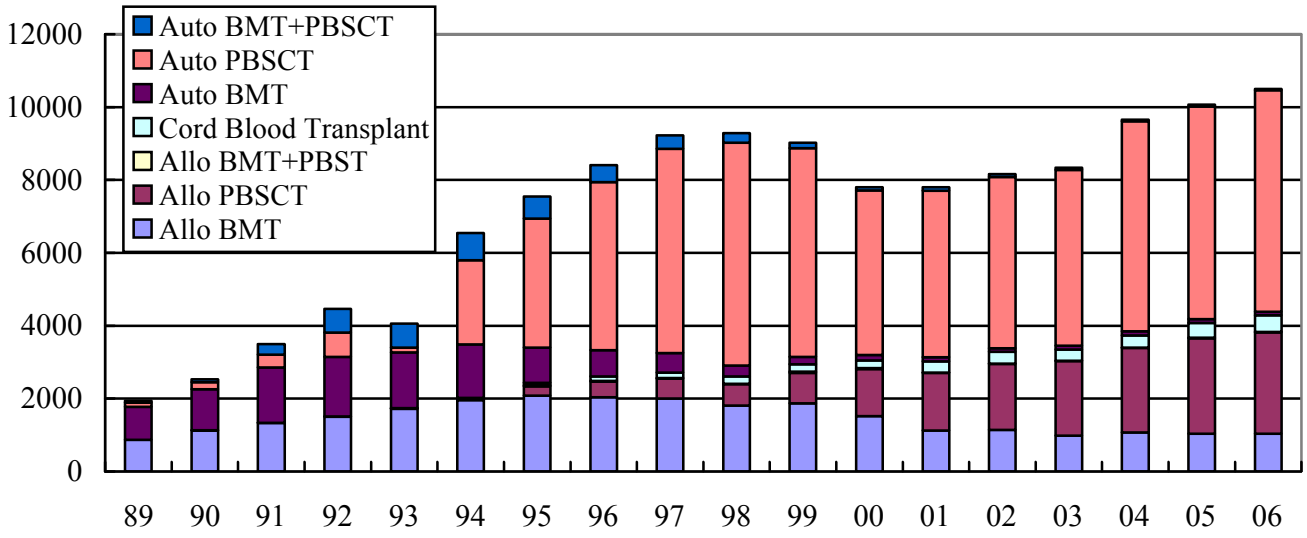


Figure 5-8. **HSCTs carried out in the US (1989-2006)**

Data sources: CIBMTR (personal communication)

Note*:* 'The data presented here are preliminary and were obtained from the Statistical Center of the Center for International Blood and Marrow Transplant Research. The analysis has not been reviewed or approved by the Advisory or Scientific Committee of the CIBMTR.' The data may not be published without the approval of the Advisory Committees

The National Cancer Institute (1999) verified that leukaemia accounted for 31% of all cancer cases in people younger than 15 years of age and 25% of all cancer cases in people younger than 20 years of age in the data for the period 1990-1995. In the US, there are approximately 3,250 children a year diagnosed with leukaemia, and 2,400 with acute lymphoblastic leukaemia (ALL).[139] Since the early 1970s, the incidence rates of lymphoma in the US have almost doubled[140], while those of other cancers have been steady or have been decreasing. In the US, the lifetime risk of being diagnosed with leukaemia is 1.03%, and the risk of dying on account of leukaemia is 0.73% (as estimated based on the SEER database), while the risks of acquiring NHL are 1.71% and 0.89%, respectively. The risk of being diagnosed with multiple myeloma is 0.50% and the risk of dying on account of it is 0.38%.

[139] The proportion of leukaemia in the total childhood cancer cases varies markedly with age—17% in the first year of life, rising to 46% for two- and three-year-olds, and then decreasing to only 9% for 19-year-olds.

[140] The reasons for this increase are not certain. Persons infected with the human immunodeficiency virus (HIV) have a much higher risk of developing lymphoma.

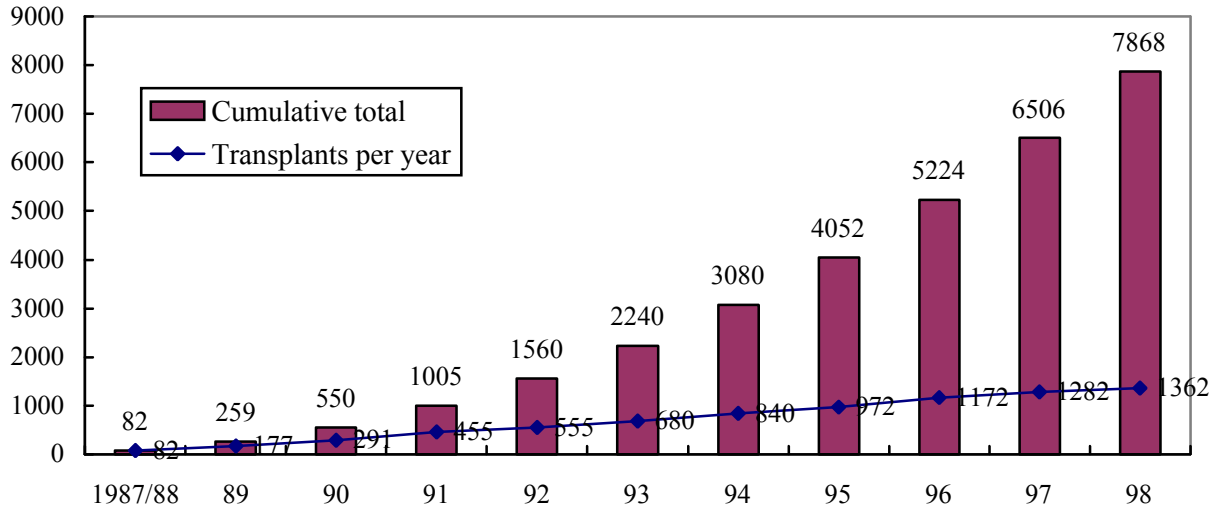


Figure 5-9. HSCTs from unrelated donors by year (1987-1998)
Data Sources: NMDP (2001)

The major factor influencing the increase in the overall number of HSCTs has been the extensive adoption of auto PBSCT in the US, which has increased significantly since 1993. The National Marrow Donor Programme (NMDP) has significantly contributed to the rise in the number of BMTs performed in the US. By the end of October 2000, NMDP had facilitated 11,422 unrelated stem cell transplants (NMDP 2000), and by the end of 1999, NMDP had facilitated 9,237, 1,357 of which have been for racial-minority patients (National Marrow Donor Program 2000). As shown in *Figure 5-9*, the number of donors in the registry and that of the HSCTs from unrelated donors have increased every year.

5.5. Conclusion

As a relatively expensive procedure, its overall advantages needed to be confirmed in both economic and clinical terms. The cost burden to a patient undertaking HSCTs varies by procedures depending on patient's condition and co-payment rules. Amongst HSCTs, some procedures have better outcomes in economic terms as detailed in *Table 5-4*. Peripheral blood stem cell transplant (PBSCT) was estimated to be less expensive, approximately 80-85 % the cost of BMT in the short term but equivalent in the long term (Kasteng et al, 2007). The prolongation of life and QoL has yet to be reliably proven among the procedures of HSCTs.

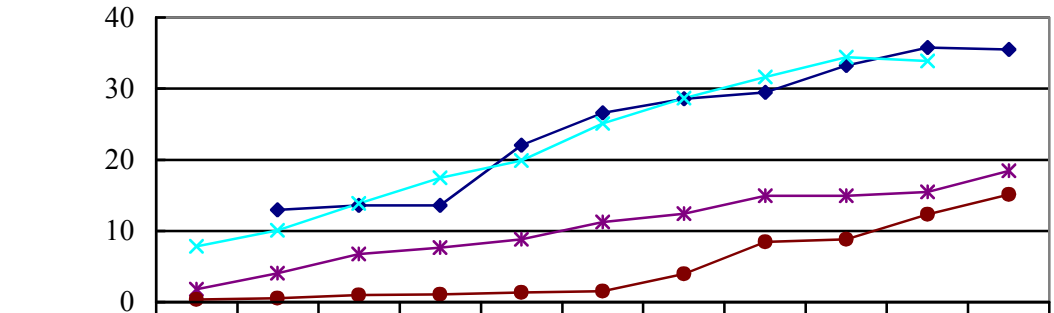
Table 5-4. **The costs of HSCTs, by procedure**

Researcher	Data collection	Setting	Disease	Costs	
				BMT	PBSCT
Kasteng et al (2007)	Literature review	Canada Italy, France, Netherlands, UK, US	Leukaemia	$50,000~ $100,000	80~85% of BMT
Waters et al (1997)	1994-96	US	haematological malignancies	$114,862[a]	$100,542
Woronoff-Lemsi et al. (1997)	1992-1993 (ABMT) 1993-1994 (PBPC)	France	NHL	$35,381[b]	$41,759
Uyl-de Groot et al (1995)		US		$30,592[b]	$21,809
Faucher (1994)		US		$23,290[b]	$19,770
Bredeson et al (1997)	April 1993-Dec. 1994	Canada	NHL, HD, MM	$32,289[b]	$22,089
Black et al (1982)	Jan. 1982-June 1982	UK	AML	£37-54,000	

Note: a. total costs
b. per life year added
c. average hospital charge
d. average hospital length of stay
e. Office of Health Technology Assessment (1995*)*

Figure 5-10 shows that HSCTs are much higher in the UK and the US than Japan and Korea. IBMTR/ABMTR (International Bone Marrow Transplant Registry and the Autologous Blood and Marrow Transplant Registry) considers the real number of HSCTs is up to twice as high. If correct, the true number in the US would be more than twice as much in comparison with the UK. Reflecting the incidence rate, the level of HSCT adoptions is similar in three countries; Japan, Korea and Korea, except the US. In all countries, the number of peripheral blood stem cell transplant s rapidly increased from the early 1990s. Rapid increases occurred in the UK in 1993 and followed by the US in 1994 and in Japan in 1995. The transformation of BMT is considered to have been mainly driven by clinical reasons. The use of peripheral blood stem cells has become routine, as they can be collected on an outpatient basis and also promote a consistent acceleration in haematopoietic reconstitution after engraftment (Byrne JL and Russel, 1998)[141].

[141] The more rapid haematological recovery with peripheral blood stem cell transplant reduces the mortality associated with autografting to 2% (Holyoake and Franklin, 1994).



	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999
UK		12.9	13.6	13.6	22	26.6	28.6	29.5	33.3	35.8	35.5
US	7.85	10.1	13.82	17.46	19.9	25.1	28.68	31.65	34.4	33.9	
Japan	1.8	4.05	6.7	7.6	8.8	11.25	12.4	14.89	14.91	15.47	18.4
Korea	0.32	0.53	0.99	1.05	1.38	1.5	4	8.49	8.83	12.3	15.1

Figure 5-10. **The trends of BMTs in pmp**

Data sources:
1) For the UK- Data provided by the A.Gratwohl and H. Baldomero, EBMT Activity survey, Basel Switzerland (personal communication).
2) For the US- International Bone Marrow Transplant Registry/Autologous Blood and Marrow Transplant Registry (personal communication on 22 Feb.2001 with Melodee L. Nugent, Information Specialist/Biostatistician). The raw data are confidential. The analysis has not been reviewed or approved by the Advisory Committees of the IBMTR and ABMTR. The data may not be published without the approval of the Advisory Committees.
3) For Japan- the Japan Society for Hematopoietic Cell Transplantation, Annual Report of Nationwide Survey, 1998, 1999, 2001.
4) For Korea- Korean Haematopoietic Stem Cell Transplantation Nurse Association, 2001
Note: IBMTR and ABMTR regard the data represent approximately 40 % of all the allogeneic transplants and about half of all autotransplants in the US. Taking this into account, the number of BMT is assumed as 63 in pmp in 1998, which is approximately twice higher than current capture.

The adoption of HSCT increases in all four countries. In the UK, the adoptions took up during 1990s, afterward the market reforms. In Korea, the increase has been more intensive during the late 1990s. Auto peripheral blood stem cell transplant is growing significantly in both the UK and the US, while allo-peripheral blood stem cell transplant and cord blood transplants are increasing at remarkable levels in Japan. According to the technology assessment in the terms of on economic and clinical aspects, peripheral blood stem cell transplant is commonly preferred because the unit costs are lower and the length of hospital stay is shorter compared to other procedures.

Chapter 6: Cochlear Implantation

6.1 Introduction

A cochlear implant is an electronic device designed to support the hearing and communication functions of individuals who have a profound hearing impairment and who are thus unable to hear even with hearing aids. A deaf person is typically unable to recognise sounds as the sensory receptors of his or her inner ear, called *hair cells*, are damaged or diminished. Cochlear implant provides two classes of patients with sound inputs (Summerfield and Tomlison 1996), namely:

- children and adults who lost their hearing after learning a spoken language (postlingually deafened); and
- young children who either lost their hearing before acquiring a spoken language or who were born deaf (prelingually deafened).

A cochlear implant bypasses the damaged hair cells of the inner ear and electronically stimulates the auditory nerve, enabling individuals to receive sound inputs. Part of the device is surgically implanted in the skull, behind the ear, and tiny electrode wires are inserted into the cochlear. The other part of the device is external and has a microphone, a speech processor that converts sounds into electrical impulses, and connecting cables.

Cochlear-implant technology has evolved from a device with a single channel to systems that transmit more sound information through multiple channels. Single-channel systems deliver one stream of electrical information to a single electrode placed in the outer turn of the cochlear. Multi-channel systems deliver quasi-independent streams of information to several electrodes simultaneously.

WHO estimates the global cases of disabling hearing impairment as 250 million as of the year 2001, which was approximately 4.2% of the world's population then (Smith 2004). As of 1999, an estimated 32,000 patients worldwide have received cochlear implants, and annually, approximately 6,000 implants are performed on a global basis, and the numbers increase each year (Sargent 2004).

6.2. Micro Factor Evaluation

6.2.1. Economic Factors

Cochlear implants, which are highly sophisticated devices, are expensive and require a careful evaluation of the candidates for receiving them, a delicate surgery, and, in many cases, years of training in order to provide optimum benefits (Cohen 1995). According to Summerfield and Marshall (1995), the cost of cochlear implants greatly varies between an adult and child, as shown in *Table 6-1*, but is generally higher for children than for adults primarily due to the longer time required for assessing the suitability of child patients, for maintaining their implants, and for follow-up treatments.

Table 6-1. **Cost comparison of cochlear implant for adults and children**

	Adult	Child	%*
Cost of managing the implant in the first year	£8,039	£11,320	140.8
Hardware (Nucleus 22-channel)	£20,969	£24,250	115.6
Cost of management over the subsequent 11 years, including the cost of upgrading the hardware	£23,318	£42,565	182.5

Note: * cost of cochlear implant for a child as a percentage of that for an adult

The data shown in *Table 6-2* indicate cost effectiveness of cochlear implants in terms of cost per QALY.[142] On account of controlling factors such as potential pre-operative complications, morbidity, and shorter life expectancies, Wyatt et al. (1996) concluded that the cochlear implant is highly cost-effective for geriatric patients as well. National Institute of Health (NIH) of the US (1995) also argued that cochlear implants for adults are quite favourable compared to other medical procedures. NIH also regards the cost-utility estimates for children quite favourably, but withholds its conclusion on the cost or the potential cost-saving effects that will accrue in the area of rehabilitation and education. Francis et al. (1999), however, concede that there are significant short-term effects on the use of educational resources, reducing the demand for support services by children with profound hearing impairments and diminishing the expenditures by the school systems throughout the US.

[142] Summerfield and Tomlinson (1996) emphasise that the cost effectiveness of cochlear implants may be improved by ensuring that the procedure is carried out by appropriately trained specialist teams, with a sufficient caseload to maintain their skills, and by operating specialist centres.

***Table 6-2*. Data on the cost effectiveness of cochlear implants**

Source (Year)	Country	Cost-Utility Ratio (Cost/QALY)	Remarks
Summerfield and Marshall (1995)	UK	£11,440[a]	Multichannel
Summerfield and Tomlinson (1996)	UK	£13,300[b]	
Hutton (1995)	UK	£24,257 £15,293	Prelingually deafened Postlingually deafened
Wyatt et al. (1995)	US	US$15,593	
Evans et al. (1995)	US	US$15,900	
Cheng et al. (1999)	US	US$12,787	
Palmer et al. (1999)	US	US$14,670	Multichannel

Note: a. If the benefits are discounted at 6% per annum or £5,722/QALY if the benefits are not discounted

b. The discounted cost of implantation and long-term management was £36,400 for adults and £57,400 for children.

c. Applying the improvement of the quality of life of adults, which is calculated as 0.23 points per annum, to children receiving implantation at age 4 (years), and assuming a life expectancy of 74 years, the QALY to be gained is calculated to be 16.33 in children. The cost per undiscounted QALY gain is estimated to be £1,345.70, and per discounted QALY gain, £10.341.

6.2.2. Clinical Factors

Many factors affect auditory performance after cochlear implantation. Overall, multichannel cochlear implants significantly improve the recipients' performance in terms of speech understanding, and achieve a rating of health utility within six months of the implantation (Palmer et al. 1999).[143] In the Nottingham Paediatric Cochlear Implant Programme, the majority of children who received cochlear implants below the age of five years developed intelligible spoken language three years after the implantation (O'Donoghue 1996). The clinical outcomes of cochlear implants are summarised in *Table 6-3.* Cheng et al. found (1999) that more rapid gains in speech perception are associated with undergoing a transplant at an earlier age, and that speech perception results are independent of cause or age of deafness after 1 year of implant use. Geier et al. (1999) identified that the patient's duration of being deaf, and age at which the patient had the transplant have significant and independent effects on short-term postoperative performance. In addition, the results show that the improvement rate of speech recognition

[143] The authors measured health utility using the Health Utility Index (UHI). The HUI incorporates domains related to spoken communication and hearing.

is dependent upon the duration of deafness, at least in the first three months after implantation.[144]

Table 6-3. **Outcomes of cochlear implantation performed on postlingual adults**

Outcome Measure	Researches	Achieved
Identification of some common environmental sounds	Summerfield and Marshall (1995)	97%
	Horn et Al. (1991)	85%
	Kelsall et al. (1995)	100%
	Summerfield and Tomlinson (1996): in children	70%
Greater benefits to lip-reading than those achieved pre-operatively with an acoustic hearing aid	Summerfield and Marshall (1995)	80-90%
Correct identification of some words in sentences without lip-reading	Summerfield and Marshall (1995)	50%
	Summerfield and Tomlinson (1996): in children	50%

According to Harris et al. (1995), as shown in *Table 6-4,* the overall quality of life reaches a high level one year after cochlear implantation, and is maintained at a level higher than that before the implantation. In addition, the annual-income level nearly doubled after cochlear implantation.[145] Depression widely varied according to time, with the level dropping significantly until one year after implantation, and worsening over time.

The National Institute of Health Consensus Development Conference Statement (1995) clarified that the cost benefit of cochlear implant for adults are quite favourable compared to other medical procedures. Although the procedure for children could not yet be evaluated as it was still in the early stages, the statement concluded that the cost-utility estimates for children were also quite favourable.

[144] Patients who had been implanted at a younger age and those who have had deafness for smaller percentages of their lives achieved the highest levels of short-term postoperative speech recognition. Patients who had been deaf for ≥60% of their lives demonstrated a slower rate of speech recognition improvement than those with shorter durations of deafness, but still continued to improve with increased implant experience.

[145] Palmer et al. (1999) also support the improved income levels of those who had undergone cochlear implantation, compared with those who had not undergone the procedure.

Table 6-4. **Time series evaluation of the improvement after cochlear implantation**

Scale	Time Related to Implantation					
	Before	**6 Mos**	**1 Yr**	**2 Yrs**	**2 1/2 Yrs**	**3 Yrs**
Depression[a]	14.78	11.00	6.5	11.7	12.2	20.3
Satisfaction with life areas[b]	3.72	4.24	4.53	4.18	4.46	3.98
Quality of life and well-being[c]	639	645	720	698	686	711
Personal income[d]	8.9	9.6	10.5	11.1	11.3	11.4

Data sources: Harris et al. (1995)

Note: a. Scored on a 0-60 scale, where a lower score is better and a score of 15 indicates a significant level of depression

b. Scored on a 0-6 scale, where a higher score is better. The variables that were taken into account include work, money, home life, social contacts, housing and neighbourhood, health, religion, children, recreation, and relaxation.

c. Scored on a 0-1.0 scale, where 0=death and 1.0=asyptomatic, full function. The quality of life was measured based on three scales of function: mobility, physical activity, and social activity.

d. A higher score is better in hearing..

6.2.3. Technical Factors

A cochlear implant works by providing direct electrical stimulation to the auditory nerve, bypassing the usual transducer cells that are absent or non-functional in a deaf cochlear. The implantation procedure is considered delicate but not complex or risky. Major complications are usually related to surgical technique, and they include flap necrosis, improper electrode placement, and rare facial nerve problems. Minor complications include dehiscence, infection, facial nerve stimulation, and dizziness (Kveton and Balkany 1991, Cohen and Hoffman 1991).

6.3. Macro Factor Evaluation

6.3.1. Japan

The Japanese government is greatly concerned with the early detection of hearing impairments. In 2000, the Ministry of Health, Labour and Welfare (MHLW) of the Japanese government appropriated £286k for a pilot study with the aim of developing a national screening system for the early detection of hearing impairments. MHLW classified Nuclear 22 as an Advanced Medical Technology (AMT)[146] from 1994, and extended the

[146] As of October 1, 2000, 68 new medical technologies were admitted as sophisticated HTs. The system, which approves of certain experimental technologies, including sophisticated HTs, commenced in 1984. The system encourages the development of innovative medical technologies while limiting the overuse

health insurance coverage to include it. In the past, health plans provided insurance coverage when the procedure was performed in one of three designated medical centres: Teikyo University Medical Centre, Ehime University Medical Centre, and Miyasaki University Medical Centre. As of February 2001, there were 64 hospitals that carried out cochlear implantation, and 10 rehabilitation centres that provided hearing training to those who have undergone the procedure (Association of Cochlear-Implant-transmitted Audition 2001).

Voluntary organisations that support cochlear implantation, such as the Association of Cochlear-Implant-transmitted Audition, have called for insurance coverage for the Nucleus 24 channel, and social insurance programmes began to cover it in 2000. In 1999, MHLW also classified CLARION® as an AMT and, as such, enabled its insurance coverage in 2000.

The actual cost of cochlear implantation varies according to the age of the patient at the time of surgery. As of April 2007, the cost of the procedure for children who are eligible for "self-sustenance support system" is £229 and £436 for adults. In tandem with insurance coverage, the cost of cochlear implantation is subjected to a "refund system for the high cost of medical practice," which pays back 20% of the total 30% of the patient's share when the total cost exceeds £262 (¥63k) within a month at one hospital.[147]

---

and misuse of the technologies. To qualify as an SHT, the technology should have had at least five clinical trials where its effectiveness, safety, cost benefits, and potential for propagation should have been proven.

A technology becomes an approved SHT through the following procedures:

- developing or introducing it as an innovative technology;
- proving its safety, clinical effectiveness, cost benefits, and potential for propagation;
- ethical inspection (Ethics Committee, MHW);
- evaluation, with at least five cases of clinical application;
- review in an SHT subcommittee;
- review in the Expert Committee of the Central Social Insurance Council;
- obtaining SHT approval; and
- publicising it.

To obtain qualification to adopt an AMT, medical centres should satisfy the conditions pertaining to staffing, equipment, and facilities. Medical centres that satisfy these requirements are called *AMT-approved Medical Centres*. Unless a patient goes to any of the medical centres that have been designated to perform specified AMT procedures, he or she is obliged to pay extra fees especially charged for the AMTs.

[147] If the total incurred cost within a month exceeds ¥63,600, the health insurance programme refunds the entire excess amount under the scheme for costly medical services. For the majority of patients who require cochlear implantation, local governments take responsibility for shouldering the full cost of the procedure as part of the social-welfare programmes for the disabled.

6.3.2. Korea

In Korea, the involvement of public authorities in cochlear implantation issues is limited. The only support given by the government for cochlear implantation was its exemption from import tariffs.[148] Government involvement began in 2001, when an inquiry commission was sent to Australia, spurred by the petition for insurance coverage for cochlear implantation. The appeal was made by the parents' association of deaf children "Resonance." In 2002, the Ministry of Health and Welfare allocated a subsidy of £1 million for cochlear implantation. Public subsidy continued until 2004: £0.5 million in 2003 and £1.3 million in 2004 (The Ministry of Health and Welfare 2002, 2003, 2004), supporting a quarter of the total cost for children aged below 10 years via a means test. Following the commencement of insurance coverage for cochlear implantation, donations flowed from the private sector. Korea Telecom began its related charity work in 2005, donating £275,000 a year for cochlear implantation procedures, and Samsung began undertaking related charity work in 2007, supporting cochlear implantation procedures by donating £760,000 every year. About 700 patients can benefit from both these charities, which exceeds the total number of cochlear implantation procedures carried out every year.

6.3.3. UK

As of 2001, eight programmes performed cochlear implantation procedures in the UK (National Service Division, Common Service Agency 2001).[149] In Scotland, cochlear implantation is offered in two centres (The National Service Division, Common Service Agency 2001). Cochlear implantation is currently funded through a specialised commissioning of NHS (NHS Northwest Regional Office, Annual Report on Specialised Commissioning 2000-2001). To promote efficiency in the provision of cochlear-implant services, an Audit Commission review of specialised services (1997) suggested that health authorities move from being passive purchasers to being active commissioners of

[148] According to Section 28 of the Customs Law, based on Section 37 of the Handicapped-Persons' Welfare Law, the Korean government does not charge duty for the import of implantable hearing aids from overseas. Various forms of aid for the blind, deaf, and physically impaired are exempted from surcharges.

[149] Great Ormand Street Hospital Cochlear-Implant Programme; National Cochlear-Implant Programme at Beaumont Hospital (Ireland); Northeast England Cochlear Programme; North Wales Cochlear-Implant Programme; Nottingham Paediatric Cochlear-Implant Programme; The Portland Hospital, London; South of England Cochlear-Implant Centre; University College London.

specialised services, including cochlear implantation. Although the costs are high[150], the number of patients is small: as few as two or three such procedures are being carried out by each authority, thus making annual budgeting difficult. Moreover, with the small number of cochlear-implantation patients, it was difficult for the health authorities to compare the related services across hospitals.[151] To address these problems, some authorities forged a consortium with other authorities for the purchase of specialised services and to diminish the risks involved in the procedure and improve the quality of commissioning.[152]

The British government supports the detection of hearing impairment disabilities at the earliest possible stages in order to improve the chances of hearing recovery. Public policies aimed at identifying hearing impairment disabilities have been adopted since the 1940s. The 1944 Education Act gave local authorities the means to implement hearing screening at the pre-school and grade school level (Davis et al. 1997). The pre-school screening programme was first developed in the 1950s and was administered by health visitors to children aged about 9 months. The Health Visitor Distraction Test (HVDT)[153], which included screenings for pre-school children, was used in the late 1990s to test children aged 7-8 months for hearing impairments. To detect such impairments as early as possible, targeted neonatal screening was introduced in many districts beginning in 1994. As the infant distraction test has low specificity and low sensitivity, which can lead to the worsening of hearing loss and to a situation in which it would be too late to start the proper treatment, screening for hearing impairment during the neonatal period has been stressed. According to a recent research (Fortnum et al. 2001), 16% of hearing-impaired children still need to be detected in their postnatal years using the current universal neonatal hearing screening.

[150] In the UK, the individual cost of cochlear implantation is about £30,000.
[151] According to the results of the Audit Commission national survey of cochlear implants, there is a 20% variation in the prices of cochlear implants. The components that were used to gauge the prices were inconsistent.
[152] According to the Audit Commission, less than one-third of the authorities are part of the consortium for cochlear implants.
[153] HVDT is a universal programme for detecting hearing-impaired children.

6.3.4. US

In the US, cochlear implantation costs £21,000 (Garber et al. 2002). According to the Cochlear-Implant Association, Inc. (CIAI) (2001), private health plans provide coverage for cochlear implantation procedures in almost all cases. The Medicare programme, the Veterans Administration, and Medicaid in some states, as well as Children's Special Services, Tricare[154], and Vocational Rehabilitation Agencies[155] also generally provide coverage for the procedure.

A vast majority of the patient population is covered by public insurance programmes such as Medicare and Medicaid. While the overall insurance coverage rate is higher compared with the general population[156], the reimbursement rate is substantially lower than the number of those with private insurance. Blanchfield and colleagues (2001) estimates that 31% of the patients with a severe to profound hearing impairment have only public insurance, 40% have a combination of both public and private health insurance, and only 23% has only private insurance. In contrast, an estimated 13% of the general population have only public insurance, 12% have public and private insurance, and 61% have only private insurance.

Patients pay an average minimum of 20 to 30% of the charges approved by the insurance plan (Cochlear Implant Research Centre, University of Iowa, 2001). The Medicare programme defines cochlear implants as a prosthetic device, thereby provides coverage whether the surgery is performed on an inpatient or outpatient basis that has been effective from May 1998 (Listen-up, 2008). If the surgery is taken on inpatient basis, the patient is responsible only for the deductible that was $768 in 1999. Patients are liable for their coinsurance if they undertake sugery on an outpatient basis, which is 20% of total hospital charges that are rated on the basis of Medicare fee schedule.

Due to the restrictive Medicare remuneration policies, healthcare providers for cochlear implantation have lost interest in offering this procedure (Cochlear Implant Association, Inc., 2001).

---

[154] A federally funded insurance programme for active military personnel

[155] Each state has a vocational rehabilitation agency.

[156] This is due to the large proportion of Medicare-eligible elderly in the hearing-impaired population, and the public programmes' perception that disability and eligibility are linked.

Efforts to detect babies who cannot hear started in the early 1990s in the US. In March 1993, the NIH Consensus Development Conference Statement (No. 92) recommended that all babies be screened for hearing disabilities prior to hospital discharge since they are already in the hospital. The quality standards and consensus for the early identification of permanent childhood hearing impairment (PCHI) have also been proposed by the Joint Committee on Infant Hearing (1994), which mandates that all infants with hearing disabilities should be identified before the age of 3 months, and that the treatment of the condition should be started at the age of 6 months.

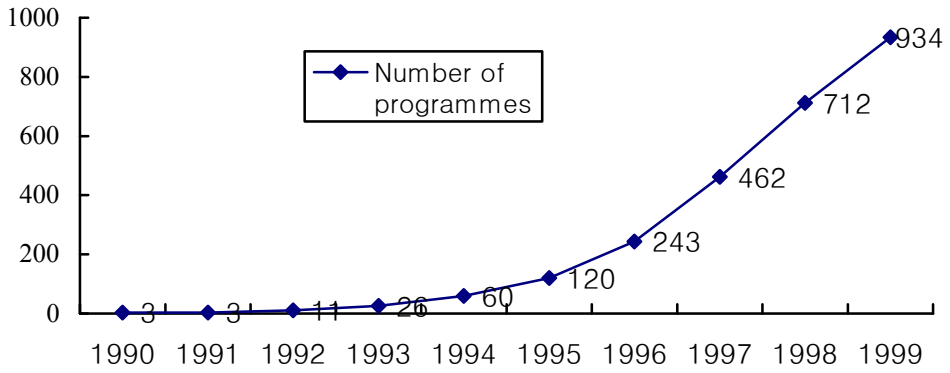


Figure 6-1. **Number of universal neonatal hearing screening programmes (1990-1999)**

Data sources: National Centre for Hearing Assessment and Management (2007)

As shown in *Figure 6-1,* the number of newborn hearing screening programmes in the US began to rise substantially in the early 1990s. According to White (1997), the reasons behind these significant increases can be summarised as follows:

- as a part of the Healthy People 2000 plan, the government set a goal that all children with a permanent congenital hearing disability would be identified before they reach 12 months of age;
- technological developments such as the development of automated auditory brainstem response (ABR) equipment, and the effectiveness of transient evoked otoacoustic emissions, provided new tools for hospitals to use in newborn hearing screening;

- the National Institutes of Health held a Consensus Development Conference, in which they examined all the data related to the early identification of hearing disability and made recommendations in March of 1993; and
- the 1994 Joint Committee on Infant Hearing (JCIH) Position Statement endorsed the goal of the universal detection of infants with hearing disability, and recommends the option of evaluating infants before their discharge from the newborn nursery.

The number of hospitals that are implementing universal newborn hearing screening has rapidly increased since the early 1990s. According to NCHAM (National Centre for Hearing Assessment & Management), 33 babies are born each day in the US with as referring 12,000 to 16,000 yearly and universal newborn hearing screening programme screened 92.9% of all newborn babies in 2005 and 95.7% in 2006 respectively (NCHAM, 2008).

6.4. The Adoption of Cochlear Implantation

6.4.1. Japan

According to a survey carried out by MHLW of the Japanese government in 2001 (MHLW 2002), there were about 346,000 individuals with hearing and language problems that grouped with over six degrees of disability. The Ministry of Health and Welfare considers that about 0.14% of the total population (about 172,000) are over three degrees of disability. The first cochlear implantation was carried out at Tokyo University Hospital in 1985. Following the approval of the importation of Nucleus 22 Contour in 1991, cochlear implants rapidly increased in 2000.

As shown in *Figure 6-2*, the number of cochlear implantation procedures performed has significantly increased since 1994, when public insurance programmes began to cover the procedure. As opposed to other countries, where the number of cochlear implantation procedures generally lies at 50%, the number of cochlear implantation procedures performed in Japan is much higher for adults than for children, reaching 66.4% of the cumulative total by the end of 2004. The advent of new products also promotes cochlear implants. Out of the cumulative total of 3,070 cochlear implantation procedures performed

by September 2003, 1,700 were carried out using Bionics products, including CLARION® and CLARION HiFocus.

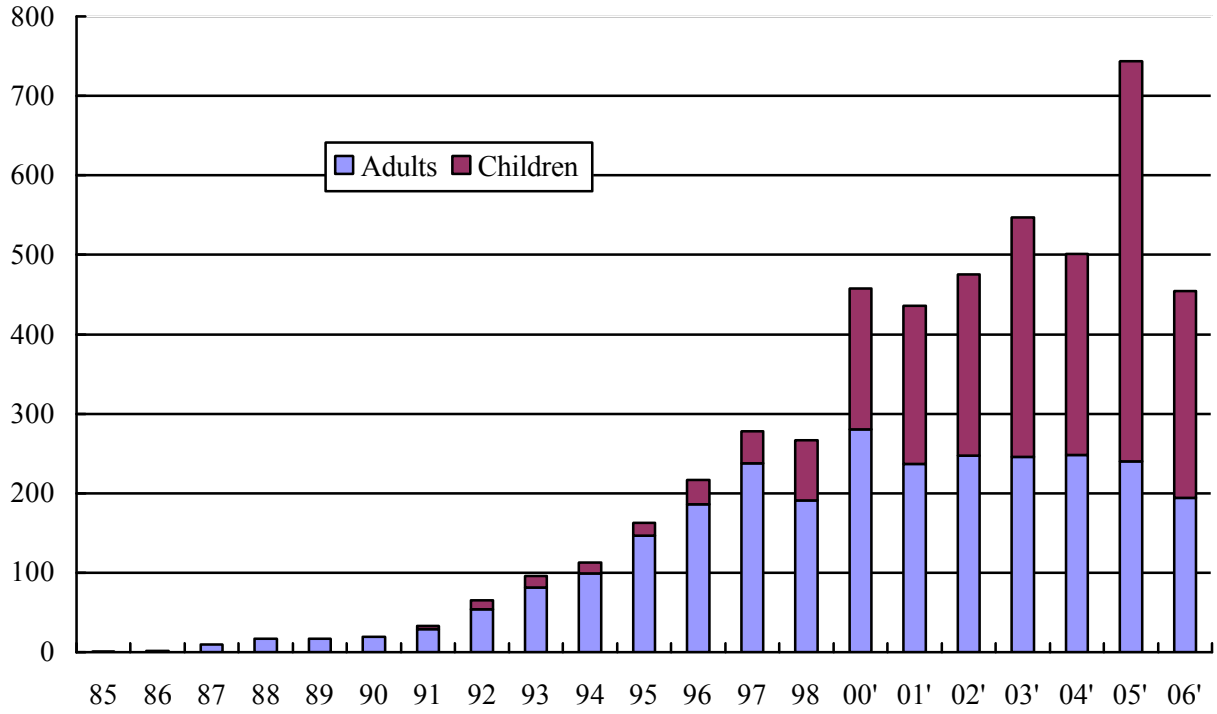


Figure 6-2. **The number of cochlear implantation, Japan (1985-2006)**

Data sources: Association of Cochlear-Implant-transmitted Audition (ACITA 2007: personal communication).

6.4.2. Korea

A total of 137,822 persons were included in the disabled-person registration list as of September 2004 (Ministry of Health and Welfare 2004), which represents 0.28% of the total population of Korea. Among these, 68,192 had disabilities with over three degrees of severity. If estimated based on the Japanese guidelines, the candidates for cochlear implantation in Korea will be around 34,000. The first cochlear implantation procedure in Korea was performed in 1988, and 2,353 cochlear implantation procedures had been carried out by the end of 2006. About half of the implantees were children, and the number of children who undergo such procedure is rapidly increasing, as shown in *Figure 6-3*.

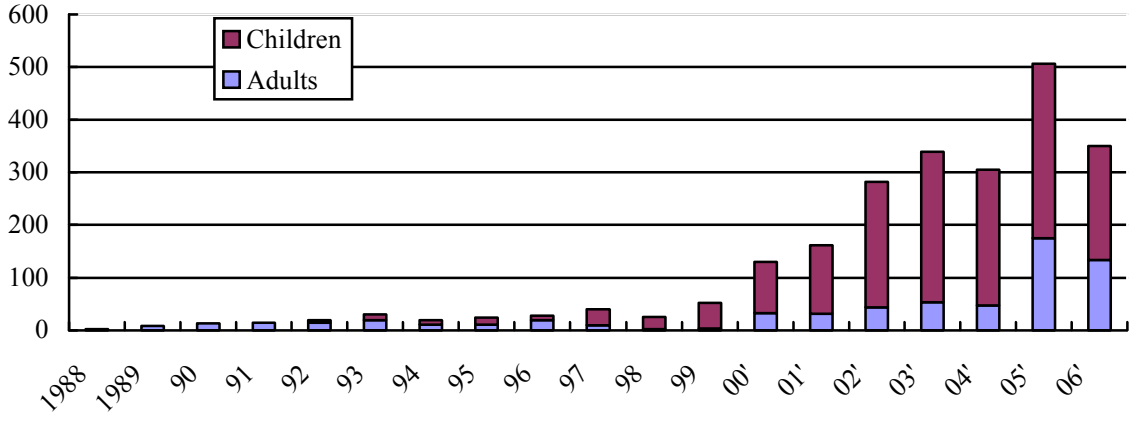


Figure 6-3. **The number of cochlear implantation, Korea (1988-2006)**

Data sources: Personal communication with the device supplier of local agents (Starkey Korea, Kwangwoo Medics).

Following the start of public subsidy for cochlear implantation in 2002, and until 2004, the number of cochlear implantation procedures performed rapidly increased. In 2003 and 2004, government subsidy benefited 58 and 100 cochlear-implantation patients, respectively (Ministry of Health and Welfare 2003, 2004b). The patient who obtains the government subsidy, however, still pays about £9,500 from his or her own pocket, which still significantly holds back the accessibility of the procedure. By virtue of the insurance coverage that was commenced in January 2005, the total share of the patient in the cost of cochlear implantation was reduced to about £2,000. In addition, charities also encouraged hearing-impaired patients to undergo cochlear implantation. Korea Telecom, for instance, shouldered the full cost of cochlear implantation and follow-up for 130 patients from September 2004 to May 2007 (Daily Seoul, May 10, 2007).

6.4.3. UK

In the UK, approximately 840 children are born each year with severe hearing impairment disabilities (Davis 1993).[157] Summerfield and Tomlinson (1996) estimate that

[157] The authors defined hearing impairment on the better ear as occurring at ≥40 dB HL over the frequencies 0.5, 1, 2, and 4 kHz. Davis et al. (1997) found that the current health services in the UK may not be able to reach about 400 of these children by the time they become one and a half years old, and about 200 of these children by the time they become three and a half years old. Using the prevailing estimates derived from Trent Region, the number of children who might be hearing-impaired in the UK was calculated.

there are approximately 4,000 suitable candidates for cochlear implantation in the UK, and 1,600 of these candidates may seek and receive the procedure. Each health authority may be required to accommodate two or three cochlear implantation procedures a year, with 0.5 cases of postlingually deafened patients and two cases of prelingually deafened patients (Summerfield and Marshall 1995).[158]

In 1990, there were very few cochlear implantation procedures performed in the UK[159] Special support from the government commenced in 1990, which encouraged many hearing-impaired individuals to avail of cochlear implantation (Summerfield and Marshall 1995). The Department of Health initiated the "The National Cochlear-Implant Programme" in 1989 and 1990. Under the programme, funding from the central government is provided to partially support the cost of cochlear implantation. The programme was launched in 1990 for adults and children who were to undergo cochlear implantation at selected hospitals. The programme was initiated in Scotland in 1991, and in Northern Ireland in 1992. Since then, most of the cochlear implantation procedures have been performed under the national programme.[160]

According to Summerfield and Marshall (1995), the national programme partially supported the cost of cochlear implantation for 92% of the adult implantees. In line with the national programme, 10 implant centres were established to improve accessibility. As a result, the number of centres providing cochlear-implantation services increased from 6 to 16. As shown in *Figure 6-4,* the number of children who undergo cochlear implantation has rapidly increased since 1994. This is partly attributed to the evaluation carried out by Summerfield and Marshall in 1995, which stated that cochlear implantation is cost-effective, and that the earlier the implantation is performed, the better the results will be. Screening programmes for hearing impairment during the neonatal period, which have been stressed since 1994, are also regarded as having facilitated the increase in the number of children who undergo cochlear implantation.

---

[158] The Audit Commission (1997) also estimates that two or three cochlear implantation procedures may be required every year for each health authority.

[159] By 1990, about 60 people in the UK had undergone cochlear implantation.

[160] Under the national programme, majority of the patients, both adults (74%) and children (96%), were implanted with the Nucleus 22-channel system. The Ineraid system was used by 12% of the adult patients and 2% of the child patients. The UCH/RNID system was used by 10% of the adult patients (Summerfield and Marshall 1995).

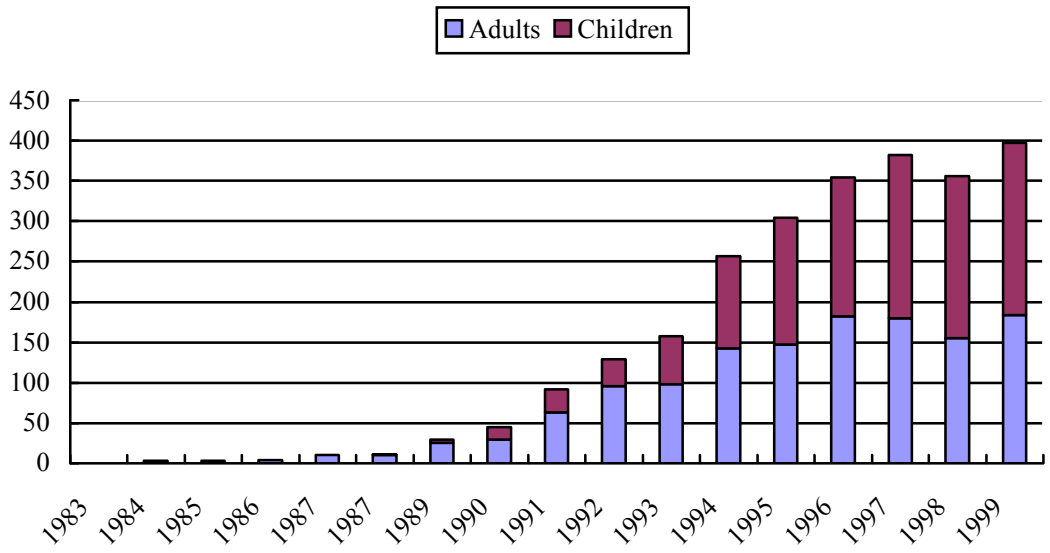


Figure 6-4. **Total cases implanted (1983-1999)**

Data sources: David Marshall (personal communication)

6.4.4. US

Blanchfield et al. (Blanchfield 2001) estimate that severe to profound hearing impairments in the US affects at least 464,000 persons, but possibly as many as 738,000. According to them, seniors represent 54% of the total, and those aged 18 to 64 represent 38%. Children under 18 years of age represent approximately 8%. Based on the Bureau of Census data from 1998, it is estimated that a minimum of 5,600 children under two years of age are profoundly hearing-impaired. According to Christiansen and Leigh (2002), 50 % of cochlear implants were performed for adults in 1990, but the proportion for children increased to 95% in 2002.

The data collected from Advanced Bionics Corporation and Cochlear Corporation reveal that 23,888 cochlear implantation procedures (82.88 pmp) have so far been carried out in the US (Summerfield et al. 2004).[161] Garber and colleagues (2002) uncovered, through a hospital-wide survey in 1999, that hospitals lost more than $10,000 per device for inpatient surgery and about $5,000 per device for each outpatient. They argued that financial disincentives are likely to curb access to cochlear implants. Rand Corporation

[161] The data were quoted from the 7th International Cochlear-Implant Conference, Manchester, UK, September 5, 2002.

(2002) also showed that insurance reimbursements that do not cover the physicians' fees, the audiologists' fees, and the hospital fees appear to limit access to cochlear implantation, especially for Medicare and Medicaid patients. In similar vein, Corporation Limited (Cochlear™, 2008), which has an approximately 60% market share in the US, estimates that a large part of the reimbursement for cochlear implantation comes from private health insurance, comprising more than 60%.

6.5. Conclusion

Cochlear implants support the hearing and communication abilities of individuals with profound hearing impairments who are unable to hear. A micro factor analysis confirms the economic, clinical and technological advantages of cochlear implants.

