Regulation of Organ Transplantation in Thailand: Does it Work?

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HEFP working paper 04/03, LSHTM, 2003

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ABBREVIATIONS

HLA

MC Medical Council

ODC Organ Donation Center

TTS Thai Transplantation Society

ACKNOWLEDGEMENTS

We are grateful for the financial contributions to the Senior Research Scholar Program in Health Policy and Systems by Thailand Research Fund and by the Department of International Development, UK through the London School of Hygiene & Tropical Medicine.

We also wish to thank the MC, the ODC, TTS, the Law Society, the Royal Thai Police, The office of Attorney, Court of justice, physicians, coordinators and patients who cooperate in this study. Without them the study is not possible.

1. INTRODUCTION

End stage organ failure is very distressing condition. Initially, there was only palliative treatment for end stage organ failure such as hemodialysis or peritoneal dialysis. Later on, the advancement of immunosuppressive drugs, surgical techniques and medical diagnostic devices gave hope for end stage organ failure patients (1, 2). With organ transplantation the failing organ is replaced with a functioning one. The results are very impressive; the 1-year survival rate was 93-98% and 5-year survival rate was 73-82% compared to those of hemodialysis and peritoneal dialysis, 78% and 29% respectively (3). Patients can function almost normally in their daily activities, play sport and do some hard work. There are also benefits for good mental health and social relationships (2, 4). In developed countries, organ transplantation is currently considered a well-established treatment for irreversible renal, cardiac and liver failure, as well as for some respiratory diseases (5). Although the operative costs and the immunosuppressive drugs are very expensive, in the long term, the total cost of kidney transplantation is lower than that of hemodialysis and peritoneal dialysis (6, 7).

The first organ transplantation in Thailand was a renal transplantation at Chulalongkorn Hospital in 1972. After that, transplantation was gradually developed, and today bone marrow, liver, heart, lung, and heart and lung transplantations are undertaken in 26 hospitals around the country (8). The most transplanted organ is the kidney with 2,173 cases to date, with 1,023 cadaver donors' cases and 1,150 living related donors' cases. In 2000, there were 200 renal transplantation cases, 91 cases were cadaver donors and the remaining were living related donors, and in 2001, there were 229 renal transplantation cases with 145 cadaver donor cases and 84 living related transplantation cases (9).

Demand for organ transplantation has increased significantly and disproportionately to any increase in donation (3), leading to a problem of organ shortage. As of June 20, 2002 there were 1,029 patients registered for organ donations and 200 transplantation cases were operated during that period with the ratio of donor to recipient ranging from 7-11 to 100 (10). It will take approximately 5 years to treat all patients on the waiting list without new registered patients. In the USA, because of this problem 6,678 and 5,821 patients were removed from the national waiting list in 2001 and 2002, respectively, due to death (11).

In some countries, this extreme demand may lead to immoral actions to get more organs for

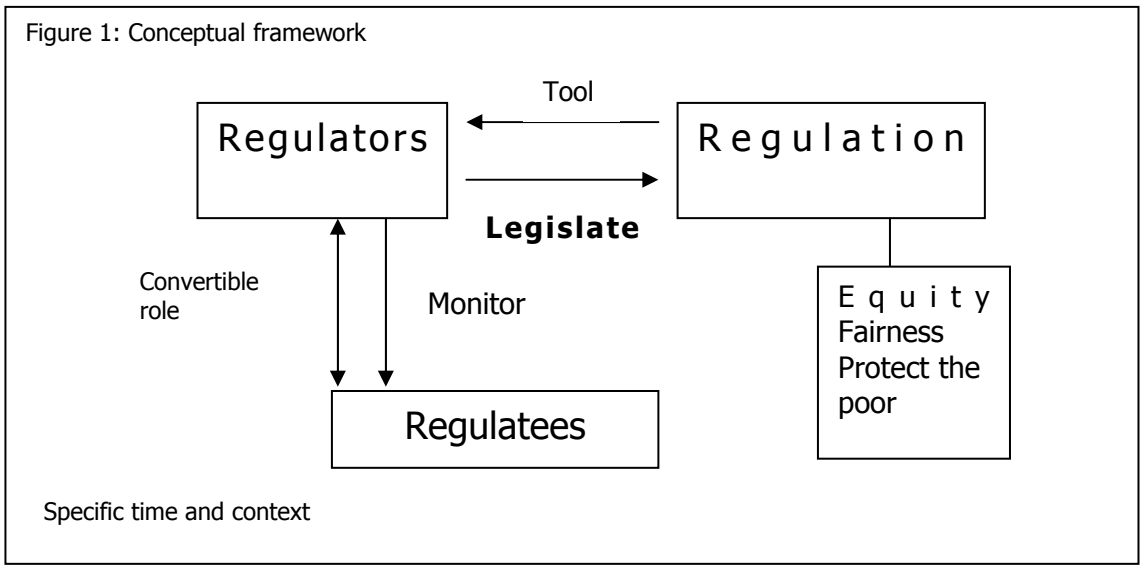
transplantation, such as harvesting organs from executed prisoners and buying organs from the poor in developing countries (12-20). Some believe that it is the right of the poor to sell their organs to relieve their debt, provide their family some foods or get a dowry for their daughters. But according to the studies of Madhav Goyal and Zargooshi, selling a kidney does not lead to a long-term benefit and may be associated with a decline in health, negative effects on employment and human dignity (21, 22). Eighty percent of kidney vendors would not recommend selling a kidney. Trade in organs also creates distrust in the transplantation system and has adverse effects on organ donation (23).

On May 13, 1989, the World Health Assembly endorsed a series of guiding principles on organ transplantation, which intended to provide an orderly, ethical and acceptable framework for regulating the acquisition and transplantation of human organs for therapeutic purposes (24). They also unanimously resolved to condemn trading and commerce in human organs, and called on all members and governments to enact the law (regulation) to make such practices illegal (17).

In Thailand, a scandal about illegal kidney transplantation in 1997-2000 had an extensive impact on the transplantation system (25-27). It raised questions about the effectiveness of the recent regulatory system. It also undermined trust in the doctor-patient relationship built up in the past. Teerawatananon et al. found that the existing overall rules and regulation of the Thai health system are firmly established (28). But they also found that the regulatory function performed incompletely resulting in problems of overburdened staff and delays in the performance of functions.

1.2 Conceptual framework

Figure 1 depicts the conceptual framework used in this study. Regulation refers to an action to manipulate the prices, quantities (distribution) and quality in order to obtain a number of objectives such as improved equity and increased access to service (29). It also refers to a system that supervises certain activities and controls them in line with moral and legal standards. It is composed of three important parts, which are regulation, regulators and regulatees. These three components have very a intimate relationship and are markedly influenced by history, culture, social and economic environment (30).



Regulation is the instrument or tool that regulators use to manipulate, monitor or control the regulatees. It can be divided into two categories. The first is Government regulation, that is legislation, direct command and control (legal sanction). The other is self-regulation such as through legislation, mandatory, self-regulation by professional councils, codes of practice, incentive or punitive measures. Governmental regulation is more powerful and influential than self-regulation but self-regulation is highly sensitive. If self-regulation is practicable, it could detect very tiny illegalities in the system.

The regulator is the individual or the organization that enforces or legislates the regulation to manipulate the regulatees. Regulators have their own regulation instruments, roles, interest, power and influence. They can be divided into many groups based on their legitimacy, power and urgency. In each system, it is important to have more than one regulator in order to that power is balanced.

