

FEASIBILITY OF AN ORGAN DONOR REGISTRY IN MUMBAI

FEASIBILITY OF THE DEVELOPMENT AND IMPLEMENTATION OF AN ORGAN
DONOR REGISTRY IN MUMBAI, INDIA

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ABSTRACT

Background: Organ donation in India is a complex issue due to the country's large population, diverse religious beliefs and myths surrounding organ donation, varying literacy rates, nation-wide focus on disease control, and the commercialization of organs. India has only made marginal steps to address the significant obstacles in order to ensure adequate supplies of organs are available to meet the demand.

Purpose: The purpose of this study is to analyze the feasibility of implementing an organ donor registry in Mumbai, India. This is achieved by reviewing current organ donation policies and processes in Mumbai, exploring perceptions of key informants about Indian government health priorities, and identifying possible reasons why the Indian government has not made efforts to increase the deceased donor rate.

Methods: This qualitative policy analysis employs semi-structured interviews with physicians, transplant coordinators, and representatives of organ donation advocacy groups in Mumbai to explore key informants' perceptions about the feasibility of developing and implementing an organ donor registry. The 3-I framework (ideas, interests, and institutions) is used to analyze the results and frame the discussion and their implications.

Results: Key informants cite various barriers to the implementation of an organ donor registry in Mumbai, including public misconceptions about organ donation, competing health priorities on the government agenda, and limited hospital infrastructure.

Conclusion: In the absence of a focusing event or a policy entrepreneur who is able to push the issue of organ donation onto the health policy agenda, both central and state

governments may have little incentive to aggressively pursue the implementation of a donor registry in more than a superficial way. Moreover, even if the issue reached the government's policy agenda, current barriers may be too overwhelming to overcome. This suggests that implementing an organ donor registry in Mumbai as a means of enhancing organ availability is not feasible in the current environment. Instead, efforts to enhance the transplant system should focus on alternate strategies, such as public education, until the policy environment becomes more amenable to change.

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LIST OF ABBREVIATIONS

ICU	Intensive Care Unit
MCGM	Municipal Corporation of Greater Mumbai
NGO	Non-Governmental Organization
WHO	World Health Organization
WMA	World Medical Association
ZTCC	Zonal Transplant Coordination Center

DECLARATION OF ACADEMIC ACHIEVEMENT

The following is a declaration that the content of the research in this document has been completed by Diana Vania and recognizes the contributions of Dr. Glen Randall, Dr. Maureen Dobbins, and Dr. Gillian Mulvale in both the research process and the completion of the thesis.

INTRODUCTION

Every year, thousands of people die while waiting for a vital organ transplant. Organs can be obtained from either living donors or cadaver donors. Generally, the transplant of organs retrieved from cadavers (post-mortem organ donation) is more regulated by governments and encounters less fraud than the transplant of organs from living donors. Although international guidelines have been developed to facilitate the removal of organs from deceased donors, each year millions of potential organ donors die but their organs are not retrieved for transplantation. Many factors contribute to the unavailability of organs, including lack of knowledge about organ donation, lack of familial consent, insufficient hospital infrastructure, and the potential donor not meeting medical criteria for organ donation (Howard & Byrne, 2007; Rithalia, McDaid, Suekarran, Myers, & Sowden, 2009a; Sque, Long, Payne, & Allardyce, 2008). One of the many ways in which the cadaver organ donation rate can be increased, in addition to public awareness campaigns and hospital infrastructure development, is the implementation of an organ donor registry (Coppens, Friele, Gevers, Blok, & van der Zee, 2008; Rithalia et al., 2009a; Rosenblum et al., 2012b).

A donor registry would allow residents of a particular geographic region (city, state, or country) to declare that once they die, they consent to their organs being retrieved for transplant into a recipient. Maintaining a donor registry creates public awareness about post-mortem organ donation and also allows health care providers to demonstrate to families that their relative wished to become an organ donor (Rosenblum et al., 2012b; Sque et al., 2008). Registries are typically maintained through a computer database:

individuals can register their consent online and their information is stored in a central database. The transplant coordination centre and hospitals are able to access the central list of donors to determine if a patient had previously agreed to organ donation.

Alternatively, many countries combine a donor registry with existing government documentation by allowing residents to consent to or decline organ donation when applying for a health card or driver's license. A registry will be more accepted in regions where there is strong public and government support for organ donation and where the population can more easily be educated about organ donation registration options.

India has an especially low deceased organ donation rate compared to developed countries. In many developed countries, deceased organ donation rates typically range from ten to 25 deceased donors per million population per year (Abadie & Gay, 2006). In India, however, the deceased donation rate is much lower, at 0.08 per million population (Abraham et al., 2012). If India could overcome political, social, and infrastructural obstacles to increase the deceased donation rate to just one donor per million population per year, this would meet the current demand for all livers, hearts, lungs, and some kidneys for the entire country, thus eliminating the need for transplants from living donors (Abraham, John, Shroff, Fernando, & Reddy, 2010). In developing countries such as India, it is preferable not to rely on organs from living donors, as there is greater chance for exploitation of the poor for their organs, and donors typically experience lower health-related quality of life after organ removal (Goyal, Mehta, Schneiderman, & Sehgal, 2002).

Additionally, the number of patients in India requiring transplants is expected to increase over time. Recent research evidence shows that India is experiencing a double burden of disease, in which both the communicable and non-communicable disease rates are increasing (Srinath Reddy, Shah, Varghese, & Ramadoss, 2005). India has the largest diabetic population in the world, which will only increase with time; by 2025, it is expected that over 57 million Indians will be diagnosed with diabetes (Srinath Reddy et al., 2005). Diabetes can cause issues with multiple vital organs, which further exacerbates the need for organ transplants (Barsoum, 2006). Until the underlying causes and risk factors of diabetes are addressed, its prevalence and incidence will only increase and more patients will require renal therapy (dialysis and kidney transplants) (Barsoum, 2006). Dialysis is associated with ongoing costs, time drain for the patient and his or her family, and loss of work and the resulting loss of income, often impacting the family's standard of living. Thus, in the long-term, transplant therapy is more cost-effective than dialysis and provides better health-related quality of life for patients and families, enabling people to live and work longer and contribute to the Indian economy instead of being a drain on health care resources (Laupacis et al., 1996).

However, as the Indian government tackles severe and pervasive health issues, including widespread infectious diseases and poverty, it is difficult for organ donation to become a priority. The state of Maharashtra has one of the highest deceased donor rates in India (0.3 donors per million population), but the supply of cadaver organs harvested is still not adequate to meet the demand (Abraham et al., 2010). Although a state-wide registry may be a possibility in the future, it is important to first assess whether the

implementation and operation of an organ donor registry is advisable and feasible in the city of Mumbai. As India's largest city, it is more likely that Mumbai will have adequate infrastructure and resources to support a registry. However, due to Mumbai's many different religious and cultural sub-populations, variations in education and literacy levels, corruption, and lack of infrastructure, affecting change in organ donation procedures and policies may prove difficult and impractical. In addition, the greater context of widespread poverty and inequity in India needs to be taken into account.

Overall Goals of the Study

This study aims to determine the feasibility of enhancing the deceased donor rate in Mumbai, India through the implementation of an organ donor registry. This study will also examine how government decisions surrounding organ donation policies are shaped by the 3-I framework (ideas, interests, and institutions) within the health care policy context in India. In addition, this paper will explore possible reasons why the Indian government has not made sustained large-scale efforts to increase the deceased donor rate despite evidence that increasing the donor rate could meet almost all demand for solid organs.

This study considers organ donation within the current health care system in India. Although it is impossible to study organ donation in any developing country without taking into account the wider extent of ethical issues, this paper is approached primarily from a policy analysis perspective. The broader national context of poverty and health inequity is considered, but the research mainly focuses on the implementation of an organ donor registry in Mumbai within the existing infrastructure and current practices of the

health care system. Any in-depth discussion of related ethical issues is beyond the scope of this study.

Contribution of Study to Existing Literature

Much of the current organ donation literature worldwide focuses on the type of registration system (informed consent, presumed consent, and mandated choice), the influence of the family's decision on organ donation, societal and religious attitudes towards donation, and the ethics surrounding organ donation. However, most of this research concentrates on developed countries in the western world with established donor registries and strong societal and government support for organ donation. Little research attention has been given to developing countries; most organ transplant studies in India focus on medical tourism and the illegal commercialization of organs. This paper will help fill the knowledge gap by extending current organ donation research to India and will contribute to the organ donation literature in the health policy field by outlining current organ donation procedures and examining the political environment within which organ donation policy decisions are made. Furthermore, this research will analyze how policy decision are made within India's social, political, and economic environment, and will identify circumstances that might promote or prohibit certain policy decisions.

Organization of this Paper

The 3-I framework takes ideas, interests, and institutions into account when analyzing policy development processes. Ideas are the values and knowledge that help inform policies. Values, including ideologies and philosophies, are normative (what ought to be), while knowledge, such as research evidence and cultural-specific

knowledge, is descriptive (describing what is). Research evidence can help to shift peoples' beliefs, but values and beliefs can be deep-rooted in a society and may be difficult to change. Interests refer to the goals and objectives that different policy actors and organizations pursue. These actors are influenced by the political and socioeconomic structures of the institutions around them. Institutions focus on the organization of states, countries, and international systems and the procedures and rules for making policies. The rules for making policies are often exclusive and restrict decision making to the elites and those with power. Each of these components shapes policy decisions, from placing issues on the government agenda, policy formulation and decision-making, implementation, through to the evaluation of existing policies. The 3-I framework has been applied to this research to examine how ideas, interests, and institutions influence organ donation policies in India, and subsequently, the feasibility of an organ donor registry being adopted.

This paper begins by providing a brief background on health care and organ donation legislation in India, and the criteria and ethics of organ donation. Next, a literature review provides an overview of the current research on organ donation. Study methods and findings from key informant interviews are presented, followed by an analysis and discussion of the results, framed within the broader context of Indian society, and conclusions about the feasibility of an organ donor registry.

BACKGROUND

This section describes the health care system and organ donation legislation and briefly discusses the commercialization of organs in India. In addition, it focuses on organ donation criteria and types of donor registries while touching on ethical issues surrounding organ donation.

Health Care in India

India ranks among the lowest countries in the world in government health spending (Central Intelligence Agency [CIA], 2012). With no national health insurance schemes, the Indian health system is primarily funded through out-of-pocket payments. In 2011, the Indian government spent a relatively low 3.9% of GDP on health care per year (World Health Organization [WHO], 2013). Comparatively, the world average for health expenditure in 2011 was 10.1% of GDP (World Bank, 2014).