There are currently about 120,000 people worldwide with cochlear implants, which increased from about 20,000 in 1998 (Cochlear Implant Online, 2008). The choice to give children the opportunity to hear through the cochlear implant is increasing at a remarkable rate. The estimation for the prevalence of the hearing impaired and the candidate for cochlear implants widely varies among the selected countries.

As described in detail in chapter 6, the estimation for the demand of cochlear implant varies among four countries. The Ministry of Health, Labour and Welfare (2002) of Japanese government regards that there are about 385,000 people with hearing and language problems. Among them, about 86,000 individuals may require a cochlear implant

In Korea, the Ministry of Health and Welfare (2004) estimates that about 0.28 % of the total population (representing 137,822 people) has hearing impairment. Among them, around 34,000 people are regarded as potential beneficiaries of a cochlear implant.

In the UK, approximately 840 people are reported as having a permanent hearing impairment at birth (Davies, 1993). There are approximately 4,000 suitable candidates for cochlear implants in the UK, or 133 per 100,000 populations (Summerfield and Tomlison, 1996).

More than 25 million Americans suffer from hearing loss, including one out of four people older than 65 (FDA, 2001). The prevalence of severe to profound hearing impairment in the US accounts for at least 464,000 persons but possibly as many as

738,000 persons (Blanchfield et al, 2001). The data on *Table 6-5* shows the number of cochlear implants per million populations from 1996 to 2004. Until 1996, the number of implants was much higher in the UK and the US with 23.7 and 20.1 in pmp than the Japan and Korea that was 5.9 and 3.5 in respectively. Although the level of cochlear implant has been rapidly increased in both Japan and Korea, accumulative sum in pmp is still much lower than the UK and US. The increases were fast in Japan and Korea, with Korea at the front. The level of diffusion was the highest in the US.

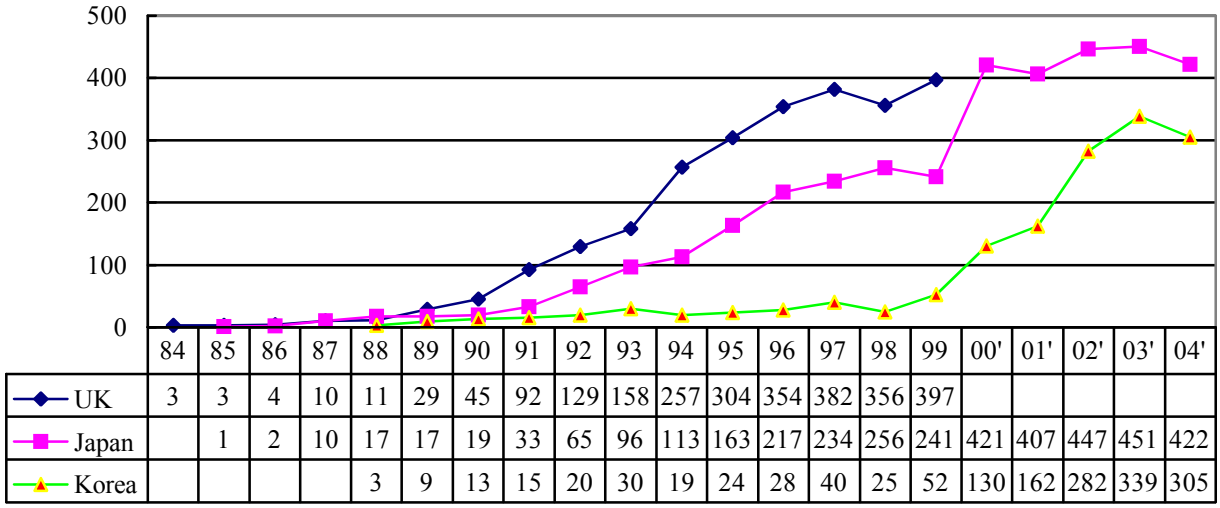
Table 6-5. **Comparisons of changes in cochlear implant**

	1996		2002-2004	
	Cumulative total	PMP	Cumulative total	PMP
Japan	753	5.9	3,632	28.3 (2003)
Korea	161	3.5	1,496	32.3 (2004)
UK	1,399	23.7	3,872	65.2 (2003)
US	5,343	20.1	21,688	72.7 (2002)

Data sources: 1) Association of Cochlear-Implant-transmitted Audition (ACITA 2007: personal communication). Available at: http://www.normanet.ne.jp/~acita/info/arekore2.html#arekore1 (only a bar chart is provided, without the actual numbers). Accessed April 21, 2007.
2) Personal communication with the device supplier of local agents (Starkey Korea, Kwangwoo Medics).
3) Personal communication with Dr. David Marshall at the Medical Research Council Institute of Hearing Research, University Park, Nottingham, England
4) Summerfield, A.Q., G.M. O'Donoghue, J. Graham (2002). Cochlear implantation and meningitis in the UK, 7th International Cochlear Implant Workshop, 15 September 2005, Manchester, UK.

Figure6-5 shows the number of cochlear implants in the three countries[162]. Because the manufacturers were reluctant to release sales data, it was impossible to collect true data for the US by year.

[162] Due to very low volume in Korea un the end of 1990s, the graph was composed with number of transplantation rather than in imp. To help recognition in pmp, Table 6-6 provide cumulative total numbers with counts in pmp



	84	85	86	87	88	89	90	91	92	93	94	95	96	97	98	99	00'	01'	02'	03'	04'
UK	3	3	4	10	11	29	45	92	129	158	257	304	354	382	356	397					
Japan		1	2	10	17	17	19	33	65	96	113	163	217	234	256	241	421	407	447	451	422
Korea					3	9	13	15	20	30	19	24	28	40	25	52	130	162	282	339	305

Figure 6-5. **Number of cochlear implant by countries (1984-2004)**

In Japan, the first cochlear implant was carried out in 1985. There were 3,632 cochlear implants by the end of 2004. Since public health insurance programmes began coverage of Nucleus 22 implantation in 1994, cochlear implants have increased. There are 69 hospitals carrying out cochlear implants in 2004. Rapid increase during the year of 2000 is mainly attributed to the provision of insurance benefits from social insurance programmes for both Nucleus 24 channel and CLARION®. Based on 'high unit cost refunding system,' which paybacks exceeding certain amount of patient's share incurred within a month, the patient pays up to about £270 (￥63,000, exchange rate at August 2007) and get refunds from insurance exceeding it, meaning that the bulk of £14.3k cost is covered by insurance. For the disabled registered as first degree and second degree, the patient pays only £8.6 (￥2,000) and the remaining is supported by local government based on welfare benefit programmes for the disabled.

In Korea, the first cochlear implant was performed in 1988, 408 cochlear implants had been carried by the end of 2000 and 2,353 by the end of 2006. 72 % were in children. The higher proportion of cochlear implant in children is attributed to the government's subsidy that supported aged under 10 in the period 2002~2004 periods. No subsidy is provided for adults. Charities also aided children under 18.

There are some other reasons behind this hasty increase from 1999: 1) the local agency providing Nucleus products changed in 1999. Advanced Bionics and Med-El began

marketing in Korea since 2000 and competition among them has been increasingly, 2) public insurance programmes began to cover the cost from 1 Jan. 2005 lowering patient's share from about £13,382 to £2,000 meaning that about £9,382 is covered by insurance, 3) charities from private sector flooded in tandem with the commencement of insurance coverage.

In the UK, the first adult was given a cochlear implant in 1983, but it was not until 1987 that the first child received a cochlear implant. 180 profoundly deaf children who may require a cochlear implant are born annually. The unit cost of one type of multi-channel implant, with surgery and rehabilitation programme about £22,000 (£30,000 for a child). 19 centres in the UK perform cochlear implant operations for children (RNID Helpline)[163]. "The National Cochlear Implant Programme" from 1990 encouraged cochlear implants. Central funding supports a portion of costs for cochlear implantation. The majority of patients have had cochlear implants under the national programme. The programme supported parts of costs for 92 % in adults. 10 implant centres were established to improve accessibility. As Cochlear implants in children have rapidly increased since 1994 as a result of financial supports and expansion of implant centres. Economic evaluation (Summerfield and Marshall, 1995) also may have spurred cochlear implantation. Screening programmes for hearing impairment in neonate, which has been stressed from 1994 may have facilitated cochlear implants in children.

In the US, Medicare and Medicaid provide coverage for cochlear implantation. Most health insurance health plans also provide some level of benefit for cochlear implantation. Commercial health insurance programmes, such as Aetna, Blue Cross and Blue Shield, and Prudential have been the least restrictive for cochlear implants while managed care plans, especially HMOs, remain the most restrictive.

Blanchfield et al. (2001) estimated that 71 % of cochlear implant procedures and users were covered under public insurance programmes of a federal or state health plan, such as Medicare, Medicaid, Veterans Administration, or Vocational Rehabilitation. The devices and other services associated with cochlear implants are covered by Medicare, Medicaid, the Veterans Administration and most private health insurance programmes. Private health

[163] The Royal National Institute for Deaf People. Cochlear implant fact sheet.

programmes provide coverage for prosthetic devices and necessary procedures related to diagnosis and implantation including post-operative rehabilitation. Medicare coverage for cochlear implant became effective 1 October 1986, was revised in April 1998. Coverage for cochlear implant is limited to FDA-approved devices. Coverage and payment level in Medicaid programmes for cochlear implants are widely varied among different states. Medicaid programmes in several states have provided cochlear implants for children. The Early Periodic Screening, Diagnosis and Treatment programme requires states to provide benefits to be the only medically necessary means of treating a particular child. Medicaid coverage also includes any medically necessary service associated with the cochlear implant for the patients under aged 21.

Chapter 7: Gamma Knife Radiosurgery

7.1 Introduction

Gamma Knife radiosurgery is a method of administering high-dose radiation with surgical precision to a very specific area of tissue within the cranial region, while affecting an extremely small volume of the surrounding healthy tissue.[164] Lars Leksell in Sweden developed this technology in 1967, and is currently marketing Leksell Gamma Knife®. The product has gradually gained acceptance and has spread more widely in the past 20 years.

Gamma Knife radiosurgery has been recognised as highly effective in the treatment of certain malignant and benign brain tumours, arteriovenous malformations, and trigeminal neuralgia. In addition, the use of such procedure as a treatment for Parkinson's disease, epilepsy, and intractable pain is showing promising research results. Its clinical applications continue to expand, with no mortality and minimal morbidity reported. Its present major indications include:

- benign tumours such as meningiomas, acoustic tumours, and pituitary adenomas;
- primary or recurrent malignant brain tumours;
- solitary or multiple brain metastases;
- arteriovenous malformations (AVMs);
- trigeminal neuralgia;
- intractable pain secondary to cancer; and
- movement disorders such as Parkinson's disease and essential tremor.

A non-invasive procedure, stereotactic radiosurgery reduces the surgical risk and patient discomfort, resulting in a shorter hospital stay and a lower risk of developing complications.

The first Leksell Gamma Knife® was installed in 1968 at Sophiahemmet, a private hospital in Sweden. As of December 2004, 204 units have been installed worldwide, as

[164] The individual beams do not harm healthy tissue as they travel through the brain, but as they arrive at the abnormal target tissue, the concentration of all 201 beams has the capacity to destroy that tissue's ability to survive.

shown in *Table7-1.* All in all, 42% of the total units are installed in the US, followed by Japan, which accounts for about 23% of the installed base.

Table 7-1. **Number of Gamma Knife units installed throughout the world**

North America (86)	Canada (1), US (85)
Asia (82)	Japan (47), China (16; 1 in Hong Kong), Korea (8), India (3), Philippines (1), Singapore (1), Taiwan (5), Thailand (1)
Europe[165] (25)	Austria (2), Belgium (1), Croatia (1), Czech Republic (1), France (2), Germany (5), Italy (4), Netherlands (1), Norway (1), Spain (1), Sweden (2), Switzerland (1), UK (3)
Latin America (5)	Argentina (2), Brazil (1), Mexico (2)
Middle East (6)	Jordan (1), Turkey (2), Egypt (1), Iran (2)

Data Sources: Elekta (personal communication-2004)

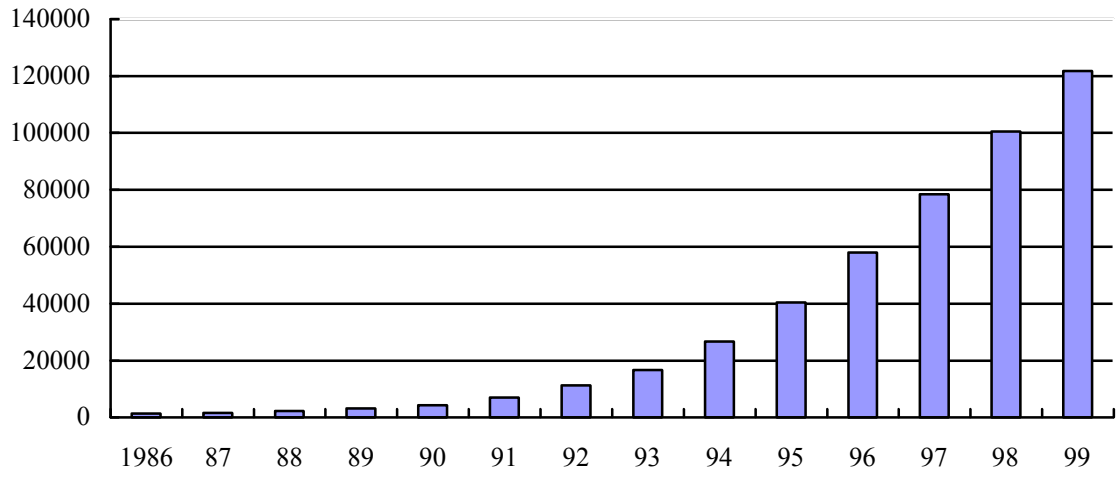


Figure 7-1. **Approximate cumulative number of patients treated with Gamma Knife (1986-1999).**

Data sources: Leksell Gamma Knife Society. Indications treated in June 1999. (personal coomunication)
Note: The 1999 data were projected from January-June 1999.

Gamma Knife has been in use for over 30 years now, and has treated more than 135,000 patients worldwide so far (American Shared Hospital Services 2000).[166] As shown

[165] Elekta is of the opinion that the number of Gamma Knife units installed in Europe is relatively low due in part to budget restrictions and uncertainties surrounding the levels of reimbursement among public healthcare principals. The company also believes that the new applications of Gamma Knife treatment methods have been an important factor in the rapid spread of Gamma Knife (personal communication with a marketing staff of Elekta).

in *Figure 7-1*, the total number of patients who had been treated with Gamma Knife doubled every two or three years.

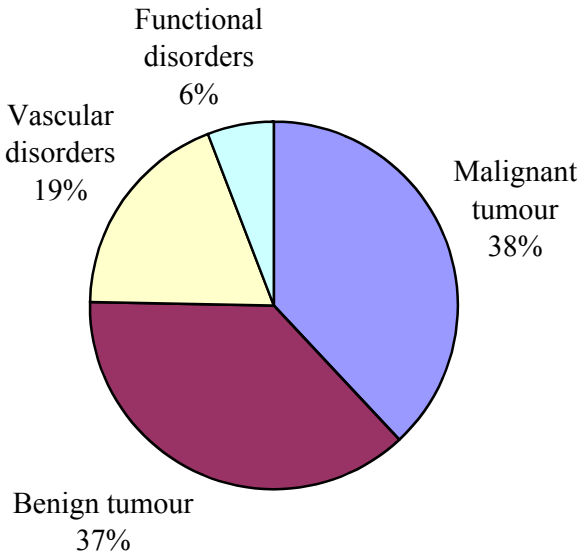


***Figure 7-2.* Cumulative indications treated with Gamma Knife.**

Data sources: Leksell Gamma Knife Society. Indications treated in June 1999. (personal communication)

Majority of the indications have been brain tumours, accounting for 75% of the total number of patients, as seen in *Figure 7-2*. Over one-hundred kinds of brain tumours have been reported to World Health Organisation. As the number of indications that may benefit from Gamma Knife radiosurgery is increasing, it is difficult to postulate the demand for its use. Bearing in mind the incidence of brain tumour, which has been a major indication of Gamma Knife radiosurgery, it is possible to approximate the demand.

7.2. Micro Factor Evaluation

7.2.1. Economic Factors

It is generally accepted that the fact that Gamma Knife radiosurgery requires shorter hospitalisation and consequently incurs lower costs is an important economic advantage of the procedure compared to the conventional surgical procedures (Unger et al. 1999,

[166] American Shared Hospital Services. The data were retrieved from the company's Web site.

Königsmaier et al. 1998[167], van Roijen et al. 1997[168], Rutigliano 1995[169]). Through a 20-year Medline database search, Mehta et al. (1997) found that the Gamma Knife radiosurgery results compare extremely well with resection in terms of the cost parameters for all the courses of the procedure.[170] In addition, Ott (1996) found that Gamma Knife radiosurgery has a 30% cost advantage over surgical resection in craniotomy. Johansson[171] in Elekta maintains that Gamma Knife technology saves roughly 3,000 hospital bed-days and 500-700 intensive-care units in Europe.

As a great deal of capital is required for equipment purchase, there is an argument that capital cost effects must be considered in a cost effectiveness analysis (van Roijen et al, 1997). In the radiosurgery treatment of patients with acoustic neurinoma, the capital cost amounts to about 40% of the healthcare cost (van Roijen et al. 1997).[172] The argument that programs with high investment costs make up only a minor fraction of the total cost of the healthcare sector may lead some people to make the conclusion that investment costs and capital costs can also be regarded as variable costs, at least in the long run. This does not imply that capital costs can be treated indirectly in a cost-effective analysis. However, the capital costs for adoption, priced at about £23.3 million, become a significant variable in the decision to adopt the treatment procedure.

There are some conflicting views, however, as regards the superiority of radiosurgery over surgical intervention. Using a decision analysis model, Porter et al. (1997) recognised

---

[167] The research compared the cost effectiveness of Gamma Knife and that of the linear accelerator.

[168] According to them, the cost of radiosurgery is much lower (the direct cost of microsurgery amounted to Dfl. 20,072, and of radiosurgery, Dfl. 14,272; the indirect costs were Dfl. 16,400 and Dfl. 1,020, respectively), while the general health rating of radiosurgery was better than that of microsurgery.

[169] Rutigliano et al. (1995) revealed that, compared with surgical resection, radiosurgery had a lower uncomplicated procedure cost (US$20,209 vs. US$27,587), a lower average complication cost per case (US$2,534 vs. US$2,874), and a lower total cost per procedure (US$22,743 vs. US$30,461). In their study, radiosurgery was disclosed as more cost-effective (US$24,811 vs. US$32,149 per life year) and as having a better incremental cost effectiveness (US$40,648 vs. US$52,384 per life year) than surgical resection.

[170] The cost of surgery, compared to that of radiosurgery, was higher for each item: hospital cost (3.1), professional fees (1.0), medial hospital days (7.2), operating room (4.4), central supply (6.6), pharmacy (11.7), radiology (2.1), recovery room (27.6), anaesthesia (3.8), laboratory (34.7), ICU (1, 35), and other costs (4.7).

[171] Personal communication. His assumption is based on the fact that the average European Gamma Knife centre treats approximately 250 patients annually.

[172] Another example of a procedure where the capital cost amounts to a significant fraction of the total treatment cost is the extracorporeal shock-wave lithotripsy of uretarial stones and gallstones. The capital cost of the equipment accounts for about 45% of the total treatment costs in the treatment of gallstones, and for about 40% in the treatment of uretarial stones (SBU 1990). Likewise, for some diagnostic procedures, such as CT scans and MRIs, the capital cost is high.

that although radiosurgery is less expensive, surgery yields almost one full quality-adjusted life year (QALY) more than radiosurgery[173] does, primarily because of the haemorrhages that occur during the latent period after radiosurgery.

7.2.2. Clinical Factors

Since Gamma Knife does not require an incision, and in most cases is applied with only a mild sedation and local anaesthetic, the risks of infection and adverse reaction are eliminated.

The benefits of Gamma Knife radiosurgery in terms of clinical effectiveness have been widely recognised in the following:

- melanoma metastases (Mehta et al. 1997, Rutigliano et al. 1995, Seung et al. 1998) ;
- meningiomas (Iwai 1999, Subach et al. 1998, Pendl et al. 1997) ;
- pituitary adenomas (Mokry et al. 1999);
- Parkinsonian tremor (Duma et al. 1998);
- epilepsy (Sims et al. 1999, Bartolomei 1999);
- glomas tumour (Sims et al. 1999, Liscak 1998, Eustacchio et al. 1999) ;
- arterio-venous malformation (Sims et al. 1999, Nicolato et al. 1997[174], Aoki et al. 1996) ;
- trigeminal neuralgia (Regis et al. 1995); and
- trigeminal schwannomas (Noren 1998, Unger 1999).

---

[173] This results in a US$7100/QALY incremental cost effectiveness for surgery, using a decision analysis model to analyse the cost effectiveness of surgery vs. radiosurgery for operable AVMs. In their research, surgery confers a 0.98 quality-adjusted life year (QALY) advantage over stereotactic radiosurgery in the treatment of small AVMs, at an additional cost of US$6,937 per patient. They thus refer to an incremental cost effectiveness ratio of US$7,100 per QALY for a patient treated surgically. According to them, such result is sensitive to only two variables: surgical morbidity and surgical mortality. The preferred treatment strategy changes to favour stereotactic radiosurgery only at the extreme high end of the possible range for these variables, when the rate of permanent neurological morbidity resulting from surgery exceeds 12%, or when the surgical mortality rate exceeds 4%.

[174] The research was carried out in Italy with 721 patients who had stereotactic GK radiosurgery from February 1993 to February 1996, including 20 who were of paediatric age (3%). Of the 78 AVMs, 7 (9%) were diagnosed in children. The results suggest that in children, as in adults, the use of stereotactically delivered irradiation represents a safe and effective technique that attains the complete obliteration of AVMs previously considered surgically inaccessible.

Whereas the uses of Gamma Knife radiosurgery indicate successful outcomes, the results are not always favourable. Although Gamma Knife radiosurgery entails highly localised therapy, thus confining the damage to the target, the risk of injury increases with the size of lesion and the radiosurgery dosage (Brada and Kitchen 2000).[175] Minor adverse effects have also been reported. Local pain, swelling in the scalp, and headaches are common complaints that have been reported in the short term after surgery. A number of patients also complained of skin reddening and irritation, nausea, and seizures. Though uncommon, some delayed complications have been reported as well, such as the local loss of hair in the superficial lesions, local brain swelling at the treatment site, and local necrosis at the treatment site.

7.2.3. Technical Factors

Gamma Knife can also be a good option for those patients who are not candidates for traditional surgery due to their age or medical conditions. Patients undergoing Gamma Knife treatment also do not need to worry about the side effects that accompany chemo or conventional radiation therapy, such as hair loss, scarring, or disfigurement.

In most cases, Gamma Knife patients resume their normal activities within one or two days following the treatment, compared to weeks or months for those undergoing conventional surgery. The advantages of the use of Gamma Knife radiosurgery can be summarised as follows (Unger, Walch, and Papaefthymiou et al. 1999; Unger, Walch, and Haselsberger et al. 1999; van Roijen 1997; Königsmaier et al. 1998; van Roijen et al. 1997):

- economic advantages;
- elimination of the risks of infection and adverse reactions;
- short treatment time;
- short hospitalisation and no convalescence;
- high cure rate;
- very low morbidity; and
- high patient satisfaction and quality of life.

[175] They found an increased risk of rebleeding in patients, with an annual rebleeding rate of 6%.

7.3. Macro Factor Evaluation

7.3.1. Japan

Gamma Knife radiosurgery had been grouped in SHT, and thus, costs were not covered under the insurance programme. Beginning April 1, 1996, public health insurance programmes in Japan began covering Gamma Knife radiosurgery.

The costs for GKR vary according to the insurance programmes providing coverage. The total cost of using GMK is about ¥700,000 (equivalent to £40,000 as of December 2000) in Japan. Currently, those belonging to the Employee Health Insurance (EHI) programme and National Health Insurance (NHI) programme, who should share 30% of the total cost, pay about ¥240,000 (£1,200), plus ¥2,400 (£120) for meal services and ¥210 (£1) for gowns.

To curtail the health expenditure increases, the Japanese government cut the compensation rate for health services by 2.7% in April 2002 (1.4% for medical practices and 1.3% for pharmaceuticals). This significantly impacted the income of hospitals. Along with health reforms aimed at curbing health spending, the Japanese government classified the hospital beds in August 2003 as acute, specialised, or nursing care through applications from hospitals and healthcare facilities. The classification of hospital beds to improve their utilisation in accordance with a patient's needs led hospitals to focus on their main competence, which increased the competition among the acute-care hospitals furnished with advance technologies (Nikkei Healthcare). Subsequently, the acute-care hospitals sought to extend their market share by building coalitions with other healthcare providers grouped in other functions.

7.3.2. Korea

In Korea, public health insurance programmes did not cover Gamma Knife radiosurgery until March 2004. In the early 1990s, the cost was about ₩9 million (equivalent to £4,500 as of December 2004), including the cost of MRI, then it dropped to

about ₩7 million (£3,500).[176] With the extension of the insurance coverage to include Gamma Knife radiosurgery, the patient paid only 20% of the total cost of the treatment (the total cost of the treatment was around £1,500). The public insurance programme in Korea refunds a patient's entire share in excess of £1,800 and incurred within a month following its coverage.

A lease company, Hanbul Lease, provided hospitals with loans to install Gamma Knife units, with the contracts redeeming within five years. The company, like others acting as intermediaries of high-cost medical equipment such as Gamma Knife, MRI, and CT, went out of business following the Asian financial crisis[177] in the late 1990s. As such, no more units were installed thereafter. The collapse of the leasing companies in the aftermath of the financial crisis was another significant factor that led to a halt in the diffusion of medical technologies in Korea. Due to the lower value of the Korean currency, the leasing company was dissolved, which discontinued the distribution of Gamma Knife in the latter part of 1997. After 2001, another company entered the market and resumed the trade of Gamma Knife.

7.3.3. UK

There are three main sources of payment for Gamma Knife radiosurgery: private insurance companies, self-pay, and NHS. Prior approval is required for both privately insured and NHS patients. The composition of patients by payment sources at Cromwell Hospital in London in 2000 is shown in *Figure 7-3*.[178]

[176] Based on Section 17 of the Detailed Enforcement Regulations of the Customs Law, imported Gamma Knife units are subject to tax cuts. According to Section 18, teaching hospitals may obtain a 50% tax cut when they use the units for clinical practices. Currently, the tariff rate in Korea is 8%. Assuming a 50% tax cut, a teaching hospital will have to pay a custom tax of about £108 thousand when importing a Gamma Knife unit. If the hospital buys any medical device or a reagent for research priced at over 1 million Korean won (equivalent to £524 as of January 2001), they will receive a 90% tax cut.

[177] In Korea, the Asian financial crisis caused numerous companies to go bankrupt. As the credit ratings for foreign loans were downgraded, the Korean currency was significantly devalued, and the country's external debt remarkably increased.

[178] A Gamma Knife unit was installed in 1988 in Cromwell Hospital.

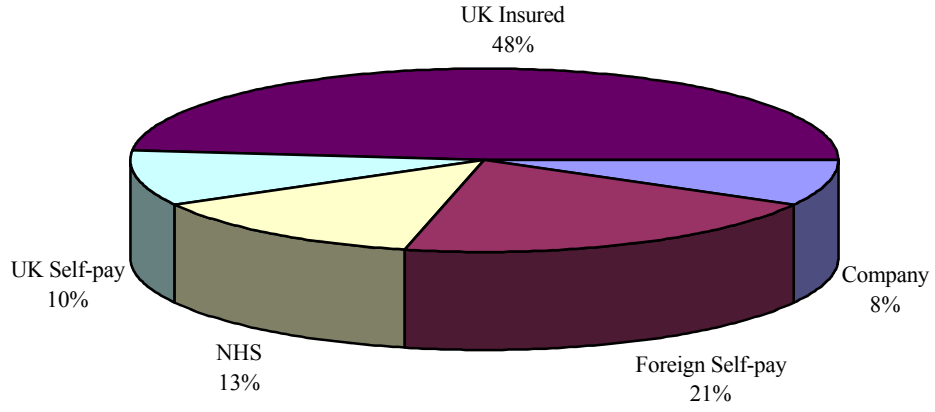


Figure 7-3. **Sources of payment for Gamma Knife use**

Data sources: The data was obtained from the website of Cromwell Hospital in London in October 2005 (personal communication)

Gamma Knife radiosurgery is an item included in specialised services, and thus should be referred to a consortium arrangement. Regional offices were made accountable for developing new and effective arrangements to address these concerns. Consequently, all regions moved to establish Regional Specialist Commissioning Groups (RSCGs) in 1998 and 1999 (NHS Executive, London Regional Specialised Commissioning Group Annual Report 1999/2000).[179]

[179] In Trent Region, the health authority placed high local priority to genetic services and stereotactic radiosurgery in the fiscal year 1999/2000. The RSCG of the Trent Region Health Authority established a review group in 1999 to consider the future provision of stereotactic radiosurgery. The review group examined the issue in light of the Region Office's decision not to support the replacement of the existing Gamma Knife unit at Central Sheffield University Hospital with a new Gamma Knife unit, but to support instead the short-term lease of a new Gamma Knife unit pending its replacement in due course with a dedicated linear accelerator (LINAC). At the May 2000 meeting of RSCG, it was agreed that Central Sheffield University Hospital NHS Trust should continue to function as a national centre for stereotactic radiosurgery, albeit using LINAC instead of Gamma Knife. The dedicated LINAC should be installed as soon as possible so that the Gamma Knife lease could end in three and a half years' time, as scheduled. The continued use of the adapted LINAC at Nottingham City Hospital NHS Trust was not supported. If the Gamma Knife unit will not be replaced when its lease ends and one more unit will be installed in London, three Gamma Knife units will be operated in London.

7.3.4. US

Since Food and Drug Agency (FDA) approval in 1989, Gamma Knife radiosurgery has been performed extensively in the treatment of various brain disorders. In the US, American Shared Hospital Services, Inc., a heavy shareholder of GK Financing LLC (GKF), plays a significant role in providing Gamma Knife radiosurgery services.[180] GKF provides Gamma Knife services, primarily on a usage-only basis, to major university hospitals and large metropolitan medical centres. GKF typically contracts with customers for periods of 10 to 15 years. Along with the provision of Leksell Gamma Knife, GKF assists the medical facility in the planning and design of its Gamma Knife centre, assists in the negotiations with the third-party payers, and provides ongoing marketing support for Gamma Knife services. Typically, GKF provides the Gamma Knife unit, which costs about US$2.9 million, and the medical centre is responsible for the site and installation costs. GKF is typically reimbursed (on a usage-only basis) between US$7,500 and US$9,500 per procedure.

Regarding the adoption of the Gamma Knife unit, the CON (Certificate of Need) requirements vary from state to state in their application to the operations of both GKF and its customers. In some jurisdictions, GKF is required to comply with the CON procedures to be able to provide its services, while in other jurisdictions, the customers must comply with the CON procedures before availing of the GKF services.

Most insurance plans (including Medicare), managed-care plans, and indemnity plans in the US cover Gamma Knife radiosurgery.[181] A significant fraction of the current contracts are reimbursed by the medical centre to the company on a fee-for-service basis.

Since October 1, 1997, the Gamma Knife services for Medicare hospital inpatients have been reclassified based on the DRG scheme. Consequently, it is estimated that

---

[180] Eighty-one % of GK Financing LLC (GKF) is owned by American Shared Hospital Services, and 19% by Elekta, the manufacturer of Gamma Knife. Currently, GKF operates nine proprietary therapy clinics using Gamma Knife units (Elekta 2000, 1998/1999 Annual Report).

[181] As an example, Aetna US Healthcare covers the following surgical procedures for the treatment of trigeminal neuralgia when the patient selection criteria listed below are met (Aetna US Healthcare Coverage Policy Bulletin, No. 374):

- percutaneous glycerol rhizotomy (or injections);
- percutaneous radiofrequency rhizolysis/rhizotomy;
- balloon microcompression;
- microvascular decompression; and
- use of Gamma Knife.

medical-centre revenues have been reduced by the Medicare DRG programme by approximately 30%. APC (Ambulatory Product Classifications) Scheme [182] categorises Gamma Knife radiosurgery as a conventional radiation therapy. Therefore, the two procedures receive the same reimbursement amounts. This categorisation makes no distinction with regard to the types of resources utilised for each procedure classification. Therefore, regardless of the resource consumption and the clinical outcomes, all the procedures within a group qualify for equal reimbursement. Specifically, stereotactic radiosurgery receives the same reimbursement per session that conventional radiation therapy does. This will result in a significant decrease in the reimbursement that will be given to Medicare-covered Gamma Knife patients who are treated on an outpatient basis.

7.4. The Adoption of Gamma Knife Radiosurgery

7.4.1. Japan

By the end of 2004, 47 Gamma Knife units had been installed since May 1990, when the University of Tokyo adopted the first unit. Currently, Japan has the second highest number of Gamma Knife units in the world, next to the US. As shown in *Figure 7-4,* hospitals adopted more Gamma Knife units when public health insurance programmes began to cover Gamma Knife radiosurgery.

Since April 2003, a high-medical-cost refunding system was introduced, which reimbursed patients who paid an amount beyond a certain limit within a month.[183] The

[182] The Omnibus Reconciliation Act (OBRA) of 1986 directed HCFA to develop a prospective payment system for hospital outpatient care. Ambulatory Payment Groups (APGs) were developed in response to this directive. The Balanced Budget Act of 1997 (BBA) requires HCFA to implement this outpatient prospective-payment system (OPPS) by January 1, 1999. It is anticipated that most hospital outpatient services will be included in the new OPPS, as well as in free-standing ambulatory surgery centres.

DHHS has proposed a new payment system, Ambulatory Product Classifications (APC), which affects all outpatient services, including those performed in a hospital-based or free-standing facility. Effective July 1, 2000, Medicare reimbursed the facility component of hospital-based outpatient services using the APC system. The APC consists of 346 clinically homogenous classifications or groupings of codes that are typically used in outpatient billing. Outpatient services is to be bundled with fixed rates of payment determined according to specific regional and national factors, similar to that of the inpatient PPS. Overall, the system is expected to reduce payments for select services and to encourage the most efficient use of resources for outpatient care.

[183] The basis for refund varies in accordance with the income level. A large-income earner who earns more than ¥560,000 (£2,800) a month can receive a refund of the entire amount paid by him or her for the treatment in excess of ¥139,800 (£700) in a month, while the ceilings are ¥73,200 (£366) for ordinary earners and ¥35,400 ((£177) for those in the lower-income bracket who are exempted from general taxation.

number of unit installations increased again as a consequence of the introduction of the refunding system. With increased units, the poor level of utilisation per unit resulted in financial burden to the hospitals. In an effort to overcome that hurdle, individual hospitals sought to increase the number of patients who have suitable indications for the application of the unit by networking with other hospitals for the sharing of the unit.

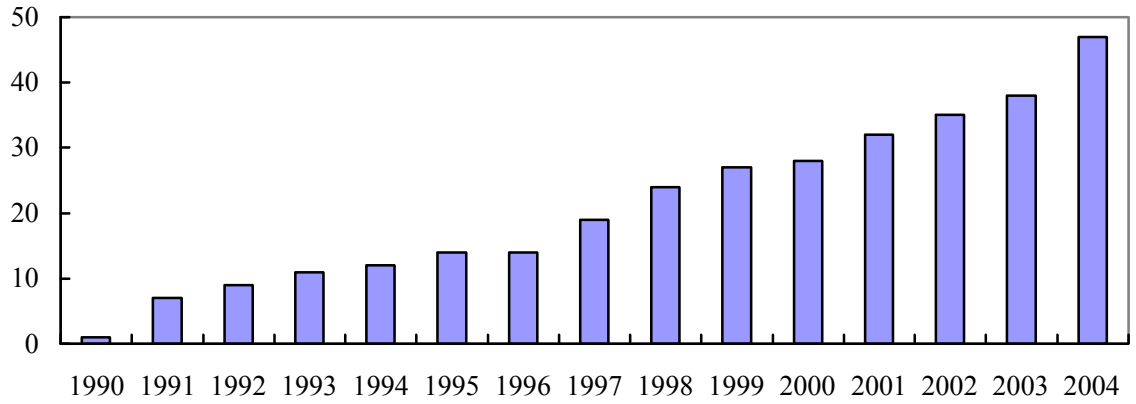


Figure 7-4. **The number of Gamma Knife units installed (1990-2004)**

Data Sources: Japan Gamma Knife Support Association (personal communication)

7.4.2. Korea

Gamma Knife was adopted in Korea before it was adopted in Japan. The Asan Medical Centre, which belongs to the Hyundai Group, introduced the first unit in May 1990. As shown in *Table 7-2*, by the end of 2005, eight Gamma Knife units had been installed in Korea, and one more unit was scheduled to be installed. There are more hospitals that are considering the adoption of Gamma Knife units. However, many hospitals hesitate to adopt the unit because of the number of hospitals that already operate the units and the difficulties in achieving profit out of the use of the unit. Those professionals who are using Gamma Knife technology acknowledge that the market for patients who require Gamma Knife radiosurgery in Korea is too small, and thus, the existing supply of the units already exceeds the demand for them. As a result, hospitals tend to drop their fees in order to compete with other hospitals.

Table 7-2. **Installation of Gamma Knife units in Korea**

Hospital	Installation
Asan Medical Centre (Hyundai Conglomerate)	May 1990/ replaced in May 1996
Kyung Hee University Hospital	March 1992
Yonsei University Medical Centre	April 1992
In Je University Paik Hospital	October 1994
Seoul National University Hospital	December 1997
Seoul Samsung Hospital	December 2001
Busan National University Hospital	October 2003
Chun-Nam National University Hospital	April 2004
Kyung-Buk National University Hospital	January 2005 (scheduled to be installed)

Data Sources: Elekta Korea (personal communication)

Increased competition and the low level of compensation for health services impel the adoption of Gamma Knife units as well as other high-end technologies in Korea. First, competition based on advanced facilities and equipment has been triggered in the aftermath of the large-scale entry of conglomerates into the hospital industry, as typified by Asan Medical Centre and Samsung Hospitals. To compete with other hospitals, the leading conventional hospitals began to construct new facilities equipped with advanced medical equipment. Second, the financial difficulties of hospitals spurred them to adopt advanced technologies. Of the total, 8.9% went bankrupt in 2001, 6.5% in 1999, and 7.4% in 2000. This phenomenon was caused not only by the introduction of a new system in 1999 that separated the dispensary from medical practice, but also by the low level of compensation, which has been the main yardstick for controlling healthcare expenditure. Ever since the policy separating medical practice and pharmaceutical services was implemented, patients have moved from ambulatory-care physicians to tertiary-care hospitals. The fall in patient numbers has resulted in the failure of many hospitals. As a strategy to improve their competitiveness and income, hospitals adopt expensive medical equipment. The following data support the claim that the adoption of the aforementioned advanced technologies is common in Korea. As shown in *Table 7-3* and *Table 7-4*, the number of expensive equipment being adopted by Korean hospitals is the highest in the world.

Table 7-3. **CT installation in 1997 (pmp)**

Nation	Japan	US	Korea	Australia
CT	55.4	26.2	17.48	13.8

Data Sources: Yoon et al. (1997)

Table 7-4. **MRI installation in 1997 (pmp)**

	MRI	**Pmp**	**GDP**	**MRI against GDP**	**MRI pmp against GDP**
US	4,002	14.2	29,964	5.88	0.95
Japan	270	21.5	33,289	3.57	1.30
Germany	650	7.9	25,596	1.11	0.62
Korea	234	5.1	10,307	1.0	1.0
UK	157	2.7	21,832	0.31	0.24
France	138	2.4	23,789	0.25	0.20

Data Sources: Ad Hoc Committee on Diagnostic Radiology, Korean Radiological Society (2000)

7.4.3. UK

The National Centre for Stereotactic Radiosurgery in Sheffield opened as the Department of Health funded the unit for a five-year research project, which commenced patient treatment in September 1985. In bringing the research project to an end in 1990, the Department of Health recognised the unit as a supra-regional speciality, once the efficacy of the treatment had been proven. The unit was the third installed for clinical use in the whole world. It remained the only unit in Britain until 1998, when a second unit was installed at Cromwell Hospital in London.

The third unit was installed at Barts and London NHS Trust in 1999, as a joint private finance initiative (PFI).[184] Since the first installation by PFI, no further adoption has been

[184] Public Private Partnerships (PPP) is the umbrella name given to a range of initiatives involving the private sector in the operation of public services. The key difference between PFI and the conventional ways of providing public services is that in the former, the public does not own the asset. The authority makes an annual payment to the private company providing the building and associated services, like a mortgage. The PFI is one of a range of initiatives introduced by the last Conservative government, aimed at increasing the private-sector involvement in the provision of public services. The Labour government has sought to "reinvigorate" PFI by streamlining the process and concentrating on "viable" projects. UNISON, the largest trade union in the UK, with over 1.3 million members, officially opposes PFI in NHS for the following three reasons. First, under PFI, the government can borrow money at preferential rates of interest. Over the long term, the cost of providing new facilities through private investment will thus become higher. Second, the banks and operating companies will also want profits, as opposed to the government's not-for-profit ethos. The profit levels are also kept confidential. Third, the private-sector

promoted so far. A new initiative involving the London Radiosurgical Centre, Bart's and The Royal London NHS Trust, and The London Clinic, together with a £3. 5-million investment, has brought the non-invasive Gamma Knife to the London Radiosurgery Centre (GP Newsletter Issue 27, December 1999, London Radiosurgical Centre, Ltd.).

7.4.4. US

In 1995, malignant brain tumours accounted for 12,062 deaths in the US, and 947 deaths were due to benign brain tumours. If the reported cases of brain tumour deaths for uncertain and unspecified behaviour were included, the total deaths caused by brain tumours would amount to 15,928 (Preston-Martin and Mack 1996). The Central Brain Tumour Registry of the United States (CBTUS) reported an incidence rate for all primary brain and central-nervous-system tumours, including the pituitary and pineal glands, of 11.8 per 100,000 for 1990-1993 (Davis, Bruner, and Surawicz 1997). The incidence rate of primary malignant brain tumours is 5.8 cases per 100,000 person-years. The rate is higher for males (7.0 per 100,000 person-years) than for females (4.7 per 100,000 person-years) (Ries 1998).

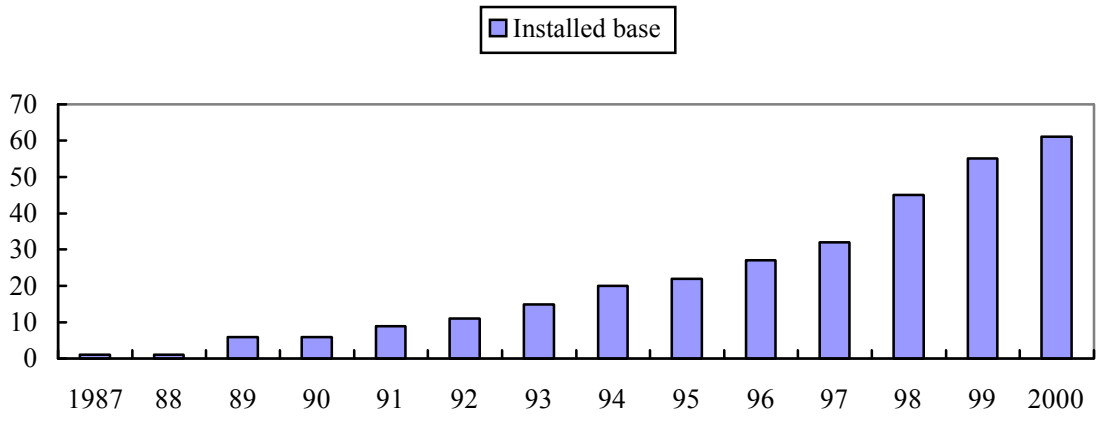


Figure 7-5. **The installation of Gamma Knife units in the US (1987-2000)**

Data sources: Elekta (personal communication)

---

provision of services will lead to a loss of accountability and control. In PFI hospitals, for example, the needs of the PFI consortium will be the key factor in decision-making, not the needs of NHS. PFI was also firmly opposed by BMA at its annual representative meeting in 1996 (BMJ News, July 6, 1996). In the words of Dr. Stephen Watkins, chairman of the BMA's Public-Health Committee, "We must say that we are not prepared to hand over NHS money to the private sector at an exorbitant interest rate."

The first Gamma Knife system was installed in 1987 in the Presbyterian University Hospital of the University of Pittsburgh in the US. From then until June 2000, 61 Gamma Knife units were installed in the US, which accounted for 43% of the total number of units installed around the world. As shown in *Figure 7-5*, the installation of Gamma Knife units has rapidly increased over the years.

GKF has played a significant role in spreading Gamma Knife units in the US. Since it is GKF that provides the Gamma Knife unit to the buyers, those hospitals that want to adopt the unit are required only to provide a site for the unit and to shoulder the installation costs. After the installation of the unit, GKF is paid from US$7,500 to US$9,500 for each procedure. Since the annual patient volume for all the reporting Gamma Knife centres is approximately 175, GKF takes in an estimated US$1.3 million to US$1.66 million a year.

Although the reimbursement policy reduces the fees for the use of Gamma Knife radiosurgery as a result of the latter's reclassification in the Medicare DRG, this has minimally influenced the adoption of the Gamma Knife unit by hospitals.

7.5. Conclusion

Potential demand for using Gamma Knife radiosurgery varies among the case study countries. According to The Committee of Brain Tumour Registry of Japan, 12.76 per 100,000 of the population have been reported as brain tumour patients in Japan. During 1993, the newly registered number of primary and metastasis brain tumour patients[185] was 5,076 in Japan. As shown in *Table 7-5*, the reported number of patients is much lower in Korea[186] than the other countries. The incidence level in the UK is quite similar to that of the US, which is about half of the incidence level in Japan. Further investigations on the incidence of brain tumours and other diseases of which Gamma knife radiosurgery can be applied are required to appropriately compare the demand for Gamma knife unit.