The regulatee is the group that is controlled or manipulated by the regulator. Regulation aims to control these groups by setting guidelines or standards to protect the disadvantaged and provide social equity.

In this study, we want to explore Thailand's regulations on organ transplantation. To do this, we consider three major aspects: regulation content, characteristics of regulators and relationships between them. For the regulation instrument, there are remarkable similarities

between widely divergent countries, suggesting that legislation often emanates from a common legislative template, so we want to evaluate the perception of the Thai regulators and regulatees on the effectiveness and appropriation of the transplantation regulation.

1.3 Research questions

The scandal of 1997-2000 raises several questions about Thailand's regulation of organ transplantation. How do the legal framework and the enforcement mechanisms on harvesting organs work? Are organs distributed equitably in a transparent manner? What are the problems with this regulation? What are the perspectives and viewpoints from the physicians who are regulated, from donors and recipients of organs regarding these rules and their enforcement? What are the challenges to regulating this field of medical practice effectively?

1.4 Objectives

The objectives of this study are to describe the regulatory framework, enforcement mechanism and its effectiveness, and to assess power, position, interests and relationships among stakeholders who are regulators and regulatees. In addition, the study will solicit opinion among the regulatees – physicians, coordinators, organ donors and recipients – on their knowledge, concerns and opinions of the regulation system.

2. METHODOLOGY

Extensive document research was conducted to describe the framework of organ transplantation regulation in Thailand, with special focus on the rules, enforcement mechanism on organ harvesting, criteria and practice by the Organ Donation Center (ODC) on organ distribution to recipients and organ donation procedure. We also asked the key informants for additional documents, in order to retrieve as many documents as possible.

Semi-structured interviews with key informants among different stakeholders were conducted to evaluate their roles, powers, positions, interests and relationships with other stakeholders. These key informants were chosen from related stakeholders and through a snow-ball technique to identify another stakeholder until no more were identified. Two representatives from the Medical Council (MC), the Secretary-general of the ODC of the Thai Red Cross Society, the former and current presidents of the Thai Transplantation Society (TTS), officers

at the Office of the Attorney and the Court of Justice, two journalists and two lawyers from the Law Society were among those interviewed.

Among the regulatees (including 9 transplant surgeons, 5 members of brain death certification panels, 1 hospital director and 7 coordinators), we conducted semi-structured interviews on their knowledge of the related regulations, implications of these regulations to them, their power, position and interest.

We also conducted a semi-structured interview survey of 20 renal recipients and 15 end stage renal disease patients who are on waiting list. We solicited their knowledge on the regulations, implications of the regulations to them, viewpoints and recommendations to improve the regulatory framework and its enforcement.

Based on findings from the document research and interviews of key informants, a stakeholder analysis (30, 31) was used to summarize in a systematic manner the roles, power, positions, relationships and interests of each key stakeholder and their impact. We also determined the effectiveness of the regulation in the light of the influencing factors (29).

A brain-storming workshop among key stakeholders was conducted to present results, verify validity of data, and assess the responses by key organizations on our policy recommendations.

This research was approved by the Ethical Committee of the Ministry of Public health. Interviewees were protected by the confidential treatment of information given and were free to leave the study at anytime. All interviews were carried out with informed consent.

3. RESULTS

3.1 Evolution of regulations

The first renal transplantation took place at Chulalongkorn Hospital in 1972. At that time, the surgical outcome was not as impressive and effective as it is today. There were few transplantation cases and no generally accepted rules. Hospital rules were used to ensure transparency and legitimacy of each hospital transplantation system (1, 32).

Around ten to fourteen years later, after the discovery of immuno-suppressive drugs (Cyclosporin) which prevented the rejection of the transplanted organ, the outcome of transplantation improved tremendously. The annual rate of renal transplantation increased rapidly, with success in other organs such as liver, heart and lung. At that time, the demand for organs for transplantation increased and one of the ways to increase organ transplantation was to harvest organs from recently dead people.

Concerns around this prompted a series of round table discussions. Two round table discussions were convened in 1988 by the MC, lawyers and transplantation surgeons at Chulalongkorn and Mahidol University. In 1989, the MC promulgated the criteria of brain death as a result of this roundtable meeting. In the same year, transplantation surgeons from various hospitals were determined that a non-profit and impartial organization needed to be established to ensure the fairness and equity of cadaver organ distribution and to maximize the utilization of donated organs. The decision to establish an ODC was also taken. The Thai Red Cross Society was proposed to house this Centre, but this did not materialize until 1994.

After 1989, rumours about organ selling in Thailand and other countries gradually spread (1, 13, 17, 33, 34). The brain death criteria played an important role in only the brain death diagnosis procedure. There were still no regulations for the overall transplantation process and the procedure for living, related donors. In 1991 and 1993, two multidisciplinary conferences on transplantation and regulation were conducted. The MC was urged to enact comprehensive regulations around transplantation.

In 1995 the Rule of the Medical Council on the Observance of Medical Ethics was stipulated for both cadaver and living transplantation. At the same time, the ODC (housed by The Thai Red Cross Society) was instituted. In 1996, debate among transplantation surgeons, neurosurgeons and neurologists on the interval between the first and second assessment for declaration of a brain death state induced the revision of the brain death criteria. It was decided to shorten the time lag between two assessments from 12 to 6 hours and make the measurement of carbon dioxide level in blood optional (instead of mandatory as in the previous rule).

During 1997-2000, there were scandals around kidney trafficking in a private hospital (paid cadaver donors and the relaxation of brain death certification procedures). This was reported

to the public throughout the media and had major repercussions on public trust in transplantation. The total number of donations and transplantations decreased significantly. The MC returned the verdict of guilty on the physicians involved and suspended/revoked their medical licenses. However, the plaintiffs and the Law Society insisted on also filing accusations in criminal and civil courts. Court trial is currently ongoing. As a result, the MC had added a new rule to the Observance on Medical Ethics 2000, which entrusts the ODC to license transplantation centres. Only licensed centres can perform transplantation.

In brief, regulation was originated by transplantation surgeons on a voluntary basis, based on scientific evidence and with reference to standards of procedures in other countries. Rules and enforcement mechanisms were gradually introduced. The ODC was instituted and hosted by an impartial reputable agency. Subsequent rules and amendments to cope with violations were introduced through the licensing of transplantation centres, but for these to be effective, the weak enforcement mechanism would need to be improved. Good rules with poor enforcement capacity and attitude cannot achieve their goals.