In 2004-2005¹, the central Indian government contributed only 19.7% of all health payments, while private spending accounted for 78.1% of expenditures (see Table 1) (Ministry of Health and Family Welfare, 2009). External flows refer to funding from bilateral and multilateral agencies to the central and state governments and NGOs; these funds mostly support reproductive child health, immunization, and AIDS control programs (Ministry of Health and Family Welfare, 2009). Health expenditure in the state of Maharashtra (where Mumbai is located) is comparable to the rest of India at 17% government and 83% private (Ministry of Health and Family Welfare, 2009). The private

¹ The National Health Accounts India 2004-2005 report from the Government of India and the WHO is the most recent data available on health expenditures.

funds come primarily from households, with a very small percentage coming from social insurance funds, firms, and non-governmental organizations (NGOs).

Type of Expenditure	Distribution of Total Health Expenditure (%)
Public Expenditure	19.67
Private Expenditure	78.05
External Flow	2.28
Total Health Expenditure	100

Table 1. Health expenditures in India (adapted from Ministry of Health and Family Welfare, 2009)

India is composed of 28 states and seven union territories. Each state and union territory is responsible for their own health system and policies, which leads to 35 different systems across the country. As per the Constitution of India (1950), the State Legislatures have exclusive authority over public health and hospitals: “The State shall regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties...” (India Const. art. 47). Any changes made by the central (national) government relating to health must be approved by the Rajya Sabha (state assembly).

The major governing body in Mumbai is the Municipal Corporation of Greater Mumbai (MCGM). The MCGM Public Health Department is responsible for the population health of Mumbai by providing preventive and curative care, maintaining the vital statistics registry, and implementing National Health Programs (MCGM, 2013). Health resources (including financial, medical, and human) in Mumbai are scarce, and both physical and financial access to health care is limited. Of the 40,000 hospital beds in Mumbai, 50% of beds are in private hospitals, while only 28% are in MCGM-funded

hospitals, and 22% are in state government hospitals (MCGM, 2008). Hospitals in these districts (Mumbai City and Mumbai Suburban) serve a population of over 12 million (Census Organization of India, 2011a, 2011b). The World Health Organization's (WHO) recommended hospital bed-to-population ratio is one bed per 550 people (MCGM, 2010). While Mumbai's private hospital bed ratio meets the WHO's recommendation with one private hospital bed per 487 people, the municipal hospital bed-to-population ratio is grossly inadequate at one bed per 1309 people (MCGM, 2010).

Poverty and Health Inequity in India

In India, access to medical treatment is often based on one's ability to pay for the service. Poverty is rampant in India; in a population of 1.2 billion, 360 million people are living below the poverty line (CIA, 2012). The private health care system, primarily funded by out-of-pocket payments, further widens the inequality gap between wealthy and poor Indians. With nearly 30% of the population living below the poverty line, many people who cannot afford health care are neglected within the health system and do not receive required medical attention (CIA, 2012). India's lack of comprehensive public health insurance forces millions of people to spend large portions of their income on out-of-pocket health payments, resulting in 39 million Indians being pushed into poverty each year (Balarajan, Selvaraj, & Subramanian, 2011). Those who are already living below the poverty line continue to suffer and experience even deeper poverty.

Hospitalization requires further financial investment: hospitalized Indians on average spend 48% of annual savings, and money is often borrowed or assets have to be sold to cover hospital expenses (Balarajan et al., 2011). In addition to the expensive

surgery, organ transplant recipients also require immuno-suppressive drugs to ensure that the body does not reject the new organ. The price of drugs has drastically increased in India over the past few decades: previously, 90% of drugs were price controlled, while now only 10% of drugs in India are price controlled (Balarajan et al., 2011). Related non-health care costs associated with seeking medical care, such as transportation and loss of wages, also account for the rising burden of health care costs (Balarajan et al., 2011).

Organ Donation Policies in India

In 1994 the Government of India's Ministry of Health and Family Welfare implemented the *Transplantation of Human Organs Act*. The purpose of the act is to regulate the "removal, storage and transplantation of human organs for therapeutic purposes" and to prevent commercialization of organs in India (*Transplantation of Human Organs Act*, 1994, p. 1). The Act outlines the authority for removal of human organs, restrictions on removal and transplantation of human organs, the registration and regulation of hospitals performing human organ retrieval or transplantation, the role of the Appropriate Authority, and punishment for unlawful removal or commercialization of human organs. Consistent with international guidelines, the Act states that certain criteria must be met to declare brain death before organs can be removed; any hospital involved in the removal, storage, or transplantation of human organs must be registered with the government; the Appropriate Authority is responsible for granting authority for hospitals to perform organ removal procedures; and removing or transplanting an organ without authority, or making or receiving payment for a human organ is punishable with imprisonment and a fine.

Since 1994, the *Transplantation of Human Organs Act* has been revised thrice (in 1995, 2005, and 2009), and the *Transplantation of Human Organs and Tissues Rules, 2013* has been drafted. The most major change comes from the *Transplantation of Human Organs (Amendment) Bill, 2009*, which aims to increase the number of cadaveric organs harvested from brain dead patients by requiring a doctor in an intensive care unit (ICU) to inform families about organ donation and obtain consent for donation. Hospitals have followed this rule by instating a transplant coordinator in their ICUs.

Conditions for Cadaver Organ Donation

In order for a potential donor to be eligible for organ removal, cardiac death or brain death must first be declared by a physician (World Medical Association [WMA], 2006a). Cardiac death occurs when the heart stops beating, either from clinical death or from removal of life support. The optimal organ retrieval time following cardiac death is extremely limited, as organ viability is compromised once the heart stops beating and no blood is perfused through the organs. Organ transplantation after cardiac death raises ethical concerns because when it is determined that an organ donor is near death, the patient is often kept alive solely for the purpose of ensuring organ viability (Steinbrook, 2007). Studies conducted in the United States have indicated that many health care providers are uncomfortable with the ethical issues surrounding organ procurement after cardiac death (Mandell et al., 2006). There is no research evidence from India regarding physicians' standpoint on donation after cardiac death.

In 1976, brain death was introduced globally as an additional accepted form of death for organ transplantation. Since donation after brain death offers more viable

organs and has fewer related ethical concerns than donation after cardiac death, it is the preferred method of organ recovery (Steinbrook, 2007). The guidelines developed by the Conference of Medical Royal Colleges and their Faculties in the United Kingdom refer to brain death as the complete and irreversible loss of brain and brain stem function (“Diagnosis of Brain Death”, 1976). A series of clinical criteria has been established to aid physicians and neurologists to properly determine brain death. Formal guidelines for the determination of brain death and the resulting acceptance of organ retrieval while the patient’s heart is still beating has allowed for a wider choice of organs to be harvested for transplant (Sells, 1994). India has accepted this definition of brain stem death when “all functions of the brain stem have permanently and irreversibly ceased” (*Transplantation of Human Organs Act*, 1994, p. 2).

Ethics Surrounding Organ Donation

There are a myriad of ethical considerations surrounding organ donation, including informed consent; privacy within organ donor registries; a physician’s obligation to adhere to professional standards; appropriate determination of the end of a patient’s life; legal and moral organ procurement; and justice in access to organs. The following sections briefly discuss these ethical issues within the context of the advisability and feasibility of creating an organ donor registry in Mumbai.

Guidance from the World Medical Association

The World Medical Association (WMA) is an international organization dedicated to the promotion of the highest standards of medical ethics and health care around the world (WMA, 2013). As one of the founding member associations of the WMA, the

Indian Medical Association is committed to improving public health in India and adheres to the principles set forth by the WMA (Indian Medical Association, n.d.). The WMA Statement on Organ and Tissue Donation declares that the “core [ethical] principles [of] altruism, autonomy, beneficence, equity and justice...should guide those developing local policies...both in relation to organ procurement and to the distribution and transplantation of donor organs” (WMA, 2012, p. 1).

Informed Consent

The WMA Statement on Organ and Tissue Donation (2012) states that all individuals should be aware of the option to donate his or her organs after death. People should also have the opportunity to consent to or decline post-mortem organ donation, usually via an organ donor registry. Information received prior to consenting to or refusing organ donation should include what organs the person is agreeing to donate, determination of death criteria, and procedures to remove organs after a patient has died (WMA, 2006b).

Privacy within Organ Donor Registries

The WMA advocates that where an organ donor registry has been established, full privacy should be granted to individuals, including registry status and medical information given to the registry (WMA, 2006b). In addition, individuals should be able to withdraw their confirmed donor status at any time without repercussion (WMA, 2006b). Regardless of the registration system type (opt-in, presumed consent, or mandated choice), individuals should not feel coerced into becoming an organ donor.

Professional Obligation of Physicians

All practicing health care providers have an obligation to ensure that organs have been procured in a legal and ethical manner and without coercion or payment for organs. The WMA Statement of 2006 declares that physicians should not perform any transplant operation if they know the organs have been obtained in an illegal or unethical manner.

Determination of Death

Determination of brain or cardiac death should be made by a physician using accepted clinical guidelines or triggers (WMA, 2006a). In order to avoid a conflict of interest, the physician who determines the potential organ donor's death should not be involved in the organ removal or transplantation process and should not be responsible for the medical care or well-being of potential recipients (WMA, 2006b).

Often, patients and their families are concerned that a physician will prematurely determine death to save health care resources and ensure timely access to the patient's organs (Morgan, Harrison, Afifi, Long, & Stephenson, 2008). In response to these concerns, India's *Transplantation of Human Organs Act, 1994* requires a committee of four physicians (the treating physician, the doctor in charge of the hospital (medical director), an independent specialist, and a neurologist) to declare brain stem death before organ removal commences.

Organ Procurement

It is the position of many international organizations, including the World Health Organization and the World Medical Association, that direct payment for organs, whether

the donor is living or deceased, should be prohibited (WHO, 2009; WMA, 2006b). The reasons are described later in this paper.

Justice in Access to Organs

There should be fair and equal access to available organs for all patients who are in need of a transplant. A patient's receipt of an organ should be based on relevant medical criteria, including severity of need, length of time on the transplant wait list, and medical probability of transplant success (WMA, 2006b). Potential recipients should not be discriminated against based on economic status, social status, lifestyle, or behaviour (WMA, 2006b). In addition, it is deemed discriminatory for a donor to place conditions on who can or cannot receive his or her organs (WMA, 2012).

Ethical Issues in India

Issues encountered in developing countries compound ethical concerns regarding organ donation. In India, low literacy levels, poverty, perceptions of religious beliefs (versus actual religious teachings), and corruption within the government and health system must be taken into account when implementing or updating organ donation policies. Major ethical issues experienced in India will be explored further in the analysis of study findings.

Low Literacy Levels

Mumbai's literacy rate is 89%, which means that approximately 1.3 million people cannot read or write (Census Organization of India, 2011a, 2011b). Surveys have shown that the illiterate have the highest rate of being against post-mortem organ donation, and this poses several challenges (Chugh & Jha, 1996). First, information dissemination must

address the need to clearly outline the risks, benefits, and options of organ donation.

Second, different mediums must be used to reach and enlighten the general population.

Third, in order to facilitate full understanding of organ donation and its process, a registry should include translation into multiple languages. In addition to Hindi and English (the nation's official languages) and Marathi (the state language), translation is required in many languages because the city's cosmopolitan nature and large influx of migrants results in as many as 16 major languages being spoken in Mumbai (Pai, 2005).