[185] Metastasis is the spread of cancer from one part of the body to another. The original location is called the primary tumour. Metastatic tumours are tumours that arise at sites away from the original location. Cancer cells from the primary site can break away and enter the body's circulatory system blood stream, lymph system or spinal fluid and travel to distant locations. The most common pathway for metastasis to the central nervous system is via the blood stream. Tumours in the brain are the most common form of central nervous system metastasis.

[186] According to Central Cancer Registry in Korea of the Ministry of Health and Welfare, the data covers about 80 % of cancer patients across the country.

Table 7-5. **Incidence of brain tumour (per 100,000)**

Japan[a]	Korea[b]	UK[c]	US[d]
12.76	2.7	6.5	6.9

Data sources: 1) The Committee of Brain Tumour Registry of Japan. Report of Brain Tumour Registry of Japan (1969-1993) 10th Edition, Neuralgia, supp. Vol. 40, Jan. 2000.
2) Annual Report of the Central Cancer Registry in Korea (Based on Registered Data from 128 Hospitals) (2001) Central Cancer Registry Centre in Korea, Ministry of Health and Welfare, Republic of Korea
3) Office for National Statistics, Office of National Statistics Series MBI No. 25 published 1998
4) National Cancer Institute, SEER Cancer Incidence, 1992-1998

Note: a. the number refers to 1989-1993
b. the number comprising tumours in eye, brain and other parts of central nervous system
c. the number refers to 1992
d. the number refers to 1992-1998 as comprising tumours in brain and other nervous system

In terms of a million per one unit, as shown in *Table 7-6*, Japan is the highest in adopting Gamma Knife technology among the case study countries. Adoption in the US is quite similar to that of Japan, while the UK has the lowest level.

Table7-6. **Populations per one unit of Gamma Knife (Unit: million)**

Japan	Korea	UK	US
2.71	5.95	19.74	3.39

Health insurance programmes in Japan have covered Gamma knife radiosurgery since 1996. The decision for adopting Gamma Knife is fully made by health care providers including physicians or hospitals. Public insurance programmes have covered Gamma Knife radiosurgery since 1996. The situation in Korea is broadly similar to that of Japan. Taking into account the incidence of brain tumours, potential demand is believed to as much as five times higher in Japan compared to Korea. The public insurance programme has covered Gamma Knife radiosurgery since 2002 in Korea.

Gamma Knife radiosurgery is regarded as better than surgical intervention in economic, clinical, and technical terms. The Gamma Knife unit differs from other HTs with its high capital cost requirement for installation and high operation cost subsequently.

Chapter 8: Kidney transplantation

8.1 Introduction

Kidney transplantation is required when a patient has irreversibly deteriorated renal functioning generally caused by glomerulonephritis, pyelonephritis, diabetes mellitus, polycystic kidney disease, or vascular disease (chiefly, hypertension). When a patient falls into a condition in which there is a decline in the capacity of his or her kidneys to extract excess fluids and poisonous wastes from the blood, the state the patient is in is called chronic renal failure, and the patient eventually reaches the point called end-stage renal disease (ESRD).

The current possible approaches to managing ESRD patients are continuous ambulatory peritoneal dialysis (CAPD), home dialysis, hospital dialysis, and kidney transplantation. Based on the results of a cost-benefits analysis, transplantation is preferred by younger patients. Primarily, the decision as to which treatment modality will be resorted to depend on the availability of an organ donor, the physical condition of the patient, and the latter's ability to cope with the alternative treatment modalities.

Reflecting cultural heritage, there are huge differences in the legislation around the world that authorise organ procurement and direct organ donation. The primary role of legislation has been to authorise legitimacy for organ procurement from donors. It also becomes a barricade restricting organ transplant when the law prohibits commercial trading in organ donation for transplant purposes. The legislation in some countries requires medical professionals to promote organ donation, while that in some other countries stands for a passive position on organ procurement.

Among the different organ transplantations, only kidney transplantation is generally accepted as better than the other compatible renal-replacement treatments for patients with ESRD (Douzdjian et al. 1998, Evans and Kitzmann 1998).

The adoption of overall organ transplantation is greatly varied, ranging from 86.1 pmp at the highest to 9.6 at the lowest among some OECD countries, as shown in *Table 8-1*.

Table 8-1. **Organ transplants in 2003 (pmp)**

Country	Kidney	Liver	Heart	Heart+ Lung	Lung	Pancreas	Kidney+ Pancreas	Total
Austria	47.9	18.4	7.8	0.1	10.9	0.9	4.1	86.1
Spain	49.8	24.0	6.7	0.1	3.4	0.1	1.6	85.7
US	47.6	18.0	6.5	0.1	3.5	1.6	2.8	80.1
Norway	52.8	8.3	9.6	0.2	4.2	0.4	2.4	77.9
France	34.7	13.4	4.6	0.3	1.3	0.1	1.1	55.5
Sweden	38.5	13.4	4.0	0.2	3.0	1.1	0.2	55.5
Italy	29.4	15.8	5.6	0.0	1.2	0.4	0.9	53.3
Germany	28.4	10.4	4.5	0.2	2.3	0.3	2.1	48.2
Netherlands	35.5	6.0	2.5	0.1	2.0	0.1	1.0	47.2
UK	28.5	10.6	2.5	0.3	2.3	0.2	0.7	45.1
Korea*	18.0	10.2	0.3	0.0	0.0	0.2	-	28.7
Japan	6.8	2.8	0.0	0.0	0.0	0.0	0.0	9.6

Data sources: International Registry of Organ Donation and Transplantation. Definitive data of international transplant activity (IRODAT 2003

Note: * Korean Network for Organ Sharing (KNOS) 2003 Annual Report

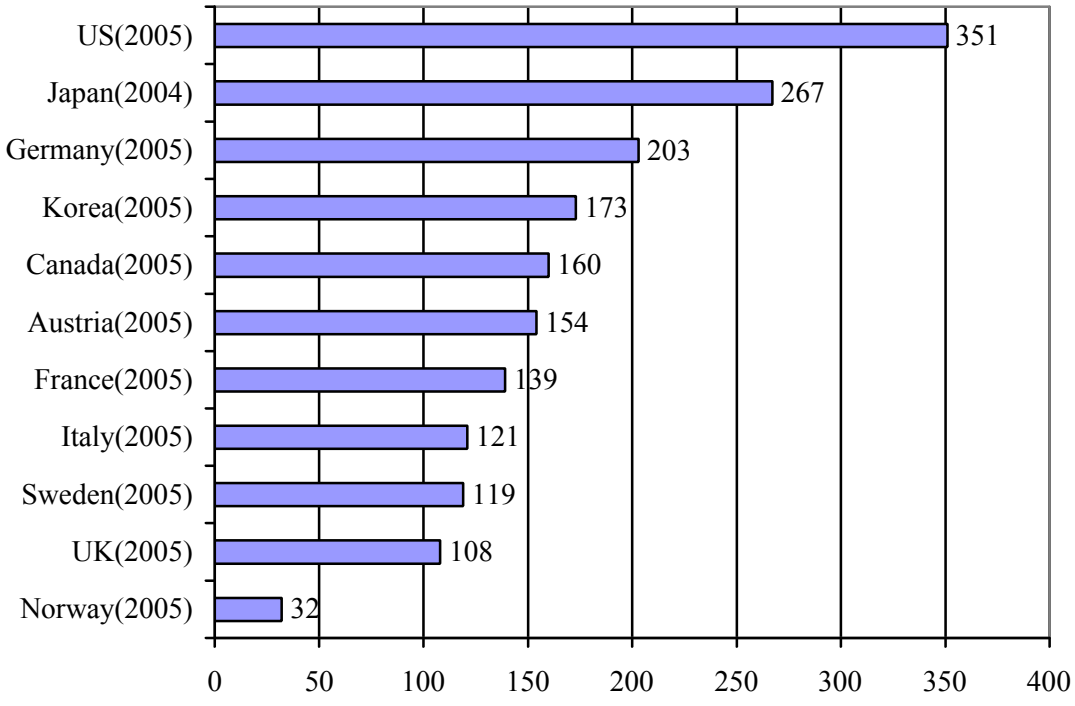


Figure 8-1. **The prevalence of ESRD therapy (pmp).**

Darta sources: United States Renal Data System (USRDS), 2007 Annual Data Report.

The prevalence of ESRD is widely varied among the selected countries. The prevalence of patients who require renal-replacement treatments is high in the US, Japan and Korea than the UK, as shown in *Figure 8-1*. The difference may primarily be due to the variation among the countries in terms of the primary diseases therein that causing chronic organ failure.[187] The incidence of ESRD patients is also greatly varied even within a country, according to the country's social and economic conditions and ethnicity. In the US, for example, the rate of ESRD incidence in 1998 in terms of pmp was 199 in the white population and 829 in the black population (USRDS, USRDS 1998 Annual Data Report 1998).

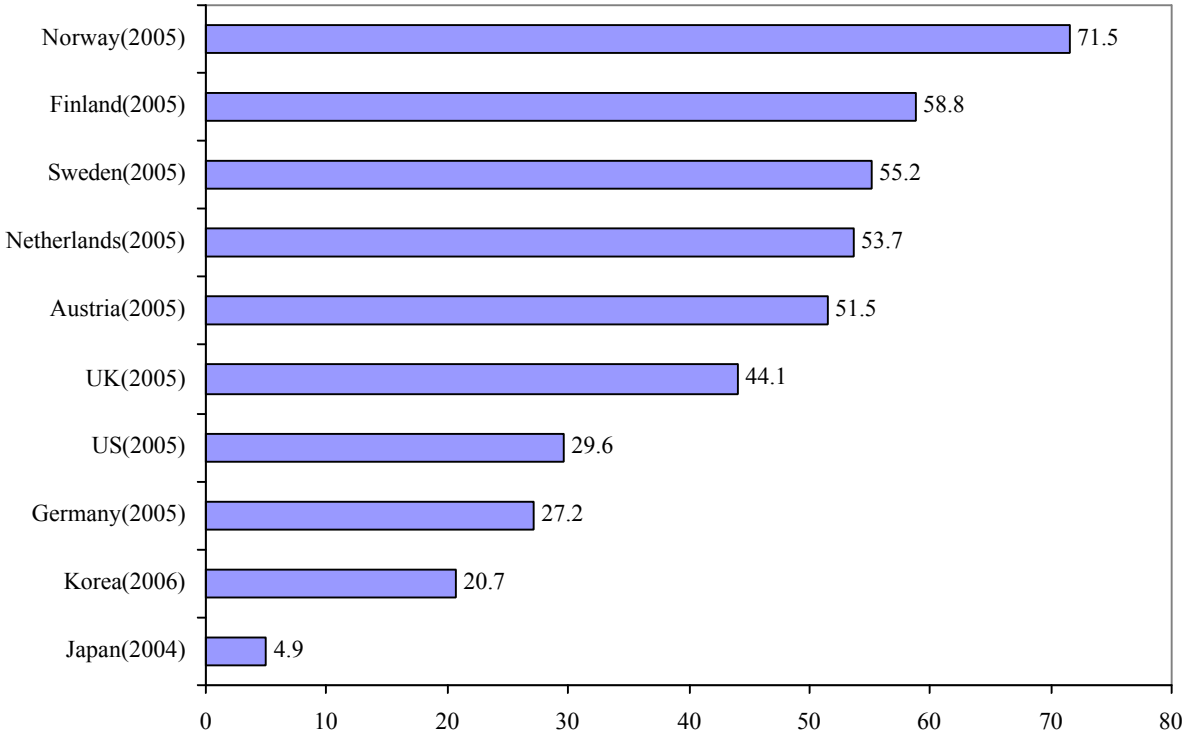


Figure 8-2. **The ratio of ESRD patients with a functioning graft.**

Data ssources: United States Renal Data System (USRDS), 2007 Annual Data Report
Note: The data for Japan is a fraction of cumulative total patients in cumulative total incidence of patients with ESRD

[187] According to the USRDS 1998 Annual Data Report, 41% of the total cases in 1994-1996 were caused by diabetes. The proportion of the cases caused by diabetes in 1996 in Korea was 30.8% (Korean Society of Nephrology 1997). The incidence of ESRD cases stemming from diabetes in the US was 113 pmp in 1996, and 39.6 pmp in Korea (in the same year).

Figure 8-2 shows the ratio of ESRD patients who live with a functioning graft. In Norway, about 80% of the total ESRD patients live with a functioning graft, while only less than 1% of the ESRD patients in Japan do so. The ratio of ESRD patients with a functioning graft in Korea is higher than that in the US, Germany, and Italy, while the adoption of kidney transplantation is the lower than in the aforementioned Western countries in terms of pmp. The proportion of ESRD patients living with functioning grafts is much higher in Norway, Sweden, and the UK, which have traditionally financed health services through a global budget system, with financial resources collected from taxes. As for the ratio of patients living with a functioning graft among the patients taking renal-replacement therapies, Norway, Sweden, and the UK are ranked the highest in descending order.

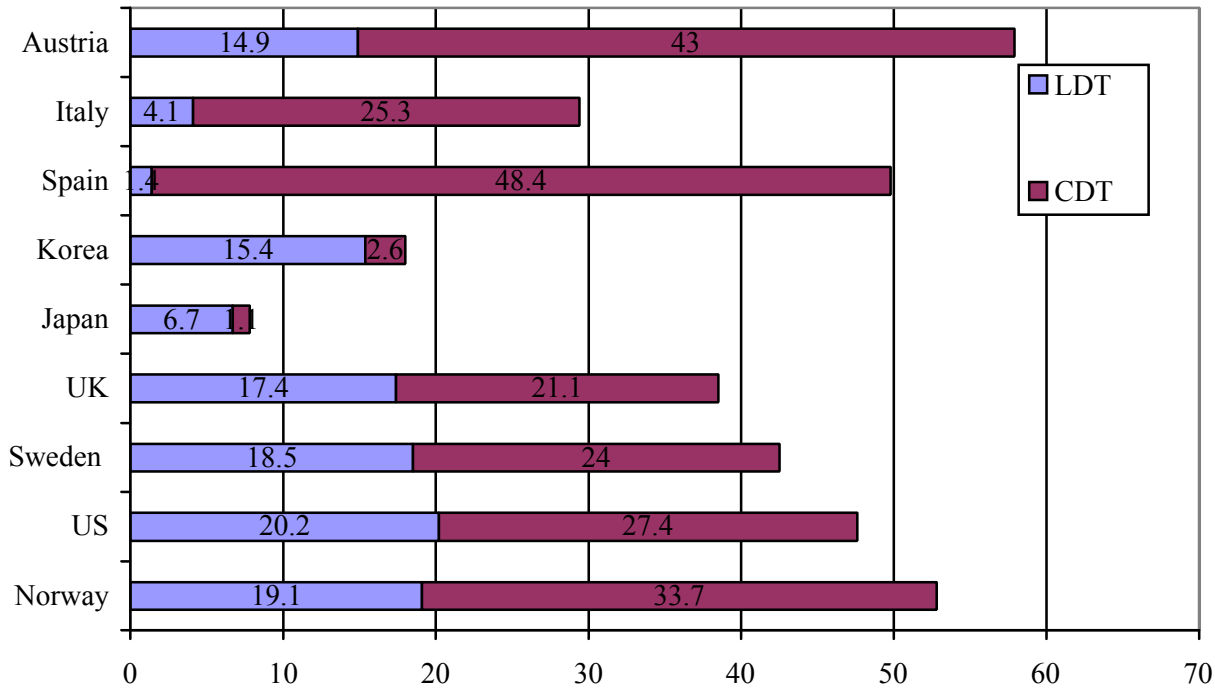


Figure 8-3. Ratio of live-donor and cadaveric-donor kidney transplants (pmp).

Data sources: 1) European Dialysis and Transplant Association (EDTA), Statistical Data 1995

2) ESRD Registry Committee, Korean Society of Nephrology (1997). Current status of renal replacement treatment in Korea. Korean Journal of Nephrology, Vol. 27(10): S459-S481.

3) United States Renal-Data System, 2004 Annual-Data Report

The source of organs for transplantation is also greatly varied from country to country. As shown in *Figure 8-3*, the number of kidney transplants performed with living donors is much higher in the northern regions than in the southern areas in Europe, and is presumably associated with the legislative variations in those areas.[188] The proportion of living-donor transplantation is extraordinarily high in Japan and Korea.

There have been various attempts to meet the organ demand for transplantation purposes, and the approaches that are employed include efforts to increase organ donation from both living and cadaveric donors. There is a consensus to ban commercial trading in human organs for transplantation purposes. As such, the major approaches to meeting the demand for organs have been focused on increasing organ donation from the deceased. These approaches have been imposed in organisational and institutional terms, which are generally put together.

In the UK, the Human Tissue Act of 1961, as amended by the Corneal Tissue Act of 1986, first authorised hospitals to presume that human tissue may be removed for transplantation purposes unless it is known that the deceased or his or her relatives object to such donation. To ensure that there is no financial loss on hospital side that cares potential cadaveric donors and carries out organ procurement, NHS reimburses a £1,000 ad hoc fund to intensive-care units for the care of cadaveric donors.[189]

In the US, the Organ Procurement and Transplantation Network (OPTN) was established by the National Organ Transplant Act (NOTA) of 1984 to increase organ donation for transplantation purposes, to promote efficiency in managing the process of organ procurement and transplantation, and to prevent the wastage of organs.[190] To ensure

---

[188] In Norway, the Transplant, Anatomy, and Organ Donation Act of 1973 permits organ donation from a living person, even from one who is under the age of 18 years, if there is parental or guardian's consent. In Austria, the principle of "presumed consent" plays a significant role in organ transplantation. The law in Austria allows automatic removal, except in situations in which the deceased has expressed an objection to such during his or her lifetime (Bill et al. 1994).

[189] Although the reimbursement policy is not positively accepted by medical professionals since they regard it as unethical and as not contributing in practice to increasing organ donations, the policy itself seeks to increase the number of organs available for transplantation purposes. Beverly Cornforth, Transplant Information Officer for the West Midland, points out that medical professionals regard the reimbursement policy as unfavourable in ethical terms and as not contributing to increasing organ donations (personal communication).

[190] OPTN, now operated by United Organ Sharing Network (UNOS), plays a central role in the whole process of transplantation, such as in organ procurement, allocation, and transplant.

that all potential cadaveric donors can be considered for organ donation, the Omnibus Budget Reconciliation Act of 1986 requires "routine inquiry," which obliges medical professionals to exhort the families and relatives of potential donors to donate their relative's organ for transplantation purposes upon the latter's demise.

The legislation can also promote organ donation from cadaveric donors by authorising organ procurement unless there is evidence that the deceased person objected to donating his or her organ when he or she was still alive. This principle is called "presumed consent." The much higher rate of adoption of organ transplantation in Austria is regarded as primarily resulting from the principle of presumed consent. The Swedish Transplant Act of 1996 also admits the principle of presumed consent.[191]

There have also been great efforts to encourage organ donation from living donors. As the available donors from among family members and relatives are inevitably limited, organ donation from unrelated living donors has been emphasised. The question is whether a donation from an unrelated donor is justifiable. Medical communities strongly support organ donation from unrelated living donors. Based on the results of in-depth studies, Daar and Sells (1990) concluded that "organ donation between non-related individuals who have a demonstrable enduring relationship is permissible."

The Department of Health of the UK has examined the legitimacy of transplantation from unrelated living donors and confirmed that it is perfectly legal in the UK for strangers to serve as organ donors (Salaman 1997). The Human Organ Transplant Act of 1989 regulates transplants from living unrelated donors, while banning commercial dealing in human organs. The Unrelated Live Transplant Regulatory Authority (ULTRA) is a special government agency that authorises organ transplantation from living unrelated donors.[192]

To increase the availability of transplantation from living donors, some organisations that are promoting organ transplantation coordinate a swap of donors among donor

[191] Section 3 of the Act allows any biological material intended for transplantation or some other medical purpose to be taken from a deceased person unless the deceased person objected to such action in writing or spoke against it when he or she was still alive, or, at the very least, if there is some other reason to regard the action as contrary to the deceased person's intentions, based on such evidence as the deceased person's participation in anti-organ-transplant group activities.

[192] In the fiscal year 2003-2004, 100 unrelated-living-donor kidney transplants were performed in the UK (UK Transplant, The Transplant Activity in the UK 2003-2004).

volunteers, mainly from the families of the recipients. By exchanging donors with better histocompatible recipients in the organ-sharing pool, the availability of kidneys for transplantation purposes can be significantly increased relative to the size of the pool sharing and the intention to swap.[193]

To meet the demand for organs for transplantation purposes, market approaches have been considered to increase organ donations (Schwindt and Vining 1986, Rinehart 1988). Arguments in support of commercialism are persuasive in the US (Spurr 1993, Brigid 1996)[194], although rampant commercialism is precisely banned by the laws in most countries and is also condemned by Word Health Organisation (1991).[195] While the laws throughout the world reject, or at least do not accept, the trade of human organs, many cases of commercial dealing have been reported across the world.[196] A review of the many reported episodes involving organ sale may prompt one to conclude that the trade of human organs seems to be flourishing in developing countries, where no systems are in place to prevent it.

---

[193] Of the total of 941 kidney transplants that were performed in Korea in 1996, 16 cases of living-donor transplants were matched by a voluntary organisation, the Organ Donation Action Centre, which coordinates a donor swap programme (personal communication).

[194] Brigid argues that the governmental policy monopolises the organ supply, causing a severe shortage of transplantable organs, as induced by the National Organ Transplantation Act of 1984.

[195] The guiding principles of WHO on human-organ transplantation (1991, EB87.R22) prohibit giving and receiving money, as well as any other commercial dealing in organ donation (Guiding Principle 5). WHO is particularly concerned with the protection of minors and other vulnerable persons from coercion and improper inducement to donate organs (Guiding Principle 4).

[196] On June 23, 1992, BBC2 broadcasted a programme entitled "The Great Organ Bazaar" (quoted from Sells, 1992). According to Sells, 2,900 such cases were reported in the Chinese People's Daily in 1991. The programme reported legalised organ selling in China. The programme organizers learned that the kidneys obtained from executed criminals were being transplanted into paying foreign recipients. The Federal Bureau of Investigation of the US revealed similar stories after they arrested two Chinese men who offered multiple kinds of solid organs for transplantation purposes, which they procured from executed prisoners (Josefson 1998). Josefson also disclosed, as quoted from *China Journal*, that 4,367 people were executed in China in 1996, and that of the 2,000 kidney transplants performed in China that year, up to 15% involved foreigners who supposedly dealt with the executed persons' organs on a commercial basis. It is also well recognised that traffic in organs is customarily settled in India, where living kidney donors are solicited by agents via advertisements (Sells 1992, Reddy et al. 1990).

8.2. Micro Factor Evaluation

8.2.1. Economic Factors

There have been various attempts to verify which approach is more useful in terms of costs vs. benefits. Kidney transplantation is generally accepted as a more cost-effective approach than any other conventional modalities to care for patients with chronic renal failure. Based on the median graft survival time that is 10 years, the cost saving for the patient with functioning graft compared to dialysis is £241,000 or £24,100 per year for each year (UK Transplant Fact Sheet 4).

Table 8-2 **.Cost-effectiveness evaluation of renal replacement modalities (per patient)**

Study	Indicator of evaluation	Discount Rate	Transplant	CAPD	Hospital Dialysis
Klarman et al, 1968, USA (£)	QALY	6%	7,460		12,100
Kontodimopoulos and Niakas, 2008, Greece (€)	QALY	5%	11,981	54,504	60,353
Kaminota, 2001, Japan (¥) (23)	DALY		CAD-2,322 LRD- 1,809		9,546

Note: 1. CAD- cadaveric donor, LRD- living related donor
2. DALY refers Disability Adjusted Life Year

The data in *Table 8-2* give an idea about the cost-effectiveness of each approach in terms of cost per QALY or DALY gained. Haemodialysis in hospital is regarded as the most expensive measure while kidney transplantation is the least costly choice in each study. It should be noted that the evaluation of the cost effectiveness of renal-replacing therapies can vary according to the time and place covered by the research. In addition, the cost of transplantation also greatly varies according to which immunosuppressive regimen the physician employs[197], and according to the other cost structures of the hospitals. The results of studies conducted on the costs and benefits of kidney transplant consistently

[197] According to Abella (24), in a research conducted in Canada, the difference between the cost of the use of Neoral and of Sandimmun was US$772 (US$2,228 vs. 3,000) during 12 weeks of treatment. Sandimun is the brand name of cyclosporine A (CyA), which is produced by Sandoz Pharma. The company also developed Neoral, which is a new microemulsion formulation of CyA that is meant to overcome the problem associated with inconsistent absorption.
Shield and colleagues (1996) found that the cost per year of the graft survival of a kidney transplant with OKT3 was US$30,474, while the cost of the conventional regimen, using CyA, was US$32,687.

indicate that kidney transplant is the most effective treatment modality in economic terms. As reviewed, the results of studies conducted on the costs and benefits of kidney transplant consistently reveal that kidney transplant is the most effective treatment modality in economic terms.

8.2.2. Clinical Factors

QoL among kidney transplant patients is generally higher than those who rely on other treatment modalities. Numerous studies have attempted to prove the changes of QoL based on longitudinal aspects comparing ex ante and post transplant situations. In most studies, patients indicate a better QoL after their transplantation in comparison with treatment with dialysis (Niechzial et al, 1997; Trobojevic and Zivkovic, 1997; Piehlmeier, 1996; Gudex, 1996).

Patients living with functioning graft regard their pre-transplant QoL as much lower than the prospect for post transplantation. Improvements of QoL are observed most significantly in social activities and working ability after transplantation compared with patients in ESRD and those undergoing haemodialysis (Trbojevic and Zivkovic, 1997.

8.2.2.1. Life-saving Effect

Lenisa and colleagues (1995) examined the cost effectiveness of haemodialysis, kidney transplantation, and kidney-pancreas transplantation for diabetic ESRD patients. As shown in *Figure 8-4*, their study indicated that the beneficial effects of both kidney and kidney-pancreas transplantation lasted throughout the lifetime of the patients who underwent them, longer than haemodialysis, which has lower care costs, did. The survival rates of the patients in the haemodialysis group were significantly lower. The survival rate of the haemodialysis patients was 55% at five years, and 94% and 87%, respectively, for the patients who underwent kidney or kidney-pancreas transplantation.

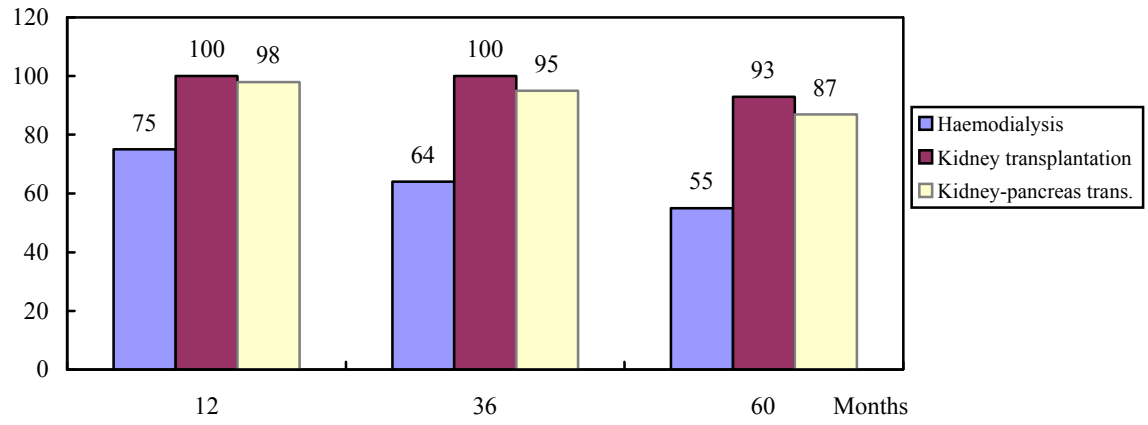


Figure 8-4. **Differences in the patients' survival rates by treatment**

Data Sources: Lenisa et al. (1995)

8.2.2.2. Quality of Life (QoL)

The QoL of kidney transplant patients is generally higher than that of patients who rely on other treatment modalities. Numerous studies have attempted to prove the changes in QoL based on longitudinal factors, comparing ex-ante and post-transplant situations. In most studies, the patients indicate a better QoL after their transplantation in comparison with those who have undergone dialysis (Niechzial et al. 1997, Trobojvic and Zivkovic 1997, Piehlmeier 1996, Gudex 1996).

Patients living with functioning graft regard their pre-transplant QoL as much lower than the prospect for post-transplantation.[198] Improvement in QoL are observed most significantly in the social activities and working ability of the patients who have undergone transplantation than in the ESRD patients and those undergoing haemodialysis (Trbojevic and Zivkovic 1997).[199]

---

[198] In a research done by Adang et al. (1998), QoL prior to transplantation was prospectively given a mean rating of 5.23 on a 10-point scale; this score increased to 7 after successful transplantation. During follow-up assessment at 5, 12, and 18 months after successful transplantation, patients retrospectively scored their pre-transplant QoL as 3.27, 3.14, and 3.05, respectively.

[199] According to the 1997 annual report (20th Annual Report) of the Australia and New Zealand Dialysis and Transplant Registry (ANZDATA), 86% of all the patients with functioning grafts in Australia indicated that they are normal or able to carry out normal activity. Only 49% of all the patients with dialysis scored themselves as normal (12%) or able to carry out normal activity (37%). The patients' recognition of QoL is slightly higher in New Zealand in both groups of patients (91% and 52%, respectively).

8.2.3. Technical Factors

Organ transplant is not an easy choice on the part of both the patients and the surgeons because of organ shortages, high costs, and psychological distress from the fear of graft failure and the loss of one's life. Apart from the costs incurred at the time of transplant and afterwards for immunosuppressive therapies are availed of, organ transplant entails enormous social costs for the management of infrastructure related to organ procurement, the matching between the donors and the recipients, and delivering the harvested organs to the transplant centres.

As for ESRD, kidney transplant is regarded as also offering a technical advantage as patients can save the time they would otherwise spend for dialysis. Whether the patients choose hospital or home dialysis, the modalities take considerable time, and they would be prone to infection if they choose to undergo home dialysis.

As such, it can be concluded that kidney transplant has more technical advantages than any other modality of renal-replacement therapy, while heart and liver transplant are hard to regard as offering technical advantages for the patients.

8.3. Macro Factor Evaluation

8.3.1. Japan

The major events in Japan in relation to organ transplantation are as follows (Transplant Communication 2001):

1956 First kidney transplant
1964 First liver transplant
1968 First heart transplant
1980 Cornea and Kidney Transplant Act came into effect
1983 Study Group for Brain Death was established in the Ministry of Health and Welfare
1984 First heart transplant of a Japanese citizen in the US
1985 Study Group released the Guideline for Brain Death Judgement
1989 First case of partial liver transplant from live donor
1990 Ad Hoc Committee on Brain Death established

1994	Organ Transplant Act was introduced in the House of Commons
1995	Japan Kidney Transplant Network established
1996	Amended Organ Transplant Act was introduced in the House of Commons
1997	Organ Transplant Act came into effect
	Japan Organ Transplant Network (JOTNW) established (extended from Japan Kidney Transplant Network)
1999	First legal organ transplants (heart, liver, kidney and cornea) from brain death donor

Regarding organ transplantation from cadaveric donors, a brain death bill came into effect in Japan at the end of 1997 after a debate that lasted for 30 years. In Japan, early transplantation attempts using organs from cadaveric donors were strongly condemned by the public and even by medical communities. The first case of heart transplant was performed in Japan in 1968, when there was neither an accepted guideline on brain stem death nor a law authorising organ transplant from cadaveric donors. Moreover, there was no consensus among medical professionals regarding transplantation using organs from cadaveric donors. Such practice sparked mistrust in physicians strong enough to impede the development of brain death criteria by medical professionals (Feldman 1994).

The second attempt, which was made in 1984 with an allegedly mentally incompetent cadaveric donor, spurred official involvement in brain death issues and organ transplantation using organs from deceased persons. Two months after the controversial transplants were carried out, the Life Ethics Problem Study Parliamentarians League was formed, with professionals and officials as members.

MHLW organised the Brain Death Advisory Council, and the Council declared the criteria for brain death in December 1985. In 1988, an investigative team of the Liberal Democratic Party (LDP) recommended the establishment of the Ad Hoc Committee on Brain Death and Organ Transplantation as a consulting body to the Prime Minister. In January 1992, the Ad Hoc Committee on Brain Death and Organ Transplantation submitted a final report that defined brain death as being equivalent to the conventional concept of death.

In 1994, the draft of a law on human-organ transplants using organs of brain-dead persons was proposed. The enactment was voted into a law in 1996, and the legislation was enacted on October 16, 1997. Meanwhile, JOTNW was established in 1995. Currently, organ procurement and distribution is managed by JKTNW as a single entity. The nationwide network consists of seven regional blocks. The scope of JKTNW was extended to cover all organ transplants in October 1997, and the Japan Organ Transplant Network (JOTNW) was launched as a corporation aggregate. To promote organ donation from potential brain stem death donors, JOTNW made donor cards available at city halls, public health centres, post offices, and driving test centres across the country.

There was considerable controversy surrounding the first case of brain death organ transplantation. Although the public attitudes on the use of organs of deceased persons in transplantation appear to be positive[200], there are practical impediments to organ transplantations using organs from cadaveric donors. First, although the opinion poll suggested positive views on the transplantation of an organ from a deceased person, the will to donate an organ when they become potential donors was weak.[201] Second, the law limits harvesting organs from a deceased person if his or her relatives object to such, even when the deceased left consent (Hiraga 2000).[202]

The cost information in Japan for the treatment of renal failure is summarised in *Table 8-3*. The costs of kidney and liver transplantation have been covered by public health insurance since 1978. The insurance programme also covers the overall care following the operation, at an approximate cost of £7,800-£10,500 a year after the transplantation. Since kidney transplantation is categorised as an "advance medical technology (AMT)," the public health plan shoulders its overall cost in excess of £332 (¥63,600). Patients who are

[200] According to a Minichi Daily News poll, 74% of the public had a positive view of organ transplants conducted from the first brain-dead donor (Minichi Daily News, May 13, 1999).

[201] According to the survey by Home Office of the Japanese government, 35.4% of the respondents indicated they would not donate while 32.6% of them responded they would donate if they were in a brain death state (Asahi Newpaper, August 26, 2000- The result of a survey on the attitudes towards organ donation).

[202] By law, nobody younger than 16 years old can donate organs, and children younger than six may not receive them. Relatives have the power to veto organ donation even though the deceased person left written documents for organ donation.

According to the survey by the Home Office, 69.9% responded that consent from both the potential donor and relatives is required. 20.6% responded it would be acceptable to donate through the consent of the potential donor only. Very few respondents (2.1%) accepted donation through the consent of relatives only.

taking dialysis therapy that is fully subsidised by public funds are regarded as disabled, according to the Disabled Act.

Table 8-3. **Cost comparison by treatment**

Kidney transplant	one month after transplantation, including surgical costs	£12,500	£29,000 for the first year
	up to two years	£520-£780/month	£6,200-£9400
Hospital dialysis		£2,700/month	£31,300/year
CAPD		£2,660/month	£31,000/year

Data sources: Transplant Communication No. 4

In summary, organ transplantation, particularly from cadaveric donors, has not been accepted in Japan because the early attempts to gain public support failed even within the medical community. Although the Organ Transplantation Act came into effect more than 30 years after the first attempt of transplantation using an organ from a cadaveric donor was made, the public attitude towards the donation of an organ from the deceased is still largely negative.

Public insurance programmes cover the overall cost of kidney transplantation, and the patients who avail of dialysis therapy receive full support for their dialysis treatment through the latter's full subsidy by public funds.

8.3.2. Korea

There have been long debates on brain death in Korea. The Korean Society of Nephrology, the Korean Society of Transplantation, and the Seoul National University Hospital initiated public debates on cadaveric transplants in March 1988, when a proposal requiring brain stem death legislation was conjointly issued to the Korean Medical Association.[203]

[203] In October 1988, the Korean Medical Association held public hearings on brain stem death and proposed that the Korean government legalise brain stem death after achieving a consensus on the definition of death and on the criteria for brain stem death among medical professionals.

The first case of cadaveric-kidney transplant was performed on January 25, 1990. Since then, the public concern regarding kidney transplant has flourished. The first successful transplant case motivated medical professionals to rush into the practice of cadaveric-organ transplant. Seoul National University Hospital's issuance of brain stem death criteria on December 2, 1992 spurred debates on brain stem death. Subsequently, the Korean Medical Association released its Decree on Brain Death on March 4, 1993. Since then, most teaching hospitals carrying out organ transplantation set transplant coordinators in place to enhance integrated collaboration among the transplant teams within the hospital. Transplant coordinators also cooperate with the transplant teams in other hospitals, and with voluntary organisations, in terms of organ procurement and delivery.

The Ministry of Health and Welfare (referred to at that time as *Ministry of Health and Social Affairs*) asked the Korean Medical Association to study brain stem death in response to the proposal submitted by the Korean Medical Association, and as a reaction to the first successful cadaveric-kidney transplant case. Debates on brain stem death among the public have also become fiercer, as organ procurement from the deceased is strongly opposed by the Academy of Confucianism.[204] The Academy of Confucianism strongly stands against brain stem death and cadaveric-organ transplant as the philosophy of Confucianism regards any hurt or harm inflicted on a person's body as an act of impiety against his or her parents.

Although there was significant resistance against cadaveric-organ transplantation, the legal basis for the use of organs procured from cadaveric donors was introduced in 1995. The Cadaver Anatomy and Preservation Act of 1995 authorised the use of tissue and organs from the deceased for the purpose of research and treatment.[205] The Act authorised the use

---

[204] The Academy of Confucianism is centred on "Sung Kyun Kwan," which has been a centre of Confucianism tradition in Korea. Sung Kyun Kwan was established more than 600 years ago. There are a number of Confucian schools, though, that are independent institutes. The Academy of Confucianism, which represents all Confucian schools in the country, has a significant influence on legislation related to cultural traditions, such as the Family Law.

[205] Tissue and organs can be used, and authorisation should be given by the family of the deceased person (Section 4). It is not necessary to obtain the permission of the family in the following circumstances:

- when the deceased person has agreed to the matter in writing;
- when no family or relative has appeared to take over the cadaver for more than 60 days after the person's death; and
- when all the physicians, at least two, who have been in charge of the treatment of the deceased person agree that there is a particular reason to carry out an anatomical procedure to identify the cause of death of the deceased person (Article 3).

This article is premised on the fact that an anatomical procedure must be immediately carried out, but that it is impossible to find the family to obtain permission from them.

of human organs and tissues with the consent of the deceased person's family or relatives, and thereby legalised cadaveric-organ transplantation. Before the law was enacted, organ transplantation had been performed under an implicit consensus accepting that the results of organ transplantation are desirable for individual patients and for the society as a whole insofar as it does not cause any harm to the persons who donate organs.

Under this tacit consensus, public authorities had never been involved in organ transplant activities until police arrested a group of brokers, even though several episodes of commercial dealing in human organs had been revealed by the media. In August 1997, the government submitted a draft of the Organ Transplant Act to the Parliament, and the Act came into effect in January 2000. The Act admitted brain stem death and legalised organ transplant from cadaveric donors.

Meanwhile, the Ministry of Health and Welfare established the Organ Transplantation Information Centre (OTIC) in the National Medical Centre in July 1998.

The primary role of OTIC is to coordinate between organ transplant centres and voluntary organisations promoting and managing registries in their own organisations. The government's intention in establishing OTIC was to put up a single network throughout the country that could match organ donors and recipients based on a single list.

As there was remarkable opposition from existing non-governmental organisations (NGOs) involved in donor recruitment and matching that were reluctant to give up their roles, OTIC was unable to centralise the functions of matching patients with donors and of registering volunteer organ donors. There were six active NGOs involved in the promotion of organ donation and in the registration of organ donors then. Some of them specialised in certain organs while others dealt with all kind of organs, including those from cadaveric donors and from living donors, as well as cadavers, and provided the latter to medical schools for research purposes .

As the Organ Transplant Act came into effect, the Korean Network for Organ Sharing (KONOS) took over the role of OTIC as a national authority responsible for: (1) matching recipients and donors; (2) authorising organ transplant; and (3) managing the data regarding organ transplants. KONOS is commissioned to prevent commercial organ dealing, manage the fair distribution of organs for transplantation purposes, and foster organ transplant activities to save those patients with irreversible organ failure.

So far, KONOS's role of centralising organ transplant activities related to the management of donors, and of matching donors with recipients, has not yet been properly settled. Some NGOs still hold tenaciously to their role of matching and registering donors.

Regarding the funding for kidney transplantation, the costs are remunerated by the public health insurance programme based on a fee-for-service scheme in Korea. Since the insurance scheme was gradually expanded, the scheme's growth might have a significant influence on the adoption of kidney transplantation in the country.[206] Although public health insurance covers the costs, the patient should still pay about £11,000, including the costs incurred for donor-patient matching.

In addition to the legal and reimbursement system, there were several events that influenced the adoption of kidney transplantation in Korea. First, brokerage was promoted as the mass media frequently debated on brain stem death and condemned commercial dealings in human organs. Although the intention of the media was to give a warning regarding brokerage, the profuse media attention ended up boosting commercial dealings in human organs in the country in the late 1980s.

To tackle the serious problem of kidney sales from living donors, Yonsei Medical Centre's Severance Hospital[207] voluntarily launched a programme in December 1991, in which it scrutinised the recipient-donor relationship and tried to determine whether a kidney donation is motivated by a commercial purpose. The programme confirms recipients and donors only if the "Screening Committee," of which the Department of Social Services is in charge, deems that the case does not involve commercial dealing. The programme diffused into other hospitals, and the programme had spread throughout most of the country's teaching hospitals by the end of 1993. Reflecting on the voluntary activities in the hospitals, the police investigated brokerage in organ trafficking. As a result of its efforts,

[206] A social insurance scheme for health services was launched as a compulsory programme in July 1977, covering wage earners and their dependants in firms with 500 employees or more. The scheme covered 8.6% of the total population in the first wave of social insurance in Korea (Shin and Lee 1997). In 1979, the insurance scheme was expanded to include public-sector employees and employees in private schools and universities. In the same year, the scheme was also expanded to include employees in firms with 300 employees or more. As a result, by 1979, the health insurance scheme had covered 37.3% of the total population. The scheme continued to expand, covering employees in smaller firms as well as those who were self-employed. By July 1988, the employees in firms with five employees or more were required to join the health insurance scheme. By 1988, the insurance scheme had covered 45.5% of the total population, and by July 1989, it had been expanded to include the whole population of Korea.

[207] A leading figure in the field of kidney transplantation in Korea, Severance Hospital has performed more than one-third of the total kidney transplants in the country.

the police arrested a cohort of brokers in February 1994. The screening procedure is routinely required for all living-donor transplantation cases, including transplantations using organ donations from families and relatives, by the amended Organ Transplantation Act of 2001.

NGOs also played a significant role in matching patients with donors. Particularly, an agency named "Korean Organ & Tissue Donation Programme (KOTDP)" started a relevant programme in 1991. KOTDP operates a donor swap programme, which exchanges donors in the donor-sharing pool to ensure the high quality of HLA matching. As there were many patients for whom it is impossible to secure an organ for transplant purposes despite the existence of willing donors, the KOTDP launched this programme. In principle, a patient is required to bring one donor in order to be matched with a suitable donor.[208]

8.3.3. UK

Organ transplantation in the UK was initially authorised by the Human Tissue Act of 1961, as superseded by the Corneal Grafting Act 1952. A special health authority, the United Kingdom Transplant Service Support Authority (UKTSSA), was established in 1968 to coordinate transplantation activities. UKTSSA holds information on the recipient candidates and the possible organ donors, provides organ-matching and tissue-typing services, and can also arrange for the transport of organs for transplantation. The Authority was originally established in 1991 as the UK Transplant Support Service Authority (UKTSSA), which was the only special health authority in the UK In July 2000, UK Transplant was formed, with the new, extended mandate of increasing the organ donation rates.

The Human Tissue Act of 1961, as amended by the Corneal Tissue Act of 1986, sets out the condition in which cadaveric donations shall be legal. After a public scandal over the sale of organs for transplantation in a private hospital in London in 1988, the Human Organ Transplant Act was enacted in 1989. The Act bans commercial dealings in human

[208] Since KOTDP does not restrict the donor within the bloodline family, the possibility of commercial dealing involved still exists in the donor swap programme of KOTDP. The chances that commercial purposes can be involved, however, are very low because social workers in KOTDP scrutinise the relationship between the patients and the donors they have brought with them if money is involved in such relationship.

organs and creates a number of offences related to this, among these being that an offence is committed by any person who pays or accepts payment for the supply of an organ intended for transplantation. It does not matter whether money changes hands before or after the organ is removed. The Act regards transplantation taking place outside the UK as an offence if there is any commercial dealing involved in it. Brokers of organs involved in organ dealing are also committing a criminal offence. According to the law, the Unrelated Live Transplant Regulatory Authority (ULTRA) assesses unrelated living donors if they intend to get monetary rewards for their organ donation.

The Act penalises all of those involved in commercial transactions related to organs for transplantation. Organ transplant activities in the UK are managed by UK Transplant. As a public health authority, UK Transplant manages all the donors and recipients in the UK, and its services also cover the Republic of Ireland. The major task of UK Transplant is as follows:

- management of the organ donor register;
- matching and allocation of organs for transplantation;
- maintenance of the database for all patients waiting for an organ donation;
- maintenance of a comprehensive database that includes the clinical data regarding the transplant recipients, their donors, and the outcomes of the graft; and
- analysis and audit of all organ transplants.

The National Organ Donor Register was launched on October 6, 1994 as a computerised database of potential organ donors, including information on people who wish to donate their organs when they die. As of February 1997, about four million people were on the register. The number of individuals on the NHS Organ Donation Register (ODR) registration list has increased to 11.2 million at the end of fiscal year 2003-2004. Majority of the new registrants continue to come from driving license applications and reminders through the Driver and Vehicle Licensing Agency (DVLA), from the General Practitioner registration, and through applications for a Boots Advantage Card (UK Transplant, Transplant Activities in the UK 2003-2004).