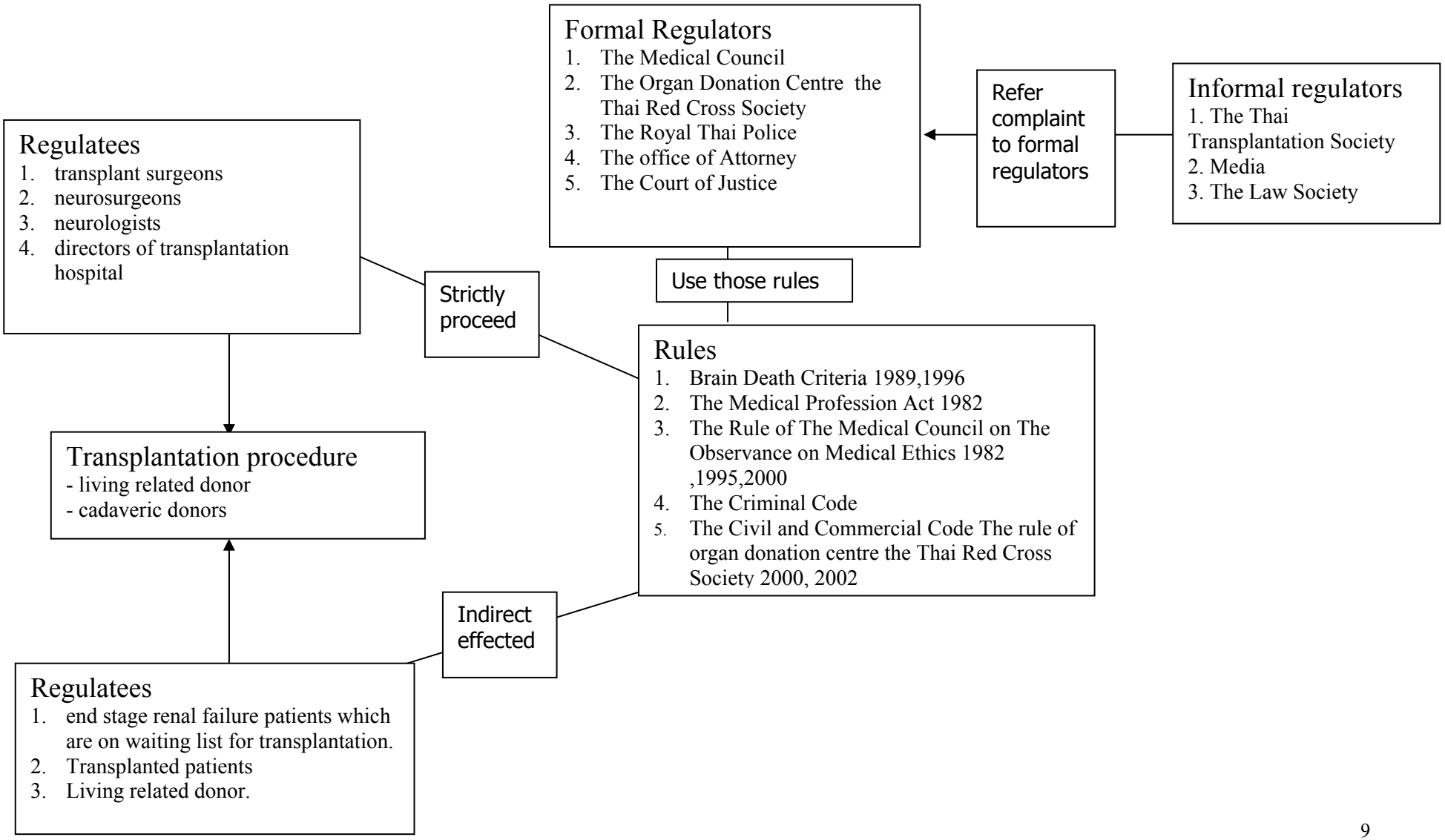
3.2 Regulation of transplantation

Consumer protection in transplantation system comprises two important parts: firstly, the fair and equitable distribution of cadaver organ donations; and secondly, a procedure to prevent organ trafficking, which involves rules on the cadaver and living related donor procurement method.

Rules, regulation and enforcement agencies are depicted in Figure 2. An understanding of the evolution of rules in response to violations and changes in context provides better insight into the important role of stakeholders.

Figure 2 shows the transplantation regulation framework. Formal regulators have legal authority and sanctions when necessary. The informal regulators have neither legal nor enforcement authority; they work through or refer to formal regulators. The regulatees (physicians) must strictly comply with these rules, which aim to protect donors from organ abuse and recipients from inequitable allocation and transmissible diseases from organs. Details on each regulator and related enforcement tool are provided in the stakeholder analysis section below.

Figure 2: Organ transplantation regulatory framework in Thailand



3.3 Cadaver organ distribution

Organ failure patients who need transplantation must register with a hospital capable of performing transplantation; patients cannot register with more than one hospital. The register is copied to the ODC. The ODC then compiles a national waiting list for cadaver donors.

ODC's objective criteria for matching a recipient with a cadaver donor are based on ABO blood group, the HLA, antibody to HLA, age of the recipient and waiting time. Clinical match (ABO, HLA and antibody to HLA) is the major criteria set, which determines the success of the operation and survival of grafts. This is followed by a minor criteria set, including waiting time and a higher preference to younger patients. These criteria were well accepted by most stakeholders. The system design ensures maximization of benefit from donors based on good clinical outcome; fair organ distribution is not interpreted on a 'first come, first served' basis alone.

In 2003, there were altogether 22 (public and private) hospitals capable of transplantation, only five of which are located outside Bangkok. Patients at provincial level have limited access or else a higher cost to reach these regional centres. Patients in Bangkok have a higher chance of receiving a transplant.

3.4 Organ harvest procedure

Living related donors are in more or less equal proportion to cadaver donors. Records from the TTS showed 45.5% of kidney transplants are living related and 54.5% are from cadaver donors (9).

3.4.1 Cadaver donor procedure

When a patient is in a brain dead state, an attending physician will contact the ODC, which coordinates and notifies both harvesting and transplantation surgical teams. Either the attending physician (if experienced) or the coordinator will ask the dying patient's relatives, who can decide on behalf of the patient, if they are willing to donate the organs.

After the entrusted representative of the deceased has agreed, the Brain Death criteria 1989 and 1996 should be strictly applied for the diagnosis of brain death status by a panel of three impartial physicians who are not involved in transplantation. Panelists consist of the

attending physician, a neurologist or neurosurgeon and another physician. The panelists and the director of the hospital (or representative) must co-sign the approval of brain death status and certify that the patient is dead. Only through this strict procedure can organs be harvested.

In addition to the Brain Death Criteria, the Observance on Medical Ethics 1995 promulgated through the Medical Professional Act also ensures the unpaid status of the donors and protects the recipients against potential transmission of diseases through organs (e.g. HIV/AIDS, CJD). The most recent version of the Observance on Medical Ethics stipulated that transplantation shall only be performed in hospitals that are certified as members of the ODC. Licensing of transplantation hospitals may be a good opportunity for closer monitoring and enforcement of transplantation regulations.

3.4.2 Living related donor procedure

The transplantation team must ensure that a living related donor is blood-related or a spouse, and shall assign a committee responsible for this process, but no detail is laid down of the committee composition and working procedure.

There is no explicit statement by the MC (the Observance on Medical Ethics 1995, 2000) or ODC on what specific evidence is required. However, in practice, documents such as evidence on living relation, e.g. marriage certificate, having children born from such marriage or co-habitation, and HLA compatibility are used. These are required to be retained in the recipient's medical records for future inspection, but the ODC have never asked to inspect such documents.

In addition, transplantation surgeons shall fully inform the donor of potential risks during and after the harvesting operation. When the donor clearly understands and accepts these, the donor must sign the informed consent document. We provide further information in the stakeholder analysis section.

3.5 Stakeholder analysis

We categorized stakeholders into two groups, primary and secondary (35). The primary stakeholders are the regulatees who are primary beneficiaries from transplantation, for example, surgeons who get prestige and a surgical fee (in private hospitals), organ failure

patients who have their organ replaced, and donors who are satisfied with their philanthropic deeds.