Computer Literacy and Access to Computers

In addition, a computerized, web-based donor registry necessitates knowing how to access the registry and properly input one's information. An online registry may not be easily accessible to the section of the population that cannot access the Internet. A study by the Internet and Mobile Association of India and Indian Market Research Bureau estimates that there are 6.2 million active Internet users in Mumbai ("India's Internet users top 100 m in Sept," 2011). Although Mumbai has the highest number of Internet users in India, they still only constitute half the city's population.

Medical Tourism

Medical tourism is a relatively recent phenomenon in which patients from western countries travel to developing countries to receive medical procedures at a lower cost (Connell, 2006). Medical tourism evolved as a response to mounting health care costs and extensive wait times in developed countries, and high quality of care and increasing technology and expertise in developing countries (Connell, 2006). By 2017, there will be

an estimated 23 million medical tourists globally (Hopkins, Labonté, Runnels, & Packer, 2010).

India attracts medical tourists from around the world using various strategies. India promotes physicians who have been trained abroad; partners with leading hospitals and universities, such as Harvard University; and joins medical brokerage firms to encourage patients from abroad to select India as the destination for their medical vacation (Turner, 2007). In 2007, India treated over 450,000 foreign patients, which generated over US\$480 million in revenue for the Indian health economy (Hopkins et al., 2010). Medical procedures in India can cost as little as 6% of what the treatment or service would normally cost in the United States, making India a prime medical destination for westerners (Connell, 2006). Figure 1 shows medical costs in the United States compared to costs in popular medical tourism countries.

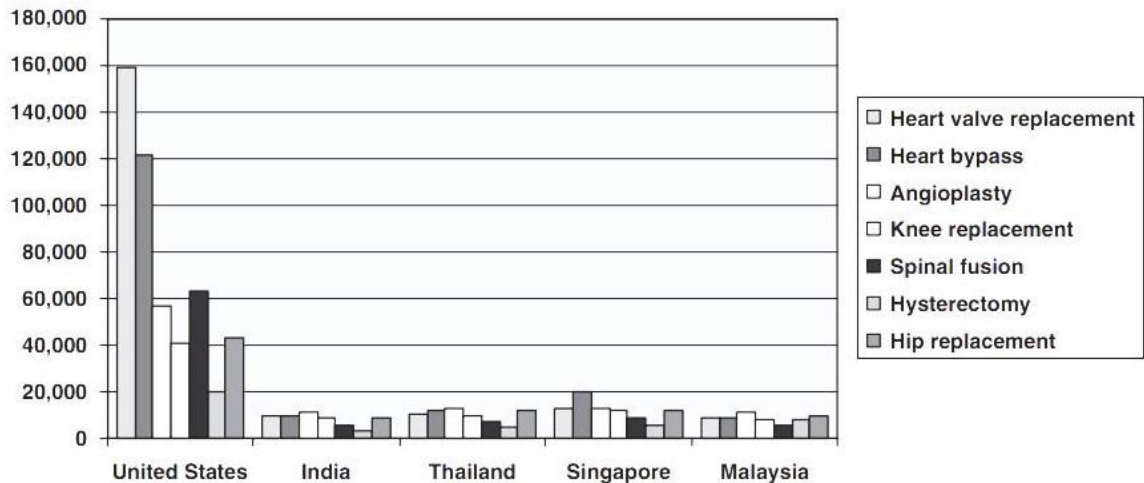


Figure 1. Comparison of costs of selected medical services (US \$) (Hopkins et al., 2010)

Medical tourism in India often weakens existing health care infrastructure, as discussed in what follows (Hopkins et al., 2010). Proponents of medical tourism suggest that attracting foreign patients benefits the country by increasing tourism, thereby stimulating the local economy (Turner, 2007). The Indian government views medical tourism as an opportunity to diversify the economy, increase foreign investment, and stimulate job creation (Turner, 2007). As international patients often pair their medical procedures with a conventional vacation, the restaurant and hotel sectors also profit; it is estimated that medical tourism contributes at least US\$2 billion to India's economy (Connell, 2006; Shetty, 2010). Several authors have argued that revenue earned from foreign patients should be returned to the country's health care system to fund the public health sector, but the majority of India's population do not receive the economic benefits that international patients bring (Hopkins et al., 2010; Ramírez de Arellano, 2007; Turner, 2007).

Despite the economic advantages associated with medical tourism, there are health and economic consequences associated with increased international patients. In India, millions of people live below the poverty line with no access to health care (Connell, 2006). As medical tourism becomes more prevalent, health care providers are often enticed into moving to large cities and practicing in the private health sector to increase their income, rather than practicing in government or rural hospitals. This internal brain drain prevents low-income Indians and those who live in rural areas from accessing health care:

The poor in India have no access to health care because it is either too expensive or not available. We have doctors but they are busy treating the rich in India. For years we have been providing doctors to the western world. Now they are coming back and serving foreign patients at home. (qtd. in Ramesh, 2005, para. 20)

Furthermore, regarding medical tourism in India, “promoting the notion that medical services can be bought off the shelf from the lowest priced provider anywhere in the globe...takes away the pressure from the government to provide comprehensive health care to all its citizens” (Sen Gupta, 2004). The increase in the number of foreign patients means that the Indian government focuses on private health care at the cost of the public health care sector (Sengupta & Nundy, 2005).

Many western patients seek organ transplants in India, where there is a lesser wait time and out-of-pocket payments can guarantee almost immediate access to an organ from an individual who is willing to sell an organ (Hopkins et al., 2010). Due to the time constraints of cadaveric organ transplants, the majority of procedures in transplant tourism occur between local live donors and recipients from wealthy countries that are willing to pay for an organ (Hopkins et al., 2010). Although medical tourism can have adverse effects on the country’s health system, generally those in need of organ transplants do not travel to a country and wait for a cadaver organ to become available. For this reason, medical tourism is not a direct threat to improving cadaver organ donation in India.

Black Market Organ Donation

The World Health Organization has estimated that as much as 10% of all organ transplants worldwide involve the sale of organs and organ trafficking (Rudge, Matesanz, Delmonico, & Chapman, 2012). Although India's *Transplantation of Human Organs Act* states that commercial transactions for human organs is prohibited and clearly outlines the punishment for violation of the rule, the commercialization of organs is commonplace in India. Every year about 2000 Indians sell a kidney for payment (Shimazono, 2007).

Since poverty is a driving factor in the decision to sell one's organs, wealthy people often exploit financial need in poorer people by offering payment for organs. Wealthy recipients justify the purchase of an organ by claiming that their payment will help the donor financially (Goyal et al., 2002). In actuality, studies support concerns that selling an organ can be detrimental to the donor, both financially and health-wise. For example, despite earning an average of US\$1070 for a kidney, most families experience a decrease in family income after kidney removal. This is because the majority of kidney donors report a decline in health status which in turn can affect the ability to earn income (Goyal et al., 2002).

While the commercialization of organs is prevalent in India, this type of transaction typically occurs between unrelated living donors and does not involve cadaveric organs. Therefore commercialization of organs will not be explored further in this thesis.

Summary

This section provided background information on organ donation in India by describing health care in India within the greater context of poverty and inequity,

reviewing the history of organ donation legislation and practices in India, explaining the necessary conditions for cadaver organ donation, discussing general ethical issues of organ donation (ethics specifically surrounding organ donation in India will be examined in the Discussion section), and providing a brief overview of the impact of medical tourism and the commercialization of organs in India. The following section will provide an overview of the existing organ donation literature.

LITERATURE REVIEW

The purpose of the literature review is to explore the social aspects of organ donation and gather information on existing organ donation literature before beginning key informant interviews. The review examines the types of donor registries and their effects on deceased donor rates, factors that influence donor rates, why people decide to become an organ donor, and the economics of organ transplants. This information is meant to help guide the key informant interviews and subsequent analysis of how to improve the deceased donor rate in Mumbai.

Search Strategy

A search of the electronic databases PubMed, CINAHL, and MEDLINE was conducted. Keywords and phrases including ‘organ donation’, ‘organ donor register’, ‘organ donor registry’, ‘organ donation ethics’, ‘organ donation in India’, ‘informed consent’, ‘presumed consent’, ‘mandated choice’, ‘brain death’, ‘decision to donate’, and ‘organ donation religion’ were used to search for relevant documents. Literature sources included published articles, electronic journals, international organization reports and policies, government laws and acts, and information from government websites. Inclusion criteria included articles published after 1994 and written in English. Relevant articles from the bibliography list were also included. Information pertaining to tissue or blood donation, live donor donation, the medical/biological aspects of transplantation, or non-human organ donation was excluded.

Types of Organ Donor Registries

There are three alternatives for centralized registration systems: informed consent (opt-in), presumed consent (opt-out), and mandated choice. Each system has practical and ethical benefits and consequences. None of these registry systems discriminates against socioeconomic status, gender, or race. Therefore, each system is available to anyone regardless of his or her circumstances. The rule of reciprocity, discussed below, can be an addendum to any donor registration system.

Scholars and practitioners are still undecided as to whether an opt-in registry or an opt-out registry is more effective in increasing deceased donation rates. This is because even if a country shows a marked increase in the donation rate after implementing an opt-out policy, it is unclear whether the increase is attributable solely to the new policy, or to accompanying awareness campaigns.

Informed Consent

In an informed consent registration system, an individual must explicitly state his or her preference to become an organ donor by voluntarily registering with a central registry (Coppen et al., 2008). This type of registration system maximizes freedom of choice and autonomy and minimizes coercion of individuals into making a decision. An opt-in registry allows the public to proactively register their consent for post-mortem donation. On its own, it can be used “in the promotion of deceased donation, and can be utilized to target, measure and evaluate public awareness campaigns in support of organ donation” (Rosenblum et al., 2012b, p. 810).

Many people may be in favour of post-mortem organ donation, but unfortunately there is a disconnect between intention (wanting to be an organ donor) and behaviour (actually registering to be an organ donor); there is a vast discrepancy between willingness to donate one's organs after death and the percentage of people who actually sign their donor card. In the United States, public surveys have reported that as many as 80% of people are willing to sign an organ donor card, but in actuality, less than 20% of the population have signed a donor card (Weber, Martin, & Corrigan, 2007). This substantial loss in organ donor registrants can be reduced in a presumed consent registry system.

Presumed Consent

Under presumed consent legislation, the default is that all residents are registered to be post-mortem organ donors unless someone specifically withdraws from the registry list (Johnson & Goldstein, 2003). There are three general attitudes toward organ donation: for, against, or indifferent. In a system of presumed consent, those who support organ donation will remain registered, while those who are against donation will unregister. However, those who are indifferent will most likely not make the effort to unregister from the system (similarly, those who are indifferent in an opt-in system will not take the time to register to be donors). Johnson and Goldstein (2003) have found that if people do not feel strongly toward one situation or another, they will go with the default. The presumed consent system ensures that those who do not feel strongly one way or another about organ donation are registered, thus increasing the supply of potential cadaver organ

donors. This system can be especially beneficial for countries in which support for post-mortem organ donation is high, but registration rates are low.