In pursuit of fair and effective matching of the donor and the recipient, the Tissue-typing Reference Laboratories of UK Transplant also serve laboratories associated with transplantation in the UK and the Republic of Ireland. Some transplant units' tissue-typing laboratories in the UK are linked with the computer systems of the UK Transplant is a network system, called the UK National Transplant Network (UKNTN). Through an onsite PC linked with UKNTN, transplant units can send patient registration and follow-up data to update the national transplant database.

While organ transplants from cadaveric donors and related living donors are directly managed by UK Transplant, those from unrelated living donors are carried out after receiving permission from the Unrelated Living Transplant Regulatory Authority (ULTRA), having confirmed that no payment is involved.

There are a number of voluntary charity organisations that promote organ donation. Transplants in Mind (TIME), which was founded in 1990 and has 27 member organisations, including the British Organ Donor Society (BODY) and The Kidney Foundation, plays the role of an umbrella organisation for charities with an interest in promoting organ donation. As a part of its activities, TIME organises and coordinates the British Transplant Games (BTG), which were launched in 1978 and are held annually, in July. BTG aims at catching the attention of the public and media. Combined with BTG, every year the Torch Relay links the previous venue to the current year's venue.

8.3.4. US

Regulatory development related to organ transplant in the US has a long history, and there have been various events related to organ transplantation. As it is difficult to describe these events in detail, this section attempts to summarise the major events, as follows (Sloan et al. and Schuck 1989, Childress 1989, Rettig 1989):

- 1968 - the Uniform Anatomical Gift Act of 1968 approved the use of organs from brain-dead donors
- 1970 - the "brain death" legislation in Kansas became the first state to enact "brain death" legislation
- 1972 - through the Social Security Amendments, Medicare started to provide benefits for patients with ESRD, including kidney transplantation;

the Medicare programme covers immunosuppressive therapies after kidney transplants for one year

- 1974 – the National Health Planning and Resources Development Act applied for a Certificate-of-Need (CON) of the system (regionalism in organ transplants)
- 1976 – the Southeast Organ Procurement Foundation (SEOPF) organised the acquisition and sharing of organs among transplant centres

- 1978 – through the Social Security Amendments, Medicare coverage was extended to include immunosuppressive therapies from one to three years
- 1979 – the Medicare coverage for the heart was limited to the transplantation procedures performed by Dr. Shumway at Stanford University
- 1984 - the National Organ Transplant Act (NOTA) established the Organ Procurement and Transplantation Network (OPTN) and prohibited commercial dealing in human organs
- 1986 – the United Network for Organ Sharing (UNOS) was awarded a contract to operate OPTN
- 1986 – the Omnibus Budget Reconciliation Act required membership in OPTN for all transplant hospitals, for organ procurement and routine inquiries(required request)[209], and for potential cadaveric donors
- 1986 – it was indicated in the Report of the Task Force on Organs that organs and tissues ought to be distributed on the basis of objective criteria and not on the basis of accidents of geography
- 1986 - Federal Register 37164 was established to expand the Medicare coverage to include heart transplants for limited beneficiaries and that are performed in limited centres that meet the specific criteria

[209] In response to the organ shortage, Arthur Caplan (1984) suggested a "required request" approach to increase organ donation. The rapid spread of the "required request" approach indicates that it has been strongly endorsed by majority of the US states (Anderson and Fox 1988).[209] The Omnibus Budget Reconciliation Act of 1986, which came into effect in November 1987, made procurement organisations contingent upon the establishment of a required-request protocol, to be reimbursed by the Medicare/Medicaid fund (Culpepper 1996).

- 1987 - the Catastrophic Health Insurance Act of 1987 authorised Medicare reimbursement for outpatient-based immunosuppressive therapies
- 1987 – the Amendment to the Uniform Anatomical Gifts Act simplified the process of organ donation and endorsed the right of individuals aged beyond 18 years, of their families, and their guardians (by extension) to make a decision regarding organ donation
- 1987 – through Federal Register 10935, HCFA formally rescinded its rule that barred heart transplant from coverage as a medically reasonable and necessary service
- 1988 – the Amendment to NOTAprovided for the fair allocation of organs for transplantation purposes
- 1990 – the Amendment to NOTAprovided for the equitable distribution of organs among patients nationwide who need transplantation
- 1990 - when OPTN was inspected by the Office of the Inspector General, the latter pointed out that organ distribution remains confined primarily to the individual service area of the OPOs, and as such, does not meet the expectations
- 1990 - the Patient Self-Determination Act was created to enhance patient awareness of organ donation through the issuance of advance directives
- 1997 – the National Organ and Tissue Donor Initiative (NOTDI) was organized to increase consent to donation and to ensure that the families of cadaveric donors are asked to donate their deceased relative's organs

The following paragraphs describe the major events in greater detail. In the US, organ transplantation was initially authorised by the Uniform Anatomical Gift Act of 1968, which legitimised the use of organs from the deceased. The Social Security Amendments of 1972 admitted all ESRD patients as Medicare beneficiaries by categorising them as disabled.

In October 1984, the US Congress passed the National Organ Transplant Act (NOTA). The law marked a historical turning point in the organ transplantation activities in the US by introducing the Task Force on Organ Procurement and Transplantation and the Organ Procurement and Transplantation Network (OPTN). The Act also clearly proclaimed anti-

commercialism in organ transplantation. Before this Act was passed, there was no specific regulation forbidding commercial trading in human organs.

In 1986, the newly passed Omnibus Budget Reconciliation Act of 1986 was introduced, which mandated that all organisations involved in organ procurement and transplantation be members of OPTN[210], and that unless a hospital is a member of OPTN and abides by its rules and requirements, Medicare and Medicaid programmes that are the primary payers of organ transplantation[211] will not reimburse the costs incurred for such procedure.

In the US, organ transplant activities are performed within the centralised Organ Procurement and Transplant Network (OPTN). The United Network for Organ Sharing, a non-profit company, was awarded the federal contract in 1986 to establish and operate OPTN. The Department of Health and Human Service (DHHS) of the US government renews the contract every three years.

The Omnibus Budget Reconciliation Act of 1986 also has a significant role in the history of organ transplants in the US. The Act obliges medical professionals to ask all potential organ donors if they have an intention to donate their organs. This obligation has been termed "required request" or "routine inquiry." The NOTA Amendment of 1988 proclaimed the fair allocation of organs for transplantation, and the 1990 Amendment to NOTA required the equitable nationwide distribution of organs among patients who need organ transplantation.

On December 15, 1997, the US Vice President announced a series of new US government initiatives to increase organ donation, and launched the new National Organ and Tissue Donation Initiative (NOTDI). The Clinton Administration's new NOTDI seeks to achieve a substantial increase in organ donation and transplantation (DHHS, 1997 Federal Register, December 19, 1997: 66745-48).[212]

---

[210] The Omnibus Budget Reconciliation Act added Section 1138 to the Social Security Act, which obliges hospitals to be members of OPTN to be able to perform organ transplantation. OPTN is a central organisation that performs a variety of functions under a contract with DHHS of the US government. OPTN is a non-governmental organisation that is responsible for the procurement and allocation of organs for transplantation.

[211] Since 1993, Medicare and Medicaid have reimbursed 93% of the total cost of transplants (HCFA 1996).

[212] The new NOTDI seeks to improve the collaborative organ donation process, specifically between hospitals and OPOs, and to increase organ donation (Federal Register, December 19, 1997: 66745-48). According to DHHS (1998), the primary goal of NOTDI is to increase the consent to organ donation. To increase the families' willingness to consent to organ donation, NOTDI encourages all citizens to make a

The Beneficiary Improvements and Protection Act (BIPA, or Public Law 106-554) provides a significant enhancement in Medicare coverage for immunosuppressive medications needed by a transplant recipient (HRSA 2001). It started extending coverage for the transplant recipient for life on December 21, 2001, whereas it previously extended coverage for the transplant recipient only for 36 months.

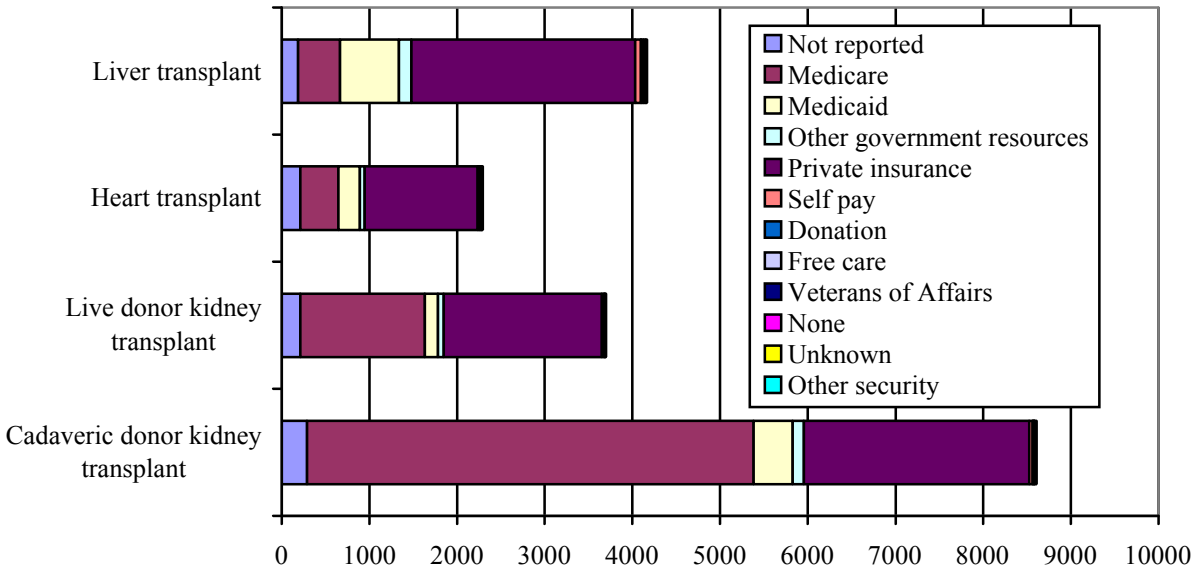


Figure 8-5. **Primary sources of payments for organ transplantation in 1997**

Data Sources: UNOS (personal communication, unpublished)

As shown in *Figure 8-5*, the primary source of payment for transplants is greatly varied. Although the Medicare programme covers the cost of all kidney transplants, private insurance programmes finance a large proportion of such transplants. In 1997, the Medicare programme covered 59.1% of all cadaveric-donor kidney transplants in the country, and 38.35% of all living-donor kidney transplants. In the case of living-donor kidney transplants, private insurance programmes covered 48.7% of the total cost. For other organ transplants, private insurance programmes have shouldered a large part of the total cost:

---

personal decision and to share that decision with their families through a nationwide campaign with the message "Organ and Tissue Donation: Share Your Life, Share Your Decision.[SM]"
NOTDI also enjoins hospitals and health professionals to expedite their identification of deaths that could result in organ donation, and to ensure the referral of identified potential donors to the OPOs in their region.

61.9% for liver transplants and 56.2% for heart transplants. The Medicare programme shouldered 11.5% and 19% of the costs, respectively, of liver and heart transplants in 1997.

8.4. The Adoption of Kidney Transplantation

8.4.1. Japan

In Japan, there were 264,473 patients with renal failure at the end of 2006 (Japanese Society for Dialysis Therapy 2006). As shown in *Figure 8-6,* the number of patients with chronic renal failure who require dialysis or transplant increases every year. During 2006, 21,034 patients died of CRF.

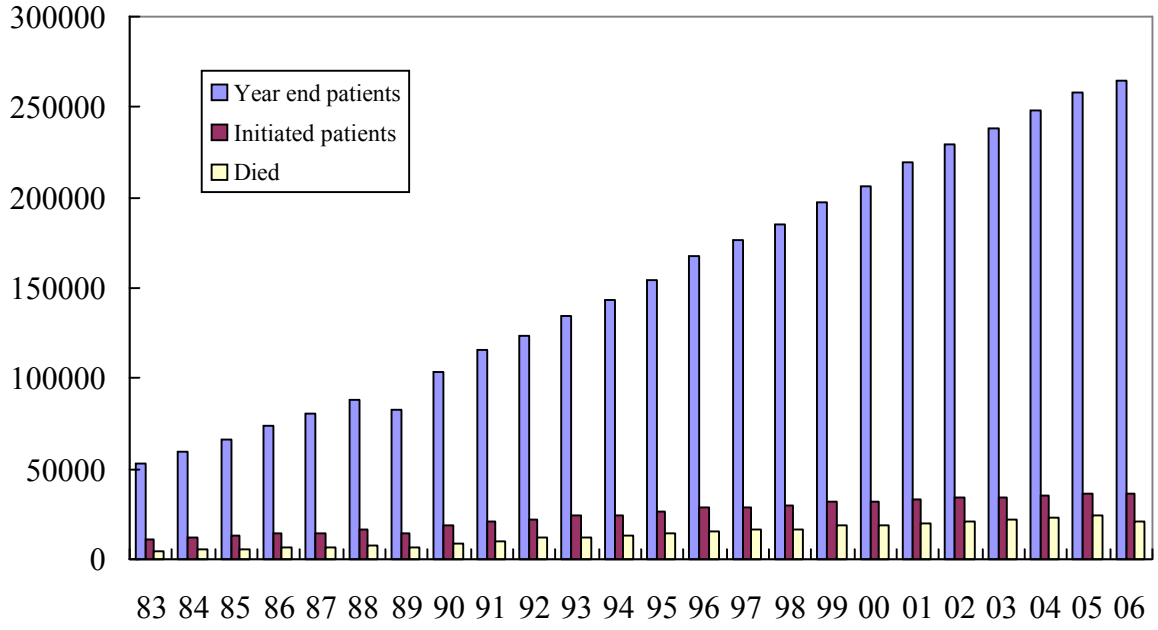


Figure 8-6. **The number of patients living with dialysis therapy (in pmp) (1983-2006)**

Data sources: Japanese Society for Dialysis Therapy (2008)

As summarised in the above section, there have been some major turning points in the history of organ transplantation in Japan. Since 1980, when the Cornea and Kidney Transplant Act was passed, the number of kidney transplant procedures rapidly increased until 1984. During that time, a new immunosuppressant, Cyclosporine A, was introduced in Japan. When the Ministry of Health and Welfare declared the brain death criteria in 1985 (the Takewochi Criteria), the number of kidney transplants both from living and cadaveric

donors rose remarkably until the end of the 1980s. In 1990, the Ad Hoc Committee on Brain Death was organised to draw up brain death criteria, and the committee submitted a final report to the Ministry of Health and Welfare in 1992, where it defined brain death.

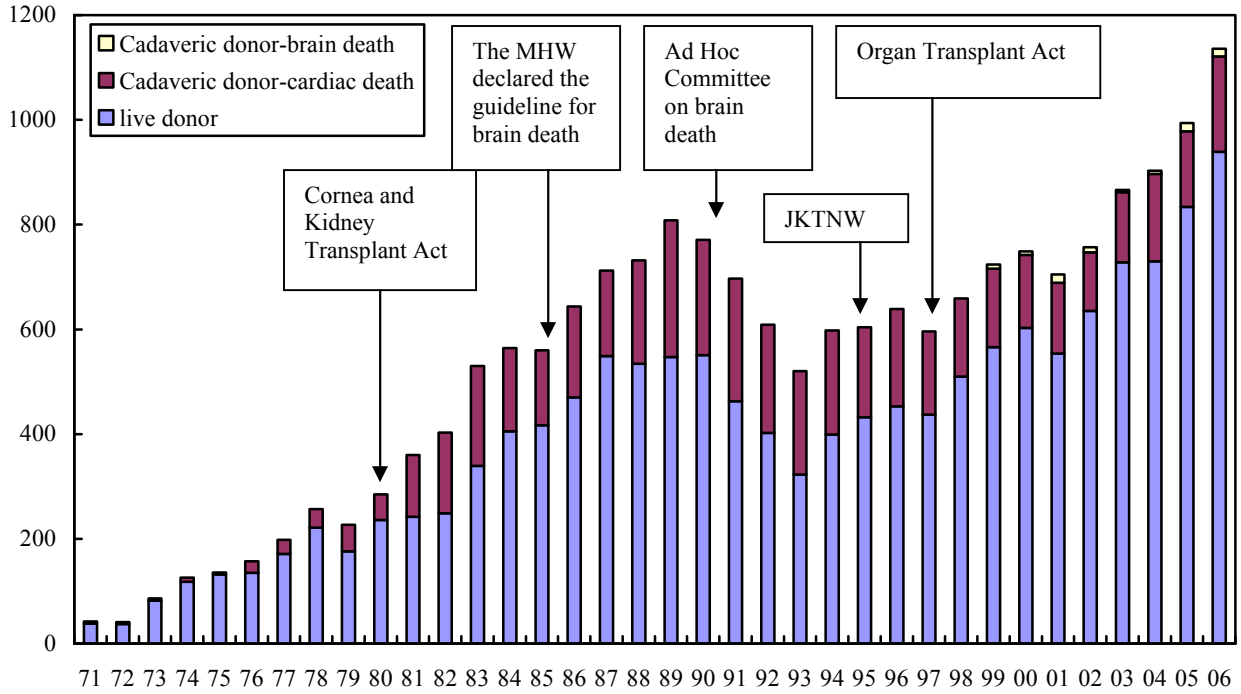


Figure 8-7. **The number of kidney transplants performed (1971-2006)**

Data Sources: 1) Japan Organ Transplant Society, http://www.medi-net.or.jp/tcnet/JST/fact_06/fact06_03.html accessed on 30 March 2008
2) Cosmos Charity Fund for Organ Transplantation, http://cosmoskikin.org/jinzou.html accessed 30 March 2008

As shown in *Figure 8-7*, since 1990, the number of kidney transplants with living donors quickly decreased in the circumstance accepting brain death following the establishment of the Ad Hoc Committee on Brain Death in 1990.

A controversial phenomenon is the increase in the number of kidney transplants performed using kidney donations from living donors, and the decrease in the number of kidney transplants performed using kidney donations from cadaveric donors, following the passage of the Organ Transplant Act of 1997. Patients who might have been expected to receive organ donations from cadaveric donors became more likely to receive organs from

living donors. Contrary to expectations, the enactment of a law authorising organ transplantation from brain-dead donors was delayed because medical professionals hesitated to perform organ transplantation using organs from deceased persons. Although the Organ Transplant Act regularised brain death and transplantation using organs from cadaveric donors, there was no attempt to carry out organ transplantation with cadaveric donor until February 1999.

In Japan, considerable controversy surrounded the first case of brain death organ transplantation. Although public attitudes on the use of organs of deceased persons in transplantation appear to be positive, there are practical impediments to organ transplantations using organs from cadaveric donors. First, although opinion polls suggested positive views on the transplantation of an organ from a deceased person (Minichi Daily News, 13 May 1999), the preparedness to donate an organ when they become potential donors was weak (Asahi Newspaper, 26 August 2000). Second, the law limited harvesting organs from a deceased person if his or her relatives objected, even when the deceased left consent (Higara et al 2000).

Table 8-4. **Kidney transplants by donor types**

Year	Cadaveric donor	Living donor				Total
		Blood line	Non-blood line	Unknown	Sub-total	
~1970	37	131	43 (24.7%)*		174	
~1994	2,724	6,796	241 (3.4%)	20	7,057	9,801
1983~1997	2,649	5,511	249 (4.3%)		5,760	8,918
1998	143	430	35 (7.4%)	5	470	613
2000	146	517	68 (11.3%)	15	600	746

Data sources: 1) Japanese Society for Dialysis Therapy. An overview of regular dialysis treatment in Japan as of Dec. 31, 2006. http://docs.jsdt.or.jp/overview/ppt/jsdt2006.ppt accessed 28 April 2008

2) Japan Organ Transplant Society, http://www.medi-net.or.jp/tcnet/JST/fact_06/fact06_03.html accessed on 30 March 2008

3) Cosmos Charity Fund for Organ Transplantation, http://cosmoskikin.org/jinzou.html accessed 30 March 2008

4) The Japan Society for Transplantation (2001). Results from 1999 follow-up survey. The Japanese Journal of Transplantation, Vol. 36(2): 91-105. [Japanese]

Note: the number in the blank refers the reference for the data source

* The percentage refers the fraction of unrelated among total living donors.

Table 8-4 indicates the number of non-blood line donor transplants in Japan. Most of non-blood line donors were spouses. According to The Japan Society for Transplantation (The Japan Socisty for Transplantation 2001), all 43 non-blood line donors were spouses up to 1970. Among 68 non-blood line donors in 2000, 50 were spouses. Another report (Mori 1992) indicated that almost all non-blood line donors were related relatives like mother's sister or relatives outside the guideline suggested by Japan Transplantation Society. Accordingly, unrelated donor transplants were very few in Japan. As Haruki reported (Hiruki 2004), however, there might be cases involving commercial dealing. The brokerage in matching donor and recipient has never been reported and only a small number of cases were allegedly involved in commercial dealing.

8.4.2. Korea

By the end of 2006, 16,324 kidney transplants had been carried out in Korea since the first successful case was transplanted in 1969. Among them, living donor transplants, 14,195 cases dominated (87%) with cadaveric donor transplants amounting to 2,129 cases (13% of total).

As shown in Figure 3, there were significant increases in 1979 and from 1984 through 1992. The increase was highest in 1989 with big decreases in 1993 and 1994. The primary base for the take-up since 1984 is due to the adoption of cyclosporine A. One of the remarkable changes since 1991 is the increase of cadaveric donor transplant from 1991 through 1999. Following the introduction of Organ Transplantation Act in 2000, both living and cadaveric donor kidney transplants decreased with a significant drop in the donation from the deceased. The increases in 1979 and 1989 can be attributed to the expansion of the insurance coverage with historical events of commencement of health insurance programme based on social insurance system on 1979 and coverage of full population on 1989. The increase in 1992 was largely related to the involvement of non-governmental organizations (NGOs) in the matter, including Korean Organ & Tissue Donor Programme (KOTDP) launched in 1991. These were actively involved in the task of matching the patients with the volunteer donors. In this vein, KOTDP operated a donor swap programme,

which exchanged donors in the donor-sharing pool to ensure the high quality of HLA matching. The live donor exchange programme is an established method to resolve donor shortage in Korea. As an example, of total 411 living donor kidney transplants in Hanyang University Hospital between January 1991 and December 1997, 61 patients received grafts from exchange donors that were equivalent to 14.4% (Kwak et al 1999).

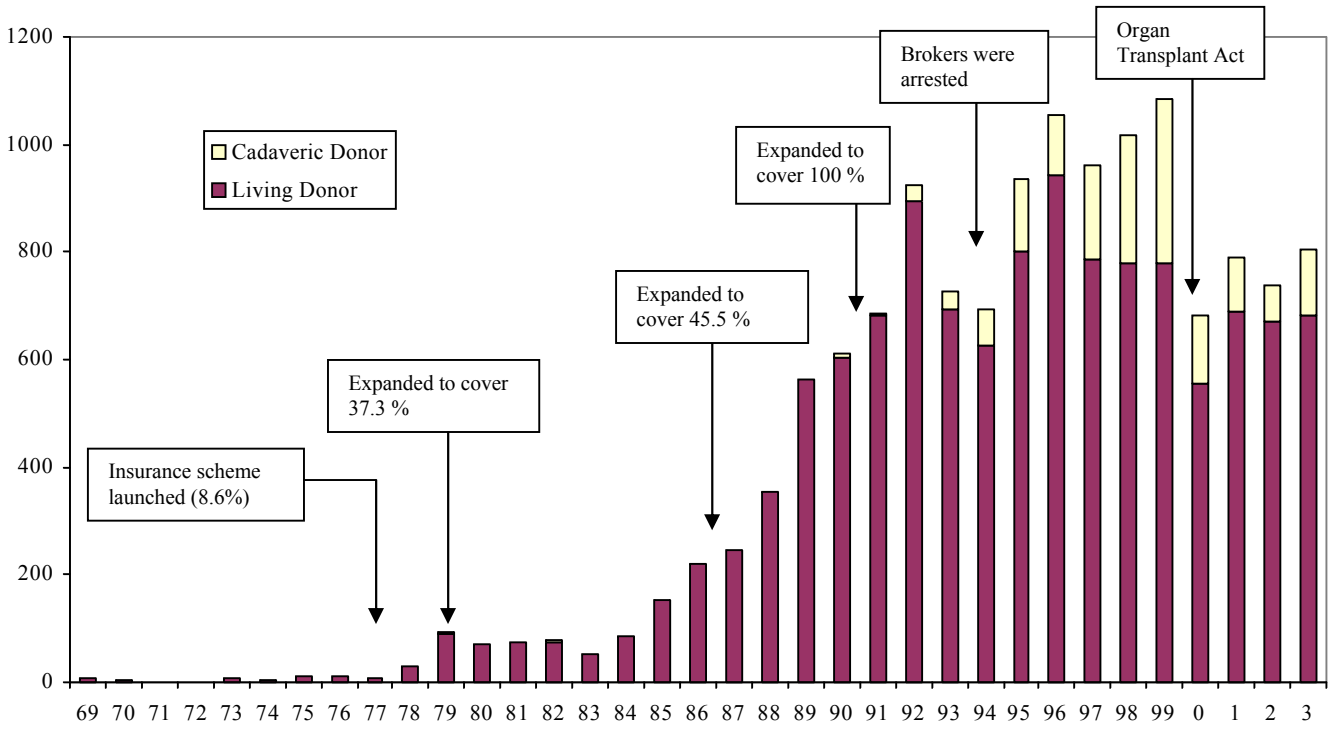


Figure 8-8. **Kidney transplantation in Korea (1969-2003)**

Data Sources: 1) The Korean Organ Transplantation Coordinators Society (1997). 3rd Academic Meeting of Organ Transplantation Coordinators, Seoul, July 13–14.
2) Korean Transplantation Society (1997). Organ transplantation report on 1996. *Korean Journal of Organ Transplantation, Vol. 11(2): 183-199* [Korean]
3) Korean Transplantation Society (1998). Organ transplantation report on 1997. *Korean Journal of Organ Transplantation, Vol. 12(2): 152-160* [Korean]
4) Korean Transplantation Society (1999). Organ transplantation report on 1998. *Korean Journal of Organ Transplantation, Vol. 13(2): 185-194* [Korean]
5) KONOS, 2006 Annual Report. [Korean]

The rapid increase by 1992 was also promoted by the private brokerage in matching the patients with the donors. Although attempts were made to ban commercial dealing in their matches, it was impossible to screen all the donors disguised as volunteers. At the same

time, private brokers organised nationwide networks, and some opened offices. Accordingly, the increases in the early 1990s were stimulated by the NGOs' campaign for organ donation and by the flourishing business of brokers involved in commercial dealing of human organs. To tackle commercial dealing in human organs and the involvement of brokerage, Severance Hospital, a major kidney transplant centre in Korea, launched a "donor investigation programme" in October 1992. The programme reviewed a large number of matched cases and the review identified suspected cases on the basis of examining matched cases which were rejected. Since the hospital had been carried out the vast majority of kidney transplants in Korea, the programme caused a great repercussion and cutailed a large number of transplant cases and the effort directly resulted in a remarkable reduction in national statistics in 1993. Reflecting on the effect of the screening programme, a television documentary programme discovered the problems related to kidney transplants and pointed an accusing finger at the flourishing business of private brokers. Immediately after the programme, the police investigated the brokerage in kidney transplants and arrested five private brokers. As a result, kidney transplants significantly declined in 1994. Brokerage businesses were not completely wiped out, though their networked activities were largely destroyed.

The brokerage scandal propelled public debates on brain death, and the NGOs drew attention to organ donation from brain-dead donors. Their campaign contributed to promoting cadaveric-donor transplants. As seen in Figure 3, the number of kidney transplants from cadaveric donors rapidly increased after police involvement was reported.

The issues on brain death were provoked by the Korean Society of Nephrology, the Korean Society of Transplantation, and the Seoul National University Hospital. They initiated public debates on cadaveric transplants in March 1988, when a proposal requiring brain stem death legislation was conjointly issued to the Korean Medical Association. The first case of cadaveric kidney transplant, performed on January 25, 1990, focused public concern on brain death and organ procurement from the deceased person. The first successful transplant case motivated medical professionals to rush into the practice of cadaveric organ transplant although there was no regulation legalising organ procurement from cadaveric donor. Seoul National University Hospital's issuance of brain stem death criteria on December 2, 1992 spurred debates on brain stem death. Subsequently, the

Korean Medical Association released its Decree on Brain Death on March 4, 1993. Since then, most teaching hospitals carrying out organ transplantation have transplant coordinators in place to enhance integrated collaboration among the transplant teams within the hospital. Transplant coordinators also cooperate with the transplant teams in other hospitals, and with voluntary organisations, in terms of organ procurement and delivery.

The Ministry of Health and Welfare endorsed the Korean Medical Association studies of brain stem death. Debates on brain stem death among the public have also become fiercer, as organ procurement from the deceased is strongly opposed by the Academy of Confucianism. The Academy of Confucianism strongly stands against brain stem death and cadaveric-organ transplant. The Confucian tradition regards any hurt or harm inflicted on a person's body as an act of impiety against the deceased.

Although there was significant resistance against cadaveric-organ transplantation, the legal basis for the use of organs procured from cadaveric donors was introduced in 1995. The Cadaver Anatomy and Preservation Act of 1995 authorised the use of tissue and organs from the deceased for the purpose of research and treatment. The Act authorised the use of human organs and tissues with the consent of the deceased person's family or relatives, and thereby legalised cadaveric-organ transplantation. Before the law was enacted, organ transplantation had been performed under an implicit consensus accepting that the results of organ transplantation are desirable for individual patients and for the society as a whole insofar as it does not cause any harm to the persons who donate organs.

Contrary to expectations, the number of kidney transplants sharply decreased after the Organ Transplantation Act was introduced in January 2000. Many commentators pointed out that the legal requirement to secure family consent discouraged organ donation from the deceased person. The much lower number of transplants in Korea using organs from the deceased as compared to that in Western countries is primarily attributed to the passive attitude of the Korean public towards organ donation. According to Lee and Kim (2003), 66.7% of the respondents disagree to cadaveric-organ donation because they regard it as an act that impairs the body of the deceased person, a belief that is supported by precedent research (Kim 1999). This attitude towards the deceased is closely related to

cultural tradition, which emphasizes the body of the dead should be respectfully treated without any harm.

The most distinctive feature in Korea is the world highest level of living donor transplantation with a significant fraction of unrelated donors, as depicted in Figure 4. Transplants using kidneys from unrelated living donors are also numerous in Korea. Of the total, 42.3% of living-donor kidney transplants in Korea from 1991 to 1993 were performed with unrelated donors (Koean Transplantation Society 1999).

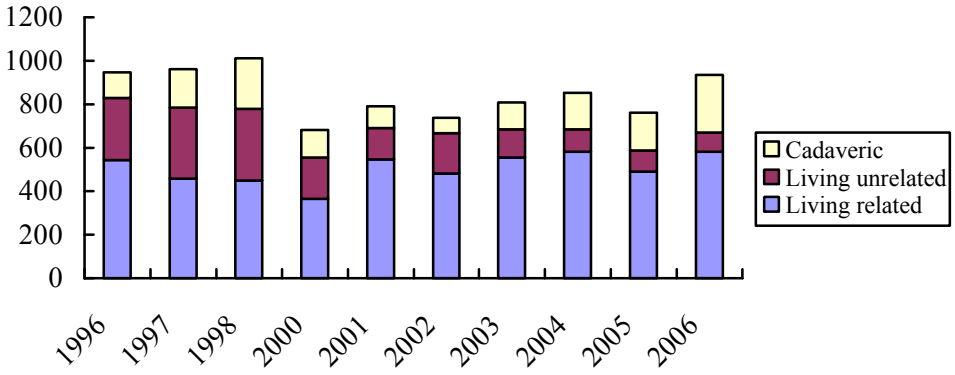


Figure 8-9. **The composition of kidney transplantation by donor type (1996-2006).**

Data sources: 1) Korean Transplantation Society, 1998
2) Korean Transplantation Society, 1999
3) KONOS, 2006

The fact that 71.8% of total living donor transplants performed in a Catholic University Hospital from 1989 through 1991 were unrelated donors (Yoon 1992) suggests that the most of living donor transplants were involved in commercial dealing. Insofar as there is no scientific investigation in place to confirm the relationship of the kidney donor and the recipient, the data relating to such relationships are not reliable. Many cases were reported of counterfeit rings being arrested by police in Korea especially following the introduction of Organ Transplantation Act of 2000, who forged passports of donors involved in commercial dealing of organs. By forging passports, commercial donors attempted to show the donor as a member of family of the recipient. Figure 4 shows significant decreases in unrelated live donor transplantation since 2000, suggesting that the Organ Transplant Act of 2000 successfully eradicated commercial dealing of organs for transplantation. In reality many cases went to China to evade the law in Korea.

8.4.3. UK

The number of kidney transplants in the UK most significantly increased in 1984 and 1989. The number reached its highest level in 1989, as shown in *Figure 8-10*. Although the number of such transplants increased in 1995, the general trends show that the number of kidney transplants using organs from cadaveric donors has declined while the number of those that use organs from living donors has increased significantly since the Human Organ Transplant Act was introduced.

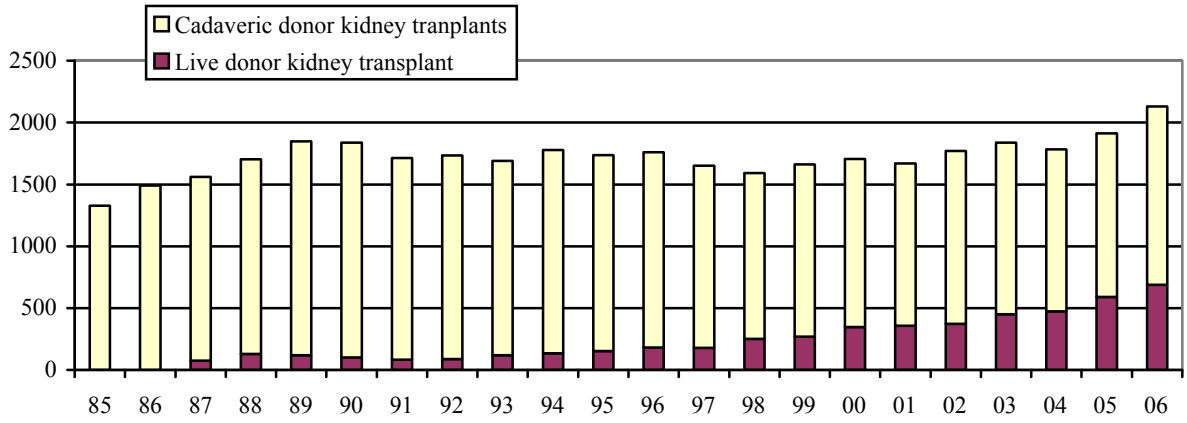


Figure 8-10. **The number of kidney transplants in the UK (1980-2003).**

Data sources: 1) UK Transplant, Transplant Activity Report 2001
2) UK Transplant, Transplant Activity in the UK 2002-2003
3) UK Transplant, Transplant Activity in the UK 2003-2004
4) UK Transplant, Transplant Activity in the UK 2004-2005
5) UK Transplant, Transplant Activity in the UK 2005-2006
6) UK Transplant, Transplant Activity in the UK 2006-2007
7) UKTSSA, Transplant Activity Report 2000

The turning points in the history of kidney transplants in the UK can be summarised as follows:

- there were huge increases in the number of kidney transplants in the UK in 1984 and 1989; and
- the number of kidney transplants using kidneys from cadaveric donors gradually decreased after 1989, while the number of transplants using kidneys from living donors remarkably increased.

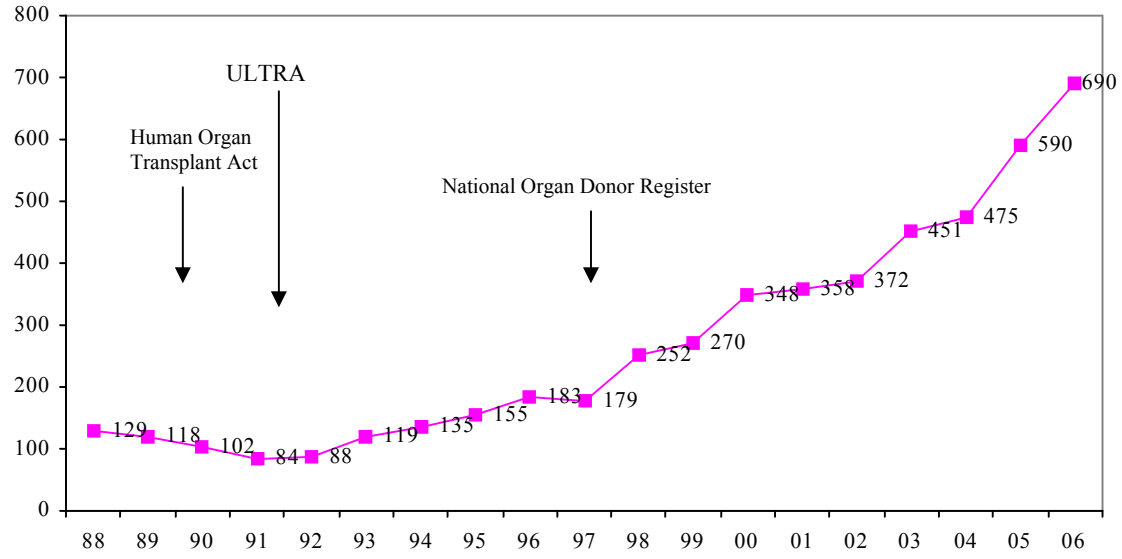


Figure 8-11. **Changes in the number of living-donor kidney transplants (1988-2006)**

Data sources: 1) UK Transplant, Transplant Activity Report 2001
2) UK Transplant, Transplant Activity in the UK 2002-2003
3) UK Transplant, Transplant Activity in the UK 2003-2004
4) UK Transplant, Transplant Activity in the UK 2004-2005
5) UK Transplant, Transplant Activity in the UK 2005-2006
6) UK Transplant, Transplant Activity in the UK 2006-2007
7) UKTSSA, Transplant Activity Report 2000

The reasons behind these characteristics are explained in the following statements. First, the increase in 1984 is interpreted as reflecting the adoption of the immunosuppressant cyclosporine. Afterwards, kidney transplants were well accepted as having superior benefits over any other treatment modality for ESRD patients in terms of both cost effectiveness and life-saving effect. Second, there was a new legal development. The figures, which show the transplant numbers in 1989 and 1990, were influenced by the controversies in the process of legalising the technology. The debates at this time promoted cadaveric-organ transplants while condemning commercial dealing in human organs. In 1988, a strong emphasis was placed on spurring medical professionals to increase organ donations, and on a campaign to encourage people to carry donor cards. In 1989, there were extensive efforts to ban commercial dealing in human organs as a result of the scandal involving organ sale solicitation in a Turkish newspaper for transplants in London. While there was strong opposition to commercial dealing in human organs, there were also active

movements encouraging cadaveric and unrelated living donations. On November 5, 1989, *The Times* reported that "organ donations have doubled because of the recent publicity."

The decline in the number of kidney transplants in the 1990s is largely associated with the following two elements: the shortage of available organs, and the shift in the reimbursement policy for dialysis. There have been both theoretical discussions of explicit rationing and open initiatives to target dialysis for rationing (Stanton 1999). As a consequence, owing to the public efforts to increase organ donation from living donors, the increases in the number of living-donor kidney transplants in the 1990s were considerable, as shown in *Figure 8-11*.

Table 8-5 shows that the number of living-donor kidney transplants performed in the UK has risen over the last decade in both the related- and unrelated-donor groups.

Table 8-5. **Living-donor kidney transplantation in the UK (adult only)**

	Related	**Unrelated (% of total)**
1993	119	3 (2.4)
1994	121	1 (0.8)
1995	150	6 (3.8)
1996	177	6 (3.2)
1997	164	11 (6.2)
1998	225	20 (8.1)
1999	232	37 (13.7)
2000	267	68 (20.2)
2001	285	87 (23.3)
2002	285	91 (24.2)
2003	311	102 (24.6)
2004	314	113 (26.4)
2005	406	136 (25.0)
2006	438	203 (31.6)

Data sources: 1) UK Transplant, Transplant Activity Report 2001
2) UK Transplant, Transplant Activity in the UK 2002-2003
3) UK Transplant, Transplant Activity in the UK 2003-2004
4) UK Transplant, Transplant Activity in the UK 2004-2005
5) UK Transplant, Transplant Activity in the UK 2005-2006
6) UK Transplant, Transplant Activity in the UK 2006-2007
7) UKTSSA, Transplant Activity Report 2000

8.4.4. US

In 2000, 13,372 kidney transplants were performed in the US, and a considerable number of recipients were older patients.[213] Each year in the United States, more than 50,000 people are diagnosed with ESRD (USRDS 1998). Diabetes is the most common cause of ESRD, resulting in about one-third of the new ESRD cases. The incidence rate of ESRD patients in 1996, which pertains to the number of patients who started medical treatment for ERSD, was estimated at 270 pmp. The total ESRD patients in the same year, pertaining to the accumulated number of ESRD patients at the end of the year, were 1,041 pmp.

Of all the ESRD patients, 27.41% were living with a functioning graft while the majority of the patients were living with dialysis, as shown in *Figure 8-12*. Among the patients living with dialysis, the largest group consisted of those who were living with hospital haemodialysis (84.27%). The next largest group was that consisting of patients the group with CAPD and CCPD (23.28%).

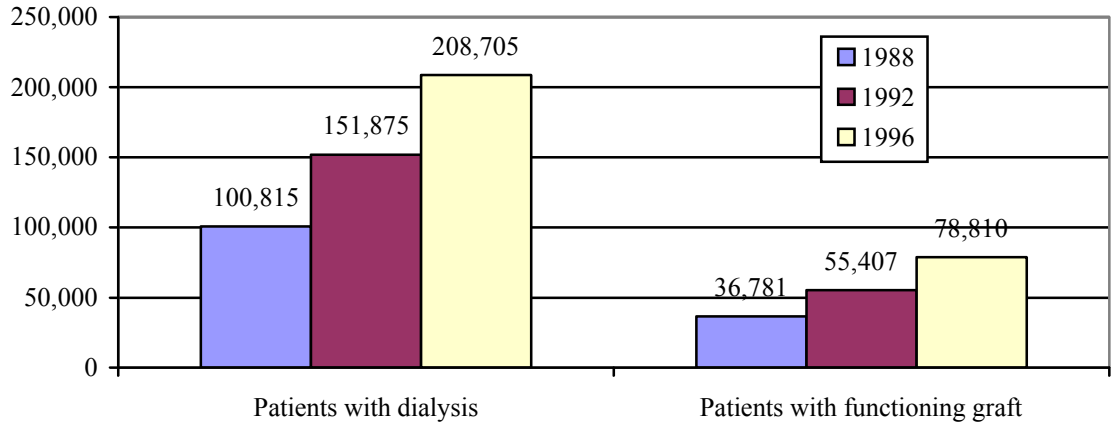


Figure 8-12. **Changes in the number of patients in each treatment modality**

Data Sources: United States Renal-Data System (USRDS) (1998). The USRDS 1998 Annual-Data Report.

The number of ESRD patients increased by 108.95% from 1988 to 1996. The increase was greater in the number of patients living with a functioning graft (114.28% from 1998).

[213] The recipients aged 50 years and older received 36% of all the cadaveric-donor kidneys in 1996, up from 27% in 1988. This age group also received 24% of the living-donor kidneys in 1996, an increase from 11% in 1988.

The increase in the patients living with dialysis was also considerably high, although lower than that in the patients living with a functioning graft.

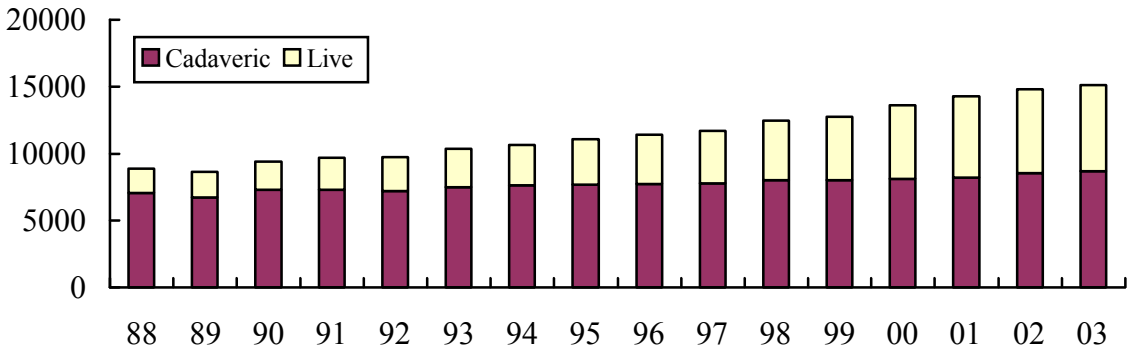


Figure 8-13. **Total number of kidney transplants and organ donors by year (1988-2003)**

Data sources: The Organ Procurement and Transplantation Network, Donors Recovered in the U.S. by Donor Type: Jan. 1, 1988- Jan. 31. 2008

As shown in *Figure 8-13,* the total number of kidney transplants has increased more than the number of cadaveric donors has since 1991. Thus, the gap between the two fractions has become wider over time.