Secondary stakeholders are the regulators and other related intermediaries who ensure the system achieves its objectives. Secondary stakeholders were categorized into seven groups according to power, legitimacy and interest in transplantation (36) (see Figure 3). Power is the legal authority to monitor and/or enforce the regulation. Legitimacy is the right and knowledge in monitoring and enforcing the regulation.

It is useful to categorize the secondary stakeholders according to these properties. The situation analysis and strategy to improve the system can be obtained from this method.

The intercept slice one is the definitive stakeholders. They have power and interest and are legitimate on regulation. These stakeholders are important for either success or failure determinants of regulation.

The intercept slice two is the dominant stakeholders. They have power and legitimacy but lack interest in the matter. They could be mobilized to be interested in the subject matter and become definitive stakeholders.

The intercept slice three is the dangerous stakeholders. They have power and interest but not legitimacy, e.g. they lack of knowledge or correct understanding. When they are mis-informed, they can create serious problems.

The intercept slice four is the dependent stakeholders. They have interest and are legitimate, but lack power and authority to move the issue, for example academia. They can form an alliance with dominant and definitive stakeholders to provide valid information.

The non-intercept slice five is the dormant stakeholders. They have power but lack legitimacy and interest.

The non-intercept slice six is the discretionary stakeholders. They are legitimate but have no authority and interest.

The non-intercept slice seven is the demanding stakeholder. They have interest but no power and are not legitimate.

In addition, there are external stakeholders who normally are not involved with the transplantation businesses unless there is something wrong, such as organ trafficking. They become internal stakeholders temporarily until the specific issue is resolved. These agencies are the media, the Law Society, the Royal Thai police, the Office of Attorney and the Court of Justice.

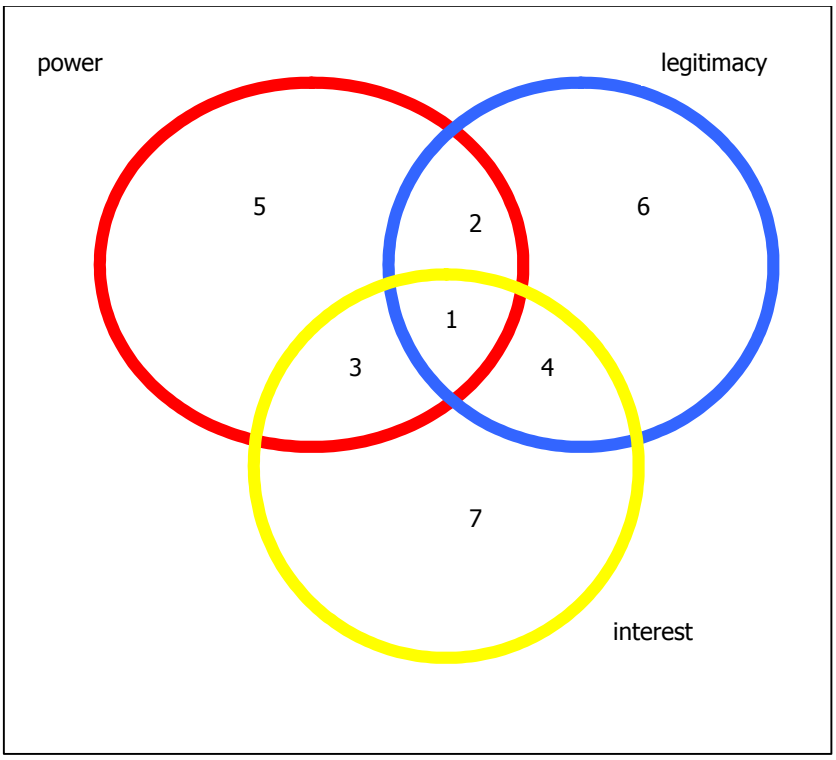


Figure 3: Types of stakeholder

To fulfil the objective of the transplantation system, we need a strong batch of definitive stakeholders. The dominant and dangerous stakeholders could be mobilized and equipped with interest and knowledge, respectively, to become an alliance with the definitive stakeholders. However, it is difficult to mobilize the dependent stakeholders with legal authority, as this requires legislation, which is a lengthy process. It is also important to have more than one key stakeholder in each system to balance their powers.

Based on findings from in-depth interviews, Table 1 summarizes our assessment of the interest, power and influence of each primary, secondary as well as external stakeholder.

Table 1: Stakeholder characteristics around the development of organ transplantation regulation

Stakeholder	**Involvement in the issue**	**Interest in the issue**	**Power**	**Influence**
Primary Stakeholder				
Transplantation related physicians	Process transplantation or related procedure such as declaration of brain death stage.	High	Medium*	High
End stage organ failure patients who need organ	Need organ to relief their suffering	High	Low	Medium to High**
Secondary Stakeholder				
The Medical Council	Legislate the rule and control the physician's behavior	Medium	High ***	Medium
The Organ donation Centre, the Red Cross Society	Distribute cadaveric donor organ Institute for transplantation hospital to register.	High	Low to High(after 2000)	Medium
Transplantation society of Thailand	Cooperate with the Medical Council to institute transplantation rule.	High	Low	Low
Coordinators	Coordinate between transplantation team and donor hospital	High	Low	Medium
External Stakeholders				
Media	Public information, stimulate format regulator	Low to Medium ****	Low	Medium to High****
The Law society	Channel of the poor to seek the justice	Medium	Low	Low to Medium
The Royal Thai Police	Prevent and protect the safety of the people	Low	Medium	Low
The Office of Attorney	Evaluate the evidence and send the case to the Court of Justice	Low	Medium	Low
The Court of Justice	Consider and give the verdict	Low	High	Low

* The transplantation related physicians also helps the Medical Council to stipulate or revise the regulation.

** If the patients have a great demand on organ transplantation and they can afford. That demand is against the regulation.

*** The influence is theoretical high but actually medium, because of lack of enforcement

**** The media influence/power and the impact to actor depend on the period, during the illegal organ selling period their influences is high but when the time pass it gradually decrease

3.6 Primary stakeholders

Primary stakeholders are those who are ultimately affected by the intervention, either the losers or the winners from the rules of the game.

3.6.1 The physicians

Physicians are the key people in this system because they have the right to perform transplantation. The main objective of the physicians is the same as that of transplantation system, relieving the suffering of the patients. Their individual ethical standards dictate whether they conform to the regulations.

Transplantation surgeons, neurologists, neurosurgeons, forensic physicians and directors of the hospital are directly governed by the regulations. They are required to strictly comply with them. Although the rules create a cumbersome process, it helps in testifying the transparency and integrity of physicians.

Our assessment found that the power and influence of physicians are at medium and high levels, respectively. External enforcement on physicians is less important than internal enforcement and self-control from their ethical and moral standards.

One key informant said, “Evidence could be made-up and fake produced, for example, perfect brain death assessment. Regulations have loopholes and external enforcement is difficult. It is the ethical standards that help comply with the rules.”

3.6.2 The coordinators

Coordinators are doctors and nurses who are responsible for requesting cadaver donation and communicating between the transplantation team, donor hospital and ODC. They facilitate a

successful transplantation. Coordinators have an important role in increasing transplantation in several countries (5, 37).

Almost all coordinators are nurses in the dialysis units who work part-time as coordinators. They have sympathy over patient suffering and are keen on counselling. They have high interest in transplantation but low power and influence.