Critics have argued that there is no room for freedom or personal choice under the presumed consent system, and people may feel coerced into remaining organ donors (Gundle, 2005). However, it is argued that the ethical benefits achieved from a presumed consent registration system greatly outweigh the harms. In both opt-in and opt-out systems, there is an assumption made about the donation preferences of the population, and under these defaults two misclassifications can result: willing donors who are not identified (opt-in system) and people who are automatically listed as organ donors against their wishes (opt-out system) (Johnson & Goldstein, 2003). Under the utilitarian principle of providing the greatest benefit to the greatest number of people, those who unwillingly become organ donors produce less harm than those who are willing but do not take the steps to become organ donors at all (Chouhan & Draper, 2003).

Some researchers and policy-makers believe that the number of deceased donors per million population will increase under a presumed consent system. As per Rithalia et al. (2009b), presumed consent legislation is associated with an increase of deceased donor rates ranging from 2.7 to 6.1 donors per million population. Johnson and Goldstein's (2003) findings report that there is a 16.3% increase in donation rates with an opt-out registry. Other studies have indicated an increase of between 21% to 30% in deceased organ donation rates under presumed consent legislation (Rithalia et al., 2009b). After Belgium switched to an opt-out system in 1987, the number of organs available for transplantation has risen by over 110% and the country now has one of the highest organ

donation rates in the world (Chouhan & Draper, 2003; Roels, Deschoolmeester, & Vanrenterghem, 1997). Denmark's post-mortem organ procurement rates were 200% higher under opt-out, before the country transferred to an opt-in policy (Chouhan & Draper, 2003). Eight years after Austria introduced the presumed consent law, donation rates have quadrupled (Gundle, 2005).

Interestingly, other studies have found that presumed consent policy does not lead to a significant increase in deceased donor rates (Abadie & Gay, 2006; Coppen et al., 2008). Countries employing the opt-in system have an average of 14.2 cadaveric donors per million population per year and opt-out countries have 17.3 donors per million population, but this difference is not statistically significant (Abadie & Gay, 2006). It is unclear to what extent the increase in donors is due to the change in donor registration system, or due to efforts to increase organ donation awareness, such as mass media campaigns, and modifications to organ procurement policies. Rosenblum et al. (2012b) have found that while an opt-in system can help promote deceased organ donation, an opt-out registry is only used for individuals to withdraw consent and therefore has no significance on increasing public awareness without accompanying campaigns.

Some countries actually experienced a decline in cadaver organ donations following the transition to a presumed consent registry. In Chile, Domínguez and Rojas (2013) found that implementation of a presumed consent policy resulted in a decrease in potential organ donors as well as an increase in family refusal rate. This was attributed to a general resistance of a policy advocated or forced upon them by a government

distrusted by its people. Figure 2 shows cadaver donation rates in 36 countries, identified as either presumed consent or explicit consent registries.

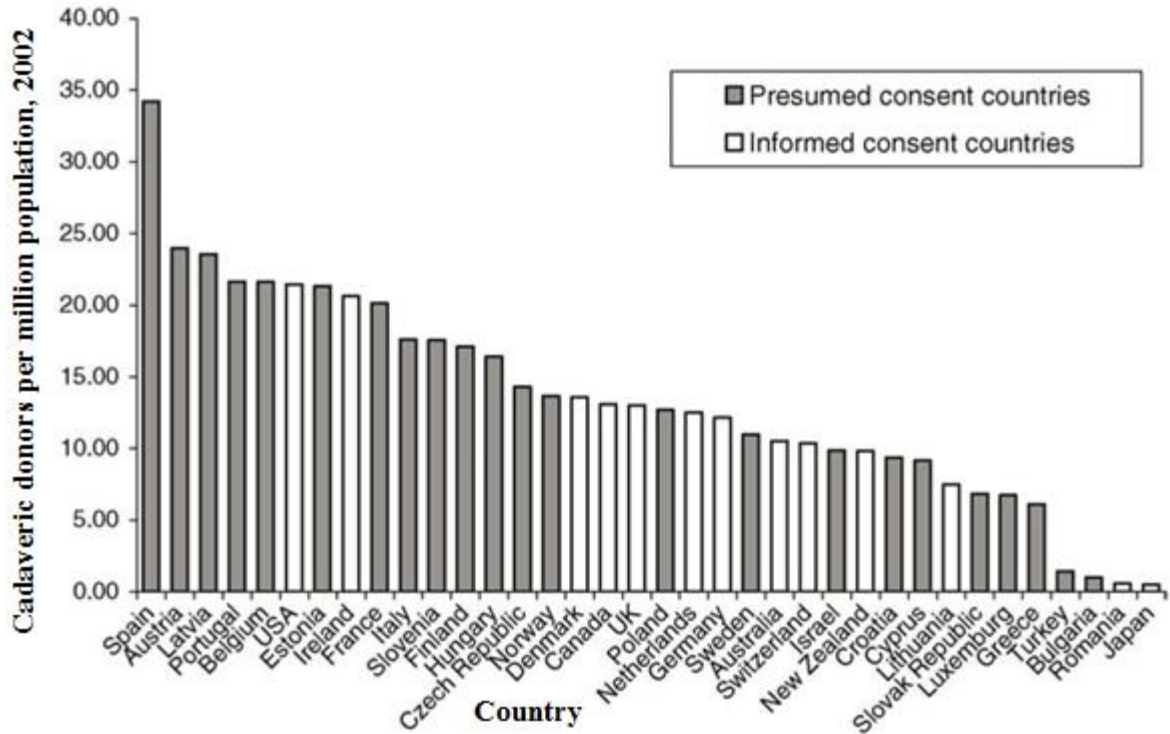


Figure 2. Cadaveric donation rate per million population, 2002 (Abadie & Gay, 2006)

Abadie and Gay (2006) stress that family consent has more effect on the deceased donor rate than does the type of registry. One of the reasons for this could be that under presumed consent policy, family are not supposed to be given the final decision in donating their relative’s organs, but in order to avoid lawsuits and to show respect, the family are often consulted (Abadie & Gay, 2006). This practice results in lower donation rates regardless of the country’s stated organ donation policy. Under both presumed and explicit consent systems, the family consent rate is between 62-66% (Rosenblum et al.,

2012a). However, Bilgel (2012) has found that donation rates are still higher under presumed consent, even when the family is consulted: opt-out countries that ask the family were found to have deceased donor rates 8% higher than explicit consent countries. From that standpoint, opt-out countries still do achieve better organ donation rates.

Mandated Choice

An alternative to opt-in and presumed consent is mandated choice. At a specific point in time, such as when one applies for a driver's licence or fills out tax forms, the individual must decide whether he or she wishes to become an organ donor (Chouhan & Draper, 2003). If a decision is not made, the driver's licence application or tax forms would be considered incomplete. Before the point of decision there is no assumed consent one way or another. Currently, New Zealand is the only nation that employs mandated choice (Rosenblum et al., 2012b).

This system allows individuals to consent to or refuse becoming an organ donor without feeling slotted into a decision. Spital (1996) argues that mandated choice allows people to demonstrate pure altruism instead of being forced into a default. This is important because in some societies, it may not be acceptable to force people into making a choice, as "compelling people to choose undermines their autonomy" (Chouhan & Draper, 2003, p. 158). Applying the ethical principle of utilitarianism, the potential harm caused by making people choose is greatly outweighed by the benefit of increasing the supply of potential cadaveric organs to save more lives. There is little research focused on mandated choice and it is only implemented in New Zealand with inconclusive results.

Reciprocity

While not a type of registry, reciprocity can be added to any of the three registration types. In this scheme, given the same circumstances for two individuals who require an organ transplant, the candidate who is a registered organ donor will be given higher priority on the transplant wait list than the patient who is not an organ donor (Lavee, Ashkenzi, Gurman, & Steinberg, 2009). It is important to note that in order for reciprocity to be applied, a well-established and well-documented donor registry system must first be in place. Israel and Singapore are the only nations that assign priority status on the organ wait list to those who have already registered to be donors (Rosenblum et al., 2012b).

This system operates under the notion of reciprocal altruism: “each partner helping the other while he helps himself” (Lavee et al., 2009, p. 2). This differs from the typical definition of altruism, which does not involve any *quid pro quo* compensation (Lavee et al., 2009). It has been shown that people are more likely to take actions to avoid a negative outcome than to obtain a comparable good result (Nadel & Nadel, 2005). That is, people are more likely to register to be an organ donor to avoid not receiving an organ for himself or herself when in need, than to potentially benefit another patient.

Preliminary data from Israel indicates that after the 2008 Organ Transplantation Law instituting reciprocity the country has observed increased organ donation and consent rates (Lavee, Ashkenzi, Stoler, Cohen, & Beyar, 2013). However, these promising increases in consent and donor rates could also be attributed to awareness campaigns that accompanied the legislation (Lavee et al., 2013). An experimental model

by Kessler and Roth (2012) indicates that the reciprocity rule increases organ donation registration rates.

Other Influences on Deceased Donor Rates

Research suggests that changing to a presumed consent system will not necessarily increase the deceased donor rate and that other efforts must be made to increase the number of potential organ donors. It is generally accepted that public awareness campaigns, encouraging people to discuss organ donation with their family, and expanding post-mortem organ donation criteria to increase the eligible donor pool are fundamental methods to increasing the deceased donation rate (Coppen et al., 2008; Spurr, 1993).

Several studies indicate that mass media campaigns, which lead to a more informed population, do more to increase donation rates than switching to a presumed consent system does (Coppen et al., 2008; Mossialos, Costa-Font, & Rusisill, 2008; Rithalia et al., 2009a). For example, Italy was already witnessing increasing donor rates prior to the introduction of a presumed consent system in 1999, and consent rates continued in the same manner after the policy change (Coppen et al., 2008). Several studies conclude that in order to increase cadaver donation rates, communication campaigns should focus on increasing knowledge about organ donation, clarifying myths and misconceptions, and encouraging people to discuss their donation decision with their family (Kopfman & Smith, 1996; Weber et al., 2007). Sque et al. (2008) argue that it is of utmost importance that the family is made aware of one's decision to donate, as families are more likely to consent to donation if they know that their loved one wanted to become a donor. Lange

(1992) found that in over 90% of cases, family will consent to organ donation if they are cognizant of the wishes of their relative. In many countries, regardless of the donor's wishes, it is ultimately the family's decision that prevails, so their knowledge of and commitment to organ donation is equally important.

In addition to the possible positive effects of communication campaigns, researchers have found that the donation rate increase could also be attributed to other factors such as the optimization of the donor procurement process (by introduction of transplant coordinators), and changes in how organs are procured (for example, using organs from anencephalic babies, increasing maximum donation age, or allowing diabetic or meningitic patients to donate) (Coppens et al., 2008; Spurr, 1993). Hence, while the literature suggests that the opt-out approach can be beneficial, the surrounding factors likely play a large role in increasing donor rates.