The increase of organ donation among the living donors was due to a huge increase in the number of unrelated donors, as shown in *Figure 8-14.* While organ donation from people with a direct bloodline relation to the recipient has been in a steady state, that from unrelated donors and extra-lineal relatives has constantly increased, accounting for 10.5% of all the living-donor transplants from 1988 to 2003

Various events in the US in the 1980s might have affected kidney transplantation in the country, as follows:

- the introduction of the new immnumosuppressive drug cyclosporine, which was approved by FDA in 1983;
- the passage of the National Organ Transplant Act (NOTA) by the US Congress in 1984;

- the introduction of the Organ Procurement and Transplantation Network (OPTN) in 1986;
- the passage of the Omnibus Budget Reconciliation Act of 1986, which mandated that all organisations involved in organ procurement and transplant be members of OPTN, and which obliged medical professionals to ask all potential organ donors if they have an intention to donate their organs upon their demise. This has been termed as "required request" or "routine inquiry";
- the awarding to UNOS in 1986 of the first contract to operate OPTN; and
- the taking over by UNOS of the full operation of OPTN on October 1, 1987;

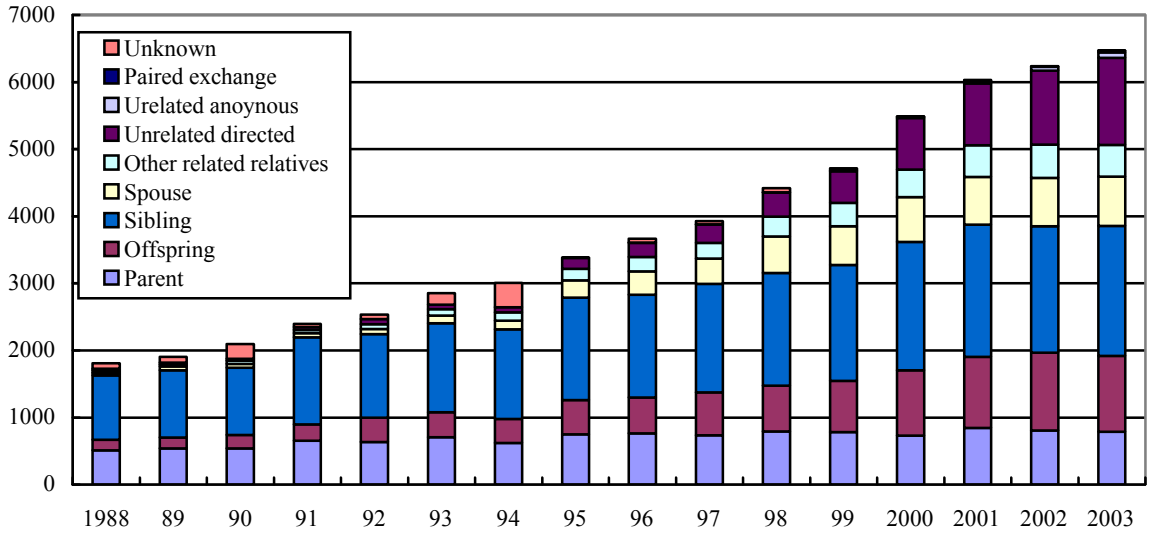


Figure 8-14. Living-donor relation to the recipient (1988-2003)

Data sources: The Organ Procurement and Transplantation Network, Donors Recovered in the U.S. by Donor Type: Jan. 1, 1988- Jan. 31. 2008

Figure 8-15 shows the trend in kidney transplants from 1981 to 2003. The proportion of ESRD patients with functioning grafts stayed at the same level from 1988 to 1992 (26.73% of the total ESRD patients). The number increased by 28.29% in 1996, as the increase in transplants has prevailed over the increase in the patients with dialysis since 1992. As shown in the figure, the number of kidney transplants rapidly increased from 1984 to 1986, and has shown a steady increase since the early 1990s.

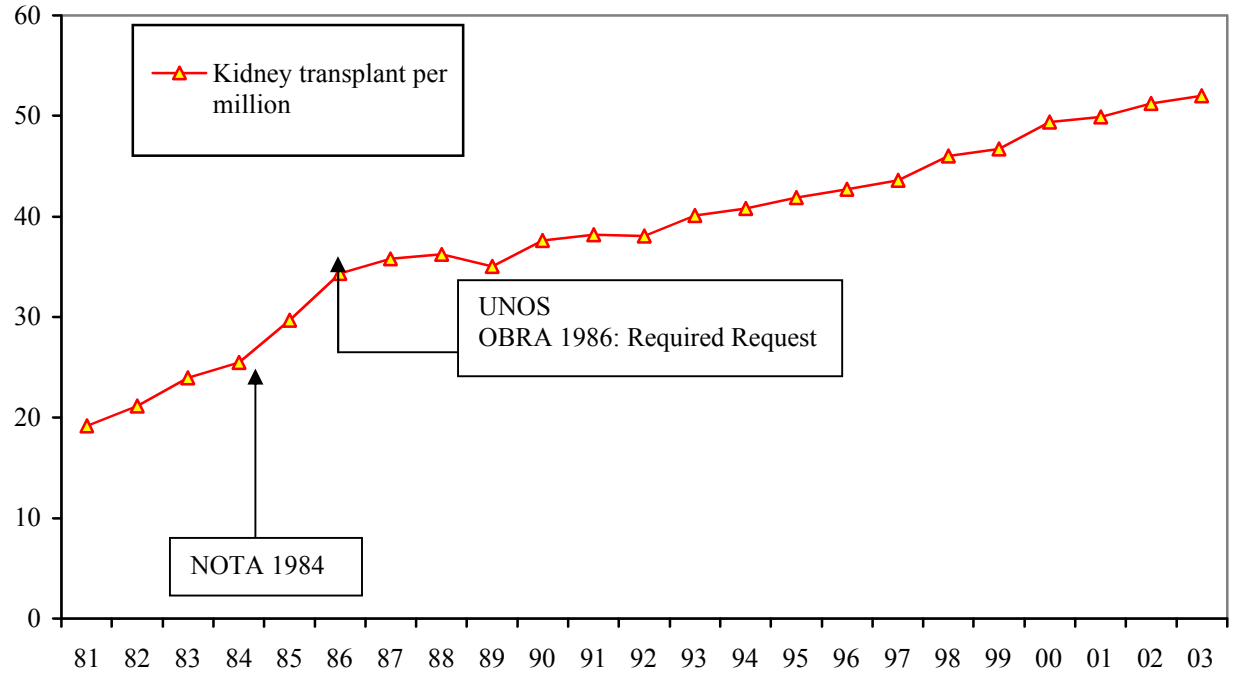


Figure 8-15. **Major events and kidney transplants (1981-2003)**

Data sources: 1) from 1981 to 1987: Schuck, P.H. (1989). Government funding for organ transplants.*Journal of Health Politics, Policy and Law, Vol. 14(1): 169-190*
2) from 1988 to 2003:The Organ Procurement and Transplantation Network, Donors Recovered in the U.S. by Donor Type: Jan. 1, 1988- Jan. 31. 2008, http://www.optn.org/latestData/rptData.asp retrieved 8 April 2008.

The "required request" approach has not significantly increased organ donation in the long term, although there is some evidence that the law has contributed to increasing organ donation for a short period after the enactment (Anderson and Fox 1988).[214] The arrangements regarding the improvement of organ transplantation activities were settled in legal and organisational terms. The efforts have been focused on increasing organ donation from the deceased. Since the early 1990s, public efforts in kidney transplantation from cadaveric donors have been focused on the fair allocation of organs for transplantation.

While the demand for kidneys and other organs is rapidly increasing, the number of those donating organs upon death (cadaveric donors) is increasing only slightly. The total number of people who were on waiting list for a kidney donation increased by 8.5% from

[214] In New York, where the "required request" law was passed in 1985, heart donations increased by 94%, liver donations by 96%, and kidney donations by 23%. The director of the Regional Organ Procurement Agency in Los Angeles stated that in the first year of the implementation of the "required request" approach, the number of referrals increased, but the number of donors largely remained the same. Then, the number of local referral calls dropped by over 500 in 1987.

the last day of 1999 to the end of 2000. The number of kidney transplants performed in the United States increased by 6.5% from 1999. The increase in transplants using kidneys from cadaveric kidney donors was only 0.7%, while the increase in the number of cadaveric donors between 1999 and 2000 was 16%.

In a similar vein, the increases in the number of kidney transplants performed in the 1990s were mainly due to the rise in the number of living-donor transplants. From 1991 to 2000, living-donor kidney transplants increased by 119.7%, while the increase in the number of cadaveric-donor organ transplants in the US was only 10.9%.

8.5. Conclusion

Kidney transplants provide great benefits to patients suffering from irreversible organ failure by extending and improving the patient's quality of life. As kidney transplants not only require human organs either from someone alive or deceased, but also entail high costs, there has been much debate on issues about organ procurement and compensation by third party payers. With wide variation across the countries, it has been regulated on various levels, especially relating to organ procurement and allocation, as a way of dealing with commercialization.

Three non-transplant approaches have been adopted as alternatives to kidney transplants to manage ESRD patients; continuous ambulatory peritoneal dialysis (CAPD), home dialysis, and hospital dialysis. The choice whether to switch from dialysis depends on the availability of an organ donor, physical condition of patient, and the ability to pay for the transplant.

Globally, the ratio of ESRD patients living with a functioning graft varies greatly, particularly high in northern Europe including Norway, Sweden, the UK, Austria, the Netherlands, and Luxemburg. The ratio is less than 1 % in Japan. In general, the proportion of ESRD patients living with functioning grafts is much higher in countries where health services are traditionally financed by a global budget system with financial resources collected from taxes.

Kidney transplants are generally more cost-effective and the least costly method of treatment compared to other conventional dialysis approaches. Empirical studies on costs

and benefits of treatments for patients with ESRD consistently show kidney transplants as the most effective option. Besides an improved QoL, extended life of a patient, the time saved that would otherwise have been spent on dialysis as well as lower the risk of infection are additional benefits gained from a kidney transplant.

The coverage for kidney transplant varied across the selected countries. In Japan, the cost of a kidney transplant has been covered by public health insurance since 1978. The programme covers all follow-up medical procedures after the transplant approximately £7,800- £10,500 a year. Since kidney transplants are categorised as a 'Sophisticated High Technology', the public insurance programme covers overall costs exceeding £332. The insurance also covers the cost of dialysis and patients receive public funding during the time on dialysis based on the Disabled Act.

In Korea, the public health insurance programme remunerates the costs on an FFS schedule. Although public health insurance covers some of the costs, patients still end up paying about £10,000 out of pocket, which includes the procedural costs related to the kidney donor.

In the UK, the NHS regards all solid organ transplants (except liver transplants related to alcoholic liver disease) to be cost-effective, particularly in relation to the amount NHS spends (Anyanwu et al., 2002). 3 % of the NHS budget is spent on kidney failure treatments. The NHS reference cost 2000 put a kidney transplant at £10,249 for elective and £11,397 for non elective surgery per patient per transplant. The costs for the patients with renal failure vary by procedures (Roderick et al., 2002); about £20,000 per patient per year for peritoneal dialysis, about £34,500 for haemodialysis, and about £3,500 in the first year and £23,500 in subsequent years following kidney transplant. The cost benefit of a kidney transplant compared to dialysis over a period of nine years (the median graft survival time) is about £191,000 to £21,200 per year the kidney transplanted functions. In 2002-03, the NHS saved about £37.6m in dialysis costs each year the kidneys of the 1,775 people that benefited from a kidney transplant continued to function. (UK Transplant, *Activity Report 2002-2003)*.

In the US, the primary source of payment for transplants varies greatly. Though Medicare covers all kidney transplants, private insurance plans finance a large proportion

of kidney transplants. In 1997, Medicare covered 59.1 % of cadaveric donor kidney transplants and 38.35 % of living donor kidney transplants. In the case of live donor kidney transplants, private insurance plans covered 48.7 % of the total. Medicare has two types of coverage: Part A and Part B. Part A covers 100 % of most inpatient expenses and is guaranteed for those who made Social Security payments. Part B of Medicare pays only 80 % of outpatient treatment after of an annual deductible, so additional insurance is necessary to cover the remaining 20 % of outpatient-based medications. Medicare pays 80% of immunosuppressant medications for 44 months following kidney transplantation. As for dialysis, Medicare pays inpatient hospital stay and Medicare also pays 80% of the monthly amount after the patient pays $100 yearly deductible (Health Care Financing Administration, 2001).

In terms of regulation, legislation has been instituted to regularise organ procurement and ban commercial trade of organs in each country. With public funds, public authorities are involved in the procurement and allocation of organs to promote organ donation especially from the deceased and ensure fair allocation of harvested organs. Organisations for organ procurement and allocation have been established and operated by public authorities in all the four case study countries; JOTNW in Japan, KONOS in Korea, UK Transplant in the UK, and UNOS in the US. Public involvement in organ transplantation is generally favoured within the public welfare context, although there are differences in terms of when they were established and range of activities.

In Japan, a centralized, nationwide kidney transplant network JNOS was launched in 1995. This network expanded according to the Organ Transplant Law of 1997, which enabled multi-organ transplants. With a centralized office, the network has seven regional kidney transplant centres. Through these facilities, the Ministry of Health and Welfare seeks to improve the equity and appropriateness of organ distribution by selecting transplant candidates based on universal standards. There are 44 kidney banks used to promoting kidney transplants, especially from cadaveric donors. Public involvement has lagged in Japan compared to western countries mainly due to a lack of success during early attempts at organ transplants. The first heart transplant performed in 1968 received public criticism as many were not willing to accept brain death. The second attempt performed in

1984 involving a mentally disabled donor worsened public sentiment surrounding organ transplants. Reflecting world wide views, a joint movement between the Japanese government and the National Assembly sought to regularise organ transplants from cadaveric donors starting in the early 1990s.

In Korea, the Organ Transplant Act of 2000 authorised transplants with cadaveric donors. The national organisation, KONOS, was established to oversee organ procurement and allocation. KONOS manages the matching of recipients and donors, and authorises organ transplants. To rule out commercial dealing especially regarding live donor transplants, KONOS reviews records submitted by individual transplant centres and selectively authorises transplant cases having determined it is not a commercial arrangement between the donor and recipient. With a long history of organ commercialisation, public authorities have been cautious. Recently, there have been many cases involving the selling of organs from China, a major concern in Korea.

In the US, the first successful human kidney transplant was performed by Dr. Joseph Murray of the Harvard Medical School in 1954 at the Peter Bent Brigham Hospital. Six years later, the pioneering living kidney donor operation was carried out at Edinburgh Royal Infirmary in the UK. Immediately after the first procedure, authorisation of organ transplants was given through the Human Tissue Act 1961 and public involvement soon followed with the establishment of the UKTSSA in 1968 to coordinate organ transplant activities. UK Transplant, which succeeded UKTSSA, oversees overall activities related to organ transplants. After a public scandal over the sale of organs to a private hospital in London in 1988, the Human Organ Transplant Act was enacted in 1989, banning the commercialization of human organs. By law, the Unrelated Live Transplant Regulatory Authority (ULTRA) assesses live donor candidates receiving monetary benefits who are unrelated, and penalises anyone in commercial transactions. The National Organ Donor Register launched on 1994 played a significant role by promoting organ donation registration, which currently has registered 20 % of the total population.

In the US, the Uniform Anatomical Gift Act of 1968 authorised organ transplants using organs of deceased donors. In October 1984, the NOTA introduced the Task Force on Organ Procurement and Transplantation and an Organ Procurement and Transplantation Network (OPTN). The Act banned commercialization of organ transplants. All organ

transplant centres are mandated to join OPTN as a member by Omnibus Budget Reconciliation Act (OBRA) of 1986, otherwise they are not eligible for public insurance programmes including Medicare and Medicaid that are the major third party payers for kidney transplants. The OBRA also has significant importance in the US organ transplant history, as it requires medical professionals to make inquires on all potential donors if they have an intention to donate organs, called "required request" or "routine inquiry." As such, UNOS provides OPTN with overall management of data and organ matching and placement process.

Approaches to promote kidney transplants have been expanded, particularly in the UK and the US. Primary concerns focus on extending donor availability while preventing commercialization and relieving cost burdens. In the UK, public authorities at the national level have carefully regulated the approaches in both legal and financial terms. Similar to the UK, public authorities in the US have supported initiatives to promote kidney transplant activities and garner support from public insurance programmes, including Medicare and Medicaid. Different from the UK, the system for organ procurement and allocation has been localised and recently integrated into a singular system networking the entire country. In both Japan and Korea, public involvement lagged behind compared to the situation in the UK and US. This was largely due to the traditional belief that a deceased person should be respected and not to be harmed. Subsequently, the government was hesitant in publicly raising the issue of organ procurement from deceased donors. As demand from both professional groups and patients has increased coupled with the instances of organ trafficking scandals, legislations have been introduced to permit organ harvesting from deceased donors and prevent commercial trade of organs. Laws were passed in 1997 in Japan and in 2000 in Korea. Different from the general approach of excluding costly medical procedures from public insurance plans, social insurance programmes in both countries covered organ transplants at an early stage of adoption.

Figure 8-16 shows the variation among the selected four countries, the US by far the highest followed by UK with Korea and the Japan at much lower levels. While the level of adoption has been consistently upward in the US, the other three countries have shown little growth since around 1990.

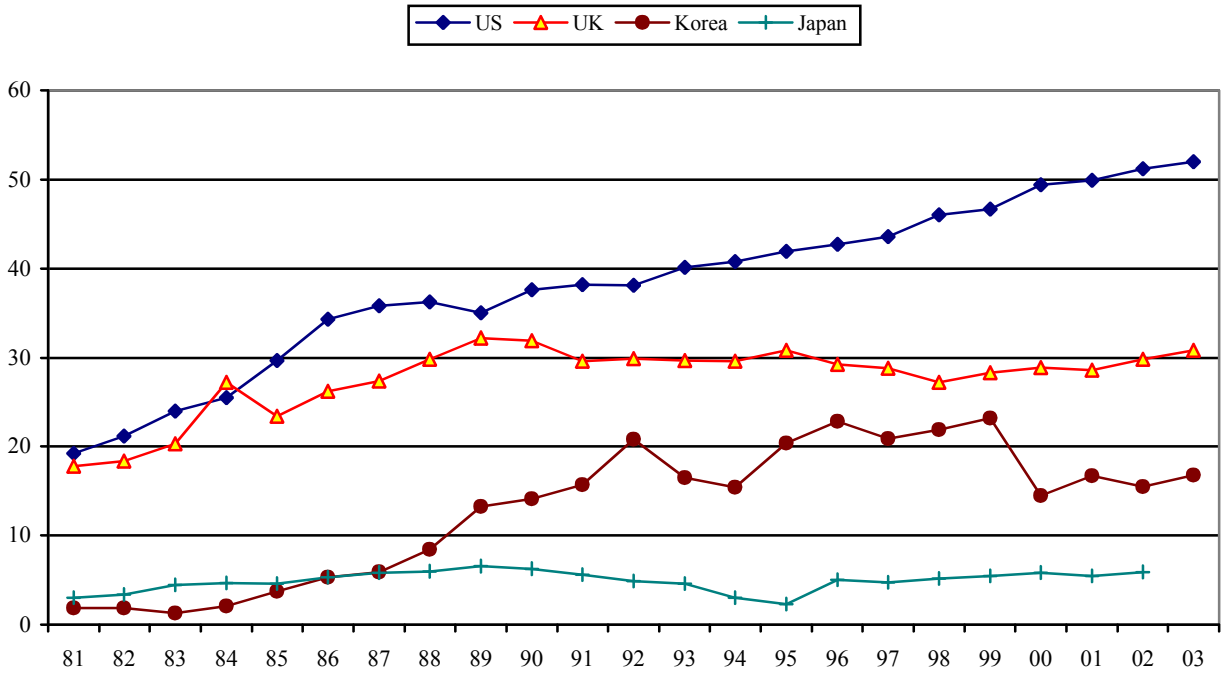


Figure 8-16. **The trends of kidney transplants in selected countries (pmp)**

Rapid expansion internationally during the 1980s and early 1990s was primarily attributable to the newly introduced immunosuppressant 'cyclosporine A.' Since then, the variations between countries are mainly due to organ availability, which depends on the country's public initiatives, legislation, and reimbursement policies of third party payers for the treatment modalities of ESRD including renal transplants.

As summarised in *Table 8-6*, the number of kidney transplants pmp is the highest in the US among the selected four countries. Although the number in terms of pmp is higher in the US than the other tree countries, the ratio of having transplantation amongst total patients with renal failure is much lower in the US than the UK and even lower than Korea. Japan is by far at the lowest while prevalence of patients with renal failure is at the highest among four countries.

Table 8-6. **Comparisons of the incidence and prevalence of ESRD and functioning transplant**

	Incidence of ESRD (pmp)	Prevalence of ESRD (pmp)	Transplant ratios[a](pmp)	Prevalence of functioning transplant (pmp)
Japan	252	1,726	5.94	0.85
Korea	114	701	15.2	29.6
UK	103	640	29.8	45.3
US	336	1,446	51.2	25.9

Data sources: 1) USRDS, 2004 Annual Data Report. Available at http://www.usrds.org/adr_2004.htm accessed 6 May 2008

2) UK Renal Registry, UK Renal Registry Report 2003. Bristol, UK. Available at http://www.renalreg.org/Report%202003/RenalReg2003AnnualReport_Colour_For_Web_With_Linksv2.pdf accessed 6 May 2008.

3) USRDS, 2004 Annual Data Report.

4) UK Renal Registry, Report 2003.

5) Korean Society of Nephrology, 1996

In the US, most of the transplant growth has been from living donor, with the greatest rate of increase involving living and unrelated or distantly related donors. During 1988-1999 period, the transplants steadily declined. In the UK, the increase in kidney transplants is mainly attributed to the growth of live donor transplants, especially from the mid- 1990s. Following the National Organ Donor Register launched on October 6, 1994, live donor transplants increased; from 8.9 % in 1995 to 24.5 % in 2003 of the total.

The most different figures are observed in Korea and Japan. 88.9 % of total kidney transplants were performed with live donors in Korea on average since the first kidney transplant in 1969. The proportion of live donor transplants was also very high in Japan at 72.7 % of total from 1978 to 2002. The US is in a unique position among western countries with a greater level of live donor kidney transplant, 45.3 % of total kidney transplant during 1988-2003 periods. In Korea, the proportion of live donor transplant is the highest among selected countries. The main reasons are that 1) organ procurement from the deceased is not legalised and 2) there is no legislation prohibiting commercial dealing in human organs resulting in high proportion of unrelated live donor kidney transplantation.

In contrast with other three countries, the proportion of unrelated donors is extraordinarily high in Korea, as indicated in *Table 8-7*. Among unrelated live donor, a substantial amount is suspected to be commercially driven. The fact that 5 people were arrested in 1994 for brokering organs of live donors, supported the suspicion that organ

commercialisation was wide spread. Criminal investigations were carried out in 2003 in which the offenders involved in a nation-wide organ dealing network were apprehended.

Table 8-7. **Comparisons of donor-recipient relationship in live donor transplant in four countries, various years**

	Periods	All live donors	Unrelated donors	% of unrelated donor
Japan	1983-1998	6,190	284	4.5
Korea[a]	2002	98	70	71.4
UK	1993-2000	1,607	152	9.4
US	1988-2003	64,985	7,277	11.2

Data sources: 1) Data Source: UKTSSA, Transplant Activity Report 2000

2) The Organ Procurement and Transplantation Network, Donors Recovered in the U.S. by Donor Type: Jan. 1, 1988- Jan. 31. 2008, http://www.optn.org/latestData/rptData.asp retrieved 8 April 2008.

3) The Japan Society for Transplantation (1995). Annual progress report from the Japanese Renal Transplant Registry, 1994. The Japanese Journal of Transplantation, Vol. 30(4): 428-449. [Japanese]

4) The Japan Society for Transplantation (2000). Annual progress report from the Japanese Renal Transplant Registry, 1999. The Japanese Journal of Transplantation, Vol. 35(2): 43-48. [Japanese]

5) The Japan Society for Transplantation, 2000 report on transplant registration, Transplantation, Vol. 36(5): 91-105, 2001

6) Korean Transplantation Society (1999). Organ transplantation report on 1996. *Korean Journal of Organ Transplantation, Vol. 11(2): 183-199* [Korean]

7) Korean Transplantation Society (1999). Organ transplantation report on 1997. *Korean Journal of Organ Transplantation, Vol. 12(2): 152-160* [Korean]

8) Korean Transplantation Society (1999). Organ transplantation report on 1998. *Korean Journal of Organ Transplantation, Vol. 13(2): 185-194* [Korean]

9) Han. Y.S. (2002). The way to improve organ transplant and evaluation system. Research Report 2002-8, Korea Institute of Health and Social Affairs

Note: a. The number does not include all live donor transplant but limited to the response on the survey.

Aside having two of the world's highest level of live donor transplants, there appears to be significant variations between Japan and Korea. Cadaveric renal transplants accounted for about 30 % of the total renal transplants in Japan. With a public outcry following a patient suffered brain death in 1985, the number of cadaveric renal transplants levelled off. After the public became more open, the number of renal transplants involving cadaveric donors increased subsequent 5 years before declining to the present levels. Live donor transplants also had been falling off until JOTNW began its activities. The level of renal transplants in Japan is the lowest among OECD countries. This is primarily attributed to the negative perception on organ transplants that stemmed from the failure of the first case in

1968, in which the surgeon was blamed and called a murderer. The second case worsened the situation, as it was performed with a mentally disabled cadaveric donor. The attention these cases received needs to be set in the context of societal values in Japan sees organ transplants with unease.

The adoption of cadaveric transplants in Korea lagged far behind. Indebted to active involvement of a voluntary agency –Korean Organ & Tissue Donation Programme (KOTDP)- in promoting organ donation, especially from deceased donors, cadaveric renal transplants increased until the Organ Transplant Act of 2000 came into effect. Even though organ procurement became legitimate in Japan and Korea, transplants from cadaveric donors did not increase; it actually decreased in Korea following the enactment. This is because of weak public consensus on organ donation from the deceased, which primarily stems from Confucianism. Due largely to that belief, the role of KONOS has mainly been focused on authorising kidney transplantation from live donors. Activities to promote organ donation from cadaveric donors have been circumscribed. Three reasons are pinpointed. First, the law blocked the involvement of non-governmental organisations from all activities related to matching donors and recipients including with cadaveric donor. By law, the matching of recipients with live donors was done anonymously activities to promote organ donation from cadaveric donor halted. Second, more significantly, any form of involvement in commercial dealing of organs was considered unlawful. Third, the organ procurement system distorted cadaveric organ donations. The hospital based organ procurement (HOPO) is responsible for organ procurement activities. The system is currently being circumscribed due to financial disincentive towards HOPO. There are 22 assigned HOPOs across Korea, taking into account medical capability and accessibility at the local level. When a potential cadaveric donor is found, a visit is made to the donor and given a pre-examination. They transfer the donor to their HOPOs when suitable. If the potential donor is found not to be suitable, as happens in 30 % of all cases, the HOPO bears all the costs incurred in the process, which otherwise the recipient pays for.

Other conditions have had a temporary impact. The upward trend until 1992 was primarily attributed to the expansion of the number of people covered by the insurance and sufficient supply of organs, which mainly come from commercial sources. At the time, commercial trade in organs was thought to be widespread.

In the UK, following factors have affected the supply of organ donors (New et al., 1994):

- death rates from relevant causes;
- level of funding;
- organ procurement arrangements;
- cultural factors.

The level of funding has been a more significant factor in instigating the level of organ transplant. Simple regression analysis reveals that the level of funding, as considered in terms of net revenue cash limits per capita for regional health authorities, was significant in determining the level of organ transplant.

Part 3

Discussion and Conclusion

Chapter 9: Discussion

This chapter draws together the findings of the case studies. Given the characteristics of the data and method of analysis, a qualitative rather than quantitative type of testing can be applied. Testing in this sense involves empirical plausibility as a guide to further explanation. Based on the empirical assessment, various important paradoxes are identified that kindle further exploration. This should be sufficient to indicate the extent to which the "micro" and "macro" aspects and associated models are sufficient to explain the observed differences. And should they be insufficient, it may be possible to identify paradoxical cases and speculate on the other, "residual" factors involved.

9.1. Assisted reproductive technologies (ARTs)

The introduction of ARTs in mainstream medical practice posed a number of challenges to health care providers, particularly due to the cost. Key issues for health administrators and policy-makers face were; deciding on what resources can be allocated to ART services, defining who can access to such services, and striking the right balance between investment in prevention and in cure (Fathalla, 2001). In addition, the emergence of ART raised issues of genetic cohesion and integrity of the traditional family identity (Dickens, 1990), triggering conservative responses.

Since infertility is not considered a disease and does not threaten a patient's life or physical health, third party payers including public health insurance programme have generally excluded it from coverage. The debate on ARTs is intertwined with complex scientific, cultural and ethical concerns including the status of an embryo and the involvement of a third party (Fathalla, 2001). Accordingly, ARTs lack public support on fee reimbursement by health insurance. ART costs were generally paid privately in all four countries. Social insurance programmes in Japan and Korea do not cover ARTs. In the UK, a large proportion of infertile couples seek ARTs in the private sector, for which they pay out of pocket or through their private insurance policy. Recently in the UK, however, an increasing number of Health Authorities purchase ARTs on a specific fertility contract

basis. The process of reimbursement is complicated, while in Scotland, up to three IVF-ET cycles are publicly funded. According to NICE (2004), about 25% of total cost in England is funded by the NHS. The NICE guideline of 2004 recommended that couples should be offered up to 3 cycles of IVF on the NHS for over 10% chance of success. In the US, most health plans do not provide coverage for the technology. Accordingly, most couples seeking fertility treatment pay out of pocket. Collins and colleagues (1995) estimated that approximately 85 % of total ART expenditure is paid by the patient. Though 14 states have mandated insurers to provide some form of infertility care, only 6 states out of the 14 oblige insurers to cover infertility treatment. The states where the provision of ART services is mandated are Hawaii, Illinois, Maryland, Massachusetts, Montana and Ohio.

The following elements may be responsible for higher adoption of ARTs in the UK. First, as the first country that has succeeded in engineering the IVF-ET technology, ARTs have been widely accepted in the UK among both infertile couples and obstetricians. Second, the cultural background regarding a baby as a child of God in Christian tradition may have facilitated support for those technologies that do not emphasize the continuation of blood lines, such as donor insemination, egg donation and surrogacy. In the UK, all those treatment activities have been regularised from the early stages of technology development. Third, although the NHS does not generally provide fund for infertility treatment, the cost itself may not be a serious barrier for infertile couples to access ART treatments as the procedures are not expensive relative to income. On the other hand, the market-orientation of ARTs might have facilitated their spread.

The factors facilitating the adoption of ARTs were largely similar in Japan and Korea. ARTs involving semen and egg donation have not been generally accepted in both Japan and Korea due to cultural traditions that emphasize the continuance of bloodlines in succeeding generations. Competition between providers triggered the adoption of newer technologies like ICSI in both Japan and Korea. Under competitive circumstances, obstetricians promote their advanced capabilities by adopting innovative technologies earlier than their competitors. Faster adoption in Japan and Korea also resulted in lower costs for using ARTs compared to the UK and US, easing their adoption.

The following may have contributed to the US lagging in the adoption ARTs. First, insurance programmes did not cover the cost associated with ARTs. Second, The Fertilisation Clinic Success Rate and Certification Act (FCSRCA) of 1992 required infertility clinics to report exact numbers of procedures and success rates resulting in live births. ART providers had to keep high success rates in a competitive market where clients consider success rates in choosing the clinics. Third, competition among clinics *per se* also has led ART providers to increase success rates. To attract clients, many clinics offered options of paying under a "shared risk," "warranty," or "outcome basis" plan. Under these arrangements, obstetricians could choose couples carefully on the basis of whether they were liable to successfully gestate.

In summary, traditional ART was accepted in countries with a Christian culture including the UK and US, while countries based on Confucian culture including Japan and Korea took a reluctant stance on donor insemination. Cultural factors helped to facilitate the adoption of ARTs related to genetic handling in the UK, which include donor insemination, egg donation and surrogate motherhood (van den Akker, 2000). The UK, the leader in developing ARTs, have established sophisticated regulations and supported the adoption of all available methods. In the US, legal arrangements and competition circumscribed overuse of ARTs. Clinics and practitioners in the US had to be cautious in deciding whether they provided infertility cycles. The situations in Japan and Korea are compatible. In both countries, cultural factor respecting the success of bloodline is a barrier to the adoption of ARTs. Public insurance programmes did not cover ART. Infertility clinics charged fees on a FFS basis. The adoption of ARTs was not monitored by any external authority, resulting in a lack of responsibility for the outcome on the part of infertility service providers. Except cultural barriers related to genetic continuance, the external environments in Japan and Korea are favourable towards the adoption of ARTs.

9.2. Caesarean section delivery

The caesarean birth ratio is significantly associated with the cost reimbursement scheme used each health system. The cost for ceasarian birth is compensated on a fee-for-

service basis in both Japan and Korea. There were huge variations however in caesarean section ratios between the two countries. The differences are primarily attributed to coverage policy of health insurance programmes. Both caesarean section delivery and natural birth are covered by health insurance in Korea while health insurance does not provide natural delivery with coverage.

Judicial rulings have had a strong influence on encouraging physicians to choose caesarean section deliveries. Defensive practices to avoid malpractice claims are widely regarded as a factor contributing to increasing caesarean section ratios (Danforth, 1985; Shiono et al., 1987; Sachs, 1989; Localio et al., 1993). In Korea, which has the highest caesarean ratio, 80 % of caesarean section deliveries were performed on recommendation of the physician. Physicians tend to recommend caesarean section deliveries expecting economic gains and avoidance of malpractice litigation. In recent years, the increases of caesarean section ratios in Japan and in the UK may also reflect judicial rulings which have often gone against physicians in malpractice rulings regarding birth procedures.

In the UK, the most common reasons offered in the absence of obstetric indications were maternal request, followed by fear of litigation, and the practice of evidence-based a study (Cotzias et al., 2001). This is different from the 1980s when the majority of obstetricians refused a maternal request as reason for performing a caesarean section during pregnancy without complications (Johnson et al., 1986; Hall, 1987), reflects the increased acceptance of the NHS's protection of consumer rights.

UK policy recommends maternal choice in obstetric decision-making. A shortage of commissioning midwives pushed women to go to hospitals for deliveries, spurring caesarean delivery. The increasing caesarean delivery ratio seems primarily a result of the UK's policy and manpower[215].

In pursuit of protecting woman's health, citizen groups have actively tryied to reduce the caesarean section delivery ratio in Korea. NGOs have played a significant role in Korea. They awakened concern that unnecessary caesarean deliveries could have adverse affects on women's health and impose unnecessary costs. They have also pressured the Korean

[215] To reduce non-clinical choices and also nationwide variations, NICE has been commissioned to produce clinical guideline on caesarean section delivery (Parliamentary Office of Science and Technology, 2002) and National Service Frameworks were introduced in care through setting national standards.

government to establish appropriate measures to constrain caesarean deliveries. Initiatives such as publicly profiling the caesarean ratio of individual clinics and hospital have raised public awareness about caesarean deliveries, which has helped to decrease the ratio from 43 % in 1999 to 38.6 % in 2000.

In the US, caesarean section deliveries were preferred among those who have private insurance policy, and less so among those who have public health insurance or no insurance. Patients who had private or HMO insurance were nearly seven times more likely to have a repeat caesarean delivery as an elective procedure compared to patients with Medicaid or self-pay schemes (Hanley et al., 1996). To tackle the issue of rising caesarean deliveries, many of private insurance plans and state Medicaid plans attempted to equalise physician fees between caesarean and vaginal deliveries. In 1993, Medicare introduced the RBRVS (Resource Based Relative Value Scale) to make higher payments for vaginal deliveries compared to caesarean deliveries based on a physician's workload by the product of time. The scheme raised vaginal delivery costs slightly higher than caesarean costs (Keeler and Brodie, 1993). Due to a lower compensation for caesarean delivery, many private practitioners turned away patients with public insurance or no insurance at all. Caesarean section ratios for HMOs are similar to private insurances where obstetricians are commonly paid on a fee-for-service basis.

Public interest in cesarean ratios stems from the National Institutes of Health Consensus Conference held in 1981 (National Institutes of Health 1981). Since repeat cesarean deliveries were the second largest contributor to the cesarean ratio, attention was focused on fostering Vaginal Births After Cesarean (vaginal birth after caesarean section) to decrease the national cesarean ratio. Clinicians and investigators advocated that the way to decrease the repeat cesarean ratio was to deter primary cesarean deliveries (Paul and Miller 1995; Sachs et al. 1999). Third-party payers and accrediting bodies began monitoring cesarean ratios as a measure of hospital performance and as a measure of maternal health care quality (American College of Obstetricians and Gynecologists 2000). Healthy People 2000 (DHHS, 1991) proposed a national ratio of 15 %, which was widely criticized because it appeared to be arbitrary and did not attempt to address issues related to patient safety or case mix (Sachs et al. 1999). Healthy People 2010 was revised to reflect the importance of case mix, by focusing the national reduction goal to low-risk nulligravid

women (Healthy People 2010). Healty People 2010 set as a specific objective to "reduce caesarean deliveries among low risk (full-term, singleton, vertex presentation) women from 17.8 % in 1997 to 15.5 % by 2010." The American College of Gynaecology (ACOG) has also made recommendations to address this issue. ACOG focused its recommendations on decreasing primary caesarean ratios and defining a stronger role for trial labour and vaginal births after caesarean within a framework of individual patient risk assessment.

9.3. Haematopoietic stem cell transplantations

HSCTs have evolved from an experimental treatment for a small group of diseases to a standard procedure for a wide range of blood and haematopoietic disorders and solid tumours. HSCTs are currently accepted as an established form of treatment for various kinds of haematopoietic diseases and solid tumours. In terms of both length of hospital stay and average hospital charges, stem cell transplants were preferred to conventional chemotherapies.

Various factors plausibly have affected the diffusion of HSCT in the four countries including:

- Incidence rates of the diseases treatable by HSCTs;
- Reimbursement policies;
- Organisations supporting HSCT activities to improve donor availability;
- Charity support.

Each of these factors is discussed as follow. First, the incidence rates of leukaemia greatly vary among the selected countries as detailed in *Table 9-1*. Huge variation between the Japan and Korea and the UK and US can be regarded as mainly stemming from differences in incidence of leukaemia, which HSCT has been mainly applied for. The incidence rates are about double in the UK and the US in comparison with those in the Japan and Korea with the highest in the US. The expanding use of HSCTs on solid tumours and increased adoption of cord blood transplants have been major factors contributing to the overall implementation of HSCTs, especially in Japan and the US.

Table 9-1. **Incidence of leukaemia (pmp)**

	Japan[a]	Korea[b]	UK[c]	US[d]
Incidence per year	154 (1997)*	138 (1998)	282 (1992)	321 (1998)

Data sources: 1) Oshima A. (ed.), 1998: Progress Report of the Research Group for Population-based Cancer Registration in Japan, 1998
2) National Cancer Institute, The Surveillance, Epidemiology, and End Results (SEER) Program, SEER Cancer Statistics Review, 1973-1998 2001
3) Department of Health, Referral Guidance for Suspected Cancer, 2001.
4) Department of Disease Control, 2000

Note: a. include malignant lymphoma, multiple myeloma and hematopoietic tissue diseases
b. includes overall haematopoietic cancers
c. includes leukaemias, NHL, Hodgkin's, myeloma
d. includes leukaemias, NHL, Hodgkin's, myeloma for adult only
* The number in the blank refers to the year relevant to the data

Second, due to its high cost, third party payers have been very cautious about insurance coverage for BMT. Health insurances in Japan cover HSCTs regardless of the condition and age of the patients. They also do not limit the coverage on account of the quality of HLA matching.

In Korea, health insurance programmes started to cover autologous BMTs in 1985, then expanded coverage for allogenic BMTs for patients under aged 40 in 1992. Coverage for allogenic BMTs was expanded to those aged up to 50. Health insurance programmes also provided coverage for autologous peripheral blood stem cell transplantation from 1997. However, eligibility for insurance coverage is strictly screened by a committee of haematologists who determine suitable cases. Insurance programmes in Korea started to cover umbilical cord blood transplants in 2003 for cases approved by the screening committee. In addition, charities have been very active to support the patients undergoing HSCTs. During 1999, charities provide full or partial financial support for about 20 % of total patients.

In the UK, the majority of transplants in the UK are performed according to standardised protocols. Following the implementation of the new NHS and the 1997 NHS (Primary Care) Act, cash-limiting gradually extended into primary health care, especially general practice. Policy-makers have provided clear direction about how to ration NHS resources. The 'Child B' case, whose funding for BMT was rejected by the regional health authority, became an epitome of public debate about NHS rationing (Ham and Pickard,

1998; Pickard and Sheaff, 1999). As hospital trusts currently carry out BMT in accordance with the agreement with PCTs within financial limits, they are cautious not to exceed the agreed budget.

In the US, the overall landscape for insurance coverage plan is difficult to illuminate for the HSCTs because funding is largely through private plans. Various health plans have different policies on HSCT coverage. As some states require health plans to cover HSCTs, there are increasingly more lawsuits against limits on insurance coverage, as often found in the media including Internet sources. Except umbilical cord blood transplants, many health plans are increasingly expanding coverage policies for other HSCTs.

Third, public support promotes donor recruitment whereas marrow donor shortage has been a major impediment. In Japan, the government has actively promoted donor recruitment in line with the programme to support Japanese victims of atomic bombings during the Second World War[216]. To facilitate BMT activities, the Japanese government introduced compensation programmes for bone marrow donors. If a bone marrow donor dies during marrow donation, the health insurance programme provides a compensation of £550,000 for the donor. If any problems occur on the donor requiring medical treatment, health insurance provides a compensation of £30 per day during admission and £17 per day for OPD follow ups. Bone marrow donors are also excused from their work with official leave. By the end of 2000, JMDP provided 3,083 unrelated donors for BMT since its involvement 8 years ago.

The Korean government appropriates Korean Marrow Donor Programme (KMDP) about £400,000 (₩ 700 million) a year to cover costs related to donor typing and operating the agency. In Korea, KMDP arranged 149 unrelated BMTs including 26 cases from Japan by November 2000.

[216] The actions supporting the victims began immediately after the Second World War with "The Assistance Act of 1952 for the Bereaved Family of the Deaths in the War." "The Special Treaty Act for the Victims of Atomic Bomb of 1968" provided a comprehensive support package including medical care and financial support for the victims. AT the passing of the 50th anniversary of the bombing, the Japanese government revised the law in 1994 to provide comprehensive support for the victims and their off-springs, extending coverage for all medical costs. The Radiation Effects Study Foundation identified (1997) 176 people among the victims who died of leukaemia.

In the UK, HSCT adoptions escalated amid market reforms, although rationing issues raised public debate on BMT, which was further fuelled by the 'Child B' case of 1995. In the following year, the adoption of HSCT was temporarily hampered. The impacts of the 1997 NHS reforms, which intensified coordination of financial resources for primary and acute care to get the most value while reflecting the health care needs of the people, have yet to be studied. The Anthony Nolan Bone Marrow Trust, founded in 1974 as the first volunteer marrow donor registry, plays a significant role in the promotion of BMT. The Anthony Nolan Bone Marrow Register had a pool of 43,000 potential donors in 1982, which increased to 345,000 registered donors as of September 2003. It matches over 300 donors for patients every year

In the US, public organizations established by the National Organ Transplant Act of 1984 and its subsequent amendment played a significant role in recruiting donors and matching with recipients on national level. The National Marrow Donor Programme began to operate in 1986 and developed the Search Tracking and Registry (STAR) in 1992 to improve the system for matching patients with marrow donors. As summarised in *Table 9-2*, the bone marrow donor registry in the US has the largest pool among the four countries.

Table 9-2. **The number of bone marrow donors in pmp inhabitants**

Country	No. of registered bone marrow donors		No. of registered donors pmp inhabitants	
	ABDR	AR+ABDR	ABDR	AR+ABDR
Japan	115,564	125,448	920	990
Korea	21,385		465	
UK	255,809	415,436	4,510	7,030
US	1,741,938	3,019,381	6,390	11,100

Data sources:

a. For Japan, UK and US from Bone Marrow Donor Worldwide, Bone Marrow Donor Worldwide-Annual Report 1999,

b. For Korea from Korean Marrow Donor Programme 20 Dec. 2000 Newsletter

Fourth, financial supports from charities have been active for the patients undertaking HSCTs, especially in Korea. More than 10 charities support about £5 million a year for patient's share in HSCTs and chemotherapies. In other three countries, charities for supporting HSCTs and chemotherapies seem to be less active but it was impossible to investigate the situations.

In addition, the leading role in the advent of HSCT of a country influences the adoption. Major advancements in the development of HSCT technology have been recorded in the US, where the adoption of HSCT is at the highest. The application of HSCTs has been significantly expanded from haematological malignancies including leukaemia to a wide range of solid tumours. As detailed in *Table 2-2* of chapter 2, about 60 % of total HSCTs in the US from the beginning of transplant registry through recent were applied for haematological malignancies. Remaining about 40 % were applied for other diseases including solid tumours and the applications other than haematological malignance keep growing Expanding the application has mainly been pioneered in the US.

Due to its high unit cost, third-party payers have been reluctant to provide coverage for HSCTs in all countries except Japan. Because of historical events, the Japanese government has supported any medical approach that helped treat leukaemia. The highest level of HSCT adoption in the US is paradoxical but may suggest that insurance coverage can promote certain forms of technology diffusion, such as for cancer. Similar to assisted reproductive technology, the case studies on HSCTs suggest that a leading role of a country in developing a technology has significant influence on the diffusion.

9.4. Cochlear implant

In summary, hearing impairments are commonly regarded as a major concern in terms of welfare public in all the four countries. However, approaches for supporting cochlear implants varied among four countries. In the UK, the cost of cochlear implants was supported by special funds allocated in the national health services budget. The US government encouraged early detection of hearing impairments and various public funds support at the state level. In Japan, public support funds finance almost the entire cost of cochlear implants for both children and adults, subsidised within the context of welfare benefits. In Korea, a public support plan was recently set out by the central government. Public support plans have directly financed implants and the insurance coverage has been extended, but only to a certain extent due to concerns surrounding equity in health insurance finance.

As indicated by the case studies, the adoption of cochlear implants is the highest in the UK in pmp, followed by the US, Japan and Korea, respectively. The number of adoptions has rapidly increased during the past decade; the number in Japan was the highest expanded four times from 1996 to 2003. The adoption in the UK is nearly 50 % higher than that of the US and 3 times than Japan. Although it is difficult to accurately make a comparison between the number of potential candidates and actual implants in the four countries, public authorities or professional groups in each country estimate the number of candidates that stand to benefit from an implant may be 673 in Japan, 897 in Korea, 67 in the UK and 1,717 in the US in pmp. Considering the number of cochlear implants carried out so far, potential candidates make up about half the population among those who may need cochlear implants in the UK, while less than 5 % of the total candidates have received implants in other three countries.