3.6.3 The patients who are organ recipients

Although the patients are not controlled directly by the regulations, they are also important players in this system. Organ failure conditions are devastating medical, social and economical problems. Everyone wants to be cured of such suffering. Some patients said that although they know organ selling is bad, if they could support the expense, they might buy an organ. The main reason is the suffering entailed in this condition, which affects not only themselves but their families. If patients were not interesting in organ trafficking, there would certainly be no trading in transplantation. Based on these findings, although the legal power of the patients is low, our assessment found that their influence level is medium to high.

The performance and effectiveness of regulation also has an indirect effect on the patients. For example, after the selling kidney scandal in Thailand, the number of transplantation cases decreased significantly due to social distrust of the system. However, if the system is transparent and philanthropic, societal trust will be gained. We believe that organ donation would increase and therefore the transplantation rate.

3.7 Secondary stakeholders

3.7.1 The Medical Council (MC)

The MC is the juristic agency. It has objectives, authorities and duties as prescribed in The Medical Professional Act 1982. The MC is entrusted by the Royal Thai government to ensure standard and ethical practices among medical professionals in general, and in specific on organ transplantation, through the promulgation of related rules and regulation. Key rules and regulation are worth mentioning

a. The Observance on Medical Ethics 1983, 1995 and 2000

The Rule of the Medical Council on the Observance on Medical Ethics 1983 is a general rule by which the medical practitioners are to comply with the medical ethics. The mechanism to

investigate charges of misconduct is well in place, through *prima facie* sub-committee and investigative sub-committee. Medical licenses would be temporarily suspended or, in serious cases, revoked if guilt was found.

The Observance on Medical Ethics 1995 and 2000 is stipulated specifically to ensure an ethical standard of transplantation. Transplant surgeons shall ensure that recipients and the living related donors are blood-related kin or spouse. In addition, risks to the living related donor shall be fully informed, and the document and evidence must be retained in the patient file for future inspection. Interviews of stakeholders showed that this clause was hardly exercised. For cadaver donors, this regulation compels the medical panel to strictly apply the brain death criteria. It is mandatory to declare that living related donors and the representatives of cadaver donor have no financial incentives for such donation.

b. Brain Death Criteria 1989 and 1996

Brain death criteria for the diagnosis of the brain death status were promulgated by the MC in 1989. This is essential for cadaver donation. The criteria compel the medical practitioner to ensure that potential donors are actually in a brain death state by excluding some medical causes such as hypothermia, metabolic disturbances and drug intoxication. Performing brain stem reflex and apnea tests is mandatory. Subsequently, in 1996 an amendment of the criteria was made (see detail in the evolution of regulation).

The MC has high legal power and high legitimacy in enforcing the regulation due to its entrusted authority from the government, but it has only moderate influence on account of its performance. From the interview, the representative of the MC said that the structure of the organization is not suitable for a monitoring function. He believed that medical societies such as the TTS could play the monitoring role for the MC.

A transplantation surgeon who joined the TTS said in an interview that he believed the MC has low interest in this system because their activity in transplantation is very minimal. Our findings from interviews and document review indicated that while the MC has plenty of responsibility, transplantation has become less of a priority for them, so they have assigned their authority to the ODC. Our assessment indicated that the MC has medium interest.

The MC should be the definitive stakeholder, but from their medium interest, we classify the MC as a dominant stakeholder. In addition, it is difficult to stimulate and ensure sustainable interest of the MC on this issue.

3.7.2 Organ Donation Center

The ODC is a non-profit organization with an important responsibility in allocating cadaver organs. It was established in 1994 by groups of persons involved in the transplantation system who wanted to ensure fairness and equity in the distribution system and that organs were used in the most effective way.

In the past, rich patients could register for transplantation in several hospitals; this provided them more opportunities for transplantation. After the setting up of the ODC, registration with only one hospital is allowed, providing equal opportunity to the poor and the rich in access to transplantation. The ODC compiles individual hospital registries into a national registry of waiting lists.

The ODC sets up its rules and acts as enforcer. The objectives of the center are to distribute organs in an equitable manner, provide public education, serve as a place where organ demand meets supply through a national registration of organ waiting lists, and take care of the national registration of (prospective cadaver) donors. The center serves as a national focal point for international collaboration and exchange of information. It is managed by a Governing Board with full representatives from most stakeholders. Several sub-committees help its functions such as fundraising, advocacy, technical and general administration.

The ODC applied two key rules (2000 and 2002). These rules involve the organ distribution criteria, harvesting process and transplantation process, both in cadaver and living donors. The organ distribution criteria depend on the ABO, HLA and HLA antibody, waiting time and age. The rules of the ODC contain more detail than that stipulated by the MC.

Initially, the ODC had no legal authority to enforce the regulation. After 2000, the MC authorized the center to accredit transplanting hospitals, mostly regarding quality of surgery and surgeons. Only accredited members of the ODC can perform transplantation.

The ODC has high acceptance by most stakeholders for its distribution responsibility. There are still questions regarding equity in access to transplantation by geographical region, gender and patient financial status.

Due to the incomplete records on patient domicile, it is difficult to demonstrate geographical inequity in organ distribution, but 49% of transplanted patients live in Bangkok and surrounding provinces. The ratio of male to female recipients is 3:2. But from the viewpoint of the patients, coordinators and physicians, ODC performance is good.

Our assessment indicates that ODC interest and legitimacy is high. Its power increased from low to high after being entrusted to perform the legal function of accreditation from the MC in 2000. The ODC influence level is still medium because of the ODC inclination for a more relaxed regulation environment. It felt that too restrictive regulation may have a detrimental effect on transplantation, from which the patients would ultimately suffer.

The ODC is the definitive stakeholder because they have all three important characteristics. If they improve the monitoring or reporting system, which is currently weak, the Thai transplantation system would appear more transparent and trustworthy to the public to increase donation.

The problem of the ODC is its small agency and limited budget mainly from the charitable donation. We observed little conflict between the Center and others. The ODC sticks with the philosophy of voluntary and charitable works, e.g. no financial incentives to the organ harvest team, despite their extreme hard work. However, the poor participation of several *ex officio* members in the Governing Board is not contributing to the policy direction and improvement of ODC functions. External review of the ODC is needed.

3.7.3 Thai Transplantation Society (TTS)

The Thai Transplantation Society, established in 1989, is the society of transplantation surgeons and nephrologists with an interest in transplantation. This organization has a great concern and high interest in transplantation, especially in academic and treatment aspects.

Their power and influence are low because they have no legal sanction and power to punish members' poor behaviour. But their knowledge gives them the legitimacy to monitor the

transplantation system. The MC wants this organization to monitor physicians' ethical principles, but its effectiveness in this is open to question because of the mutual respect that exists among physicians in the society, which makes it difficult to suggest or inform others of any possible transplantation scandal. During the scandal in 1997-2000, the TTS notified the MC about the suspected illegal acts but the MC responded inappropriately. Due to its interest and legitimacy, the TTS is the dependent stakeholder. The TTS strongly voiced that its members should be consulted by the regulators on suggested amendments or promulgation of new rules.

3.8 External stakeholders

3.8.1 The media

The media have several roles to play, e.g. provide public information, improve public awareness and advocacy of donation. In cases of irregularity, they draw public attention and push responsible agencies to take serious action. They have no legal authority but have strong social sanction. The problem is in the accuracy of their information sources, sometimes unfairly maligning coordinators and transplant surgeons.