Other factors can also affect organ donation rates independently from the type of registry. The following have a positive correlation with deceased donation rates: road traffic accident mortality rates, a city's transplant capacity, gross domestic product and health expenditure per capita, education level, and public information (Rithalia et al., 2009a). Transplant capacity (the number of transplant centres per million population), has been positively associated with higher donation rates and is the greatest predictor of deceased donation rates (Rithalia et al., 2009a). The percentage of the population with access to the Internet is positively correlated with donation rates, suggesting a positive link between greater access to information and donation rates (Anbarci & Caglayan, 2005).

Incentives for Organ Donation

Academics, policy-makers, and health care providers have debated whether to provide incentives for organs to increase the cadaver donor rate. The World Health Organization and the World Medical Association strictly maintain that payment for organs should not occur and that purchasing organs should be prohibited (WHO, 2009; WMA, 2006b). Payment for organs is currently illegal in all countries except Iran and the Philippines (Anbarci & Caglayan, 2005). In Iran, the enactment of legislation allowing compensation for kidneys from living-unrelated donors completely eliminated the renal transplant wait list (Ghods & Mahdavi, 2007).

Many may object to payment for organs because it benefits the rich while exploiting the poor. However, Radcliffe-Richards et al. (1998) advocate that a central system to regulate the selling and purchase of organs would be largely beneficial as it would help mitigate the exploitation of the poor by being able to regulate an organ economy. The authors write,

There is much more scope for exploitation and abuse when a supply of desperately wanted goods is made illegal. If we want to protect the exploited, we can do it only by removing the poverty that makes them vulnerable, or, failing that, by controlling the trade. (Radcliffe-Richards et al., 1998, p. 1951)

While Jha (2004) agrees that a central body to regulate financial incentives can be beneficial to donor families and organ recipients, he also acknowledges, “[commercial transplants] could be allowed in countries where the social system is mature enough to handle the problems that will be encountered” (p. 542). However, in India with a

reputation for rampant corruption, western standards of justice and fair play may not be upheld and monies paid for an organ may not ultimately reach and benefit the donor.

Sells (1994) states that the value of a new life is immeasurable, so the price of a new organ cannot be calculated and that offering any financial gain for an organ indicates that the body is a commodity that can be sold or profited from. Becker and Elías (2007) note that since there is such a large discrepancy between supply and demand of cadaver organs and the medical criteria for cadaver organs is so limited, offering financial incentives would still not help meet the demand for organs.

Small but meaningful non-financial incentives may motivate families to consent to organ donation. Proponents of incentives for organ donation have suggested providing a donor medal of honour to patients' families, offering tax credits to donors, or reimbursing funeral expenses of the deceased donor (Delmonico et al., 2002). However, many governments are still concerned about possible exploitation or coercion if incentives for organs are provided.

Decision to Donate

Many studies focus on the psychosocial and demographic profiles of those who are most willing to donate their organs and those who are most resistant to organ donation. However, this research has been conducted in the United States or Europe, and thus may not be completely applicable to India, where the culture and values are significantly different. Studies have found that younger, white, educated, and high socioeconomic status individuals are more likely to sign a donor card (Conesa et al., 2003; Morgan & Miller, 2001). One of the strongest predictors of willingness to donate is one's

knowledge of and attitude toward donation (Morgan & Miller, 2001). Those who are familiar with the concept of brain death and who are knowledgeable about organ donation are more likely to support post-mortem organ donation (Conesa et al., 2003). People who have already signed a donor card or those who have high intent to sign a card are well-informed about organ donation, do not view signing a donor card as a fearful activity, are altruistic, and tend to have a positive attitude towards the donation procedure (Kopfman & Smith, 1996).

Other research has shown that those who are older than 40 years, non-white, have lower levels of education, and have no knowledge about brain death will not typically be in favour of organ donation (Conesa et al., 2003; Sque et al., 2008). Reasons people do not support cadaver organ donation include distrust of the medical system, not wanting to violate the body after death, belief that donation is against one's religion, and belief that potential recipients may not be deserving enough (Morgan et al., 2008; Morgan & Miller, 2001; Sque et al., 2008). In addition, Sque et al. (2008) report that some family members feel that they must witness the end of observable life (cessation of the heartbeat) in order to fully accept the death of their loved one; this desire generally indicates non-willingness to donate their relative's organs. Consistent with findings from developed countries, Table 2 shows that in India, willingness to donate one's organs increases as education level increases.

Education Level	% Willing	% Not Willing	% No Opinion
Illiterate	17.76	77.57	3.67
Primary School	52.05	42.47	5.48
High School	61.00	35.00	4.00
Undergraduate	74.29	25.71	0.00
Graduate	75.89	20.54	3.57

Table 2. Level of education and willingness to donate organs (adapted from Mani, 2002)

Cost-Effectiveness of Organ Transplants

Most research on the economics of organ transplantation compares the cost of ongoing dialysis to kidney transplantation. Renal transplantation is not only more cost-effective than dialysis in the long run; it also provides improved health-related quality of life (Laupacis et al., 1996). Some studies have indicated that transplantation is cost-saving for the government and that “the procurement of additional organ donors would constitute a good health investment” (Mendeloff, Ko, Roberts, Byrne, & Dew, 2004, p. 1709; Schnitzler, Lentine, & Burroughs, 2005). However, Axelrod (2013) writes that unless new approaches are designed to reduce the financial burden of the high cost of transplants, then access to transplant care is compromised. It is important to note that most studies on the cost-effectiveness of transplantation are conducted in the United States, where the patients often have health insurance to help cover their transplant expenses. No research has been done in India comparing the cost-effectiveness of transplantation to alternative therapies.

Howard and Byrne (2007) believe that because organ donation is such a rare event (due to stringent donor criteria), registries alone may not be cost-effective, even if the actual transplant is economical. They emphasize that donor registries are useful only if

the resources needed to operate the registry are proportional to the expected benefits from additional potential donors. They suggest using already established administrative capacities, such as driving licence registration or renewal, to run a donor registry.

Summary

A review of the existing literature on organ donation revealed that there is a major deficit of academic literature on organ donation in India. Most research related to transplants in India focus on the commercialization of organs. It is therefore difficult to determine whether findings from North America and Europe can be applied to India. Researchers are divided on whether an opt-in or an opt-out donor registry produces better donor registration rates, as organ donor rates might be affected by other factors, including public awareness campaigns and changes in organ transplant procedures. This information indicates that a variety of factors influence deceased donation rates, and efforts to increase rates must take into account the population's education and acceptance of organ donation.

The findings from this study will help fill gaps in the existing literature by providing a clear picture of current organ donation procedures in Mumbai and identifying ways to increase the deceased donor rate. In addition, the policy analysis will help define the political environment in which health policy decisions are made and how this affects organ donation.

METHODS

This policy analysis employed qualitative methods to collect data: key informant interviews with physicians, transplant coordinators, and representatives from organ donation advocacy groups. The 3-I framework guided the research to determine the underlying influences on organ donation policies in India and to guide the analysis of results. An analysis of key informant responses framed within the broader context of the Indian political and health care systems identified how ideas, interests, and institutions shape health policy decisions, and how organ donation policies may be affected by this.

Geographical Setting

This study was conducted in the district of Mumbai City (as defined by the 2011 Indian Census) (Census Organization of India, 2011a). The hospitals in this district are registered with Mumbai's Zonal Transplant Coordination Center (ZTCC), an organization that promotes deceased organ donation and oversees the distribution of cadaver organs. The study was conducted in private and government hospitals and non-governmental organizations within Mumbai.

This study focused only on Mumbai; as the largest city in India, it is more likely that Mumbai has sufficient infrastructure to effectively develop and implement a donor registry. The city's resources and diverse and cosmopolitan nature make it difficult to generalize findings to other parts of Maharashtra or India. Smaller cities may not have the adequate resources and infrastructure to perform organ transplants.

Protection of Human Subjects

This study was reviewed and approved by the McMaster University Hamilton Health Sciences/Faculty of Health Sciences Research Ethics Board in January 2013. A Letter of Information and Consent Form was understood and signed by all participants prior to beginning the interview (see Appendix A). A copy of the Letter and Consent Form was provided to and retained by interviewees. Participants were informed that participation is completely voluntary and that they may withdraw from the study at any time with no consequences. Participants were assured anonymity; all interview recordings and transcriptions were assigned an alphanumeric code and identifiers were removed from transcripts. Interview recordings, transcripts, participant information, and the alphanumeric codes assigned to participants are kept on a password-protected computer, to which only the Principal Investigator has access. All interview recordings will be deleted from the computer after completion of the study. Signed consent forms and any additional notes are kept in a locked cabinet to which only the Principal Investigator has access.

Participant Selection

Participants who are knowledgeable about health policy and who are involved in organ donation in Mumbai were selected, so as to gain maximum representation of views from the identified groups (physicians, transplant coordinators, and organ donation advocacy groups). Only employees of Mumbai hospitals registered with and authorized by the Maharashtra government to perform organ transplants were contacted. Participants were not excluded based on age, gender, religion, or race.

Potential participants and their contact information were obtained from publicly available data from hospital, government, and organization websites and directories. Potential interviewees were emailed or phoned to determine if they were interested in participating in the research. In addition, snowball sampling, in which current participants were asked to provide names of potential participants, was used (Biernacki & Waldorf, 1981). This method is useful in qualitative research amongst groups of participants who share a common trait (in this case, involvement in organ transplantation in Mumbai) (Biernacki & Waldorf, 1981).

Sample Size

As per Corbin and Strauss (2008), data saturation is reached when no new information is being collected from participants; the purpose of data collection is not to obtain the maximum absolute number of responses, but rather the maximum quality and amount of information. In this study, a saturation of views emerged after interviews with eight physicians, five transplant coordinators, and two representatives from organ donation advocacy groups.

Interviews

Interviews were conducted in person at the participant's office or clinic and lasted approximately half an hour. Using a semi-structured interview guide, a predetermined set of questions was asked, with flexibility to alter, add, or omit questions based on the participant's responses (see Appendix B for interview guide). The interview guide was organized along the following themes: current organ donation procedures, barriers to organ donation, and ways to increase the deceased donor rate within the broader

framework of ideas, interests, and institutions in the Indian context. Interviews were recorded and notes were taken during interviews to ensure all information provided was captured. Recorded interviews were transcribed verbatim by the primary researcher.

Data Analysis

Analysis of notes and transcripts occurred concurrently with data collection. Interim or continuous analysis was utilized. With this approach, the researcher continually refines and modifies interview questions based on previous participant responses, develops hypotheses, and explores themes as they emerge from interviews (Pope, Ziebland, & Mays, 2000). Once all interviews had been conducted, the complete transcripts were read by the primary researcher for a preliminary impression of responses.