In the four countries, public concerns for the potential candidates are currently well established and included in national welfare programmes though the extent varied. Public programmes support the early detection of cochlear implant in the UK and provide full funding. In the US, the Joint Committee of Infant Hearing (1994) mandated all infants with hearing loss should be identified be the age of 3 months. “Health People 2000” project also pursues to identify all children with permanent hearing loss before 12 months of age. Public supports for early identification of hearing impairment lacked in both Japan and Korea.

Financial supports from public funds also started earlier in the UK and US than the Japan and Korea. In the UK, the British government began to support cochlear implantation with special funding from 1991 stemming from the national cochlear implant programme commenced in 1989/90 fiscal year. As mentioned earlier part of this section, the US government also provide public insurance for the disabled with hearing impairment. In the Japan and Korea, the cost for cochlear implant was provided insurance coverage in recent; 1994 for 22 channel and 2000 for 24 channel in Japan, and 2005 in Korea. Without insurance coverage, it was hard to have cochlear implantation in Japan and Korea due to its high cost.

As a technology that does not highly requires sophisticated skills but demands high unit cost, the result of this research suggest that the diffusion of cochlear implantation is

significantly influence by insurance coverage. Since the influence of residual factors such as cultural or historical, insurance coverage and other welfare benefit policy of a nation appears to be significantly important.

9.5. Gamma Knife Radiosurgery

In summary, case studies indicate that the adoption of Gamma knife unit is influenced mainly by the ability of providers to purchase the unit. The situation in the UK is notably different from the other three countries. First, the decision for adoption is not in the hands of individual health care providers but under the public authority's control. The NHS budget has long been subject to complaints of under-funding and issues of equitable access. To overcome the cost burdens, the NHS attempted to provide funding through the "private finance initiative (PFI)." PFI funding for Gamma Knife technology however was halted after the first installation in 1989. Thus the UK lagged other countries.

Funding for the other three countries share similarities. In the US, one company, GK Financing, LLC (GKF), played a key role in driving the adoption of the technology by hospitals. Hospitals are responsible for site and installation costs only. GKF charges the hospitals a fee of between $7,500 and $9,500 per procedure. In Japan and Korea, lease companies provide the equipment to hospitals through loans, and receive a return on contracts for 5 to 10 years. In all three countries except the UK, hospitals decide whether to purchase the technology, with the option of making a one time payment or paying by procedure.

Market conditions are also comparable in all three countries, epitomized by intense competition and rivalry. An FFS based retrospective compensation scheme has been fuelling adoption of this HT as the fees are remunerated for each usage.

There are several other reasons contributing to these trends. First, competition among health providers is intense in these countries. In Japan, classification of hospital beds into acute, long-term care, and special disease, has spurred competition especially among acute care hospitals. To attract patients and physicians who may refer patients, acute care

hospitals tend to reinforce their competitiveness with high technological equipment. In Korea, the entrance of a conglomerate stimulated fundamental changes in hospital industry. The first Gamma knife unit was adopted by a conglomerate owned hospital (Hyundai) in 1991. Since then, company owned hospitals and university hospitals have been competing against each other to adopt this technology. The Asian financial crisis of 1997 caused by lack of foreign exchange holdings led to an economic downturn in Korea, weakened the purchasing power for expensive equipment. The increase in the number of adoptions halted for until 2001 when the economy began to recover. Insofar as the use of Gamma Knife unit had not been covered by insurance, health care providers were free from external monitoring. In tandem with insurance coverage, adoption tends to be accelerated by increasing demand on the patients' side both in Japan and Korea.

9.6. Kidney transplantation

The major findings can be summarised as follows. First, the number of organ transplants performed depends on the availability of organs for transplant rather than economic advantage, and this trend is more obvious where health services are provided based on free competition market mechanism. In the US, the number of organ transplants is more closely correlated with the number of hospitals involved in transplant than in the UK. This is primarily resulted from the UNOS's guidelines requiring transplant centres to perform certain number of transplants to be a member of OPTN, which is essential in order to receive qualification for Medicare reimbursement.

Second, the number of organ transplants performed is greatly influenced by income level in terms of GDP. This trend is more obvious in the US and Korea, where the patients should bear a large amount of the costs for transplant. The more costly the procedure, the more the procedure is significantly correlated with income level. In the UK, the levels of organ transplants are higher than in the US as compared with health expenditure in terms of per capita power purchasing parity. Particularly, the number of liver transplants performed was much higher, which indicates that financing measures in the UK are more benevolent but of inferior approach in terms of cost-effectiveness. This also applies where cross-subsidies are minimised and the costly measures of health services are likely to be

restrained. In the UK, preventive approaches to reduce coronary heart disease result in a decreasing number of heart transplants. This indicates that if the central government is a third-party payer, it may be more effective to avoid costly treatments by preventing people from becoming patients who will require expensive medical choices. To achieve this, the government can engage in national campaigns. Such policies are generally hard to implement in a free competition market. Insofar as the insured can switch over the insurer and the insurers can enjoy reverse selection of the insured, it is hard to implement consistent approaches across the country.

In summary, organ transplants are significantly affected by both health care law and the measures for financing health services. As for the health care law, the characteristics in authorising organ procurement and how to operate organsational infrastructures have significant influences. Since the number of organ transplants performed largely dependend on the availability of organs, lesgislative and organisational arrangements for organ transplant are essential elements in organ transplant levels. In all case study countries, the choices of organ transplants are not likey to be based on economic advantages in terms of cost-effectiveness, but largely driven by clinical advantages with life-saving effects at the front.

The number of organ transplants performed are greatly affected by the level of income, and the more costly transplant procedures are much more significantly influenced by income level. The level of income is more significantly influential in the circumstances where cross-subsidies within or amongst insurers are minimised.

The four comparison has shown; 1) big difference in the level of kidney transplant with highest in the US, followed by UK and Korea, especially Japan at low levels, 2) these differences do not appear to be due to the micro characteristics of the technology which offers major gains in terms of life expendency, QoL, and good cost effectiveness, 3) the procedure is generally covered by public or social insurance although the patient has to bear a considerable % of cost in Korea, 4) the low levels in Korea and Japan reflect religious views specifically Confucian tradition that requires not to make deceased body any harm.

Chapter 10: Conclusion and research recommendations

This chapter aims to draw conclusions from the work reported in previous chapters in order to identify research recommendations. It does this by considering the case studies against the model outlined in chapter 2.

10.1. Findings

10.1.1. Micro characteristics of HTs

Micro factor analysis proved that cochlear implant and kidney transplant are more cost-effective compared to compatible approaches. For the remaining four technologies, it was impossible to prove cost-effectiveness in terms of QALY in comparison with alternative choices. The evaluation for assisted reproductive technologies was not possible to compare with natural conception but available to discriminate by unit costs and success rates amongst the procedures. Since the choice of procedure is largely determined by the condition of infertile couple, the evaluation of micro factor influence in the diffusion is inevitably limited. Regarding caesarean section delivery, it was impossible to make cost-effectiveness comparable with natural birth. Economic evaluation was done by comparing the unit cost between caesarean section and normal birth. Regarding HSCTs, micro factor evaluations in the literature reviews have not yet confirmed. In terms of cost, peripheral blood stem cell transplantation costs higher than chemotherapy but less costly compared to bone marrow transplant. The advantage of HSCTs in terms of prolongation of life and improvement of QoL also has not yet been proved both in bone marrow and peripheral stem cell transplantation. Gamma knife radiosurgery offers the lower cost per treatment than open surgery due to shorter hospitalisation. In addition, less pain and shorter period of time for recovery also become major reason to choose Gamma Knife radiosurgery. In clinical aspects, Gamma knife radiosurgery is often chosen when the surgical approach is impossible mainly because of its location. The main impediment for the installation of Gamma Knife unit is high capital cost.

The adoption of ARTs and caesarean section delivery seem to have been motivated mainly to meet individual desire. Caesarean section delivery has been preferred by both of obstetricians and women. For the obstetrician, caesarean section delivery makes it possible

to schedule for labour time and help to avoid malpractice litigation while bequeath better in income. For the women it offers less pain during labour. In addition, in some countries, it enables women to give birth in "lucky" days. Patients choose HSCTs in the hope of a cure for fatal diseases. Gamma knife bestows shorter length of stay and less time for recovery on patients but it requires initial high capital costs to install.

According to economic incentive of adopters and the principal value of a technology, the 6 HTs can be categorised into two groups; welfare-oriented versus private benefit -oriented technologies, as shown in *Figure 10-1,* below.

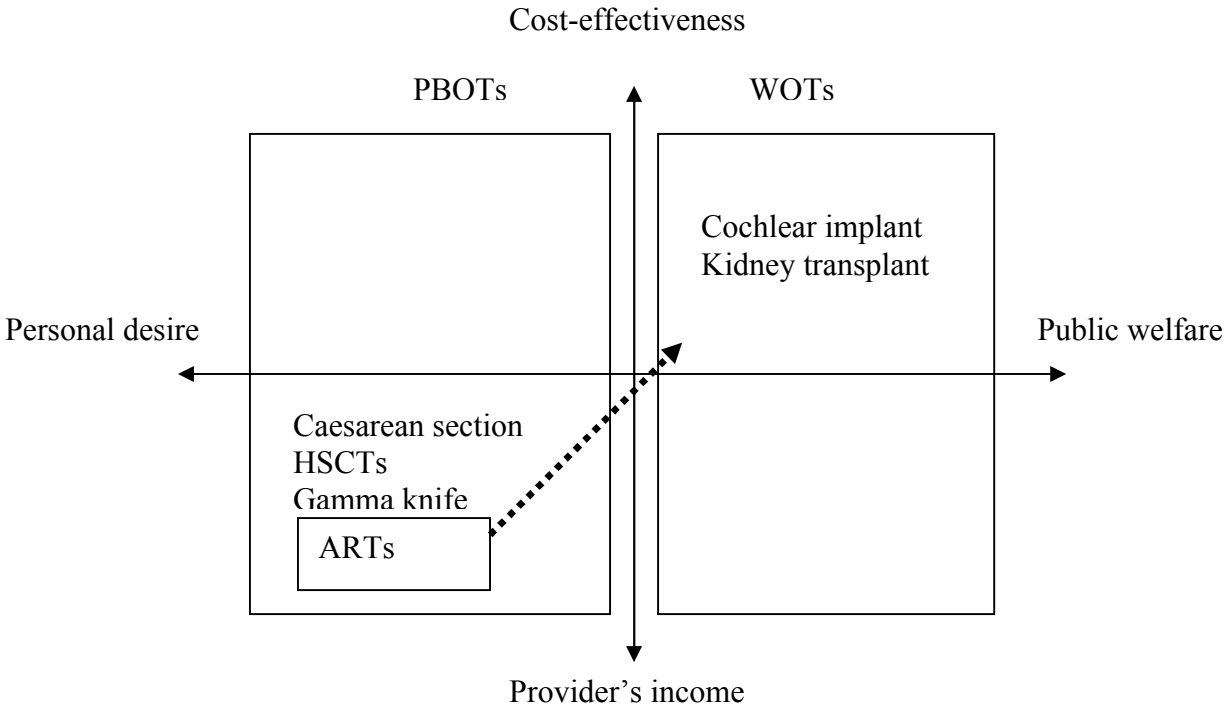


Figure 10-1. **Classification of HTs by economic and benefit function**

Cochlear implant and kidney transplant are clustered into welfare-oriented technology for two reasons; first, the candidate who gets benefit from the technology is regarded as a disabled perspm who benefits from of the national welfare programme, and second, the cost for the adoption is largely subsidised by the public fund. In all four countries the patients with ESRD and those who were profoundly deaf are regarded as disabled by law. In Korea, a special fund subsidised cochlear implant until health insurance commenced to provide coverage. Early detection programmes for the profoundly deaf have

been established under national plans in Japan, in the UK, and in the US. Regarding kidney transplant, the support from public sector has commonly focused on promoting organ donation as well as including the transplant procedure within coverage.

ARTs, caesarean section delivery, Gamma knife units, and HSCTs can be classed as private benefit oriented technologies because they are preferred by providers who pursue profit or by patients seeking to avoid pain, even though their cost-effectiveness is poor or yet to be confirmed.

ARTs are unique. To promote birth which is sometimes linked to population growth, ARTs were subsidised by public funds in many countries. ARTs could be seen as being a transition from private benefit oriented technology to welfare oriented technology. In the past, infertility has not been regarded as a disease, so that insurance coverage has not generally included ART. This may be changing however.

Caesarean section delivery is clearly a matter of choice of which the selection is spurred by provider or patient, and often by both. Excepting Japan where the caesarean section delivery ratio is relatively low, the other three countries have been struggling to limit or reduce the caesarean birth ratio.

HSCTs have been experimental until recent. Due to their high cost, applications for use have been restricted particularly in the UK. HSCT has required prior approval in Korea and most of private health plans in the US before the procedure. Japan, due to its history, appears to have a more favourable approach to HSCT.

Gamma knife requires high capital cost for installation and has high unit cost. Third-party payers have generally been reluctant to pay for it but applications for use have been recognized in economic terms. It offers benefits for patients including shorter LOS and recovery with less pain. However, it is not yet generally approved due to its high cost and its use has therefore become a matter of choice.

10.1.2. Interactions between micro and macro factors in the diffusion of health technology

The results show that health providers under national planning systems tend to prefer cost effective treatments while those in more market systems tend to adopt

technologies that may contribute to improving revenue. The much higher level of cochlear implantation and the greater proportion of patients with renal failure living with functioning grafts in the UK provide the best example.

In contrast, health providers under national health planning system tend to be unable to purchase costly medical equipment unless they get special budgets, for example Gamma knife unit in the UK. The adoption of Gamma knife units has been much more extensive in health systems that are more market oriented. Distinctions between national health planning systems and health systems with market mechanisms are summarised in *Table 10-1*.

Table 10-1. **Motives of HT adoption in national plan and market mechanism**

	National plan	Market mechanism
Positive motive for HT adoption	- Cost-effectiveness - Cost saving for provider - Accomplish public welfare	- High income for provider - Personal desire accomplishment of user - Time saving for provider and/or user
Negative motive for HT adoption	- High capital cost - High cost for use	Income reduction for provider

The number of ARTs performed was highest in the UK. Limited to IVF-ET that includes ICSI, the adoption level has surpassed by Japan and Korea at the end of 1990s. There have not been any specific changes in terms of either payment system or regulation which would account for this. The costs for ARTs are only partly funded by the NHS and therefore couples seeking fertility treatment must pay most of the cost out of their pocket, which is same in the other three countries. This is a something paradox, since the UK was a leader in this area, but seems to be due to infertility not being seen as a disease or ART not being seen as a welfare oriented health technology. The recommendation by NICE of limited NHS provision of ART may signal changes in the status of ART.

The ratio of caesarean section deliveries is lower in the UK compared to the other countries except Japan. Recent increases are largely a result of the NHS guidelines that advice obstetricians to respect maternal request for caesarean section deliveries in respect of the consumers' rights, in addition to the fear of a malpractice litigation. Under a market principle, unrestricted discretion towards caesarean section deliveries has led to a rapid

increase in the number of procedures, especially in Korea. Coupled with cultural reasons, the ratio in Korea is the world's highest. It is however interesting that Japan has the lowest ratio. Due to the shortage of obstetricians and womens' change in attitude regarding pain in labour and safety in birth, however, the ratios rapidly increased to 21.4% of hospital births in 2005.

HSCTs are very expensive but the effectiveness in clinical terms is yet to be confirmed. Insofar as the procedures are often undertaken as a last resort and the majority of the candidates are children, there have been active public supports in all four countries which are limited to bone marrow or cord blood donation. Without public financial support, the majority of the costs are financed privately, although charities provide significant financial support in some countries. HSCTs adoptions are much higher in the US compared with those in the UK. Due to expanding insurance coverage and donor matches, HSCT adoptions are getting increased in both Japan and Korea.

Kidney transplants are recognised to have better outcomes in terms of cost-effectiveness in comparison with compatible treatments. In terms of the prevalence of functioning graft, the level of adoption is the highest in the UK among the selected countries. Although the level in terms of pmp is the highest in the US, the interpretation should go with the prevalence of functional graft against total prevalence of ESRD patients. Accordingly, it also support that the adoption of welfare-oriented technology is preferred by health systems under national health plan. High level of kidney transplantation in the US insinuates that the procedure is profitable due to its high fees. As kidney transplant requires human organ to transplant, it is significantly influenced by cultural tradition. Confucian tradition among far eastern countries that regards the deceased person should not be harmed, hamper organ donation from the deceased person.

In summary, this research attempted to examine the interaction between micro and macro factor in the adoption of HTs. In published researches exploring the determinants for HT adoption, the concerns were mainly focused on external factors which are termed "macro" factors in the present research. Some studies separated internal and external or

intrinsic and extrinsic factors similar to “micro” and “macro” in the present research, few effort has examined interaction between micro and macro factors.

This research suggests that clustering HTs into “welfare oriented technology” and “private benefit oriented technology” by taking into account economic incentive of adopters. Private benefit oriented technologies are those which adopters expect to increase income from provider side or meet personal desire by consumer side. For welfare oriented technology, adoption decision is dominated by the aim of public welfare.

As presumed by the model, among the selected HTs, the adoption levels of cochlear implant and kidney transplant were higher in the UK where health services are provided under national plan than other three countries that have market condition in health service provision. The adoption levels of Gamma knife unit and caesarean section delivery are much higher in those countries under market condition. The case of caesarean section delivery in Japan was exceptional, where caesarean section delivery is the lowest among the countries while situated in market condition. Japan is the only country that health insurance programmes do not cover natural birth as they do not regard the delivery as medical practice. The highest level of caesarean section delivery in the world recorded in Korea was primarily attributed to market mechanism that allow both women giving birth and obstetricians to choose caesarean section delivery in their own decision. Furthermore, cultural tradition of which people believe the fate of a person is determined by the time of birth almost certainly led to the remuneration system being so structured. Almost all Korean parents want their children to be born at a “good time” and hence many try to schedule delivery times in consultation with fortune-tellers. This provides an interesting example of the interaction of micro (parents’ wishes) and macro (remuneration methods).

The high level of ART adoptions in the UK is also consistent with interaction of micro and macro factors. ARTs can be classified as private benefit oriented technology, and accordingly presumed to be higher in market condition. Contrary to expectations, the adoption levels of ARTs were much lower in the market oriented health system of Japan and Korea. This can be attributed to the UK’s leading position in the development of the technology and the cultural traditions in Japan and Korea. The UK has been the leading country for the advent of ARTs, while ART applications have been restricted in Japan and

Korea due to the cultural traditions which respect blood line. The family host system in both Japan and Korea means that the man who has success in extending the family blood line can be the family host.

The installation of Gamma knife units shows the most typical distinction in micro and macro interaction in HT adoption. To adopt, it requires enormous capital cost which needs special budget in NHS, while the adopters in three other countries try to install the unit earlier than others to acquire competitiveness. As a technology that can be classified into private benefit oriented technology, the adoption of Gamma knife units has been mainly promoted in pursuit of income. The adoption behaviours were much more active before health insurance provides coverage for the use of Gamma knife unit, when external inspection for the use (eg, from third-party payer) is minimal and providers have discretion for deciding the fees.

Incentives for health providers in adopting HTs differ according to the health system. The adopters under national health planned systems such as NHS financed by general tax are more likely to adopt welfare oriented technologies while those health systems which are market oriented tend to adopt private benefit oriented technologies. The result implies that some HTs who might be of benefit are neglected under market condition. Health providers however can be restrained by public control. For example, the world's highest caesarean section delivery ratio in Korea has stopped rising due to the inspection programme of Health Insurance Review Agency (HIRA) which investigates whether the choice of caesarean section is clinically appropriate. Relatively lower caesarean section ratio in the US can be attributed to legal regulation that requires peer review for the rational choice of caesarean section delivery NIH has taken action to encourage vaginal births after caesarean. The lower caesarean section ration in Japan may be due to limits on insurance coverage. Since health insurance in Japan does not cover natural birth, health providers, especially private, prefer to choose normal delivery which has no external inspection.

10.2. Limitations

As this research deals with 6 topics in 4 countries, it comprises 24 case studies. Limitations were inevitable. First on data, the study required time-series and cross-sectional data but it was unable to obtain them with same quality for each of 24 examples. *Table 10-*

2 summarises the data quality for each HT. The data for cochlear implant in the US estimates by professionals based on statistics obtained from suppliers.

Table 10-2. **Data quality**

	Japan		Korea		UK		US	
	Source	DQ	Source	DQ	Source	DQ	Source	DQ
ART	JSOG	IC	KSOG	IC	HFEA	C	ASRM	C
caesarean section delivery	MHLW	C	NHIC	C	DOH	C	CDC, NCHS	C
HSCT	JSHCT	C	HSCT Nurse Association	C	BSBMT	C	ABMTR, IBMTR	IC
Cochlear implant	ACITA	C	Local agents	C	D. Marshall	C	A.Q. Summerfield	IC
Gamma Knife	Manufacture (Elekta) JGMSA	C	Manufacture (Elekta)	C	Manufacture (Elekta)	C	Manufacture (Elekta)	C
Kidney transplant	JOTS	C	KONOS	C	UKTSSA	C	UNOS	C

Note: 'C' refers complete data and 'IC' refers incomplete data

The data for HSCTs in the US was also partial although ABMTR (Autologous Blood and Marrow Transplant Registry) collect on regular basis. ART statistics for both Japan and Korea were based on surveys and so represented only for those involved in survey although it covers over 90 %. Although the US has registration system for HSCT, about half of facilities were joint rather than individual registrations. Overall, however, the data are believed to be of sufficient quality to draw the conclusions outlined.

Second, the methods of micro factor evaluation for each HT varied and some of them were impossible to compare with compatible options. As seen on *Table 10-3*, the result of micro factor evaluation in caesarean section delivery is impossible to compare with normal delivery. The only available measure was overall cost, the incidence of complication, and LOS, but technical advantages, such as for women, avoiding pain, and for obstetricians, income and availability of scheduling, were impossible to estimate. It is impossible to measure micro factor influence to a comparable standard across the range of HTs. Nonetheless, the advantages of micro factor could be roughly assessed through the comparison of overall cost, QoL, success rate, and/or survival rate.

Table 10-3. **Availability of micro factor evaluation**

Topic	Method of micro factor evaluation		Comparableness
	Economic	Clinical	
ARTs	WTP Overall cost per cycle	Success rate	Among ARTs
caesarean section delivery	Overall cost per procedure		×
HSCTs	Overall cost per procedure	Survival rate QoL	Among HSCTs and with chemo therapy
Cochlear implant	Costs per QALY, Costs per life year gained	QoL	With other hearing aids
Gamma knife	Costs per QALY, Costs per life year gained	Successful outcomes	With open surgery
Kidney transplant	Costs per QALY, Overall costs per procedure	Survival rate QoL	With dialysis

Third, the macro factor evaluation mainly focused on the provision of insurance coverage and/or public funding. The interpretation of legal environment was limited to ARTs and kidney transplant, linked to concerns for the use of human organs and control over genetics

The frailty of this model is essentially attributed to the scope of evaluation especially for macro factors, which is hard to confirm in quantitative terms. In reality, the component constitute macro factor is actually impossible to define. Accordingly, reimbursement plan of third-party payers, public subsidy, and regulation that may have influence on the technology are of possible evaluation. As found, cultural factor and leading position in the development of health technology has nothing to do with legal aspect although they are parts of environments for HT adoption.

10.3. Conclusion and recommendations

It has been a great concern to policy makers why some health technologies spread faster than others, especially on the international level. Language barriers and

inconsistencies in the quality of data have been major obstacles. The main weaknesses of comparative studies regarding the dissemination of HT essentially stem from the lack of theory, and parochialism that has led to comparison within the limited context such as those limited to European countries. Few HT diffusion studies spanned globe. Existing researches focused on one country or the countries sharing common languages, cultural traditions and institutional similarities.

The research is primarily was designed to cope with these two shortcomings by an empirical study comparing four prominent countries – Japan, Korea, UK, and US - with very circumstances in terms of health systems and cultural tradition. Given the minimal literature available, inclusion of the two East Asian countries merits the attention of those interested in further developing the discipline. These countries offer unique insights into the diffusion of HT in rapidly developed economies and countries with health systems financed by social insurance. In this study, these countries were compared with the UK and the US, which have been the main subjects in assessing the determinants of HT dissemination.

In general, the tax funded NHS had tighter control especially a capital spending. More market oriented health systems had more rapid diffusion of HTs offering profit potential and /or meeting patient preferences. Accordingly, this model may be useful for policy makers to recognise what sorts of HTs are more likely to be disseminated in each country. On the other hand, it may be also useful to forecast what kinds of HTs are likely circumscribed in adoption. This model also can be of use for the manufactures of HTs to appraise the opportunity for marketing.

However, there were some paradoxes. First, the caesarean section delivery ratio is the lowest in Japan where the health services are provided under market mechanism. As mentioned already, natural birth is not covered by insurance allowing obstetricians to be free from external monitoring, which offers more financial advantages.

Second, overall ART adoptions are the highest in the UK although IVF-ET procedures including ICSI were greater in Japan and Korea. The UK lead is due to its leading position of the development of technology. Specific practice codes outlined by Human Fertilisation and Embryology Act facilitate ARTs. As procedures related to genetic

linkage such as donor insemination and egg donation have been restricted by the professional community in Japan and Korea, dissemination has been lower and slower.

Third, the adoption of cochlear implants was higher in the US than the UK. The relatively high adoption level is primarily attributed to the public insurance plans in the US including Medicare and Medicaid which cover about 80 % of total patients undertaking the procedure. In addition, legal obligation to diagnosis hearing impairments soon after birth is also regarded to facilitate medical interventions. However, the level of adoption is still higher in the UK than the US in terms of the ratio of the implanted against the estimated population that might benefit.

Fourth, kidney transplant adoption was significantly high in the US in terms of pmp, but much lower than the UK if assessed in terms of the prevalence of functional graft. In the US, patients suffering from ESRD are included in Medicare, which regards it as a disability

A health system paradox is that the adoption of welfare oriented technology is high in the US. Although the health system in the US is market driven in terms of health care services delivery, it has a great deal of public involvement, especially in compensating health providers via public insurance programmes including Medicare and Medicaid, as indicated in *Table 2-4* in Chapter *2*.

Table 10-4. **Level of HT adoptions of each country**

Health system / Technolgy adoption	National plan	Market mechanism		
	UK	Japan	Korea	US
High	ARTs HSCTs CI KT	ARTs Gamma Knife	CS delivery Gamma Knife	HSCTs CI Gamma Knife KT
Medium	CS delivery	CI HSCTs	CI HSCTs KT	ARTs CS delivery
Low	Gamma Knife	KT CS delivery		

Overall, the levels of HT adoptions in the UK and US were higher compared to the Japan and Korea shown in *Table 10-4*. The UK and the US have following characteristics against the Japan and Korea;

- Higher income in terms of GDP at power purchasing parity
- Leading position in the advent of HTs (especially for ARTs, HSCTs, cochlear implant, and kidney transplant)
- Christian culture

In any further explorations, the impacts of the following factors need to be carefully considered. First, cultural traditions have critical influences for certain technologies like caesarean section deliveries in Korea. Second, the influence of personal income also needs to be considered as confirmed in the kidney transplant case, particularly when patients have to pay some or all of the cost provably. Third, patient involvement in the decision making as well as issues of patient rights may be increasing influences for technology adoption, as instanced in the NHS.

These countries provide a good reference point to widen academic interest beyond the existing set of 6 HTs in reckoning the determinants of HT diffusion. The scarcity of empirical evidence on the interactions between micro and macro factor may also further research particularly on pharmaceuticals.

The present research attempted comparative studies exploring patterns of HT diffusion in four different countries. Depending on literature reviews and data analysis, its main frailties include difficulties in establishing cause and effect especially in explaining the interactions between micro and macro factors.

The trajectory of each HT is complex and often unique. It may be not be possible to find a model that can be applied to all kinds of HT, which reflects the influence of health systems, inherent characteristics of HT, and other possible factors. Case studies show the attempts to recognise the diffusion of HTs reckoning micro and macro factor to be useful but limited. Case studies also uncover other factors of importance but which vary by country and technology. The findings suggests that Japan and Korea are different not only health systems but also in ways that culture and HTs interact.

To be generalised as a tool analyse HT diffusion, more research is needed with more HTs and in more countries with wider variety of health systems and cultural tradition.

References

Chapter 1

Abel-Smith, B. (1994). An Introduction of Health: Policy, Planning and Financing. London: Longman.

Anderson, G., M.A. Hall, T.R. Smith (1998) When courts review medical appropriateness, *Medical Care*, Vol. 36 (8): 1295-1302.

Anderson, G.F,.J. Hurst, J. Hussey, J.P. Jee-Hughes (2000). Health spending and outcomes: trends in industrialized countries, *Health Affairs*, Vol. 19 (3): 178-192

Damanpour, F. (1991). Organisational innovation: A meta-analysis of effects of determinants and moderators. *Academy of Management Journal,* Vol. 34(3): 555-590.

Damanpour, F. and W.M. Evan (1984). Organizational Innovation and Performance: The Problem of 'Organizational Lag', *Administrative Science Quarterly,* Vol. 29: 392-409.

Darley, J. M. & Beniger, J. R. (1981). Diffusion of energy conserving innovations. *Journal of Social Issues, Vol.37: 150-171.*

Datar, S., C. Jordan, S, Kekre, S. Rajiv and K. Srinivasan, (1997) 'New product development and time-to-market', *Management Science*, Vol. 43(4): 452-464.
Davies, S. (1979). The diffusion of process innovations. Cambridge: Cambridge University press.

Davis, F. D. 1989, 'Perceived usefulness, perceived ease of use, and user acceptance of information technology', *MIS Quarterly*, Vol. 13 (3): 319-40.

Department of Health. Assessing the effects of health technologies: principles, practice, proposals. London: Department of Health; 1992.

Escarce, J. J. (1996). Externalities in hospitals and physician adoption of a new surgical technology: An exploratory analysis. *Journal of Health Economics,* Vol. 15: 715-734.

Ferguson, J.H., M. Dubinsky, and P.J. Kirsh. (1993). Court-ordered reimbursement for unproven medical technology: circumventing technology assessment. *JAMA, V0l. 269 (16): 2116-2121.*

Fineberg, H. V. and Hiatt, H. H. (1979). Evaluation of medical practices: the case for technology assessment. *New England Journal of Medicine,* Vol. 301 (20): 1086-1091.

Frambach, R. T. and N. Schillewaert. (2002). Organizational innovation adoption: a multi-level framework of determinants and opportunities for future research. *Journal of Business Research, Vol.55(2):163-176*

Fuchs, V. R. (1996). Economics, values, and health care reform. *American Economic Review,* Vol. 86(1): 1-24.

Gatignon, H. and T.S. Robertson. (1989). Technology diffusion: an empirical test of competitive effects. *Journal of Marketing,* Vol. 53: 35-49.

Gelijns A. and N . Rosenberg (1994). The dynamics of technological change in medicine. *Health Affairs* (Summer): 28-46.

Gomulka, S. (1990). 'The theory of technology change and economic growth, London: Routledge. p.80.

Hurley, R.F., G.T.M. Hult (1998). Innovation, market orientation, and organizational learning: An integration and empirical examination. *Joumal of Marketing, Vol. 62(3):42-54.*

Jonsson, E. and D. Banta. (1999). Management of health technologies: an international View. *BMJ,* Vol. 319: 1293-5.

Kalb, P. E. (1990). Controlling health care costs by controlling technology: a private contractual approach. *Yale Law Journal,* Vol. 99: 1109-26.

Kimberly, J. and M. Evanisko. (1981). Organisational Innovation: The influence of individual, organisational, and contextual factors on hospital adoption of technological and administrative innovations. *Academy of Management Journal,* Vol. 24: 689-713.

Knight, K.E. (1967). A descriptive model of the intra-firm innovation process. *Journal of Business,* Vol. 40: 478-496.

Mahajan, V. and Peterson R.A. (1985). Models for Innovation Diffusion. Newbury Park, CA: Sage Publications.

Mansfield E. (1993).The diffusion of flexible manufacturing systems in Japan, Europe and the United States. Manage Sci Vol. (39): 149 – 59

Mansfield, E. (1968).Industrial Research and Technological Innovation. New York: W.W. Norton.

Mella, P. (2001) Cominatory system theory: a theory for understanding and controlling collective phenomena. NEW- New Economic Windows: New Paradigms for the New Millennium, Università deli Studi di Salerno. Salerno (Italy), Semptember 13, 15, 2001. Obtained from http://www.ea2000.it/cst/cst_salerno.pdf accessed on 29 April 2008

Newhouse, J. (1992). Medical care costs: how much welfare loss? *Journal of Economic Perspective,* Vol. 6: 3-21

Nystrom, P. C., K. Ramamurthy and A. L. Wilson(2002). Organizational context, climate and innovativeness: adoption of imaging technology. *Journal of Engineering and Technology Management, Vol.19(3-4):221-247*

Oates, L. (2000). The court's role in decisions about medical treatment. *BMJ, Vol.321: 1282-4.*

OECD, (1993) 'OECD Health Systems: Facts and Trends 1980-1991', OECD Health Policy Studies No. 3.

Office of Health Economics, (1994) 'The impact of behavioural and biomedical advance on health trends over the next 25 years', *OHE briefing*, No. 31 (November).

Office of Technology Assessment, Strategies for Medical Technology Assessment, U.S. Congress, NTIS order No. PB83-113274 (Washington, DC: U.S. Government Printing Office, September 1982).

Office of Technology Assessment. Development of medical technologies: opportunities for assessment. Washington, DC: US Government Publishing Office; 1976.

Okunade, A. A. and V. N. R. Murthy. (2002). Technology as a `major driver' of health care costs: a cointegration analysis of the Newhouse conjecture. *Journal of Health Economics,* Vol 21(1): 147-159

Perry S. and M. Thamer (1999). Medical innovation and the critical role of health technology assessment. JAMA. Vol. 17;282(19):1869-72.

Poulsen, P. B., Adamsen, S., Vondeling, H., and Jørgensen, T. (1998). Diffusion of laparoscopic technologies in Denmark. *Health Policy, 45*(2), 149-167.

Raftery J, Roderick P and Stevens A. (2005). Potential use of routine databases in health technology assessment, *Health Technology Assessment* Vol. 9(20): 1-106

Robert, G., A. Stevens and J. Gabbay. (1999). Early warning system for identifying new healthcare technology. *Health Technology Assessment,* Vol.3(13)

Robinson, W.T. (1990). Product Innovation and Start-Up Business Market Share Performance, *Management Science,* Vol. 36(10): 1279-1289.

Rogers E.M. Diffusion of Innovations. 4th edn. New York: Free Press, 1995.
Rogers, E. and F. Shoemaker. (1971). Communication of innovation: a cross cultural approach. New York: The Free Press.

Schoonmaker, M.M. (1998). Reimbursement issues in genetic testing: the role of the payer in the diffusion of new medical technologies. Dissertation, The Johns Hopkins University.

Schwartz, W. and D. Mandelson. (1992). Why managed care cannot contain hospital costs without rationing?. *Health Affairs,* Vol. 11(2): 100-107.

Stocking, B (1985) Initiative and inertia: case studies in the NHS, London: Nuffield Provincial Hospitals Trust.

Szczepura, A. J. Kankaanpaa (eds) Assessment of health care technologies. Case studies, key concepts and stragetic issues. Cambridge: Wiley, 1996.

Williams, A. (1997). "The role of economics in the evaluation of health care technologies." Pp. 203-237 in Being reasonable about the econimics of health: selected essays, Alan Williams, Cheltenham A.J. Culyer and A. Maynard (ed). : Edward Elgar,.

Chapter 2

Balder, R.A. (1996). Managed Care Made Simple. Ann Arbor: Blackwell Science, Inc. pp. 22-27.

Blanchette, C. (1997), Public and Private Sector Involvement in Health Care Systems: An International Comparison, Bulletin 438E, Library of Parliament.

Collins, J.A., M. Bustillo, R.D. Visscher, L.D. Lawerance and D. MHA Lynne. (1995). An estimate of the cost of in vitro fertilisation in the United States in 1995. *Fertility & Sterility,* Vol.64(3): 538-545.

Custer, S. W. and P. Ketsche (2000), *The Changing Sources of Health Insurance*, Health Insurance Association of America.

Davis, K., G.F. Anderson, D.Rowland and E.P. Steinberg. (1991). Health care cost containment. Baltimore: The Johns Hopkins University Press.

Deber, R., L. Narine, P. Baranek, N. Sharpe, K.M. Duvalko, R. Zlotnik-Shaul, P. Coyte, G. Pink, and P.Williams (1998), The Public-Private Mix in Health Care, in Striking a Balance: Health Care Systems in Canada and Elsewhere, Canada Health Action: Building on the Legacy Papers

Enthoven AC. (1978). Consumer choice health plan. *New England Journal of Medicine Vol.28:650–8.*

Feder, G. and L.V. Uy (1985). The determinants of international creditworthiness and their policy implications. *Journal of Policy Modeling, Vol.7(1):133-156.*

Garber S., M. S. Ridgely, M. Bradley, and K. W. Chin (2002). Payment under public and private insurance and access to cochlear implants, Archives of Otolaryngology, Head and Neck Surgery, Vol. 128: 1145-1152.

Hailey, D.A. (1997). Australian economic evaluation and government decision on pharmaceuticals, compared to assessment of other health technologies. *Social Science Medicine, Vol.45(4): 563-581.*

Ham, C., R. Robinson and M. Benzeval. (1990). Health Check: Health care reforms in an international context. London: King's Fund Institute. p.71.

Henderson, J., McCanlish, R. Kumiega, L. and Petrou, S. (2001). Systematic review of economic aspects of alternative modes of delivery. *British Journal of Obstetrics and Gynaecology.* Vol. 108: 149-157.

Hideo, Y., Hiroo, D. Tomoaki, I. and Kazuhiko, H. (2005). International Heart Journal, Vol. 46(5): 855-866

Himmelstein, D.U. (2005) Illness and Injury as Contributors to Bankruptcy, *Health Affairs - Web exclusive*; W5-63 (347.65/H57). www.healthaffairs.org/WebExclusives.php

HM Treasury, Budget 2007, HC 342, London: The Stationery Office.

HM Treasury, Spending Review 2002, Opportunity and security for all: Investing in an enterprising, fairer Britain. HMSO cm 5570.

Hunter, D.J. (2000). Managing the NHS. *Health Care UK, Winter: 69-76.*

Ikegami, N. (1991). Japanese health care: low cost through regulated fees. *Health Affairs*, Vol. 10(3): 87-109.

International Monetary Fund, World Economic Outlook Database, April 2007, for the year 2006: IMF source.

Johannesson, M.(1995). Economic evaluation of health care and policymaking. *Health Policy, Vol. 33: 179-190.*

Keren R, Helfand , MHomer, . C. , McPhillips , H. and Lieu, T.A. (2002) Projected cost-effectiveness of statewide universal newborn hearing screening. *Pediatrics* Vol. 110(5): 855-64.

Kernick, D. P. (1998). Economic evaluation in health: a thumb nail sketch. *British Medical Journal,* Vol.316: 1663-1665. (p.1663).

Klose, T. (1999). The contingent valuation method in health care. *Health Policy, Vol. 47: 97-123.*

Kongstvedt, P.R. (1993). The managed care health care handbook. Maryland: Aspen Publishers, Inc.

Legris, P., J. Ingham and P. Collerette. (2003). Why do people use information technology? A critical review of the technology acceptance model. *Information & Management, Vol. 40(3): 191-204.*

Lloyd A, R Kennedy, J Hutchinson and W Sawyer. Economic evaluation of highly purified menotropin compared with recombinant follicle-stimulating hormone in assisted reproduction. *Fertility and Sterility*, *Volume 80, Issue 5*, *November 2003*, *Pages 1108-1113*

Managed Care On-Line™, Managed Care Fact Sheet, Managed care national statistics, http://www.mcareol.com/factshts/factnati.htm retrieved on 6 January 2002.

Michael F. Drummond, Mark J. Sculpher, George W. Torrance, Bernie J. O'Brien, Greg L. Stoddart.(2005). Methods for the Economic Evaluation of Health Care Programmes, Third Edition. New York: Oxford University Press.

National Federation of Health Insurance Societies (1997), Health Insurance and Health Insurance Societies in Japan 1997. [Japanese]

National Institute of Clinical Excellence (NICE) (2004), Secta - Costing clinical guidelines: fertility (England), http://www.nice.org.uk/pdf/CG011_Costing_for_clinical_guideline_england.pdf accessed 26 July 2007.

Neumann, P.J., K. Claxton, and M.C. Weinstein. (2000). The FDA's regulation of health economic information. *Health Affairs, Vol.19(5): 129-137.*

NHS Executive (2001) The New NHS- Reference Costs 2000
OECD, OECD Health Data 2000

OECD, OECD Health Data 2001

OECD, OECD Health Data 2003

OECD, OECD Health Data 2005

OECD: New directions in Health Care Policy. OECD Health Policy Studies No 7, Paris 1995.

Office of Technology Assessment.(1983). Diagnosis Related Groups (DRGs) and the Medicare Program: Implications for Medical Technology-A Technical Memorandum, OTA-TM-H-17. Washington, DC: U.S. Congress.

Palmer, C.S., J. Niparko, J.R. Wyatt, M. Rothman, G. de Lissovoy. (1999). A prospective study of the cost-utility of the multichannel cochlear implant. *Otolaryngology-Head & Neck Surgery, vol.125(11): 1221-1228.*

Pashayan, N., Lyratzopoulos, G and Mathur. R. (2006). Cost-effectiveness of primary offer of IVF vs. primary offer of IUI followed by IVF (for IUI failures) in couples with unexplained or mild male factor sub-fertility. *BMC Health Services Research,* Vol. 6:80 doi:10.1186/1472-6963-6-80

Princeton Reimbursement Group, Key Elements of Reimbursement, http://www.prgweb.com/resources/elements.html retrieved 6 January 2002

Propper, C. and Green K. (2001). A large role for the private sector in financing UK health care: the arguments and evidence. Journal of Social Policy, Vol. 30:685-704.

Raftery, J. (1998). Economic evaluation: an introduction. *BMJ, Vol 316: 1013-1014.*

Roemer, M. (1991). National Health Systems of the World: The Issues (National Health Systems). Oxford: Oxford University Press

Rosen R. and Mays N. (1998). The impact of the UK NHS purchaser-provider split on the "rational" introduction of new medical technologies. *Health Policy, vol.* 43:103–123. p.106.

Ruttens, F. (1996). Economic evaluation and health care decision-making. *Health Policy, Vol. 36: 215-229. p.216*

Sloan, F.A.m J. Vlavona, J.M.Perrin and K.W. Admache. (1986). Diffusion of surgical technology- an exploratory study. Journal of Health Econimics, Vol. 5(1): 31-61.

Tradewell, R.L. (1998) Privatizing Public Hospitals: Strategic options in an era of industry-wide consolidation, Reason Public Policy Insitute, Policy Study No. 242.

UK Transplant, Fact sheet 4: The cost effectiveness of transplantation. http://www.uktransplant.org.uk/ukt/newsroom/fact_sheets/cost_effectiveness_of_transplantation_2007-01.doc

WHO, World Health Statistics 2006

Yang, B.M. (1996). The role of health insurance in the growth of the private health sector in Korea. *International Journal of Health Planning and Management, Vol. 11: 231-252.*

Chapter 3

American Society for Reproductive Medicine (ASRM). (1999a). State infertility insurance laws. http://www.asrm.org/patient/insur.html accessed on 22 January.

ASRM. Patient's fact sheet: infertility. Available at: http://www.asrm.org/Patients/FactSheets/Infertility-Fact.pdf. Accessed January 24, 2002.

Baker, D. and M.A. Paterson. (1995). Marketed sperm: use and regulation in the United States. *Fertility and Sterility, Vol. 63(5): 947-952.*

BBC News, NHS to offer one free IVF cycle, 25 Feb. 2004.

Blank, R. and J.C. Merrick. (1995). Human reproduction, emerging technologies, and conflicting rights. Washington, D.C.: CQ Press, A Division of Congressional Quarterly.

Boivin, J. L. Andersson, A. SkoogpSvanberg et al. (1998). Psychological reactions during in-vitro fertilisation: similar response pattern in husbands and wives. *Human Reproduction*, V*ol.13(11): 3262-3267.*

Brahams, D. (1990). Ethics and the law: the law and assisted human conception. *British Medical Bulletin, Vol.46(3): 850-859.*
Brazier, M. (1992). Medicine, Patients and the Law. London: Penguin Books [Second Edition]

Brazier, M., S. Golombok and A. Campbell. (1997). Surrogacy: review for the UK Health Ministers of current arrangements for payment and regulation. Department of Health, UK.

Brinsden, P. R. (1994). Tax on infertility is increased. BMJ Vol. 309:806.

Burridge J. IVF-ET treatment: an end to the postcode lottery. Available at: http://www.ivillage.co.uk/pregnancyandbaby/fertility/infertility/articles/0,9547,4_167331,00.html. Accessed November 24, 2001.

Causio, F., R. Fischetto, L.M. Schonauer, T. Leonetti. (1999). Intracytoplasmic sperm injection in infertile patients with structural cytogenetic abnormalities. *The Journal of Reproductive Medicine, Vol.44(10): 859-864*

CDC (1999). Implementation of the Fertility Clinic Success Rate and Certification Act of 1992- A Model for the Certification of Embryo Laboratories; Notice, Federal Register, vol. 64(139): 39374-39391

CDC (2000). 1998 Assisted Reproductive Technology Success Rates: *National Summary and Fertility Clinics Reports.*

CDC (Centres for Disease Control and Prevention), Department of Health and Human Services. (1999). Implementation of the Fertility Clinic Success Rate and Certification Act of 1992- A Model for the Certification of Embryo Laboratories; Notice, Federal Register, vol. 64(139): 39374-39391

Collins, A., E.W. Freeman, A.S. Boxer, R. Tureck. (1992). Perceptions of infertility and treatment stress in females as compared with males entering in vitro fertilisation treatment. *Fertility and Sterility*, *Vol.57(2): 350-356*

Collins, J.A., M. Bustillo, R.D. Visscher, L.D. Lawerance and D. MHA Lynne. (1995). An estimate of the cost of in vitro fertilisation in the United States in 1995. *Fertility & Sterility, Vol.64(3): 538-545.*

Dalton M, R.J. Lilford. (1989). Benefits of in-vitro fertilization [letter to the editor]. *Lancet December 2:1327.*

Dcikey, R.P. (2007). The relative contribution of assisted reproductive technologies and ovulation induction to multiple births in the United States 5 years after the Society for Assisted Reproductive Technology/American Society for Reproductive Medicine recommendation to limit the number of embryos transferred. Fertility and Sterility, Vol. 88(6): 1554-1561.