The media's interest, power and influence depend greatly on the context and time. In cases of high public concern, and when there are no other competing, interesting issues, they may have high interest, power and influence. However, their attention fades quickly and moves on to other topics. For this reason, the media are designated a demanding stakeholder.

3.8.2 The Law Society

The Law Society is the professional organization for lawyers; the society is a juristic agent. One of its objectives is to protect and help the poor facing injustice. The Society is the channel for the poor to access the legal process. Despite a heavy workload, it arranges a team of lawyers to help the complainant relatives in court and at the MC.

This agency has low to moderate interest because they are involved in various consumer protection problems. Transplantation is one among many topics of concern. By the nature of the Law Society, its power and influence are low.

Similar to the media, the Society has an interest in transplantation but has no legitimacy and power, and is classified as a demanding stakeholder.

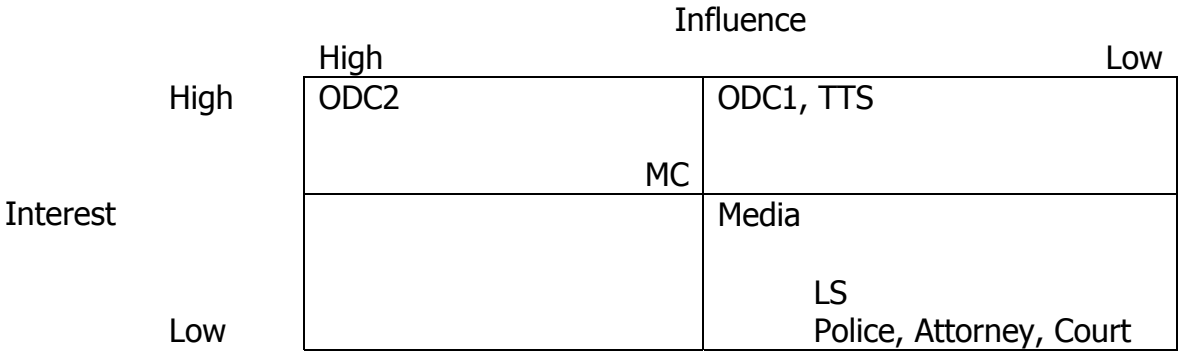
3.8.3 The Royal Thai Policy, The Office of the Attorney and The Court of Justice

These three organizations are the government offices with key roles in illegal activity. The Royal Thai Police has an obligation to protect the safety of the people and their property, to investigate and submit reports to the Office of the Attorney, who is the lawyer for the State. The Office of the Attorney considers the evidence, and if it judges the case to be illegal, the case will be filed with the Court of Justice to try and pronounce a verdict. The regulations used are The Criminal Code and The Civil and Commercial Code.

The Criminal Code and the Civil and Commercial Code are two important basic laws ensuring safe and peaceful society. They prevent and protect the safety and property of all citizens. The MC is responsible for enforcing the licensing of medical practitioners, but no compensation is granted by the MC. Instead, the Court of Justice can rule that the defendant must compensate the plaintiff through the application of the Criminal Code and or the Civil and Commercial Code.

As these three agencies have no specific responsibility on transplantation, their interest and influence are low. However, they have high to medium legal power, and are classified as dormant stakeholders.

Figure 4: Influence and interests of the stakeholders



MC: the Medical Council
ODC: Organ donation Centre, ODC1: before 2000; ODC2: after 2000
TTS: Thai Transplantation Society
Court: Court of Justice
Attorney: The office of Attorney
Police: Royal Thai Police
LS: Law Society

In conclusion, we have assessed the position of each stakeholder based on their interest and influence, which is important for executing and improving the regulations. The MC, ODC and TTS have much more interest than the external stakeholder group. However, the interest of the MC is less than that of the ODC and TTS. The influence and interest of the external stakeholder group is low, but the influence of the media, with their ability to lead and drive the social interest and social sanction, is greater than that of the TTS and ODC (before 2000). We believe that the key players in the Thai transplantation system should be the ODC (definitive stakeholder), the MC (dominant stakeholder) and the TTS (dependant stakeholder). Because the influence of the key stakeholders is not of a convincing level, steps should be determinedly undertaken to improve it. The stimulation of the interest of the MC and the strengthening of the power of the TTS are more arduous options.

3.9 Knowledge, attitudes and opinions on the regulatory system

3.9.1 Medical practitioners

We interviewed 9 transplant surgeons, 5 members of the brain death certification panel and one hospital director. We found that physicians have good knowledge on their related rules, for example, neurosurgeons know the Brain Death Criteria very well, and transplantation surgeons also have good knowledge of the Rule of the Medical Council on the Observance on Medical Ethics.

Transplantation surgeons have a good attitude toward the existing regulations, and believe that if they strictly comply with these rules, this will benefit not only the organ donors and the patients, but also the transplantation surgeons themselves. If the physicians strictly comply with these regulations, they will have no fear of any legal action.

Most physicians agreed that the OCD plays a regulator role. In addition it was believed that the transplantation hospitals should play some role. Most physicians viewed that ODC organ distribution is fair and effective; only two questioned the fairness of organ distribution between patients in Bangkok and the provinces.

This group voiced several problems, for example, lack of organ donation, expensive medication and operations that the poor cannot access, that the ODC has no incentives for its harvest team, and that the ODC is too demanding on voluntary and charitable works.

3.9.2 Coordinators

Coordinators have good knowledge of and attitude towards the regulation system. They indicated that the MC, ODC and transplantation hospitals (hospital director) should play important regulatory roles. They highlighted the lack of effective monitoring and strict compliance with the system, and mentioned similar problems of transplantation to the practitioners; for example, lack of organ donation, expensive procedures and inadequate incentives for harvest team members.

3.9.3 Organ recipients

Twenty transplanted patients and 15 renal failure patients (in the waiting list) were interviewed. We found very limited knowledge and understanding of the regulatory mechanism among patients; they could only recall a limited part of the rules. Their source of information was the transplantation team, especially the coordinators. Although they had limited knowledge of the regulatory system, they had great trust in the transplantation team and the transplantation system.

In their opinion, an important organization in regulating organ transplantation is the ODC. Those interviewed trusted in the transparency of the organ distribution system.

One particular concern of the patients is the cost of transplantation surgery. Some of them reported that they could only afford if they were government officers or beneficiaries of the social security scheme. They are also concerned about the lack of public information, awareness and organ donation.

An interesting viewpoint reflected the extent of suffering involved in renal failure, which is impossible to judge without hand-on experience. Several patients knew about organ trafficking and mentioned that it is not only unethical, but also illegal. However, sometimes they think it (buying an organ) is the only way to alleviate their suffering.

3.9.4 Living related donors

Unfortunately it is difficult to identify the relatives of cadaver donors for study, thus only three living related donors were interviewed. They showed a positive attitude to donation, and supported the idea of having a living donor registration to follow up post-transplant clinical consequences among them.

They had limited knowledge on regulation, with most information coming from the transplantation team. They reflected on the long process involved in ensuring their intention to donate (e.g. counselling with psychiatrist) and health status. After donation, they also went to the hospital for an annual health check up.

3.10 The effectiveness of the regulation

The effectiveness of transplantation regulation was determined by using five factors taken from Hongoro et al (29): the regulation design, information of regulator and regulatees, capacity and power/authority of regulators, and context.

3.10.1 Design

Transplantation regulations have gradually evolved over the past 14 years with strong participation by stakeholders. Our findings indicate that regulation for the cadaver donor is strong, but the monitoring mechanism on living related donors is weak and can easily slip. There was no active monitoring process such as mandatory reporting system.