Constant comparison was employed throughout data analysis, in which a transcript is compared within itself, against other interviews with similar participants, and against interviews from different groups (Boeije, 2002). This method of qualitative analysis allows the researcher to determine if study participants' responses are similar or divergent and to identify similarities and differences between groups of respondents (Boeije, 2002).

The first stage of data analysis was familiarization, in which the researcher examined the raw data and identified key ideas and recurring themes (Pope et al., 2000). In this study, data was divided into sections based on a predetermined framework derived from the study aims and topics raised by respondents. This deductive approach allows the researcher to use a pre-set structure on the data to analyze transcripts and notes (Burnard, Gill, Stewart, Treasure, & Chadwick, 2008). Interview data was then indexed

by marking the transcripts and categorizing responses into themes and sub-themes that arose; participant quotes were identified at this time as well.

RESULTS

This section will outline major topics and themes raised by key informants, framed within the ideas, interests, and institutions framework. Interview respondents discussed factors that influence organ donor rates in Mumbai, outlined transplant data and procedures in Mumbai, identified actors who have an interest in organ donation, and examined institutional structures that may hinder the advancement of the transplant program in Mumbai.

Participant Demographics

Interviews were conducted with 15 key informants in Mumbai. Eight physicians who are involved in organ transplantation as nephrologists, urologists, or cardiologists were interviewed; three transplant coordinators who are educated as medical social workers and two transplant coordinators who are trained as physicians were also interviewed. In addition, two interviews were held with employees of organizations involved in organ donation in Mumbai. Ten participants are male and five are female; the physicians are heavily represented by males, while the majority of transplant coordinators are represented by females.

Ideas – Knowledge, Beliefs, and Values

A key finding of the research is that values, beliefs, and knowledge influence organ donation rates in Mumbai. Important factors identified include the lack of public awareness and widespread public support, perceptions of one's religious teachings and myths that hinder family consent for organ donation, the equitable transplant wait list process, and the distribution of organs based on ability to pay. Interestingly, while other

health care services may put added value on the needs of comparatively wealthy international patients who can pay for services, according to participants, foreign patients do not directly affect cadaver organ donation in Mumbai. Since the time between death and organ procurement and transplantation is limited, and death could occur unexpectedly, a foreigner is unlikely to be waiting nearby.

Religious Beliefs and Myths

Many key informants claim that even if a donor registry was implemented in the city, garnering support for organ donation and increasing the cadaver donor rate would still be difficult due to perceived religious beliefs. Participants believe that despite the fact that all major religions in Mumbai consider organ donation an acceptable practice, individuals may still incorrectly object to donation on the basis of religion: “All religions support organ donation. But [people] may not be aware that their religion [supports it].” [R2] Other participants feel that “the attitude is changing” [R5] within the population and that “If the religious leaders, the spiritual leaders, consent that organ donation is important, definitely [people] will take the initiative.” [R9]

Lack of awareness about organ donation criteria, procedures, and familial preferences often result in refusal from families to donate their relative’s organs. Myths are an impediment to garnering support for organ donation. Some families may worry that “there is scare of disfigurement. Or that you should have the whole body at time of cremation.” [R2] Other families fear that the harvested organs will be sold instead of being transplanted into a wait-listed recipient. In brain death, the preferred criteria for retrieving organs from deceased patients, the “heart is still beating so they feel that the

patient is still alive, or maybe [there is] chance of survival.” [R2] Transplant coordinators and physicians believe these perceptions should be addressed in public awareness campaigns to properly inform people about organ donation. Educational campaigns that create awareness about the criteria for and the positive impact of cadaver organ donation may convince families to consent to organ donation. Although it is important for family members to know if their relative was in support of organ donation, two respondents indicate that the prospect of death is not talked about in families; typically, “the older people are somehow a little averse to being told that they’re going to die one day. They don’t want to hear that.” [R8]

Public Awareness

Some participants see merit in introducing a donor registry, as it would create awareness about organ donation, but they feel it would not necessarily directly lead to an increase in donor rates. The vast majority of key informants assert that more direct public awareness campaigns about organ donation are needed to make people more receptive to the idea of organ donation as this would help increase the cadaver donor rate in Mumbai. While the Zonal Transplant Coordination Center (ZTCC) does try to spread awareness through lectures, newspaper articles, and donor felicitation ceremonies, participants feel these attempts are not widespread enough; large-scale campaigns, especially in the media, are required to garner support for organ donation across the city. Many interviewees are very adamant that public awareness is the only way to increase support for organ donation. One respondent summarizes his views on how cadaver organ donation could be increased in the city:

It's just public awareness, there's just no other way. People just have to want to do it, they have to be convinced that it's a good thing to do, and when you die you are fit to save a few other lives. I think it's a wonderful thing. [R8]

One key informant believes that while the registry may have cosmetic value, it would not be productive or cost-effective; rather, that money should be spent on outreach and “[sensitizing] normal people to the thought of organ donation.” [R1]

Newspapers such as The Times of India and the Mumbai Mirror have begun to feature success stories of people who have been saved by an organ transplant to encourage others and show that organ donation can save lives. Participants suggest that although the print media is “[giving a] lot of coverage...there...[needs] to be [a] nationwide campaign on electronic media, which is not happening.” [R2] Likewise, television and movie media has not been as supportive in the endeavour to increase awareness about organ donation. One respondent remarks that television channels “are supposed to have some slots for social awareness,” [R13] but they do not always abide by this because broadcast time is expensive and organ donation messages may not be as lucrative as other popular topics. Respondents indicate that Bollywood stars are starting to show their support for organ donation “by becoming organ donors themselves.” [R8] Participants feel that it is important for “role models like that to sort of get involved in this program to help” [R8] garner widespread support.

As well as educating the general public about organ donation, some participants indicate that educating health care providers is also an important step to increasing organ donation. One transplant coordinator feels that “because there is no study of organ

donation as a particular topic taken up even in the medical studies,” [R5] physicians who are not involved in transplants may not support organ donation because they are not aware of the potential benefits. This coordinator believes this could hinder the expansion of the transplant program. One physician believes that targeting “ICU doctors, ICU nurses, social workers in the hospital who are in charge of transplant coordination and making them aware” [R1] is important because they are the ones directly involved in convincing the family to consent to donation.

Transplant Wait Lists

In Mumbai, 2523 people are currently waiting for a kidney and 136 patients are waiting for a liver. Unfortunately, “this year [June 2013] to date [Mumbai has] got eleven [deceased] donors, [this] means around 20 kidneys. And eleven livers.” [R2] Kidneys are the most sought-after organ. This is because India has “the largest diabetic population in the world [and] kidney failure is a huge problem.” [R8] Patients who require a kidney are placed on two wait lists: the first is a hospital list and the second is a city-wide list with the ZTCC. Because of the fragmented transplantation system, patients are able to register themselves on multiple hospital kidney wait lists to improve their chances of receiving a kidney:

So what patients do is go and put their names in many hospitals to take advantage of that. So suppose my patient feels that his number is a bit low in my list, he’ll go to a newer hospital where there are less patients, put his name there also. [R1]

Several participants express that the organ transplant wait list procedure in Mumbai is very transparent. While key informants state that although the order of the wait list is

always adhered to and no patient can pay for higher priority on the wait list, Figure 3 illustrates that patients with adequate financial resources have an increased likelihood of receiving an organ. Patients who can afford to place their name on multiple hospital wait lists have a higher chance of being the next compatible recipient in a hospital.

When a patient is declared brain dead in a registered hospital and the family has consented to organ removal, the ZTCC is contacted to oversee organ allocation. As per standard practice in Mumbai, the liver and one kidney are reserved for the retrieving hospital (where the patient died) if there is a compatible recipient. If there is no compatible recipient at the retrieving hospital, the organ is given to the city-wide wait list. The other kidney is distributed to the next compatible recipient on the city-wide wait list. All other organs, including the heart, pancreas, and lungs are allocated to recipients on the Mumbai-wide wait list. If there are no compatible recipients in Mumbai, the organ will likely go to waste, as there is no inter-city sharing program.