Deech, R. (1999). "A fine conception – the experience of the Human Fertilisation and Embryology Authority (HFEA)", Speech to the 13th Congress of the European Association of European Association of Gynaecologists and Obstetricians (EAGO), Jerusalem, 11 May 1998. In European Journal of Obstetrics and Gynecology and Reproductive Biology, Volume 85, Number 1, July 1999 , pp. 3-5(3)

Department of Health (DoH), Survey of NHS Infertility Services (1997-1998)

Devreker,F., M. Van den Bergh, J. Biramane, R.M.L. Winston, Y. Englert and K. Hardy (1999). Effects of taurine on human embryo development *in vitro. Human Reproduction, Vol. 14(9):2350-2356.*

Dickens, B.M. and R.J. Cook. (1999). Some ethical and legal issues in assisted reproductive technology, International. *Journal of Gynecology & Obstetrics, Vol.66: 55-61.*

Donner, D., V. Maertelaer, P. Simmon et al .(1990). Multiple pregnancy reduction: a Belgium experience. *European Journal of Obstetrics & Gynecology and Reproductive Biology Vol. 38: 183-187.*

Doyle, P. (1999). The U.K. Human Fertilisation and Embryology Authority: how it has contributed to the evaluation of assisted reproduction technology. *International Journal of Technology Assessment in Health Care, Vol.15(1): 3-10.*

Edelmann, R.J., K.J. Connolly and H. Bartlett. (1994). Coping strategies and psychological adjustment of couples presenting for IVF. *Journal of Psychosomatic Research, Vol.38(4): 355-64.*

Eugster, A. and A.J.J.M. Vingerhoets. (1999). Psychological aspects of in vitro fertilisation: a review. *Social Science & Medicine, Vol.48: 575-589.*

Evans, D. (1995). Infertility and the NHS. *BMJ, Vol. 311: 1586-7. [Editorials]*

Fishel, S., I. Aslam, F. Lisi, L. Rinaldi, J. Timson, M. Jacobson, L. Gobetz, S. Green, A. Campbell and R. Lisi. (2000). Should ICSI be the treatment of choice for all cases of in-vitro conception?. *Human Reproduction, Vol. 15 (6): 1278-1283.*

Foster, H. (1998). The legal and ethical debate surrounding the storage and destruction of frozen human embryos: a reaction to the mass disposal in Britain and the lack of law in the United States. *Washington University Law Quarterly, Vol.76 (2): 759-780.*

Fujii, S., A. Fukui, E. Yamaguchi et al. (1998). Reducing multiple pretgnancies by restricting the number of embryos transferred to two at the first embryo transfer attempt. *Human Reproduction, Vol.13(12): 3550-3554.*

Gleicher, N. (1998). Strategies to improve insurance coverage for infertility services. *Fertility & Sterility, Vol.70(6):1006-8.*

Goldfarb, J.M., C. Austin, H. Lisbona, B. Peskin and M. Clapp. (1996). Cost-effectiveness of in vitro fertilization. *Obstetrics & Gynecology, Vol. 87(1): 18-21.*

Granberg, M., M. Wikland and L. Hamberger. (1996). Cost-effectiveness of intracytoplasmic sperm injection in comparison with donor insemination. *Acta Obsterica et Gynecologica Scandinavica, Vol.75(8): 734-737.*

Griffin, M. and W.F. Panak. (1998). The economic cost of infertility-related services: an examination of the Massachusetts infertility insurance. *Fertility & Sterility, Vol.70 (1): 22-29.*

HFEA (2001) *Storage of gametes* (CH(01)06, London: HFEA.

HFEA (2007) A long term analysis of the HFEA Register Data 1991-2006, Version 1.0 Revision 2, saved date 11/07/2007, http://www.hfea.gov.uk/docs/Latest_long_term_data_analysis_report_front_cover.pdf, accessed 26 April 2008.

HFEA, 1996 Annual Report

HFEA, 1997 Annual Report

HFEA, HFEA Register data 1991-2006

HFEA, Survey of NHS Infertility Services 1997-98

Hong, Y.L. (2001). Opinion poll on the Code of Conduct of Korean Medical Association: 38 per cent accept surrogate mother. *Joongang Daily Newspaper, 27 May*. http://data.bls.gov/servlet/SurveyOutputServlet?jrunsessionid=1011774245060255010 retrieved on 23 January.

Hughes, E.G. and M. Giacomini (2001). Funding in vitro fertilization treatment for persistent subfertility: the pain and the politics. *Fertility and Sterility, Vol.76(3): 431-442.*

Im, H.K. (2001). Why the debates on abortion, surrogate mother and brain death emerge?. *Chosun Daily Newspaper, 16 November*. [Korean]

Interim Licensing Authority for Human in Vitro Fertilisation and Embryology (ILA) (1991). The sixth report of the interim licensing authority for human in vitro fertilisation and embryology. London: ILA.

Japan Society of Obstetric and Gynaecology (1984), Guideline for ARP adoption, *The Journal of Obstetrics and Gynaecology Research, Vol.* 36*:1131-1133.* [Japanese]

Japan Society of Obstetric and Gynaecology (1988), Guideline for ARP adoption, *The Journal of Obstetrics and Gynaecology Research, Vol.* 40*:519-520.* [Japanese]

Japan Society of Obstetric and Gynaecology (1994), Annual Ethics Committee Report on Assisted Reproduction Technology Registration on 1993, *The Journal of Obstetrics and Gynaecology Research, Vol.46:929-933.* [Japanese]

Japan Society of Obstetric and Gynaecology (1995), Annual Ethics Committee Report on Assisted Reproduction Technology Registration on 1994, *The Journal of Obstetrics and Gynaecology Research, Vol.47:444-448.* [Japanese]

Japan Society of Obstetric and Gynaecology (1996), Annual Ethics Committee Report on Assisted Reproduction Technology Registration on 1994, *The Journal of Obstetrics and Gynaecology Research, Vol.48:365-371.* [Japanese]

Japan Society of Obstetric and Gynaecology (1997), Annual Ethics Committee Report on Assisted Reproduction Technology Registration on 1995, *The Journal of Obstetrics and Gynaecology Research, Vol. 49:697—702.* [Japanese]

Japan Society of Obstetric and Gynaecology (1998), Annual Ethics Committee Report on Assisted Reproduction Technology Registration on 1996, *The Journal of Obstetrics and Gynaecology Research, Vol. 50:267—277.* [Japanese]

Japan Society of Obstetric and Gynaecology (1998), Annual Ethics Committee Report on Assisted Reproduction Technology Registration on 1996, *The Journal of Obstetrics and Gynaecology Research, Vol. 50:267—277.* [Japanese]

Japan Society of Obstetric and Gynaecology (1999), Annual Ethics Committee Report on Assisted Reproduction Technology Registration on 1997-98, *The Journal of Obstetrics and Gynaecology Research, Vol.51:361-367.* [Japanese]

Japan Society of Obstetric and Gynaecology (2000), Annual Ethics Committee Report on Assisted Reproduction Technology Registration on 1998, *The Journal of Obstetrics and Gynaecology Research, Vol.52:962-987.* [Japanese]

Japan Society of Obstetric and Gynaecology (2001a), Annual Ethics Committee Report on Assisted Reproduction Technology Registration on 1998, *The Journal of Obstetrics and Gynaecology Research, Vol. 53: 665-682.* [Japanese]

Japan Society of Obstetric and Gynaecology (2001b), Annual Ethics Committee Report on Assisted Reproduction Technology Registration on 1999, *The Journal of Obstetrics and Gynaecology Research, Vol. 53: 1462-1493.* [Japanese]

Japan Society of Obstetric and Gynaecology (2003), Annual Ethics Committee Report on Assisted Reproduction Technology Registration on 2000~2001, *The Journal of Obstetrics and Gynaecology Research, Vol. 55:1272-1287.* [Japanese]

Japan Society of Obstetric and Gynaecology (2005), Annual Ethics Committee Report on Assisted Reproduction Technology Registration on 2002, *The Journal of Obstetrics and Gynaecology Research, Vol. 57:118-146.* [Japanese]

Johnson, M.H. (1998). Should the use of assisted reproduction techniques be deregulated? *Human Reproduction, Vol.13(7): 1769-1776.*

Jones, H. W. and J. Cohen. (2001). IFFS Surveillance 01. *Fertility and Sterility, Vol.76 (5, Suppl. 2): S5-S36.*

Joongang Daily Newspaper, 22 November 1993 [Korean]

Jung, Y.W.m J.S. Ha and K.H. Lee. (2000). Rampant commercial surrogate mothers among Korean-Chinese. *Joongang Daily Newspaper, 9 December.*

Kennelly, C. and Reisel, J. (1998) Report of the Sixth National Survey of the Funding and Provision of Infertility Services. London: College of Health.

Ko, J.K., 10 years of IVF-ET in Korea: Korea leaped into leading country in infertility treatment, Joongang Daily Newspaper, 10 Oct. 1995.

Korean Society of Obstetrics and Gaenycologists (1997), Current Status of Assisted Reproductive Technology in Korea for 1992-93. *The Journal of Korean Obstetrics and Gaenycology, Vol.40:1557-1570.* [Korean]

Korean Society of Obstetrics and Gaenycologists (1998), Current Status of Assisted Reproductive Technology in Korea for 1994. *The Journal of Korean Obstetrics and Gaenycology, Vol.41:236-252.* [Korean]

Korean Society of Obstetrics and Gaenycologists (1999), Current Status of Assisted Reproductive Technology in Korea for 1996, *The Journal of Korean Obstetrics and Gaenycology, Vol.42:231-252.* [Korean]

Korean Society of Obstetrics and Gaenycologists (1999), Current Status of Assisted Reproductive Technology in Korea for 1995. *The Journal of Korean Obstetrics and Gaenycology, Vol.42(4):683-703.* [Korean]

Korean Society of Obstetrics and Gaenycologists (1999), Current Status of Assisted Reproductive Technology in Korea for 1996. *The Journal of Korean Obstetrics and Gaenycology, Vol.42 (10):231-252.* [Korean]

Korean Society of Obstetrics and Gaenycologists (2003), Current Status of Assisted Reproductive Technology in Korea for 2000. *The Journal of Korean Obstetrics and Gaenycology, Vol.46 (10):1888-1904.* [Korean]

Korean Society of Obstetrics and Gaenycologists (2004), Current Status of Assisted Reproductive Technology in Korea for 2001. *The Journal of Korean Obstetrics and Gaenycology, Vol.47 (12):2285-2302.* [Korean]

Korean Society of Obstetrics and Gaenycologists (2005), Current Status of Assisted Reproductive Technology in Korea for 2002. *The Journal of Korean Obstetrics and Gaenycology, Vol.48 (12):2777-2796.* [Korean]

Korean Society of Obstetrics and Gaenycologists (2006), Current Status of Assisted Reproductive Technology in Korea for 2003, *The Journal of Korean Obstetrics and Gaenycology, Vol.48(12): 2480-2497* [Korean]

Korean Society of Obstetrics and Gaenycologists (2006), Current Status of Assisted Reproductive Technology in Korea for 2003. *The Journal of Korean Obstetrics and Gaenycology, Vol.49(12): 2480-2497* [Korean]

Kutoba, T., Y. Shimizu and T. Aso. (1999). Are there disadvantages to outpatient IVF? Experience from current practice in Japan. *Human Reproduction, Vol.14(8): 1931-1933*

Mainichi Daily News, 17 Feb.2000 [Japanese]

Mainichi Daily News, 6 May 1999 [Japanese]

Mainichi Daily News, 7 January 1998 [Japanese]

Mainichi Daily Newspaper, 22 June 1998 [Japanese]

Mainichi Daily Newspaper, 30 August 1998 [Japanese]

Marshall, E.C. and D.J. Spiegelhalter (1998). Reliability of league tables of in vitro fertilisation clinics: retrospective analysis of live birth rates, *BMJ, Vol. 317: 1701—1704*

Meikle, S.F., I. Danel, and L.S. Wilcox. (1999). Surveillance of assisted reproductive technology in the United States. *International Journal of Technology Assessment in Health Care, Vol.15 (1):11-14.*

Murray, M.C., Aetna scored on dropping fertility coverage. *National Underwriter, 9 Feb.,1998.*

Murray, T.J. (1997). Money-back guarantees for IVF: an ethical critique. *Journal of Law, Medicine & Ethics, Vol.25(4): 292-294.*

National Collaborating Centre for Women's and Children's Health (2004), Fertility assessment and treatment for people with fertility problems: clinical guideline. Royal College of Obstetricians and Gynaecologist Press, Sussex Place, London.

National Institute for Clinical Excellence. Fertility: Assessmentand Treatment for People with Fertility Problems. Clinical Guideline 11. London, UK: National Collaborating Centre for Women's and Children's Health; 2004.

Neumann, P.J. (1997). Should health insurance cover IVF? Issues and options. *Journal of Health Politics, Policy and Law, Vol.22: 1215-37.*

Neumann, P.J. and M. Johannesson. (1994). The willingness to pay for in vitro fertilization: a pilot study using contingent valuation. *Medical Care, Vol.32(7): 686-699.*

Newton, C.R., M.T. Hearn and A.A. Yuzpe. (1990). Psychological assessment and follow-up after in vitro fertilisation: assessing the impact of failure. *Fertility and Sterility*, *Vol.54(5): 879-886.*

NHS Direct Online, Sub fertility, http://www.healthcareguide.nhsdirect.nhs.uk/info/advice/subfertility.stm accessed on 24 November 2001

Ola, B., M. Afnan, K. Sharif, S. Papaionannou, N. Hammadieh and C.L.R. Barratt. (2001). Should ICSI be the treatment of choice for all cases of in-vitro conception?. *Human Reproduction, Vol. 15 (6): 2485-2490.*

Organisation of Parents Through Surrogate (OPTS), Inc., Your states legal status. http://www.opts.com/states.htm accessed on 24 January 2002.

Perone, N. (1994). In vitro fertilization and embryo transfer: a historical perspective. *Journal of Reproductive Medicine, Vol.39: 695-700.*

Practice Statement Committee, ASRM. Practice Committee statement: intracytoplasmic sperm injection (ICSI). Available at: http://www.asrm.org/Media/Practice/statemnt.html. Accessed January 28, 2002.

Robertson, J.A. and T.J. Schneyer. (1997). Professional self-regulation and shared-risk programs for in vitro fertilisation. *Journal of Law, Medicine & Ethics, Vol.25(4): 283-291.*

Ryan, M and C. Donaldson. (1996). Assessing the costs of assisted reproductive techniques, *British Journal of Obstetrics and Gynaecology, Vol.103(3): 198-201.*

Seoul Broadcasting System, Secret in the veil: the truth of infertility, Mistery Document; What we want know. 10 December 1994.

Serour, G.I., M. Aboulghar, R. Mansour, M. A. Sattar, Y. Amin, H. Aboulehar. (1998). Complications of medically assisted conception in 3,500 cycles. *Infertility and Sterility, Vol.70(4): 638-642.*

Silva, P.D., M.L. Sorensen and D.E. Silva. (1997). Improving the cost-to-benefit ratio of in-vitro fertilization. *Wisconsin Medical Journal, Vol. 96(1): 36-39.*

Slade, P; Emery, J; Lieberman, B A. (1997). A prospective, longitudinal study of emotions and relationships in in-vitro fertilization treatment, *Human Reproduction, Vol. 12(1): 183-190*

Society for Assisted Reproductive Technology and American Society for Reproductive Medicine (2002) Assisted reproductive technology in the United States: 1998 results generated from the American Society for Reproductive Medicine/Society for Assisted Reproductive Technology Registry, *Fertility and Sterility, Vol. 77(1): 18-31*

Society for Assisted Reproductive Technology and American Society for Reproductive Medicine (2007) Assisted reproductive technology in the United States: 2001 results generated from the American Society for Reproductive Medicine/Society for Assisted Reproductive Technology Registry, *Fertility and Sterility, Vol.87(6): 1253-66*

Society for Assisted Reproductive Technology and American Society for Reproductive Medicine (2002) Assisted reproductive technology in the United States: 1999 results generated from the American Society for Reproductive Medicine/Society for Assisted Reproductive Technology Registry, *Fertility and Sterility, Vol. 78(5): 918-31*

Society for Assisted Reproductive Technology and American Society for Reproductive Medicine (2002) Assisted reproductive technology in the United States: 1998 results generated from the American Society for Reproductive Medicine/Society for Assisted Reproductive Technology Registry, *Fertility and Sterility, Vol. 77(1): 18-31*

Society for Assisted Reproductive Technology and American Society for Reproductive Medicine (2000) Assisted reproductive technology in the United States: 1997 results generated from the American Society for Reproductive Medicine/Society for Assisted Reproductive Technology Registry, *Fertility and Sterility, Vol. 74 (4): 641-653*

Society for Assisted Reproductive Technology and American Society for Reproductive Medicine (2002) Assisted reproductive technology in the United States: 1998 results generated from the American Society for Reproductive Medicine/Society for Assisted Reproductive Technology Registry, *Fertility and Sterility, Vol. 77(1): 18-31*

Society for Assisted Reproductive Technology and The American Society for Reproductive Medicine (1999b) Assisted reproductive technology in the united states: 1996 results generated from the American society for reproductive medicine/society for assisted reproductive technology registry, *Fertility and Sterility, Vol. 71(5): 798-807*

Society for Assisted Reproductive Technology and The American Society for Reproductive Medicine (1998) Assisted Reproductive Technology in the United States and Canada: 1995 Results Generated from the American Society for Reproductive Medicine/Society for Assisted Reproductive Technology Registry, *Fertility and Sterility, Vol. 69(3): 389-398*

Society for Assisted Reproductive Technology and The American Society for Reproductive Medicine (1996) Assisted reproductive technology in the United States and Canada: 1994 results generated from the American Society for Reproductive Medicine/Society for Assisted Reproductive Technology Registry, *Fertility and Sterility, Vol. 66 (5): 697-705*

Society for Assisted Reproductive Technology and The American Society for Reproductive Medicine (1995) Assisted reproductive technology in the United States and Canada: 1993 results generated from the American Society for Reproductive Medicine/Society for Assisted Reproductive Technology Registry, *Fertility and Sterility, Vol. 64(1): 13-21*

Society for Assisted Reproductive Technology, The American Fertility Society (1994) Assisted reproductive technology in the United States and Canada: 1992 results generated from the American Fertility Society/Society for Assisted Reproductive Technology Registry, *Fertility and Sterility, Vol. 62(6): 1121-1128*

Society for Assisted Reproductive Technology, The American Fertility Society (1993) Assisted reproductive technology in the United States and Canada: 1991 results from the Society for Assisted Reproductive Technology generated from the American Fertility Society Registry, *Fertility and Sterility, Vol. 59(5): 956-962*

Society for Assisted Reproductive Technology, The American Fertility Society (1992) Assisted reproductive technology in the United States and Canada: 1990 results from the Society for Assisted Reproductive Technology generated from the American Fertility Society Registry, *Fertility and Sterility, Vol. 59(1):15-24*

Society for Assisted Reproductive Technology, The American Fertility Society (1991) In vitro fertilization-embryo transfer (IVF-ET) in the United States: 1989 results from the IVF-ET Registry. *Fertility and Sterility, Vol. 55(1):14-22*

Society for Assisted Reproductive Technology, The American Fertility Society (1990) In vitro fertilization-embryo transfer (IVF-ET) in the United States: 1988 results from the IVF-ET Registry. *Fertility and Sterility, Vol. 53(1):13-20.*

Society for Assisted Reproductive Technology, The American Fertility Society (1990) In vitro fertilization-embryo transfer (IVF-ET) in the United States: 1987 results from the National IVF-ET Registry. *Fertility and Sterility, Vol. 51(1):13-9.*

Solursh, D.S., J.W. Schorer and M.P. Solursh. (1997). "Baby oh baby" – Advances in assisted reproductive technology. *Medicine and Law, Vol.16: 779-788.*

The ASRM Ethics Committee. Shared-risk or refund programs in assisted reproduction. Available at: http://www.asrm.org/Media/Ethics/shared.html. Accessed January 24, 2002

The Ethics Committee of the American Society for Reproductive Medicine (1994). Ethical Considerations of Assisted Reproductive Technologies. *Fertility Fertility and Sterility, Vol.62: Suppl. 1.*

The Ethics Committee of the American Society for Reproductive Medicine (1997). Informed consent and the use of gametes and embryos for research, *Fertility and Sterility*, *Volume 68, Issue 5: 780-781*

The Japanese Times, 22 May 2001

The Ministry of Health and Welfare (MOHW), Official Notice on Health Insurance Coverage No. 1492-8112, 1994 [Korean]

The Ministry of Health and Welfare (MOHW), Official Notice on Health Insurance Coverage No. 65720-404, 1993 [Korean]

The Ministry of Health, Labour, and Welfare (MOHLW), Policy Bulletin No. 96, 1 April 2004 [Japanese]

van den Akker, O.B.A. (1999). Organisational selection and assessment of women entering a surrogacy agreement in the UK. *Human Reproduction, Vol.14(1): 262-266*

Van Voorhis, B.J., A.E.T. Sparks, B.D. Allen, D.W. Stovall, C.H. Syrop and F. K. Chapler. (1997). Cost-effectiveness of infertility treatments: a cohort study. *Fertility and Sterility, Vol. 67(5): 830-836*

Weltman J.J. Points to consider on the subject of surrogacy. The American Surrogacy Center, Inc. Web site. Available at: http://www.surrogacy.com/legals/article/points.html. Accessed January 24, 2002.

Wennerholm, U. -B., C, Bergh, L. Hamberger, K. Lundin, L. Nilsson, M. Wikland, B. Källén. (2000). Incidence of congenital malformations in children born after ICSI. *Human Reproduction Vol.15(4): 944-948*

WHO (1995). Achieving Reproductive Health for All, Geneva: WHO/FHE/95.6

Wølner-Hanssen, P. and H. Rydhstroem .(1998). Cost-effectiveness analysis of in-vitro fertilization: estimated costs per successful pregnancy after transfer of one or two embryos. *Human Reproduction, Vol.13(1): 88-94.*

Chapter 4

Alan Guttmacher Institute (1987). Medicaid, Family Planning and the FY 1988 Budget: Legislative Analysis. Washington, D.C.: Alan Guttmacher Institute.

Alexander, J.M., D.D. MCIntire, K.J. Leveno. (2001). Prolonged pregnancy: induction of labour and cesarean births. *Obstet Gyecol, Vol. 97(6): 911-5.*

Al-Mufti, R., A. MaCarthy, and N.M. Fisk. (1996) Obstetricians' personal choice and mode of delivery (letter). *Lancet,* Vol. 347:544.

Al-Mufti, R., A. McCarthy and N. M. Fisk. (1997). Survey of obstetricians' personal preference and discretionary practice. *European Journal of Obstetrics & Gynecology and Reproductive Biology*, Vol. 73(1): 1-4

Amu O., S. Rajendran, and Bolaji II. (1998). Should doctors perform an elective caesarean section on request? Maternal choice alone should not determine method of delivery.BMJ. Vol. 317(7156):463-5.

Ananth, C.V., J.C. Smulian, A.M. Vintzileos (1997) The association of placenta previa with history of cesarean delivery and abortion: a metaanalysis. American Journal of Obstetrics Gynaecology. Vol. 177(5):1071-8.

Asahi Newspaper, 10 July 2006

Asakura H. and S.A. Myers (1995). More than one previous cesarean delivery: a 5-year experience with 435 patients. *Obstet Gynecol.* Vol. 85(6):924-9

Audit Commission (1997). Higher Purchase: Commissioning Specialised Services in the NHS, London: Audit Commission Publications

Bennett, V. Oh baby, do we have a problem: Britain's midwives are ignored, underpaid and angry. *The Times, Saturday May 12*. 2001.

Blanchette, H. (1995). Comparison of Obstetric Outcome of a Primary-Care Access Clinic Staffed by Certified Nurse-Midwives and a Private Practice Group of Obstetricians in the Same Community. *American Journal of Obstetrics and Gynecology*, Vol.172(6): 1864-1871

Boe, N.M., E,M. Eby-Wilkens, N.T. Fueld, H.L. Herdriana and W.M. Gilbert (1998) Maternal morbidity associated with a failed trial of labour. *Americal Journal of Obstetrics and Gynecology, Vol. 178(1S): 127S. [18th Annual Meeting of the Society of Perinatal Obstetricians; Feb. 2-7, 1998; Fontainebleau Hiton; Maimi Beech, Florida]*

Braveman, P., S. Egerter; F. Edmonston, M. Verdon. (1995). Racial/ethnic differences in the likelihood of cesarean delivery, California. *American Journal of Public Health,* Vol. 85(5): 625-630

Cai, W., J.S. Marks, C.H.C. Chen, Y. Zhuang, L. Morris, and J.R. Harris. (1998). Increased caesarean section rates and emerging patterns of health insurance in Shanghai, China. *American Journal of Public Health,* Vol. 88(5): 777-780.

CDC, Vital and Health Statistics, National Hospital Discharge Survey: 1998 Annual Summary

Centers for Disease Control (CDC) (1995) Rates of cesarean delivery - United States, 1993. *MMWR* Vol. 44(15): 303-7.

Centers for Disease Control (CDC) (2005) Trend in caesarean rates for first births and repeat caesarean rates for low-risk women: United State, 1990-2003. National Vital Statistics Reports, Vol. 54(4), p.82.

Churchill H. (1997). Caesarean Birth: Experience, Practice and History. Cheshire: England:Books for Midwives Press.

Cotzias, C S, S. Paterson-Brown, N.M. Fisk (2001) Obstetricians say yes to maternal request for elective caesarean section: a survey of current opinion, *European Journal of Obstetrics, Gynecology, and Reproductive Biology,* Vol. 97(1): 15-16.

Cowan, R.K., R.A. Kinch, B. Ellis, and R. Anderson (1994). Trial of labor following cesarean delivery. Obstetrics & Gynecology Vol. 83:933-936

Darby, M. (1992). Reimbursement has small impact on c-section rates. In Report on Medical Guidelines and Outcome Research. Alexandria, Va: Capitol Publications.

Department of Health (DoH) (2005). NHS Maternity Statistics, England: 2003-2004

Department of Health (DoH). Changing childbirth: the report of the Expert Maternity Group. London: HMSO, 1993.

Department of Health and Human Services (DHHS) HHS News, 8 August 2000

Department of Health. Reference costs 2000. London: DoH; 2000.

Drife, J. (1997). Maternity services: the Audit Commission reports. *BMJ* Vol.314:844

Eftekhar, K and P. Steer. (2000). Caesarean section controversy : Women choose caesarean section. *BMJ* Vol. 320(7241): 1072

Federal Register (1983) Vol. 63 (207): Group Health Plan and Health Insurance Issuers Under the Newborns' and Mothers' Health Projection Act; Joint Interim Rule.

Fisher J, J. Astbury, A. Smith. (1997). Adverse psychological impact of operative obstetric interventions: a prospective longitudinal study. *Aust N Z J Psychiatry, Vol.5:728-38.*

Fisher J, Smith A, Astbury. (1995). Private health insurance and a healthy personality: new risk factors for obstetric intervention? *Journal Psychosom Obstet Gynaecol*, *Vol.16(1):1-9*

Flamm, B.L. (1998). Vaginal birth after cesarean: where have we been and where are we going?. *Obstertrical and Gynecological Survey, Vol. 53(1): 661-662.*

Flamm, B.L. (1998). Vaginal birth after cesarean: where have we been and where are we going?. *Obstertrical and Gynecological Survey, Vol. 53(1): 661-662.*

Flamm, B.L., Goings, J.R., Kiu, Y. Wolde-Tsadik, G. (1994). Elective repeat cesarean delivery versus trial of labor: a prospective multicenter study. *Obstet Gynecol*, Vol. 83: 927-32.

Francome C, W. Savage, H. Churchill and H. Lewison. (1993). Caesarean birth in Britain. Middlesex University Press, London.

Gabay M and Wolfe SM. Unnecessary Cesarean Sections: Curing a National Epidemic. Washington, D.C.: Public Citizen's Health Research Group, 1994.

Garel M., N. Lelong, and M. Kaminski (1988). Follow-up study of psychological consequences of caesarean childbirth. *Early Hum Dev. Vol. 16(2-3):271-82.*

Geary, M., M. Fanagan, and P. Boylan. (1997). Maternal satisfaction with management in labour and preference for mode of delivery. *J Perinat Med* Vol. 25:433–439.

Gillman, K. (2000).Obstetrics and Gynaecology, NHSLA Review, Issue 19 Summer 2000, CNST 8-10.

Gregory, K.D. Ramicone, E., Chan, L., Kahn, K.L. (1999) Cesarean deliveries for Medicaid patients: A comparison in public and private hospitals in Los Angeles County. *American Journal of Obstetrics & Gynecology*. 180(5):1177-1184, May 1999.

Gruber J, and Owings M (1996). Physician financial incentives and cesarean section delivery. *Rand J Econ* Spring 27:99-123

Gruber, J., J. Kim and D. Mayzlin. (1999). Physician fees and procedure intensity: the case of cesarean delivery. *Journal of Health Economics,* Vol. 18: 473-490.
Guardian, September 27, 2000

Gurgan, P.Mc, C. Coulter-Smith, P.J. O'Donovan. (2001). A national confidential survey of obstetrician's personal preferences regarding mode of delivery. *European Journal of Obstetrics & Gynecology and Reproductive Biology, Vol. 97: 17-19.*

Hall, M. (1987). When a woman asks for a caesarean section. *BMJ, Vol. 294: 201.*
Hall, M.H. (1994). Mortality associated with elective caesarean section. *BMJ,* Vol. 308, 6963,1572.

Halpern MT, Read JS, Ganoczy DA, and Harris DR. (2000) Cost-effectiveness of cesarean section delivery to prevent mother-to-child transmission of HIV-1. *AIDS*, Vol. 14:691-700.

Hanley, M.L., J.C. Smulian, M.F. Lake, D.A. McLean, and AM Vintzileos (1996) Analysis of repeat cesarean delivery indications: implications of heterogeneity. Am J Obstet Gynecol. Vol. 175(4 Pt 1): 883-8

Hemminki E. and J. Merilainen (1996). Long-term effects of cesarean sections: ectopic pregnancies and placental problems. *Am J Obstet Gynecol*. Vol. 174(5):1569-74.

Henderson E and E.J. Love. (1995). Incidence of hospital-acquired infections associated with caesarean section. *J Hosp Infect* Vol.29(4):245-55

Henderson, J., McCanlish, R. Kumiega, L. and Petrou, S. (2001). Systematic review of economic aspects of alternative modes of delivery. *British Journal of Obstetrics and Gynaecology.* Vol. 108: 149-157.

Hillan, E.M. (1995). Postoperative morbidity following caesarean delivery. *Journal of Nursing,* Vol. 22: 1035-1042.

Hiller L, K. Costeloe and B. Thilaganathan. (1998). Prolonged pregnancy: evaluating gestation specific risks of fetal and infant mortality. *British Journal of Obstetrics and Gynaecology* Vol. 105: 169-73.

Jackson, N. and L.M. Irvine (1998). The influence of maternal request on the elective caesarean section rate. *Journal of Obstetrics Gynaecol,* Vol. 18:115–120.

Johnson, S.R., T.E. Elkins, C. Strong, J.P. Phelan. (1986). Obstetric decision-making: response to patients who request caesarean delivery. *Obstetrics and Gynecology, Vol. 67: 847-50.*

Judith, U.H., M.A, Ismail, Y. Wang, C. Te, T. Karrison and M.A. Ismail. (2001). Failed vaginal birth after a cesarean section: how risky is it?. *Am J Obstet Gynecol, Vol. 184(7): 1365-1373.*

Keeler, E.B. and M. Brodie. (1993). Economic incentives in the choice between vaginal delivery and cesarean section. *The Milbank Quarterly,* Vol. 71(3): 365-404.

Keeler, E.B. and T. Fok. (1996). Equalizing physician fees had little effect on caesarean rates. *Medical Care Research and Review,* Vol. 353(4): 465-471.

Kim, H.K., J.U.Lee, K.W.Park and O.R.Moon.. (1992) Regional variations in the caesarean section rate and its determinants in Korea. *Korean Journal of Preventive Medicine,* Vol. 25(3):312-329

Kim, Y.M. and S.K. Ko (2002). Factor analysis for caesarean section delivery among obstetric clinics in metropolitan area. Journal of Women's Nursing, Vol. 8(3): 389-401.

King D.E. and K. Lahiri. (1994). Socioeconomic factors and the odds of vaginal birth after cesarean delivery. *JAMA. Vol. 272(7):524-9.*

King, J. F.(2000). Consultant in Perinatal Epidemiology Obstetric interventions among private and public patients : High rates of operative vaginal interventions in private patients need analysis. *BMJ.* 321(7254):125-126.

Ko, S.K., S.A. Shin, K.Y. Kim and C.Y. Kim. (2000). Changes in caesarean birth rate after notice of caesarean rate by the National Health Insurance Corporation, Annual Conference of Korean Academy of Healthcare Administration, 117-142 [Korean]

Ko, S.K., Shin, S.A., Kim, K.Y. and Kim, C.Y. (2001). Provider's behaviour change after te public release of the information on the caesarean section rate. Korean Journal of Health Policy and Administration, Vol. 11 (3): 121-150.

Koroukian SM, Trisel B, Rimm AA. (1998). Estimating the proportion of unnecessary Cesarean sections in Ohio using birth certificate data. *Journal of Clinic Epidemiol, Vol. 51(12):1327-34*

Lee, K.J. and S.H. Yu. (1999). Medical services for caesarean section cases in one DRG pilot study hospital. *The Journal of Hospital Management,* Vol.3(2): 21-40 [Korean]

Lydon-Rochelle, M., V.L. Holt, D.P. Martin, and T.R. Easterling (2000). Association between method of delivery and maternal rehospitalization. *JAMA*, Vol..283(18):2411-6.

MacKenzie, I. Z. (1999). Should women who elect to have caesarean sections pay for them? *BMJ* Vol.318:1070.

MacKenzie, I. Z. (1999). Should women who elect to have caesarean sections pay for them? *BMJ Vol.318:1070.*

Magnier, M. (2001), Labors of a caesarean culture, Los Angeles Times, A.1. April 19.
Mascarenhas L, F. Biervliet, H. Gee and M. Whittle. (1994). Dutch model limits choice *BMJ Vol.308:342.*

Maslow, A.S. and A.L. Sweeny. (2000). Elective induction of labour as a risk factor for cesarean delivery among low-risk women at term. *Obstet Gynecol, Vol. 95(6 Pt 1) 917-22.*

McMahon M.J., E.R. Luther, W.A. Bowes and A.F. Olshan. (1996). Comparison of a trial of labor with an elective second cesarean section. *N Engl J Med, 335:689–95.*

McNally, O.M, and M.J. Turner. (1999). Induction of labour after 1 previous Caesarean section. Aust N Z J Obstet Gynaecol. Vol. 39(4):425-9.

Ministry of Health and Welfare. (2008). Survey on health care organisation and the brief summary on hospital report. http://www.mhlw.go.jp/toukei/saikin/hw/iryosd/05/kekka1-3.html accessed on 30 April 2008.

Ministry of Health, Labour, and Welfare, Japanese Government 2000 Vital Health Statistics

Murray, S. F. (2000). Relation between private health insurance and high rates of caesarean section in Chile: qualitative and quantitative study. *BMJ* Vol. 321: 1501-1505.
National Center for Health Statistics (NCHS). (2001). National Vital Statistics Reports. Vol. 49(1) 17 April

National Health Insurance Corporation (2000). A Survey for caesarean section delivery in Korea, Seoul, National Health Insurance Corporation. [Korean]

National Institute for Clinical Excellence. Fertility: Assessmentand Treatment for People with Fertility Problems. Clinical Guideline 11. London, UK: National Collaborating Centre for Women's and Children's Health; 2004.

National Institute of Health (NIH) (1980). Consensus Development Conference Statement, September 22-24.

National Institute of Health (NIH) (1981). Consensus Development Task Force Statement on Caesarean Childbirth. *Am J Obstet Gynecol,* Vol. 139(8): 902-9.

Nelson, K.B. and J.H. Ellenberg. (1986). Antecedents of cerebral palsy: multivariate analysis of risk. *New England Journal of Medicine*, Vol. 315: 81-86.

Oleske, D.M., E.S. Linn, K.L. Nachman, R.J. Marder and L.D. Thompson. (1998). Cesarean and VBAC delivery rates in Medicaid managed care. Medicaid fee-for-service, and private managed care. *Birth,* Vol. 25(2): 125-127.

Oleske, D.M., E.S. Linn, K.L. Nachman, R.J. Marder and L.D. Thompson. (1998). Cesarean and VBAC delivery rates in Medicaid managed care. Medicaid fee-for-service, and private managed care. *Birth, Vol. 25(2): 125-127*

Paterson-Brown S, .O. Amu, S. Rajendran, II .Bolaji. (1998). doctors perform an elective caesarean section on request? *BMJ* Vol.317:462-5.

Quinlivan, J., R.W. Petersen and C.N. Nichols. (1999). Patient preference the leading indication for elective caesarean section in public patients: Results of a 2-year prospective audit. *Aust NZ J Obstet Gynaecol,* Vol. 39:207–214.

Raube, K. and K. Merrell. (1999). Maternal minimum-stay legislation: cost and policy implications. *American Journal of Public Health,* Vol. 89(6): 922-923.

RCOG, Effectiveness Support Unit. National Sentinel Caesarean Section Audit Report. RCOG Press; 2001.

Reichert JA, M. Baron, J. Fawcett. (1993). Changes in attitudes toward cesarean birth. *J Obstet Gynecol Neonatal Nurs, Vol.22(2):159-67.*

Roberts**,** C. L., S. Tracy, and B. Peat. (2000). Rates for obstetric intervention among private and public patients in Australia: population based descriptive study. *BMJ,* Vol. 321: 137-141

Ryding E.L., K. Wijma, B. Wijma. (1998). Psychological impact of emergency cesarean section in comparison with elective caesarean section, instrumental and normal vaginal delivery. *J Psychosom Obstet Gynaecol,Vol.19(3):135-44.*

Sachs, B. P., C. Kobelin, M. A. Castro, and F. Frigoletto (1999) The Risks of Lowering the Cesarean-Delivery Rate. *New England Journal of Medicine 340 (1): 54-7.*

Santerre, R.E. (1996). The effect of the ACOG guideline on vaginal births after caesarean. *Medical Care Research and Review, Vol. 53(3): 315-329*

Savage, W and C Francome (1993) British caesarean rates: have we reached a plateau? *British Journal of Obstetrics and Gynaecology*, Vol. 100: 493-496.

Savage, W. (2000). The caesarean section epidemic (Review). *Journal of Obstetrics and Gynaecology,* Vol. 20(3): 223-225.

Savage, W. (2000). The caesarean section epidemic (Review). *Journal of Obstetrics and Gynaecology,* Vol. 20(3): 223-225.

Schuitemaker N., J. van Roosmalen, G. Dekker, P. van Dongen, H. van Geijn, and J.B. Gravenhorst. (1997) Maternal mortality after cesarean section in The Netherlands. *Acta Obstet Gynecol Scand.* Vol.76(4):332-4.

Scott, J.R. (1991). Mandatory trial of labor after cesarean delivery: an alternative viewpoint. *Obstet Gynecol Vol. 77: 811-814.*

Seyb, S.T., R.J. Berka, M.L. Socol and S.L. Dooley. (1999). Risk of cesarean delivery with elective induction of labor at term in nulliparous women. *Obstet Gynecol, Vol. 94(4): 600-7.*

Sheldon, T., & A. Faulkner. (1996). Vetting new technologies, *British edical Journal, Vol.313:508.*

Sims, E.J., R.B. Newman, T.C. Hulsey. (2001). Vaginal birth after cesarean: to induce or not to induce. *Am J Obstet Gynecol, Vol. 184(6): 1122-4.*

Sizer, A.R., Thomas, S.C. and Lindsay, P.C. (2000). The rise in obstetric intervention with maternal age: a continuous phenomenon. *Journal of Obstetrics and Gynaecology,* Vol. 20(3): 246-249.

Sood, A.K., J.I. Sorosky, N. Mayr, B. Anderson, R.E. Buller and J. Niebyl. (2000). Cervical cancer diagnosed shortly after pregnancy: prognostic variables and delivery routes. *Journal of Obstetrics and Gynaecology,* Vol. 95(6 Pt 1): 832-838.

Stafford, R S. (1990). Cesarean section use and source of payment: an analysis of California hospital discharge abstracts. *American Journal of Public Health, Vol. 80(3): 313-315.*

Stephenson, P. (1992) International differences in the use of obstetrical interventions. WHO Regional Office for Europe, Copenhagen.

Studnicki J, Remmel R, Campbell R, Werner DC. (1997). The impact of legislatively imposed practice guidelines on cesarean section rates: the Florida experience. *American Journal Med Qual. Vol.12(1):62-8.*

The American College of Obstetrics and Gynecology (ACOG). ACOG News Release, August 9, 2000

The International Perinatal HIV Group. (1999). The mode of delivery and the risk of vertical transmission of human immunodeficiency virus type 1 – a meta-analysis of 15 prospective cohort studies. *The New England Journal of Medicine,* Vol. 340(13):977-987.

The Ministry of Health and Welfare (2006), Caesarean section delivery rate for recent five years: a report submitted to Mr. Hyo-Seok Kim who is a member of National Assembly for the inspection of central government offices conducted by the National Assembly [Korean].

The Ministry of Health and Welfare (2006), National plan to circumscribe CS rate: A report submitted for the inspection of central government offices conducted by the National Assembly [Korean].

The Ministry of Health and Welfare (MOHW), 1999 DRG Guidelines [Korean]

The Ministry of Health and Welfare (MOHW), Brief Report on caesarean section Rates, July 26, 2006 [Korean]

The National Health Insurance Corporation (2000). A Survey for caesarean section delivery in Korea, Seoul, National Health Insurance Corporation.

The Scottish Office, Health in Scotland 1997.
The Times, November 7, 2000

Thomas J and S. Paranjothy (2001). Royal College of Obstetricians & Gynaecologists Clinical Effectiveness Support Unit. National Sentinel Caesarean Section Audit Report. RCOG Press; 2001.

Tranquilli, A.L. (2001).Cesarean section on maternal request: a four-year experience. *American Journal of Obstetrics and Gynecology.* Vol. 184(1): S184

Turnbull, D.A., C. Wilkinson, and A. Yaser A, *et al*. (1999). Women's role and satisfaction in the decision to have a caesarean section. *Med J Aust* Vol.170:580–583.

U.S. Department of Health and Human Services (1991). Healthy People 2000: National Health Promotion and Disease Prevention Objectives. Washington, DC: U.S. Government Printing Office.

Udom, N.U. and C.L. Betley. (1998). Effects of maternity-stay legislation on 'drive-through deliveries'. *Health Affairs,* Vol. 17(5): 208-215.

van Ham M.A., P.W., van Dongen, and J Mulder (1997). Maternal consequences of caesarean section. A retrospective study of intra-operative and postoperative maternal complications of caesarean section during a 10-year period. *Eur J Obstet Gynecol Reprod Biol*. Vol. 74(1):1-6.

Van Roosmalen, J. (1999). Unnecessary caesarean sections should be avoided. *BMJ Vol. 318:121.*

Wagner C.L., A.K. Metts. (1999). Rates of successful vaginal delivery after36.4% in 1996 cesarean for patients with private versus public insurance. J Perinatol Vol.19(1):14-8

Weinstein, R.B. and J. Trussell. (1998). Declining cesarean delivery rates in California: an effect of managed care? *American Journal of Obstetrics and Gynecology,* Vol. 179(3): 657-664

WHO Report ICP/MCH 102/m2(S) 1301K 10 June 1985, Joint International Conference on Appropriate Technology for Birth. Fortaleza, Brazil, 22-26 April 1985.
Women Newspaper, 24 Dec. 2004

Yeast, J.D., A. Jones ad M. Poskin. (1999). Induction of labor and the relationship to cesarean delivery: a review of 7001 consecutive inductions. *Am J Obstet Gynecol, Vol. 180(5 pt 1): 1273-4.*

Yeonhap News, July 8, 2000

Yip, W.C.M. (1998). Physician response to Medicare fee regulations: changes in the volume of coronary artery bypass graft. *Journal of Health Economic*, Vol. 17(6): 675-699.
Young, D. (1997). A new push to reduce cesareans in the United States. *Birth, Vol. 24(1): 1-3.*

Chapter 5

ABMTR and IBMTR (personal communication)

American Society for Blood and Marrow Transplantation (ASBMT) (2000). Evidence-Based Reviews and the Role of Blood and Marrow Transplantation in the Treatment of Selected Diseases: An ASBMT Policy Statement. *Biology of Blood and Marrow Transplantation, Vol. 6:523*

Andrykowski, M.A., C.B. Greiner, E.M. Altmaier et al. (1995). Quality of lofe after bone marrow transplantation: finding from a multicenter study. *British Journal of Cancer, Vol. 71: 1322-1329.*

ASBMT (2001) ASMBT News, Blood And Marrow Transplantation Reviews, Vol. 11 (2): 3.

Baker, F. J.R. Wingard, B. Curbow et al. (1994).Quality of life of bone marrow transplant survivors. *Bone Marrow Trnasplantation, Vol. 13: 589-596*

Belec, R.H. (1992). Quality of life: perceptions of long-term survivors of bone marrow transplantation. *Oncology Nurse Forum, Vol. 19: 31-7.*

Blood & Marrow Transplant Newsletter, Issue No. 51, October 2000, Vol. 11, No. 3.