The 1997-2000 organ scandal proved the ineffectiveness of the system design. In the initial phase, the MC did not take adequate action, despite the information it received from the TTS, until social pressure was generated by the media and the Law Society. The scandal had serious detrimental effects on organ transplantation in Thailand.

Having ODC accreditation for facilities is not adequate by itself. We believe that effective enforcement needs a strong oversight and monitoring system. Both cadaver and living related donors need a system of mandatory reporting to the ODC. And the ODC should exercise an authority to perform random checks and provide feedback.

3.10.2 Information

Regulator knowledge of the regulations is adequate, but there is gross lack of knowledge among recipients. This is a major problem, as reflected by the attitude among some patients in favour of purchasing organs. This attitude, if exercised, has a detrimental effect on the system.

Based on current information, we cannot accurately assess the magnitude of living unrelated transplantation. An effective information system is required for further policy interventions in this area.

3.10.3 Capacity among regulators

The structure and organization of the MC does not allow it to perform a monitoring function. We have acknowledged the strategy of entrusting the ODC to perform these functions.

However, the ODC has its own inherent problems. It is a small organization, inadequately funded by charity. It is conservative in attitude and does not allow financial incentives for its harvest team. This is too demanding and cannot be sustained in the long term. The ODC is governed through a board, *ex-officio* members of which do not fully contribute to the ODC's work.

3.10.4 Power and authority

The key stakeholder who has the definite power to adjudicate the illegal cases is the MC. The ODC has the authority to revoke transplantation center licenses. The ODC has the authority to request relevant documents from transplantation centers to ensure transparency and compliance with the rules and regulations. However, it never exercises this authority due to its philosophy that tough regulation results in a reluctance to perform transplantation. The ODC administration therefore prefers loose control.

3.10.5 Context

In the era of commercialized medicine, the altruistic trust between patients and physicians gradually decays. The traditional doctor and patient relationship has changed to one of client and service providers and become more of a business transaction. This changing context is fertile soil for a stronger and deeply rooted regulation.

From the above analysis on the effectiveness of Thai transplantation regulations, we conclude that the regulatory framework (law and rule, enforcers, knowledge and tools) is adequate but the function and performance of key stakeholders are still weak and problematic and need significant strengthening.

4. DISCUSSION

To achieve the societal objectives of ethical organ harvest, equitable distribution and good clinical outcome among recipients, and protection of the poor from exploitation, related regulations and adequate enforcement mechanisms must function properly and by complied with by all stakeholders. It is important to understand the regulation system, the stakeholders' ideas and their influence in fulfilling these objectives.

An effective and transparent regulatory system can restore full confidence to society, which is the most important determinant of a successful transplantation system. As one interviewee said “No donation, No transplantation”.

Effective regulation consists of five major elements (38):

- Criteria for verifying brainstem death;
- Requirement for the consent of living donors;
- Registry system for potential donors and recipients;
- Regulation of practitioners and hospitals for both living and posthumous donation;
- Penalization of the trade of organs.

4.1 Regulatory tools

India has a specific law called “The transplantation of Human Organs Act 1994” which enforces the legal responsibility of all concerned parties – the hospitals, the surgeons, the brokers and the patients (39). However, Indian law allows cadaver, living related and emotional related donors. Allowing emotional related donors can easily lead to commercial transactions if monitoring is weak.

There is no specific law in Thailand to control all persons involved in transplantation. The rules and regulations are fragmented, e.g. the MC enforces professional ethics through suspension or revoking of licenses, the ODC accredits transplantation hospitals but not professionals. The Criminal Code and the Civil and Commercial Code are general laws providing punitive measures for violators and compensation to plaintiffs.

The 1989 and 1996 Brain Death Criteria and the independent panel for cadaver donation seem adequate. The Observance on Medical Ethics 1983, 1995 and 2000 deal mostly with

living donors. Although they seem adequate, the enforcement mechanism is problematic. The ODC never exercises its authority to request information for monitoring and there is no mandatory reporting system.

4.2 The regulators

The MC has legal authority but is overwhelmed by other immediate needs. The MC's organizational structure does not permit a monitoring function. The legal authority for monitoring has therefore been allocated to the ODC, and the ODC has become a definitive stakeholder.

However, the ODC focuses mostly on accrediting transplant hospitals. Its top administrator does not want to take a tough stance, for fear that this will have a negative effect and not achieve the overall objective of increased transplantation. This is a controversial ideology and needs a thorough review. Our assessment indicates that the mechanism to enforce cadaver donor regulation is in a better shape than that for living related donors. The basic information for monitoring is not in place. We support a tough and transparent mechanism, especially on living related donation. This will ensure societal confidence, trust and the willingness to donate organs. It will protect professionals from abuse and close down all possible loopholes. We cannot afford a single case of exploitation of the poor, as might happen in the case of living non-related donors. This would have major negative repercussions on the overall transplantation system' public confidence is not easily to restore.

This is supported by negative attitudes among some patients; if they could afford it, it would be tempting to purchase an organ. Since the demand for paid donors exists, if control over the supply side is inadequate in both structure and function, how can the ODC ensure there are no paid donors.

We have indicated that information for monitoring living related donors is the weakest part of the ODC function. What is going on in transplant hospital regarding living related donation is unknown to the ODC. Information does not reach the ODC on ABO and HLA matching. This is left totally at the discretion of the transplant hospital. There is no mandatory reporting from the transplant hospital to the ODC. The in-depth interviews intimated the possible existence of living non-related donation but the magnitude is unknown. Living related donation forms 45% of total transplants.

The organization structure and management of the ODC is problematic and needs external review for its improvement. The ODC was criticized for belonging to one institute (it is affiliated with the Thai Red Cross but is closely labelled by that institute). It does not fulfill the mission of national agency and does not incorporate inputs from other stakeholders. Its management by Board and Committee tends to be ineffective, especially when *ex-officio* board members do not fully contribute to the design, direction and policy implementation of the OCD. The ODC is mainly financed by charity donation, but is inadequately funded. Financial incentives to the harvest team are inadequate to sustain long term commitments.

4.3 The regulatees

Transplantation teams and coordinators have strong knowledge on transplant regulations and are willing to comply with the regulations. If monitoring and enforcement capacity by the regulators is strong, violation is made difficult and wrongdoing will have serious consequences.

Though internal control through ethical standards and individual morality is the ideal option, it is not easy to regulate. External enforcement through monitoring and vigilance is more practical and effective. Closing down of possible loopholes through mandatory reporting is an important entry point.

5. RECOMMENDATIONS

A workshop with major stakeholders at the ODC confirmed our recommendations for improving the performance of the regulatory system.

1. To foster transparency of the system
    1.1 Include more outsiders in the transplantation decision process, for example,
        1.1.1 Appoint independent physicians to the committees for living related transplantation in individual hospitals. Currently, these committees involve mainly the transplant team.

1.1.2 Allow only the ODC-certified HLA laboratories to provide laboratory services in transplantation. A mandatory report by certified laboratories for every case of living related donation must be enforced.

1.2 Mandatory reports on, for example, brain death certification documents. The document should show no incentive between the donors and recipients in both living related and cadaver transplantation for each case transplanted.

1.3 Mandatory registry of all recipients and donors. Mandatory reporting benefits not only the monitoring system, but also the information system on transplantation for long-term policy and planning.