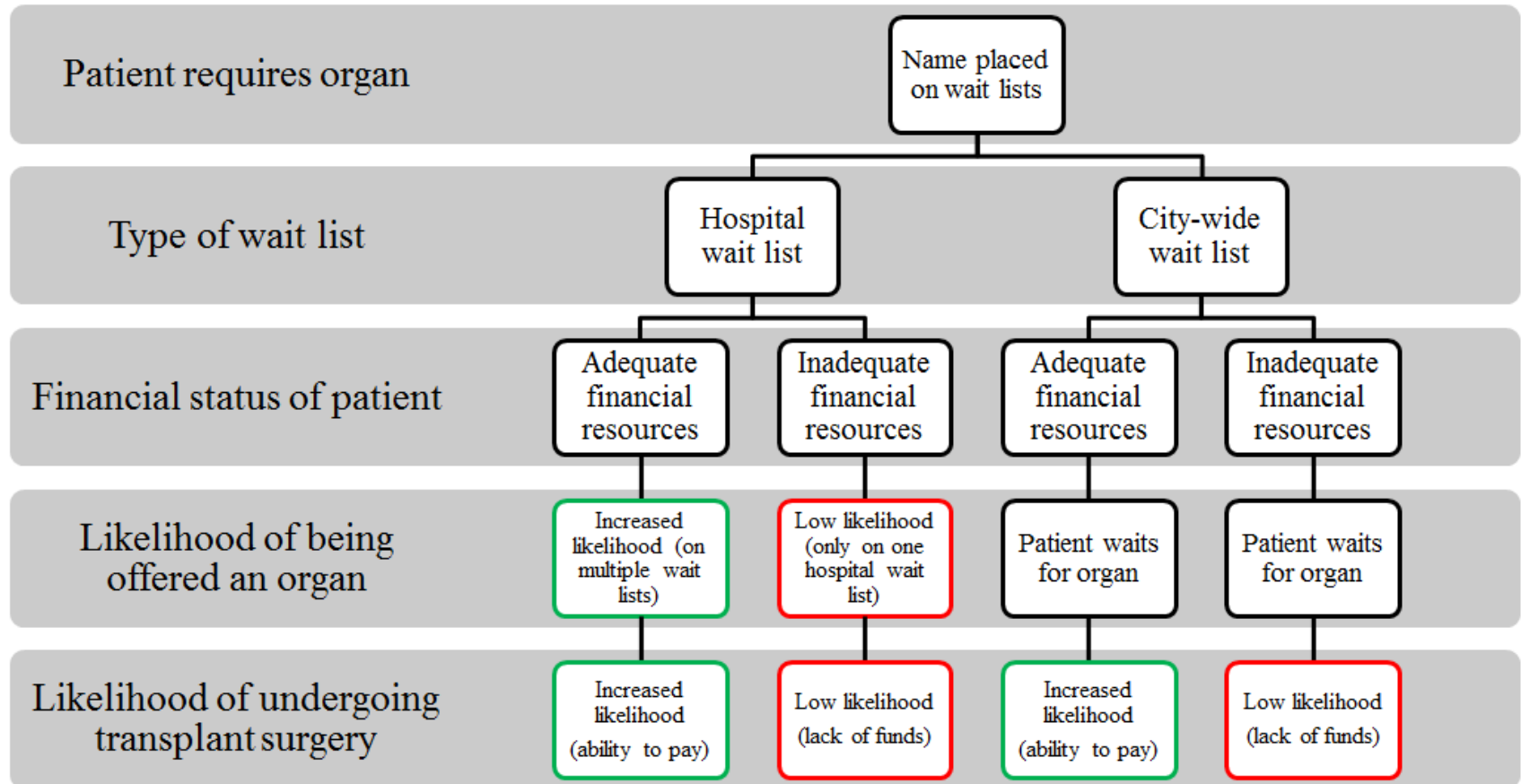


Figure 3. Likelihood of receiving an organ in Mumbai

According to the key informants, although placement on the wait list does not take into account a patient's financial or socioeconomic status, the actual organ distribution is based on ability to pay rather than on distribution equity principles. Therefore, although the wait list is technically blind to financial status, for practical purposes the system does by-pass the poor. When a deceased patient becomes an organ donor, the donor family bears no cost of the organ removal surgery. However, the organ recipient must pay for the surgery in full, as there is no national insurance scheme to help cover medical costs in India. Although "financial criteria is not considered when we're listing the [wait list] scoring," [R10] recipients are asked if they are financially prepared to undergo the transplant surgery. If a patient is unable to pay for the transplant, he or she will be passed over and the organ will be allocated to the next compatible recipient who is able to pay. The flow chart in Figure 4 shows the organ allocation process in Mumbai. This diagram illustrates the complex procedure for allocating a cadaveric organ in Mumbai, as well as shows that patients who are able to pay for surgery are more likely to undergo an organ transplant than patients who are unable to pay.

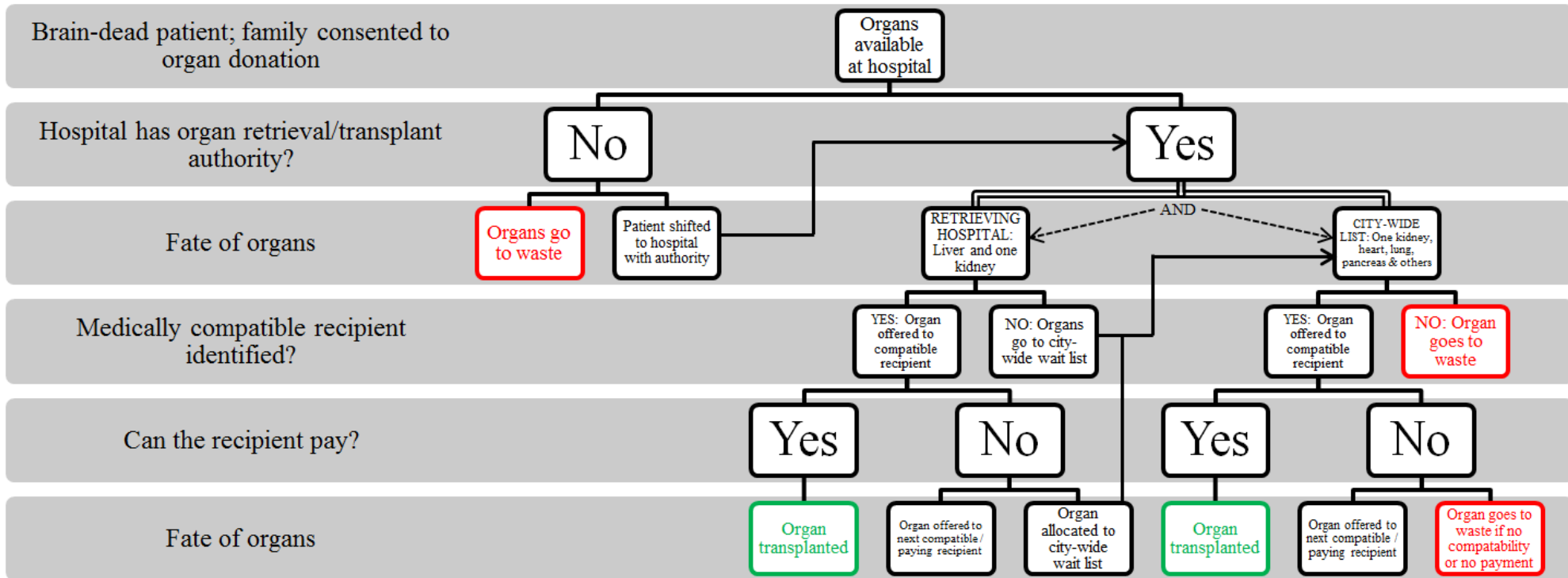


Figure 4. Organ allocation process in Mumbai

Financing Organ Transplants

While medical treatment in India is considerably less expensive than treatment in developed countries, and therefore provides attractive options for foreigners who earn in different currencies, many services are financially inaccessible to the majority of the Indian population due to India's emphasis on private care and out-of-pocket payments. Kidney transplants can cost three to four lakh rupees (US\$4,800 to \$6,400) plus the cost of the required immunosuppressive drugs after surgery. Unfortunately, "the poor [patients] can't even think about it. But of course, they have to live a life of dialysis which is equally expensive." [R8] Liver transplants cost as much as 12 to 14 lakh rupees (US\$19,200 to \$22,400). Key informants indicate, "many of our patients are not able to afford that. So definitely this becomes the service which is available to those who have [money]." [R2] One doctor quantifies the number of people able to afford expensive transplant surgeries:

Less than 5% of people with kidney failure are able to go for transplant. And another 5 to 10% can go for dialysis, so the remaining 85% to 90% may not be able to afford any treatment for kidney failure. [R12]

Commercialization of Organs and Medical Tourism

Families may also worry that their relative's donated organs may end up being sold in India's thriving black market. However, when asked to comment on illegal organ donation, all participants indicate that commercialization of organs "amongst the post-mortem donors is almost unheard of." [R7] They attribute this to the transparent procedures followed by the registered hospitals and the ZTCC: "[the ZTCC] are basically

set up by the government to regulate organ donation so there's no cheating, no miscarriage of justice, and no unfair distribution.” [R1]

Many participants mirror the sentiment that “in the deceased cadaver organ program, there is no question of medical tourism.” [R7] The time period between donor death and transplantation is very limited, so the foreign patient would need to be waiting in the country for an organ. In addition, hospitals and the ZTCC strictly follow the hospital and city transplant wait lists for cadaver transplants, so there is no opportunity for an international patient to access an organ before a local wait-listed patient. One physician says that the ZTCC follows the adage “Indians first and international later.” [R3] Furthermore, with introduction of legislation and strict rules on organ donation from living unrelated donors, there are now fewer international patients who come to India to buy an organ from a living donor.

Interests – Actors and Organizations

Many actors, including the government, physicians, and transplant coordinators, contribute to shaping organ donation in Mumbai. It is also important to consider the roles that executives (government), health care providers, and the public play in order to determine how those with more power and higher status often have more influence on policy decision making. This will be explored further in the discussion section.

Government

Participants believe the introduction of the *Transplantation of Human Organs Act*, 1994 resulted in more regulated and transparent organ transplantation procedures in India. Apart from this legislation, the government's perceived lack of priority on organ donation

is identified as a barrier to improving the organ donor rate, and the need for a donor registry will not likely gain their attention. Participants express that the Indian government needs to focus on more widespread diseases that affect greater segments of the population.

A few participants believe that organ donation is gaining popularity with the government, especially due to the recent death of Maharashtra's Chief Minister who died while waiting for a liver transplant. However, despite the initial heightened awareness of organ donation after the Chief Minister's death, "...like everything else, things die down, and the interest again fades." [R3] Conversely, most other key informants state that organ donation has "not become the priority because [India] as a country, we are facing problems. We are having people dying of cholera, tuberculosis...transplant sort of becomes [lower priority]. So actually basic health issues are the priority to the government." [R2] Others echo this sentiment and believe the government should "look into improving all sanitation and so on rather than spending huge amount on transplants." [R12] A few participants believe that because transplant surgeries are so expensive, the government would "rather spend the same amount of money to help, say, a hundred other type of patients, rather than just this one." [R8]

Physicians

Strict criteria are set out for organ transplantation staff and institutions. All informants indicate that the law requires hospitals that perform transplants to be registered with the Directorate of Health Services in Maharashtra. Hospitals that have not been registered are unauthorized to retrieve organs or carry out transplants. In addition,

physicians who declare brain death must be registered with the government to be involved in transplants. One interviewee states that it is important for physicians to be registered before declaring brain death because “the worry here is that if you ask any physician to declare brain death, there’ll be no control over who is declared, and the last thing that an early transplant program needs is a scandal.” [R3]

Transplant Coordinators

Transplant coordinators play a critical role in attaining family consent for organ donation. They are responsible for liaising with intensive care unit (ICU) patients and their families, educating families on organ donation, and informing the ZTCC when there is a potential brain dead patient. The transplant coordinator builds a rapport with the families and attempts to determine the patient’s views on organ donation: “a good hospital transplant coordinator will make a round of intensive care units and see who are potential donors and will remain in touch with the intensive care team.” [R12]

One participant contrasts transplant coordinators in private hospitals to those working in government hospitals. The participant believes that transplant coordinators in private hospitals are committed to their role and are sincerely dedicated to counselling families, encouraging organ donation, and identifying potential donors to help other patients. This participant feels that in contrast, government hospital transplant coordinators regard their role completely differently. The interviewee says that medical social workers in government hospitals are not sensitized to the benefit of organ donation, such as saving the lives of up to eight people, and as government servants, “they’re just doing it for the sake of doing it; it’s a government job.” [R10]

Institutions – Procedures and Rules

Institutions include long-standing rules and structures in a society, which may be implicit or explicit; they often constrain the decisions of actors involved in the issue and are not easily changed. Institutions often reinforce policy decisions, and subsequent policies may be hindered once the existing institutions are in place. In India, the fragmented health system, in which each city or state oversees its own cadaver transplants, and hospital capacity and infrastructure constrain advancement of the transplant program. In India, families are very involved in medical decisions; family consent must be obtained prior to a patient's organs being retrieved. This can affect donation rates, especially if the family is not aware of the patient's stance on organ donation.

Fragmented Transplant System

The Indian cadaver transplant program is very fragmented because each major city “looks after its own transplants.” [R7] One physician believes the central government needs to take the initiative to develop a central agency that is in charge of a database that allows for organ-sharing between cities and states: “What we really need is to share those [organs] across hundreds of hospitals all over India. Then the transplant program can take off.” [R7]

Hospital Infrastructure and Capacity

One major barrier to increasing the number of retrieved organs from deceased patients is the capacity and infrastructure of hospitals; health care staff and resources are often limited. One transplant coordinator indicates that physicians would rather focus

limited medical and human resources on saving a patient instead of using resources to “maintain a potential donor and then go through the whole procedure of going to the relatives and all that.” [R5]

Most respondents indicate that private hospitals typically perform more transplants because they have sufficient facilities, whereas government hospitals do not. In Mumbai, “there’s only one government hospital at the moment which does liver transplant, for example, while about six to seven private hospitals [offer] it.” [R3] In addition, “the majority of the health care...is given by the private hospitals...So you are always going to have a larger share of the donors coming from there.” [R7] Government hospitals have trauma centres and see more traffic accident victims, so “They are likely to get more potential donors.” [R13] But unfortunately, most government hospitals in Mumbai do not have adequate authority, technical capacity, and human resources to maintain brain dead patients and retrieve and transplant organs.