BMT Infonet (1999). Blood & Bone Marrow Transplant Newsletter), Issue 46, Vol. 10(2)

Borgmann, A. H. Schmid et al. (1995). Autologous bone-marrow transplants compared with chemotherapy for children with acute lymphoblastic leukaemia in a second remission: a matched-pair analysis. *The Lancet, Vol. 346: 873-876.*

British Society of Blood and Bone Marrow Transplantation. http://www.bsbmt.org/cms_pages/17-2005-Activity accessed 5 May 2008

British Society of Blood and Marrow Transplantation (BSBMT). Available at: http://www.bsbmt.org/www/activity.html. Accessed May 15, 2007.

Burnett, A.K., A.H. Goldstone et al. (1998). Randomised comparison of addition of autologous bone-marrow transplantation to intensive chemotherapy for acute myeloid leukaemia in first remmion: results of MRC AML 10 trail. *The Lancet, Vol. 351(9104): 700-708.*

Byrne JL and Russel NH Peripheral blood stem cell transplants.(1998). *Journal of Clinical Pathology, Vol.51: 351-355*

Center for International Blood and Marrow Transplant Research, CIBMTR Progress Report, January-December 2006

Davis, K. (1996). New GAO Report says insurance coverage growing for bone marrow transplants. *Journal of the National Cancer Institute, Vol. 88 (11): 711.*

Dufoir T., M.C. Saux, B. Terraza et al.(1992). Cpmparative cost of allogenic or autologous bone marrow transplantation and chemotherapy in patients with acute myeloid leukaemia in first remission. *Bone Marrow Transplantation, Vol. 10: 323-329.*

Fannie, G. and F. Martha (1996) psychosocial correlates of quality of life across the autologous bone marrow transplant experience. Cancer Nursing, vol. 19(3): 170-176.

Gradishar, W.J. (1999). High-Dose Chemotherapy and Breast Cancer, *JAMA, Vol. 282: 1378-1380*

Gratwohl, A., C. Gorin et al. (1996). The European Group for Blood and Marrow Transplantation (EBMT): a report from the president and the chairmen of the working parties. *Bone Marrow Transplantation, Vol. 18: 667-691.*

Gulati, S.C. and C.L. Bennett. (1992). Granulocyte-macrophage colony stimulating factor (GM-CSF) as adjunct therapy in relapsed Hodgikin disease. *Annals of Internal Medicine, Vol. 116: 177-182.*

Ham, C. and S. Pickard (1998). Tragic Choices in Health Care: The case of Child B. London: King's Fund.

Hillner,B.E., T.J. Smith, C.E. Desch.(1992). Efficiency and cost-effectiveness of autologous bone marrow transplantation in metastatic breast cancer: estimates using decision analysis awaiting clinical trial results. *Journal of American Medical Association, Vol. 267: 2055-2061*

Holyoake, T. L. and I. M Franklin. (1994). Bone marrow transplants from peripheral blood. *BMJ 309:4-5*

House of Commons, Parliament. Publications and records. Available at: http://www.publications.parliament.uk/pa/cm200506/cmhansrd/cm061012/text/61012w0011.htm. Accessed August 6, 2007.

Japan Marrow Donor Programme, (2008). JMDP Activities (at the end of March 2008) (http://www.jmdp.or.jp/about_us/genkyou/files/bank_genjou.pdf accessed 26 April 2008. [Japanese]

Japan Marrow Donor Registry Promotion Conference. (2001) http://www.marrow.or.jp accessed 20 December. 2004 [Japanese]

Johnson, P.W.M., S.J. Simnett, J.W. Sweetenham, G.J. Morgan and L.A. Stewart .(1998).Bone marrow and peripheral blood cell transplantation for malignancy. *Health Technology Assessment, Vol. 2 (8): 1-187*

Korean Haematopoietic Stem Cell Transplantation Nurse Association.(2003) Recent data on HSCTs in Korea. *Journal of Korean Haematopoietic Stem Cell Transplantation Nurse Association, Vol. 3 (1): 9-15.*

Lennard A. L and G. H. Jackson (2000) Stem cell transplantation. Science, medicine, and the future Topic: 76;214. *BMJ Vol.321:433–7*

Leukaemia Research. Available at: http://www.lrf.org.uk/en/1/disstahome.html. Accessed August 5, 2007.

Liberti G, Pearce R, Taghipour G, et al. (1994). Comparison of peripheral blood stem-cell and autologous bone marrow transplantation for lymphoma patients: a case-controlled analysis of the EBMT Registry data. Annals of Oncology 5(Suppl 2): 151-153

Meisenberg, B.R., K. Ferran et al. (1998).Reduced charges and costs associated with outpatient autologous stem cell transplantation. *Bone Marrow Transplantation, Vol. 21: 927-932.*

Messori, A., A. Bosi et al. (1999). Retrospective survival analysis and cost-effectiveness evaluation of second allogenic bone marrow transplantation in patients with acute leukemia. *Bone Marrow Transplantation, Vol. 23: 489-495.*

Molassiotis A. and P. Morris. (1999). Quality of life in patients with chronic myeloid leukemia after unrelated donor bone marrow transplantation. *Cancer Nursing, vol. 22(5): 340-349.*

Molassiotis A., O.B..A. van den Akker, D.W. Milligan, B.J. Boughton. (1995). Gonadal function and psychosexual adjustment in male long-term survivors of bone marrow transplantation. *Bone Marrow Transplantation, Vol. 16: 253-259.*

National Blood Service, NHS Blood & Transplant, http://www.blood.co.uk/pages/marrow_info_campaign.html accessed 5 May 2008.

National Cancer Centre, Japanese government, Cancer Statistics in Japan (99), http://wwwinfo.ncc.go.jp/statistics/stats1999/japanese/tables/t03_j.html accessed 20 Jan. 2003. [Japanese]

National Cancer Institute. (2000). SEER Cancer Statistics Review, 1973-1997 http://seer.cancer.gov/csr/1973_1997/ accessed 5 May 2008

National Marrow Donor Program (NMDP). Fact & Figures, http://www.marrow.org/NEWS/MEDIA/Facts_and_Figures/facts_figures.pdf accessed 5 May 2008.

National Marrow Donor Program. Available at: http://www.marrow.org/NMDP/history_stem_cell_transplants.html#early. Accessed December 20, 2001.

Nemunaitis J. S.N. Robinowe, J.W. Singer et al.(1991). Recombinant granulocyte-macrophage colony-stimulating factor after autologous bone marrow transplantation for lymphoid cancer. *New England Journal of Medicine, Vol. 324: 1773-1778.*

NMDP, Fact & Figure http://www.marrow.org/NMDP/general_facts_figures.html retrieved on 2 February 2000.

NMDP, Facts & Figures, Archived Facts & Figure, http://www.marrow.org/NMDP/FF_ARCHIVES/JAN_01/general_facts_figures.pdf accessed on 20 December 2001.

Office of Health Technology Assessment, U.S. Department of Health and Human Services (1995) Autologous peripheral stem cell transplantation. Public Health Service Agency for Health Care Policy and Research, AHCPR Pub. No. 95-0074.

Ohno, R. (1998) Multicenter cooperative study group in haematology in Japan: the 10-year history and role of the Japan adult leukaemia study group in Japan. International Journal of Hematology, vol. 67: 213-219.

Powles, R., J. Mehta et al. (2000). Allogenic blood and bone-marrow stem-cell transplantaion in haematological malignant disease: a randomised trail. *The Lancet, Vol. 355(9211): 1231-1237*

Radiation Effects Research Foundation, Life Span Study Cancer Incidence Data, 1958-1987. http://www.rerf.or.jp/radefx/late_e/leukemia.html accessed 28 August 2007.

Redaelli, A., M.F. Botteman, J.M. Stephens, S. Brandt, and C.L. Pashos (2004). Economic burden of acute myeloid leukemia: a literature review. *Cancer Treatment Reviews*, *Vol. 30(3): 237-247*

Schmitz, N., D.C. Linch, P. Dreger et al. (1996). Randomised trial of filgrastim-mobilised eripheral blood progenitor cell transplantation vs autologous bone marrow transplantation in lymphoma patients. *Lancet, Vol. 347: 353-357.*

Schultze, W. (1997-last update). The importance of hemopoietic stem cells in the treatment of hemo-oncological diseases, Sysmex Journal International, Vol. 7 (2): 1-6 [Online, http://www.sysmex.co.jp/j/svsp/sup/report/journal/pdf/schultze.pdf retrieved on 26 December 2001

Silberman G, e M. G. Cross, E. A. Peterson, R.C. Weston, M. M. Horowitz, F. R. Appelbaum, et al. (1994). Availability and appropriateness of allogeneic bone marrow transplantation for chronic myeloid leukemia in 10 countries. *N Engl J Med, Vol. 331:1063-7.*

The Anthony Nolan Trust. A few facts about our register. http://www.anthonynolan.org.uk/index.php?location=5.2 accessed 5 May 2008.

The Japan Society for Hematopoietic Cell Transplantation, Annual Report of Nationwide Survey 2003

The Japan Society for Hematopoietic Cell Transplantation, Annual Report of Nationwide Survey 2006

The National Cancer Institute. (1999). Cancer Incidence and Survival among Children and Adolescents: United States SEER Program, 1975-1995. http://www-seer.ims.nci.nih.gov/Publications/PedMono retrieved on 26 March 2001.

The Research Institute for Radiation Biology and Medicine, Hiroshima University (2001). A brief summary of the Assistance Act Proposal proposed by the Socialist Party.

The Special Treaty Act for the Victims of the Atomic Bomb of 1994, Section 3.
Varterasian, M., N. Janakiraman et al. (1997). Transplantation in patients with multiple myeloma: a multicenter comparative analysis of peripheral blood stem cell and allogenic transplant. *American Journal of Clinical Oncology, Vol. 20(5): 462-466.*

Wagner, J.E. (2002) Transplant Topics: Umbilical Cord Blood Stem Cell Transplantation, http://www.bmtinfo.org accessed on 15 May

Watson, M., K. Wheatley et al.(1999). Severe adverse impact on sexual functioning and fertility of bone marrow transplantation, either allogenic or autologous, compared with consolidation chemothreapy alone. *Cancer, Vol. 86(7): 1231-1239.*

Welch, H.G. and E. B, Larson. (1989). Cost-effectiveness of bone marrow transplantation inacute nonlymphocytic leukemia. *New England Journal of Medicinem Vol. 321: 807-812.*

Will, A. (2003). Recent advances in the management leukaemia. Current Paediatrics, Vol. 13: 201-206.

Winer, E.P., C. Lindley, M. Hardee et al. (1999). Quality of life in patients surviving at least 12 months following hign dose chemothreapy with autologous bone marrow support. *Psycho-Oncology, Vol. 8(2): 167-176.*

Wingard, J.R., B. Curbow, F. Baker, J. Zabora, S. Piantadosi. (1992). Sexual satisfaction in survivors of bone marrow wurvivors of bone marrow transplantation. *Bone Marrow Transplantation, Vol. 9: 185-190.*

Wolcott, D.L., D.K. Wellisch, F.I. Fawzy, and J. Landsverk (1986). Adaptation of adult bone marrow transplant recipient long-term survivors. *Transplantation, Vol. 41(4): 478-84.*

Woronoff-Lemis M-C et al. (1997). Cost comparative study of autologous peripheral blood progenitor cells (PBPC) and bone marrow (ABM) transplants for non-Hodgkin's lymphoma patients. *Bone Marrow Transplantation, Vol.20 (11): 975-982.*

Chapter 6

American Academy of Pediatrics. (1995). Joint Committee on Infant Hearing 1994 Position Statement. *Pediatrics, Vol.95:152-156*

Association of Cochlear Implant Transmitted Audition, Cochlear implant hospital list. (2001). http://www.sapmed.ac.jp/acita/hospital/index.html retrieved on 25 December.

Association of Cochlear-Implant-transmitted Audition (ACITA 2007: personal communication). Available at: http://www.normanet.ne.jp/~acita/info/arekore2.html#arekore1 (only a bar chart is provided, without the actual numbers). Accessed April 21, 2007.

Audit Commission (1997). Higher Purchase: Commissioning Specialised Services in the NHS, London: Audit Commission Publications

Blanchfield, B.B., J.J. Feldman, F.L. Dunbar, E.N. Gardner. (2001). The severely to profoundly hearing-impaired population in the United States: Prevalence estimates and demographics. *Journal of the American Academy of Audiology, Vol. 12(4): 183-189.*

Cheng, A.. G. D. Grant, and J. K. Niparko. (1999). Meta-analysis of pediatric cochlear implant literature. *Ann Otol Rhinol Laryngol Suppl 177 Vol. 108(4), Part 2: 124-128.*

Christiansen, J.B. & Leigh, I.W. (2002) *Cochlear Implants in Children: Ethics and Choices.* Washington, DC: Gallaudet University Press

Cochlear Implant Association, Inc. (CIAI), Fact Sheets, http://www.cici.org/factsheets.html accessed on 25 December 2001.

Cochlear Implant Online. (2008). http://cochlearimplantonline.com/blog/?p=29 accessed 28 April 2008

Cochlear Implant Research Centre, University of Iowa .(2001). http://www.medicine.uiowa.edu/otolaryngology/circ/operation.htm retrieved on 25 December

Cochlear™. Cochlear F2004 first half-year results. ASX/Medical Release. Available at http://www.cochlear.com/PDFs/halfyear_announcement.pdf accessed 5 May 2008

Cohen, N.L., Hoffman, R.A. (1991). Complications of Cochlear Implant Surgery in Adults and Children. Ann. Otol. Rhinol. Laryngol., Vol. 100(9):708-711, 1991

Daily Seoul, May 10, 2007

Davis, A. (1993). "The prevalence of deafness." In Deafness, J. Ballantyne, A. Martin, M. Martin(ed). London: Whurr: 1-11.

Davis, F.G., J.M. Bruner, Surawicz. (1997). The rationale for standardised registration and reporting of brain and central nervous system tumours in population-based cancer registries. *Neuroepidemiology, Vol. 16: 308-316.*

Evans, A.R., T. Seeger, and M. Lehnhardt. (1995). Cost-utility analysis of cochlear implants. *Annals of Otol Rhinol Laryngol Suppl. Vol. 104(suppl 166): S245-S248.*

FDA, Straight talk from FDA about hearing loss and hearing aids. The data retrieved from http://www.fda.gov/opacom/lowlit/hearaid.html on 7 May 2001.

Fortnum, HM, Summerfield, AQ, Marshall, DH, Davis, AC and Bamford, JM (2001) Prevalence of permanent childhood hearing impairment in the United Kingdom and implications for universal neonatal hearing screening: questionnaire based ascertainment study. *British Medical Journal*, 323; 536-539

Francis, H.W., M.E. Koch, J.R. Wyatt, J.K. Niparko. (1999). Trends in educational placement and cost benefit consideration in children with cochlear implants. *Otolaryngology-Head & Neck Surgery, Vol. 125(5): 499-505.*

Garber S., M. S. Ridgely, M. Bradley, and K. W. Chin (2002). Payment under public and private insurance and access to cochlear implants, Archives of Otolaryngology, Head and Neck Surgery, Vol. 128: 1145-1152.

Harris, J., J.P. Anderson, R. Novak. (1995). An outcomes study of cochlear implants in deaf patients: audiologic. Economic, and quality of life changes. *Otolaryngology-Head & Neck Surgery, Vol. 121(4): 398-404.*

Horn KL, McMahon NB, McMahon DC, Lewis JS, Barker M, Gherini S. (1991) Functional use of theNucleus22-channel cochlear implant in the elderly. Laryogoscope Vol. 101:284–8.

Hutton, J. Politi, C., Seeger, T. (1995). Cost-effectiveness of cochlear implantation of children-a preliminary model for the UK. *Adv Otorhinolaryngol* Vol. 50: 201-6.

Kelshall DC, Shallop JK, Burnelli T. (1995) Cochlear implantation in elderly. Am J Otol Vol.16:609–15.

Kveton, J. and T. Balkany (1991) Status of cochlear implant in children, *Journal of Pediatrics, Vol. 118: 1-7.*

Listen-up, Medicare & Cochlear Implants, http://www.listen-up.org/ci/med-ci.htm accessed 5 May 2008.

Ministry of Health and Welfare (2004a), Support Data for Cochlear Implant, Information Open Indices 18 December 2004.

Ministry of Health and Welfare (2004b), Support Data for Cochlear Implant, Information Open Indices 18 December 2004.

Ministry of Health and Welfare, Korean government (2002) Subsidy plan for cochlear implantation.

Ministry of Health and Welfare, Korean government (2003) Subsidy plan for cochlear implantation.

Ministry of Health, Labour and Welfare (2002). Survey on the actual condition of the people with physically handicapped. Available at http://www.mhlw.go.jp/houdou/2002/08/h0808-2.html (accessed 5 May 2008).

National Center for Hearing Assessment & Management (2008). State summary statistics: universal newborn hearing screening. http://www.infanthearing.org/status/unhsstate.html accessed 29 April; 2008.

National Centre for Hearing Assessment and Management. Available at: http://www.infanthearing.org/resources/fact.pdf. Accessed August 8, 2007.

National Institute of Health (1995). Cochlear Implants in Adults and Children. *NIH Consens Statement, Vol.13(2):1-30.*

National Service Division, Common Service Agency, http://www.show.scot.nhs.uk/nsd/services/cochlear/cochlear2.html accessed on 25 December 2001.

NHS North West Regional Office, Annual Report on Specialised Commissioning, 2000-2001.(2001). http://www.doh.gov.uk/pdfs/nwrospecomm01.pdf retrieved on 25 December.

O'Donoghue, G.M. (1996). Cochlear implants in children: principle, practice and predictions. *Journal of Royal Society of Medicine, Vol. 89(6): 345-7.*

Osberger, M.J., S. Zimmerman-Phillips, M. Barker, and L. Geier. (1999). Clinical trial of the CLARION® cochlear implant in children. *Annals of Otology, Rhinology & Laryngology, Suppl 177 Vol. 108 (4), Part 2: 88-92.*

Palmer, C.S., J. Niparko, J.R. Wyatt, M. Rothman, G. de Lissovoy. (1999). A prospective study of the cost-utility of the multichannel cochlear implant. *Otolaryngology-Head & Neck Surgery, vol.125(11): 1221-1228.*

Personal communication with Dr. David Marshall at the Medical Research Council Institute of Hearing Research, University Park, Nottingham, England

RAND (2002), Low Levels of Insurance Reimbursement Impede Access to Cochlear Implants, Research Briefings 2003, Santa Monica, Calif.: RAND, RB-4532-1, 2002.

Sargent, E.W. (2004) Cochlear implants, indications. eMedicine, http://www.emedicine.com/ent/topic424.htm accessed on 25 Jan. 2005.

Smith, A. (2004). The fifteenth most serious health problem: the WHO perspective. IFHOH World Congress, Helsinki, July, 2004.

Summerfield, A.Q. and D.H. Marshall. (1995). Cochlear implantation in the UK 1990-1994.Reoprt by the MRC Institute of Hearing Research on the Evaluation of the National Cochlear Implant Programme. London: HMSO.

Summerfield, A.Q., G.M. O'Donoghue, J. Graham (2002). Cochlear implantation and meningitis in the UK, 7th International Cochlear Implant Workshop, 15 September 2005, Manchester, UK.

Summerfield, A.Q., G.M. O'Donoghue, J. Graham (2004). Cochlear implantation and meningitis in the UK, Nottingham: MRC Institute of Hearing Research, Final Report: September 15, 2004.

Summerfield, Q. and J. Tomlinson. (1996). The use of cochlear implantation. Trent Institute of Health Service Research, Universities of Leicester, Nottingham and Sheffield. (Guidance Note for Purchasers: 96/03).

White, K.R. (1997), Universal newborn hearing screening issues and evidence. CDC Workshop on Early Detection and Intervention, Atlanta, Georgia, October 22-23, 1997.

Wyatt J.R., J.K. Niparko, M. Rothman. (1996). Cost utility of the multichannel cochlear implants in 258 profoundly deaf individuals. *Larygoscope, Vol. 106: 816-821.*

Chapter 7

Ad Hoc Committee on Diagnostic Radiology, Korean Radiological Society (2000), Problems and countermeasures on national policies related diagnostic radiology. Korean Radiology Society [Korean]

American Shared Hospital Services, Annual Report on SEC Form 10-K for the year ended December 31, 1999. filed March 29, 2000. Available at http://www.secinfo.com/dsVSa.5kd.htm#2j34 accessed 5 May 2008.

Annual Report of the Central Cancer Registry in Korea (Based on Registered Data from 128 Hospitals) (2001) Central Cancer Registry Centre in Korea, Ministry of Health and Welfare, Republic of Korea

Aoki, Y., K. Nakagawa, M. Tago, A. Terahara, H. Kurita, Y. Sasaki. (1996). Clinical evaluation of gamma knife radiosurgery for intracranial arteriovenous malformation. Rediat. *Med., Vol. 14(5): 265-8.*

Bartolomei F. J. Regis, Y. Kida, T. Kobayashi, V. Vladyka, R. Liscak, D,M. Forster, A. Kemeny, O. Shrotner, G. Pendl.(1999) Gamma Knife radiosurgery for epilepsy associated with cavernous hemangiomas: a retrospective study of 49 cases. *Stereotactic & Functional Neurosurgery,Vol. 72(Suppl 1):22-8.*

Beecham, L. BMA opposes NHS private finance initiative.BMJ, Jul 1996; 313: 8 (BMJ News)

Brada, M. and N Kitchen. (2000). How effective is radiosurgery for arteriovenous malformations? *Journal of Neurology, Neurosurgery & Psychiatry, Vol. 68(5): 548-549.*

Duma CM, D.B. Jacques, O.V. Kopyov, R.J. Mark, B. Copcutt, H.K. Farokhi. (1998) Gamma knife radiosurgery for thalamotomy in parkinsonian tremor: a five-year experience. *J Neurosurg Vol.88(6):1044-9*

Eustacchio S, K Leber, M Trummer, F Unger, G. Pendl. (1999) Gamma knife radiosurgery for glomus jugulare tumours. *Acta Neurochir (Wien), Vol.141(8):811-8.*

Iwai Y. K. Yamanaka, T. Yasui, M. Komiyama, M. Nishikawa, H. Nakajima, H. Kishi.(1999). Gamma knife surgery for skull base meningiomas. The effectiveness of low-dose treatment. *Surgical Neurology, Vol. 52(1):40-4; discussion 44-5.*

Königsmaier H, B. de Pauli-Ferch, A. Hackl, G. Pendl (1998). The costs of radiosurgical treatment: comparison between gamma knife and linear accelerator. *Acta Neurochir (Wien), Vol.140(11):1101-10; discussion 1110-1.*

Liscak R. V. Vladyka, G. Simonova, J. Vymazal, L. Janouskova. (1998). Leksell gamma knife radiosurgery of the tumor glomus jugulare and tympanicum. *[Journal Article] Stereotactic & Functional Neurosurgerg, Vol. 70 (Suppl 1):152-60.*

Mehta M., W. Noyes, B. Craig, J. Lamond, R. Auchter, M. French , M. Johnson, A. Levin, B. Badie, I. Robbins, T. Kinsella. (1997). A cost-effectiveness and cost-utility analysis of radiosurgery vs. resection for single-brain metastases. *International Journal of Radiation Oncology, Biology, Physics, Vol.39(2):445-54*

Mokry M, S. Ramschak-Schwarzer, J. Simbrunner, J.C. Ganz, G Pendl.(1999) A six year experience with the postoperative radiosurgical management of pituitary adenomas. Stereotact Funct Neurosurg *Vol.72(Suppl 1):88-100*

National Cancer Institute, SEER Cancer Incidence, 1992-1998
NHS Executive, London Regional Specialised Commissioning Group Annual Report 1999/2000

Nicolato A, M. Gerosa, P. Ferraresi, E Piovan, A. Pasoli, S. Perini, C. Mazza.(1997).Stereotactic radiosurgery for the treatment of arteriovenous malformations in childhood. *J Neurosurg Sci., Vol.41(4):359-71*

Noren G. Long-term complications following gamma knife radiosurgery of vestibular schwannomas. *Stereotactic & Functional Neurosurgery, Vol.70(Suppl 1):65-73.*
Office for National Statistics, Office of National Statistics Series MBI No. 25 published 1998

Ott K. (1996). A comparison of craniotomy and Gamma Knife charges in a community-based Gamma Knife Center. *Stereotact Funct Neurosurg, Vol. 66(Suppl 1):357-64*
Pendl,G. , O. Schröttner, K. Feichtinger and S. Eustacchio.(1997).Gamma knife radiosurgery of skull base meningiomas. *Clinical Neurology and Neurosurgery, Vol.99(1): S8*

Porter PJ. A. Y. Shin, A.S. Detsky, L. Lefaive, M.C. Wallace(1997) Surgery versus stereotactic radiosurgery for small, operable cerebral arteriovenous malformations: a clinical and cost comparison. *Neurosurgery. 41(4):757-64; discussion 764-6.*

Regis J, L Manera, H Dufour, D Porcheron, R Sedan, J. C. Peragut. Effect of the Gamma Knife on trigeminal neuralgia. *Stereotact Funct Neurosurg, Vol.64(Suppl 1):182-92.*

Rutigliano MJ., L.D. Lunsford, D. Kondziolka, M.J. Strauss, V. Khanna, M. Green. (1995) The cost effectiveness of stereotactic radiosurgery versus surgical resection in the treatment of solitary metastatic brain tumors. *Neurosurgery, Vol.37(3):445-53; discussion 453-5*

Rutigliano MJ., L.D. Lunsford, D. Kondziolka, M.J. Strauss, V. Khanna, M. Green.(1995) The cost effectiveness of stereotactic radiosurgery versus surgical resection in the treatment of solitary metastatic brain tumors. *Neurosurgery, Vol.37(3):445-53; discussion 453-5*

Seung SK, P.K. Sneed, M.W. McDermott, H.K. Shu, S.P. Leong, S. Chang, P.L. Petti, V. Smith, L.J. Verhey, W.M. Wara, T.L. Phillips, D.A. Larson. (1998) Gamma knife radiosurgery for malignant melanoma brain metastases. *Cancer J Sci Am, Vol.*4(2):103-9

Sims E, D. Doughty, E. Macaulay, N. Royle, C. Wraith, R. Darlison, P.N. Plowman. Stereotactically delivered cranial radiation therapy: a ten-year experience of linac-based radiosurgery in the UK. Clin Oncol (R Coll Radiol). 1999;11(5):303-20. Review.

Subach BR, L.D. Lunsford, D. Kondziolka, A.H. Maitz, J.C Flickinger.(1998). Management of petroclival meningiomas by stereotactic radiosurgery. *Neurosurgery, Vol.42(3):437-43; discussion 443-5.*

The Committee of Brain Tumour Registry of Japan. Report of Brain Tumour Registry of Japan (1969-1993) 10th Edition, Neuralgia, supp. Vol. 40, Jan. 2000.

Unger F, C. Walch, G. Papaefthymiou, M. Trummer, S. Eustacchio, G. Pendl. (1999). Radiosurgery of acoustic neurinoma as a minimally invasive alternative to microsurgery. *HNO, Vol. 47(12):1046-51.*

Unger F., C. Walch, K. Haselsberger, G. Papaefthymiou, M. Trummer, S. Eustacchio, G.. Pendl.(1999). Radiosurgery of vestibular schwannomas: a minimally invasive alternative to microsurgery. *Acta Neurochirurgica, 141(12):1281-5; discussion 1285-6.*

van Roijen L, H.G. Nijs, C.J. Avezaat, G. Karlsson, C. Linquist, K.H. Pauw, F.F. Rutten (1997). Costs and effects of microsurgery versus radiosurgery in treating acoustic neuroma. *Acta Neurochir (Wien) Vol.139(10):942-8.*

Yoon, S.J., S.M. Kim, C.W. Kang, C.Y. Kim, Y.S. Shin (1997), Factors affecting CT adoption in Korea, Korean Journal of Preventive Medicine, Vol. 30 (1): 195-207 [Korean]

Chapter 8

Abella, I. (1996). Pharmacoeconomics of Neoral, a New Formulation of Cyclosporine, in Renal Transplantation. *Transplantation Proceedings, Vol. 28(6): 3131-4.*

Anderson, K.S. and D.M. Fox. (1988). The impact of routine inquiry laws on organ donation. *Health Affairs, Winter: 65-78.*

Anyanwu, A., A. McGuire, C. Rogers and A. Murday (2002). An economic evaluation of lung transplantation. *The Journal of Thoracic and Cardiovascular Surgery, Vol. 123(3): 411-420*

Asahi Newspaper. The result of a survey on the attitudes towards organ donation, August 26, 2000

Brigid, M. (1996). Why people die waiting for transplants. *Forbes, Vol. 140 (5): 140-144.*

Caplan, A. (1984). Organ procurement: it's not in the cards. *Hasting Center Report 18 (October): 9-12.*

Childress, J. (1989). Ethical criteria for procuring and distributing organs for transplantation. *Journal of Health Politics, Policy and Law, Vol. 14(1): 87-113.*

Cosmos Charity Fund for Organ Transplantation, http://cosmoskikin.org/jinzou.html accessed 30 March 2008

Culpepper, M.I. (1996). "Legal aspects of organ and tissue procurement and transplantation." In UNOS Organ Procurement and Distribution in Transplantation. Virginia: UNOS, M.G. Phillips (ed.).

DHHS, 1997 Federal Register, December 19, 1997: 66745-48

Douzdjian, V., D. Ferrara and G. Silvestri. (1998). Cost-utility analysis of pancreas transplantation compared to other treatment options for type I diabetics with end-stage renal disease. *Transplantation Proceedings, Vol. 30(2): 278.*

ESRD Registry Committee, Korean Society of Nephrology (2007). Current status of renal replacement treatment in Korea. *Korean Journal of Nephrology, Vol. 27(10): S459-S481.*

European Dialysis and Transplant Association (EDTA), Statistical Data 1995

European Renal Association, Annual Report 2005 Available at http://www.era-edta-reg.org/files/annualreports/pdf/AnnRep2005.pdf (accessed on 6 May 2008).

Evans, R.W. and D.J. Kitzmann. (1998). An economic analysis of kidney transplantation. *Surgical Clinical of North America, Vol. 78(1): 149-74.*

Feldman, E.A. (1994). Culture, conflict, and cost: perspective on brain death in Japan. *International Journal of Technology in Health Care, Vol. 10(3): 447-463.*

Grassman, A., Gioberge, S., Moeller, S, and Brown, G. (2005). ESRD patients in 2004: global overview of patient numbers, treatment modalities and associated trends.
Nephrol Dial Transplant, Vol. 20: 2587-2593

Gudex, C. (1996). Measuring patient benefit in mental illness. *European Psychiatry, Vol.11(3):155-158*

Han. Y.S. (2002). The way to improve organ transplant and evaluation system. Research Report 2002-8, Korea Institute of Health and Social Affairs

Health Care Financing Administration (HCFA), U.S. Department of Health and Human Services, Medicare coverage of kidney dialysis and kidney transplant services. Publication No. HCFA-10128, 2001. A*vailable at* http://www.hrsa.gov/osp/dot/legislative.htm. (accessed on 4 December, 2001)

Hiraga, S., T. Mori, and Y. Asaura. (2000). Current arrangement and activity of organ transplantation after new organ transplantation legislation in Japan. *Transplantation Proceedings, Vol. 32: 86-89.*

Hiruki, S. (2004). Human nature in view of a psychiatrist on kidney transplantation, *Transplantation Monthly, Vol. 17(6): 837-840.* [Japanese]

International Registry of Organ Donation and Transplantation. Definitive data of international transplant activity (IRODAT 2003). Available at http://www.etco.org/irodat/statistics_IRODAT_2003.pdf (accessed on 6 May 2008)

Japan Organ Transplant Society, http://www.medi-net.or.jp/tcnet/JST/fact_06/fact06_03.html accessed on 30 March 2008

Japanese Society for Dialysis Therapy. An overview of regular dialysis treatment in Japan as of Dec. 31, 2006. http://docs.jsdt.or.jp/overview/ppt/jsdt2006.ppt accessed 28 April 2008

Josefson, D. (1998), Two arrested in US for selling organs for transplantation. *BMJ*, Vol. 316 (7 March): 723.

Kim, J. D. (1999). A study on the factor affecting organ transplant. *Research on Health and Social Affairs, Vol. 23(2): 96-135*

Klarman, H.E., Francis, John.O'S and Rosenthal, G.D. (1968). Cost Effectiveness Analysis Applied to the Treatment of Chronic Renal Disease *Medical Care*, *Vol. 6 (1): 48-54*

Komiota, M. (2001). Cost-effectiveness analysis and kidney transplants in Japan. *Keio Journal of Medicine, Vol. 50(2): 100-108.*

Kontodimopoulos, N. and Niakas. D. (2008). An estimate of lifelong costs and QALYs in renal replacement therapy based on patients' life expectancy. *Health Policy*, *Vo. 86(1): 85-96*

Korean Network for Organ Sharing (KONOS), 2006 Annual Report. [Korean]

Korean Transplantation Society (1997). Organ transplantation report on 1996. *Korean Journal of Organ Transplantation, Vol. 11(2): 183-199* [Korean]

Korean Transplantation Society (1998). Organ transplantation report on 1997. *Korean Journal of Organ Transplantation, Vol. 12(2): 152-160* [Korean]

Korean Transplantation Society (1999). Organ transplantation report on 1998. *Korean Journal of Organ Transplantation, Vol. 13(2): 185-194* [Korean]

Kwak, J.Y., Kwon, O.J., Lee, K.S., Kang, C.M., Park, H.Y. and Kim, J.H. (1999). Exchange-donor program in renal transplantation: a single-centre experience. Transplantation Proceedings, Vol. 31: 344-345.

Lee, S. M. and S.Y. Kim. (2003). Brain death judgement and attitude towards organ transplant from the deceased. *Autumn Conference, The Korean Bioethics Association, Kwangwoon University, Seoul, Korea: 56-72*

Lenisa, L., R. Castoldi, C. Socci, F.Motta, G. Ferrari, D. Spotti, R. Caldara, A. Secchi, G. Pozza, and V. Di Carlo. (1995). Cost-effective treatment for diabetic end-stage renal disease: dialysis, kidney, or kidney-pancreas transplantation?. *Transplantation Proceedings, Vol. 27 (6): 3108-3113.*

Minichi Daily News, May 13, 1999

Mori, J. (1992). Non-blood relative transplantations. The Japanese Journal of Transplantation, Vol. 27(5): 654. [Japanese]

Niechzial, M., E. Hampel, T. Grobe, E. Nagel, H. Dorning and H. Raspe. (1997). Determinants of the quality of life in chronic renal failure [German]. *Sozial-und Praventivmedizin, Vol. 42 (3): 162-74.*

Niechzial, M., E. Hampel, T. Grobe, E. Nagel, H. Dorning and H. Raspe. (1997). Determinants of the quality of life in chronic renal failure [German]. *Sozial-und Praventivmedizin, Vol. 42 (3): 162-74.*

OPTN Data, retrieved from http://www.optn.org/data/ on 17 Jan 2005.
Piehlmeier, W., M. Bullinger, I. Kirchberger, W. Land and R. Landgraf. (1996).
Evaluation of the quality of life of patients with insulin-dependent diabetes mellitus before and after organ transplantation with the SF 36 health survey. *European Journal of Surgery, Vol. 162 (12): 933-40.*

Reddy, K.C., C..M. Thiagarajan, R. Shunmugasundaram et al. (1990), Unconventional renal transplantation in India. *Transplantation Proceedings, Vol. 22(3): 910.*

Rettig, R.A. (1989). The politics of organ transplantation: a parable of our time. Journal of Politics, Policy and Law, Vol. 14(1): 191-227.

Rinehart, J.R. (1988). The market approach to organ shortages. JHCM, Vol. 8(1): 72-75.

Salaman, J. (1997). "Transplantation from unrelated living donors." pp.67-75 in Transplantation '97 Improving organ donation and optimising outcome, R.W.G. Johnson (ed). London: The Royal Society of Medicine.

Schuck, P.H. (1989). Government funding for organ transplants. *Journal of Health Politics, Policy and Law, Vol. 14(1): 169-190*

Schwindt, R. and A.R. Vining. (1986). Proposal for a future delivery market for transplant organs. *Journal of health Politics, Policy and Law, Vol. 11: 435-500.*

Sells, R.A. (1992). The case against buying organs and a futures market in transplants. Transplant Proc. Vol. .24(5):2198-202

Shield, C.F., Jacobs, R.J., Wyant, S., and Das, A. (1996). A cost-effectiveness analysis of okt3 induction therapy in cadaveric kidney transplantation. *American Journal of Kidney Diseases*, *Volume 27, Issue 6*, *June 1996*, *Pages 855-864*

Sloan, F.A., M.W. Shayne, and M.D. Dolye. (1989). Is there a rationale for regionalizing organ transplantation services?. *Journal of Health Politics, Policy and Law, Vol. 14 (1): 115-167*

Spurr, S.J. (1993). The proposed market for human organs. *Journal of Health Politics, Policy and Law, Vol. 18(1): 189-201.*

Stanton, J. (1999). The cost of living: kidney dialysis, rationing and health economics in Britain, 1965-1996. *Social Science & Medicine, Vol. 49: 1169-1182.*

The Japan Society for Transplantation (1995). Annual progress report from the Japanese Renal Transplant Registry, 1994. The Japanese Journal of Transplantation, Vol. 30(4): 428-449. [Japanese]

The Japan Society for Transplantation (2000). Annual progress report from the Japanese Renal Transplant Registry, 1999. The Japanese Journal of Transplantation, Vol. 35(2): 43-48. [Japanese]

The Japan Society for Transplantation (2001). Results from 1999 follow-up survey. The Japanese Journal of Transplantation, Vol. 36(2): 91-105. [Japanese]

The Japan Society for Transplantation (2002). Annual progress report from the Japanese Renal Transplant Registry, 2001. Part 1 The characteristics of the cases performed in 2000 (2). The Japanese Journal of Transplantation, Vol. 37(1): 1-11. [Japanese]

The Korean Organ Transplantation Coordinators Society (1997). 3rd Academic Meeting of Organ Transplantation Coordinators, Seoul, July 13–14.
The Organ Procurement and Transplantation Network, Annual Report 2005. available at http://www.optn.org/AR2007/download_instruction.htm (accessed 6 May 2008)

The Organ Procurement and Transplantation Network, Donors Recovered in the U.S. by Donor Type: Jan. 1, 1988- Jan. 31. 2008, http://www.optn.org/latestData/rptData.asp retrieved 8 April 2008.

The Transplant Communication, Transplant history in Japan, http://www.medi-net.or.jp/tcnet/DATA/history.html retrieved on 24 December 2001 [Japanese]

Transplant Communication No. 4. Counter-arguments on organ transplant criticism. Available at: http://www.medi-net.or.jp/tcnet/te_4/qa/html. Accessed September 7, 1998.

Trbojevic, J. and M. Zivkovic. (1997). Quality of life in chronic renal insufficiency: the effect of disease development and various method of therapy [Serbo-Croatian (Cyrillic)]. *Srpski Arhiv Za Celokupno lekarstvo, Vol. 125(7-8): 223-27.*

U.S. Renal Data System (USRDS). USRDS 1998 Annual Data Report: Atlas of End-Stage Renal Disease in the United States, National Institute of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2001.

UK Renal Registry, UK Renal Registry Report 2003. Bristol, UK. Available at http://www.renalreg.org/Report%202003/RenalReg2003AnnualReport_Colour_For_Web_With_Linksv2.pdf accessed 6 May 2008.

UK Transplant, Fact sheet 4: The cost effectiveness of transplantation. http://www.uktransplant.org.uk/ukt/newsroom/fact_sheets/cost_effectiveness_of_transplantation_2007-01.doc

UK Transplant, The Transplant Activity in the UK 2003-2004

UK Transplant, Transplant Activities in the UK 2003-2004

UK Transplant, Transplant Activity in the UK 2002-2003

UK Transplant, Transplant Activity in the UK 2003-2004

UK Transplant, Transplant Activity in the UK 2004-2005

UK Transplant, Transplant Activity in the UK 2005-2006

UK Transplant, Transplant Activity in the UK 2006-2007

UK Transplant, Transplant Activity Report 2001

UKTSSA, Transplant Activity Report 2000

United States Renal-Data System, 2004 Annual-Data Report

United States Renal-Data System, 2007 Annual-Data Report

United States Renal Data System (USRDS), 2007 Annual Data Report. Avaolable at http://www.usrds.org/atlas.htm (accessed on 6 May 2008)

USRDS, 2004 Annual Data Report. Available at http://www.usrds.org/adr_2004.htm accessed 6 May 2008

World Health Organization (1991), Guiding Principles on Human Organ Transplantation. Geneva: World Health Organization.
www.medicare.gov/publications/pubs/pdf/esrdcoverage.pdf (accessed 4 June 2002)

Yoon, Y.S. et al. (1992). Kidney transplantation activity in a Catholic Medical Centre. Journal *of Korean Society of Transplantation, Vol. 6(1): 1-19.*

Chapter 9

Bone Marrow Donor Worldwide. Annual Report 1999

Collins, J.A., M. Bustillo, R.D. Visscher, L.D. Lawerance and D. MHA Lynne. (1995). An estimate of the cost of in vitro fertilisation in the United States in 1995. *Fertility & Sterility, Vol.64(3): 538-545.*

Cotzias, C S, S. Paterson-Brown, N.M. Fisk (2001) Obstetricians say yes to maternal request for elective caesarean section: a survey of current opinion, *European Journal of Obstetrics, Gynecology, and Reproductive Biology, Vol. 97(1): 15-16*

Danforth DN (1985). Caesarean section. JAMA; 253:811-818.

Department of Disease Control, The Ministry of Health and Welfare, Korea, Annual Report of the Central Cancer Registry in Korea for 1998, March 2000.

Department of Health, UK. Referral Guidance for Suspected Cancer 2001. Available at http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4014421.pdf accessed 6 May 2008.

Dickens BM. Reproductive technology and the 'new' family. In: Sutherland E, McCall Smith A, eds. Family rights: family law and medical advance. Edinburgh, Edinburgh University Press, 1990:21–41.

Fathalla, M.F. (2001) Current challenges in assisteded reproduction. In Vayena, E., Rowe, P.J., and Griffin, P.D.(ed). Current practices and controversies in assisted reproduction. Report of a meeting on 'Medical,Ethical and Social Aspects of Assisted Reproduction' held at WHO Headquaters in Geneva, Switserland, 17-21 September 2001.

Hall, M. (1987). When a woman asks for a caesarean section. *BMJ, Vol. 294: 201.*

Hanley, M.L., J.C. Smulian, M.F. Lake, D.A. McLean, and AM Vintzileos (1996) Analysis of repeat cesarean delivery indications: implications of heterogeneity. Am J Obstet Gynecol. Vol. 175(4 Pt 1): 883-8

Johnson, S.R., T.E. Elkins, C. Strong, J.P. Phelan. (1986). Obstetric decision-making: response to patients who request caesarean delivery. *Obstetrics and Gynecology, Vol. 67: 847-50.*

Joint Committee on Infant Hearing. (1994). 1994 position statement. *ASHA, Vol. 36: 38-41.*

Keeler, E.B. and M. Brodie. (1993). Economic incentives in the choice between vaginal delivery and cesarean section. *The Milbank Quarterly, Vol. 71(3): 365-404.*

Korean Marrow Donor Programme 20 Dec. 2000 Newsletter

Localio, A.R. et al.(1993). Relationship between malpractice claims and cesarean delivery. *JAMA 269, 366–373.*

National Cancer Institute, SEER Cancer Statistics Review 1973-1998. Bethesda, Md: National Cancer Institute, 2001., Section 22: Prostate Cancer, Table XXII-1. Also available online. Last accessed December 20, 2007.

National Institute for Clinical Excellence. Fertility: Assessmentand Treatment for People with Fertility Problems. Clinical Guideline 11. London, UK: National Collaborating Centre for Women's and Children's Health; 2004.

National Institutes of Health. Cesarean childbirth. Washington, DC: National Institutes of Health, 1981. NIH publication no. 82-2067

Parliamentary Office of Science and Technology, Caesarean sections, Postnote, October 2002, No. 184.

Paul R.H. and D.A. Miller (1995) Caesarean birth: how to reduce the rate. *Am J Obstet Gynecol. Vol.172:1903-1911*

Radiation Effects Research Foundation, Life Span Study Cancer Incidence Data, 1958-1987. http://www.rerf.or.jp/radefx/late_e/leukemia.html accessed 28 August 2007.

Sachs B. P. (1989). "Is the rising rate of cesarean sections a result of more defensive medicine?." pp.27-40 in Medical Professional Liability and the Delivery of Obstetrical Care, V. P. Rostow, R.J. Bulger, (ed). Washington, DC: National Academy Press

Sachs, B. P., C. Kobelin, M. A. Castro, and F. Frigoletto (1999) The Risks of Lowering the Cesarean-Delivery Rate. *New England Journal of Medicine 340 (1): 54-7.*

Shiono PH, J. G. Fielden, D. McNellis, G. G. Rhoads, W. H. Pearse. (1987). Recent trends in caesarean birth and trial of labor rates in the United States. *JAMA.;257:494-497.*
The American College of Obstetricians and Gynecologists (ACOG) News Release, 9 Aug. 2000

The Research Group for Population-based Cancer Registration in Japan (2003). Cancer Incidence and Incidence Rates in Japan in 1998: Estimates Based on Data from 12 Population-based Cancer Registries. Japanese Journal of Clinical Oncolpgy, Vol. 33(5)241–245

U.S. Department of Health and Human Services (1991). Healthy People 2000: National Health Promotion and Disease Prevention Objectives. Washington, DC: U.S. Government Printing Office.

US. Department of Health and Human Services. Health People 2010. 2nd ed. With Understanding and Improving Health, and Objectives for Improving Health. 2 Vols. Washington, DC: U.S. Government Printing Office, November 2000.

van den Akker, O.B.A. (1999). Organisational selection and assessment of women entering a surrogacy agreement in the UK. *Human Reproduction, Vol.14(1): 262-266*