2. Strengthen the capacity of key stakeholders

2.1 Stimulate key stakeholders to exercise their legitimate power. The ODC and TTS should be provoked to use their full authority to ensure transparency. The ODC should install an intensive monitoring system of cadaver and living related transplantation.

2.2 Minimize conflicts among key stakeholders. The significant revision of the organization and management of the ODC is worth serious consideration.

2.3 Provide adequate annual budget and manpower. In the future, demand for transplantation may increase tremendously, especially when organ transplantation is included in the benefit package of the universal coverage scheme.

3. Increase organ donation

3.1 Have a clear and feasible annual target, plan and operating budget. It is recommended to have definite targets and to try to achieve them.

3.2 Increase the number of coordinators and promote their role. In Spain, coordinators play an important role in increasing organ donation.

3.3 Increase knowledge and interest among physicians. There was evidence from the president of the TTS that the interest and knowledge of physicians can improve the donation rate in some hospitals.

3.4 Promote public information. The knowledge and interest of the people in transplantation and donation are very important. The trust of the general population should help in increasing donation and transplantation.

4. Ensure an adequate transplantation information system by fostering cooperation among key stakeholders and transplantation centers. For example, a living related donor registry and annual follow-up provide invaluable information on long-term health consequences. This provides evidence for decisions on choices between cadaver and living related donors.

REFERENCES

1. The Medical-Lawyer Round-table Discussion "Law and organ selling prevention" [in Thai]; 1991 September 22; Bangkok, Thailand. Bangkok: Mahidol University; 1991.
2. Bortman G, Delgado D, Cohan Arazi H, Martin J, Valente S, Vazquez F, Santini M, Nojek C. Analysis of Quality of life Before and After Heart Transplantation. Transplantation Proceedings 1999; 31: 2555.
3. Monaco AP. Transplantation: The state of the art. Transplantation Proceedings 1990; 22(3): 891-901.
4. Insense B, Vilardell J, Aranzabal J, Lago AM. Quality of Life in Renal, Hepatic and Heart Transplantation Patients. Transplantation Proceedings 1999; 31: 2647-48.
5. Matesanz R. Organ Procurement in Spain: The Importance of a Transplant Coordinating Network. Transplantation Proceedings 1993; 25(6): 3132-35.
6. Tangcharoensatien V, Teerawattananon Y, Kasemsup V, Mukem S. The policy analysis of renal replacement therapy for end stage renal disease patients in basic care package of universal health insurance in Thailand. The Thai Medical Council Bulletin 2001; 30(3): 215-26.
7. Hu R-H, Lee P-H, Tsai M-K, Lee CY. Medical Cost Difference Between Renal Transplantation and Hemodialysis. Transplantation Proceedings 1998; 30: 3617-20.
8. Jirasirithum S. Textbook of Kidney Donation for Transplantation (in Thai). Bangkok: Krungthepwetchasan printing; 2001.
9. Renal Transplantation Registry: Thai Transplantation Society; 2002.
10. The Organ Donation Centre, Thai Red Cross Society. Data from the Organ Donation Centre,2001 [in Thai]; 2001.
11. Data Report from United Network For Organ Sharing. Available from URL: [http://www.unos.org/data/].
12. Aungprapai V. Transplantation and Law [in Thai]. Thammasat Law Journal 1989; 19(4): 17.
13. Notice board: kidney sales. The Lancet 1990; 12: 906.
14. Daar AD, Marshall P. Culture and Psychology in organ transplantation. World Health Forum 1998; 19: 124-27.
15. Kirpal SC, Vivekanand JHA. Perspectives in clinical nephrology: Commerce in transplantation in Third World countries. Kidney International 1996; 49: 1181-86.

16. Daar AS. Organ Donation - World Experience; the Middle East. Transplantation Proceedings 1991; 23(5): 2505-7.
17. Abouna GA, Kumar MSA, Samhan M, Dadah SK, John P, Sabawi NM. Commercialization in Human Organs: A Middle Eastern Perspective. Transplantation Proceedings 1990; 22(3): 918-21.
18. Reddy KC, Thiagarajan CM, Shunmugacundaram D, Jayachandran R, Nayar P, Thomas S, Ramachandran V. Unconventional Renal Transplantation in India. Transplantation proceedings 1990; 22(3): 910-11.
19. The organ market boom in Russia [in Thai]. Manager Daily News 2000, Oct 23; Sect. 1-2.
20. Increase charge of kidney transplantation in China, 2.4 million baths with risk [in Thai]. Manager Daily News 1999, February 2; Sect. 13-14.
21. Madhav G, Ravindra LM, Lawrence JS, Ashwini RS. Economic and Health Consequences of Selling a Kidney in India. JAMA 2002; 288(13): 1589-93.
22. RAM V. International traffic in human organs. Frontline 2002 April 12. Available from URL: [http://www.flonnet.com/fl1907/19070730.htm].
23. Minz M, Sood S, Kumar A, Bansal V, Mehra S, Sharma AK. Impact of Organ Trade on Attitudes Toward Organ Donation: Knowledge and Attitudes Toward Cadaveric Organ Donation in North India. Transplantation Proceedings 1998; 30: 3611.
24. Guiding principles on human organ transplantation. The Lancet 1991; 337(15): 1470-1.
25. The Kidney Scandal decreased the organ donation rate massively [in Thai]. Thai Post 1999, September 14; Sect. 12.
26. Kidney for sale? Crisis of Medical Professional [in Thai]. Daily News 1999, July 30; Sect. 1-2.
27. The surgical patients afraid of kidney trafficking [in Thai]. Thai Post 1999, August 14; Sect. 12.
28. Teerawattananon Y, Tangcharoensathien V, Tantivess S, Mills A. Health sector regulation in Thailand: recent progress and the future agenda. Health Policy 2003; 63: 323-38.
29. Hongoro C, Kumaranayake L. Do they work? Regulating for-profit providers in Zimbabwe. Health Policy and Planning 2000; 15(4): 368-77.
30. Varvasovszky Z, Brugha R. How to do (or not to do)… A stakeholder analysis. Health Policy and Planning 2000; 15: 338-45.

31. Brugha R, Varvasovszky Z. Stakeholder analysis: a review. Health Policy and Planning 2000; 15(3): 239-46.
32. The Medical-Lawyer Round-table Discussion "Death in medicine and Death in Jurisprudence" [in Thai]; 1988. Bangkok, Thailand.
33. Scheper-Hughes N. The Global Traffic in Human Organs. Current Anthropology 2000; 41(2): 191-224.
34. Sartvaha S. The Medical-Lawyer Round-table Discussion "quality of life and law" [in Thai]; 1990 July 25; Bangkok, Thailand. Bangkok: Mahidol University; 1991.
35. Philip D, Steve J, Rolf S. Development: a handbook for those engaged in development activity. 2002. Available from URL: [http://62.189.42.51/DFIDstage/FOI/tools/tools_pdf/DFID_ToolsforDevelopment.pdf].
36. Chavalier J. Stakeholder Analysis and Natural Resource Management. 2001. Available from URL: [http://www/carleton.ca/~jchevali/STAKEH2.html].
37. Bosch X. Spain leads world in organ donation and transplantation. JAMA 1999; 282(1).
38. Gabr M. organ transplantation in Developing countries. World Health Forum 1998; 19: 120-23.
39. The Transplantation of Human Organs Act, 1994. Available from URL: [http://www.indialawinfo.com/bareacts/transplant.html].