Currently, only hospitals in large cities have the capabilities to perform transplants. This means that if a person dies outside a large city, it is “very unlikely that...his organs will actually be used, simply because that smaller place may not have adequate facilities to do the harvest.” [R7] Key informants believe that expanding the capacity of all hospitals in cities and towns will allow for a larger pool of potential donors:

Theoretically you need a program where any brain dead person is a potential donor, whether he’s in a big city or a small city or a town or a village. You should be able to identify him as a potential donor and you should be able to use his organs. [R7]

This physician believes this can be done by expanding “the scope of the program so that the Grade B towns, the Grade C towns, the smaller nursing homes” [R7] can retrieve organs. Even in large cities, only hospitals that are registered with the government are authorized to remove and transplant organs. There are hospitals that are not recognized as transplant facilities, but do have “sufficient infrastructure to retrieve the organs.” [R12] Because these hospitals are unable to retrieve organs, the organs from brain dead patients in non-registered hospitals are not utilized.

One physician informant feels very strongly about the lack of infrastructure in Mumbai and believes that without improvements to hospital infrastructure and transplant capacity, organ donation would not thrive in the city. He indicates that because only select hospitals in large cities in India currently have the capacity and authorization to perform transplants,

you are losing, or you are wasting upwards of 90 or 95% of the potential donors simply because the facilities to harvest those, identify them as donors, get the infrastructure in place, even to actually do the transplant harvest, that facility exists in only few centres. [R7]

Family Consent

Even if the patient had expressed a desire to become an organ donor by signing a donor card, the family still makes the final decision at the time of brain death, so their knowledge of organ donation and consent is critical. Respondents say that as awareness about organ donation increases, families are more likely to consent to organ donation, and some families are even beginning to approach the doctor asking if they can donate their

relative's organs. Key informants indicate that "in the early years when they passed the brain dead act, we used to get about 80% rejection...Now, the majority of families would actually agree to donate the organs, and we get very few rejections." [R7] Most rejections come from families who "are not knowing about the concept of brain death" [R2] and from families who wonder "whether something can be done for the [brain dead] patient." [R3] Some participants feel that it is extremely important "that your family knows about your wish to donate, because they're going to take a decision." [R5] Three participants specifically say it is more important for relatives to know a patient's wishes rather than have the patient's name on a registry list, as families are the ones who give the final consent for organ donation.

Interestingly, only one participant mentioned offering incentives to donor families as a method to increase organ donation. This key informant believes that incentives, such as providing dependent children of the donor with educational and marital assistance, should be given, as this may persuade families to donate their relative's organs. No other interviewees propose incentives as a way to encourage cadaver organ donation.

DISCUSSION

This research assesses the feasibility of developing and implementing an organ donor registry in Mumbai, India. Input from key informants illustrated that both organ donation policy and broader health policy development are shaped by ideas, interests, and institutions within India (see Appendix C for a summary of the influences on organ donation in India). Key findings from this study are analyzed using the 3-I (ideas, interests, and institutions) framework, and their implications are discussed. This section concludes with study limitations.

Ideas – Knowledge, Beliefs, and Values

In its broadest sense, ideas encompass the elements of knowledge, evidence, beliefs, and values. Analyzing the role of ideas in policy development is important because it provides insights into how each of these elements promotes or inhibits policy change. Although knowledge and research evidence on their own are not always sufficient to lead to new or reformed policies, they can over time help slowly modify beliefs. In contrast, changing core values is much more difficult, as values tend to be deeply ingrained in individuals (and even across societies) and resist change even in the face of strong evidence.

Knowledge and Evidence

Research evidence plays three important roles in shaping the organ donor registry debate in India: 1) there is a direct role in terms of what is known about registries and donation in India; 2) there is an indirect role in stating why this issue is important in light

of the increasing chronic disease burden; and 3) there is a third role for research stressing the role of health promotion and disease prevention. Each will be discussed in turn.

Currently, there is a lack of research and substantive academic knowledge about organ donation in India. Most of the organ donation research in India centres on medical tourism and organ commercialization. Only recently have researchers started conducting organ transplant research that focuses on addressing the needs of those on a transplant wait list. Additionally, with conflicting information from the developed world about the effectiveness of different types of donor registries, it is difficult to determine which registry system would work best in India. Given the shortage of evidence surrounding organ donation in India, changing both public and government beliefs will be a laborious process. Disseminating information to the masses will require involvement from various interest holders, including hospitals, physicians, and transplant coordinators, as well as the media and religious leaders. Nonetheless, government and public education is necessary, as there will be great benefits if the transplant program is enhanced, including fewer people on a transplant wait list and improved quality of life for the organ recipients.

As research intensity related to the necessity of transplants increases, evidence available for enhanced public education has the potential to increase the deceased organ donor rate. Subsequently, as myths are clarified and people begin to understand the importance of organ donation, shifts in beliefs about organ donation would take place, garnering more support for the transplant program and government policies that are designed to increase the availability of organs for transplant.

The second role for research evidence is in making the case for a registry based on the burden of illness and capacity to benefit. India's increasing burden of chronic disease (especially diabetes and kidney disease) suggests that a growing proportion of the population will require transplants (Barsoum, 2006). This evidence should support the need to institute an organ donor registry. However, despite academic research that mortality from chronic diseases now accounts for more than half of all deaths in India, and that long-term costs of transplants are less than dialysis costs, the Maharashtra government has not yet made a conclusive decision to focus on either reducing the burden of chronic diseases or increasing the number of transplants, which chronic illness patients will eventually require (Srinath Reddy et al., 2005). If no efforts are made to decrease the number of people requiring organ transplants, there will be an increasing financial burden of people with chronic disease on the Indian economy (inability to work, drain on health care resources), and the demand for organs will greatly increase while the supply only increases marginally.

The third role for evidence is in emphasizing that government focus on health promotion and disease prevention programs could save health care resources and expenses in the long-term. With high prevalence of chronic diseases, the country would be well-served by investing in programs to prevent diseases that eventually lead to the need for transplants. These programs would considerably reduce the number of patients on dialysis, and in turn, would reduce the number of patients needing transplants. However, until recently, research on the burden of chronic diseases and their resulting strain on the health care system in India has not been conducted, and therefore has not

contributed towards getting the issue of the need for more organs on the government's policy agenda (Srinath Reddy et al., 2005).

Beliefs

Study findings indicate that one of the most common reasons to refuse organ donation in Mumbai is the mistaken belief that one's religion prohibits it. As study key informants suggest, incorrect understanding of one's religious teachings can be overcome through public awareness campaigns and stated support for organ donation from religious leaders. This is evidenced by the literature, which states that there is a distinct discord between religious teachings and peoples' perceptions of what their religion allows (Morgan et al., 2008). There are a multitude of religions in Mumbai, but none of the six major religions in Mumbai (Hinduism, Islam, Christianity, Sikhism, Buddhism, and Jainism) strictly prohibit donating one's organs after death (Census of India, 2011). Even the religions that initially state a preference against organ donation change their stance when taken holistically against the backdrop of helping others.

A main tenet of Hinduism is reincarnation: the actions of a person in this life will determine his or her fate in the next life. *Daan*, or selfless giving, and helping those who are suffering are important principles in the Hindu religion. The concepts of *atma* ('soul') and *sharira* ('body') are separate in Hinduism: once the soul has departed, the body is no longer of use, and so, organ donation is an accepted and encouraged act in the faith (Chugh & Jha, 1996). In Hindu mythology, the deity Ganesha is featured with the head of an elephant, which was transplanted on his body after his own head was cut off (Chugh & Jha, 1996). The World Council of Hindus has stated, "The important issue for

a Hindu is that which sustains life should be accepted and promoted as *Dharma* (righteous living). Organ donation is an integral part of our living” (qtd. in Oliver, Woywodt, Ahmed, & Saif, 2011, p. 440).

Sikhs, like Hindus, believe that the body is not an essential part of rebirth; it is the soul that is eternal (Oliver et al., 2011). Both Christians and Jains are strong supporters of organ donation. In 2010, Pope Benedict XVI announced that he supports organ donation and carries a donor card (Oliver et al., 2011).

In Islam, violating a human body is forbidden. However, this rule is outweighed by altruism and saving another life (Oliver et al., 2011). The Holy Quran states, “Whosoever saves the life of one person it would be as if he saved the life of all mankind” (Quran 5:32). The dilemma between violating the body and saving a life is resolved through the principle *al-darurat tubih al-mahzurat* (‘necessity overrides prohibition’) (Oliver et al., 2011). Therefore, organ donation is acceptable in the Islamic faith because it is recognized as being an altruistic act to save lives.

The Buddhist position on organ donation is complicated. Buddhists do not believe in the concept of brain death; rather, the spirit remains in the body for days after death, and any bodily disturbance, including organ retrieval, will negatively influence the person’s rebirth in the next life (Oliver et al., 2011). However, Buddhists are highly compassionate and believe in “[placing] the happiness and well being of others before his own” (Tsuji, 1988). Therefore, many Buddhist scholars and leaders have asserted that organ donation is an individual choice (Oliver et al., 2011).

Many people are unaware of their religion's stance on organ donation; correcting the myth that their religion forbids organ donation will help foster strong support for organ donation. If religious leaders in the community are able to address these misperceptions, the city might see higher donation rates even in the absence of a donor registry.

Transplant coordinators can also play an important role in disseminating information and clarifying myths. This is supported by a recent, although small, increase of cadaver donors in Mumbai. This is partly due to the introduction of transplant coordinators in intensive care units (ICUs). Coordinators are responsible for educating patients and families, encouraging families to donate their relative's organs, and liaising with Mumbai's Zonal Transplant Coordination Center (ZTCC). The transplant coordinators counsel individual families and can directly address and alleviate the family's beliefs, myths, and worries about post-mortem organ donation. After the *Transplantation of Human Organs (Amendment) Bill, 2009*, which legislated that all ICUs must have a transplant coordinator, the deceased donation rates for kidneys, livers, and lungs in Mumbai have increased from the average of the previous eleven years.

Increases in the organ donor rate in Mumbai may also be credited to increased awareness across the general population; each year, the ZTCC holds information sessions, provides donor cards, and distributes thousands of pamphlets containing information about organ donation; this mass distribution of information helps increase the number of cadaver organs donated in Mumbai (ZTCC, n.d.). Furthermore, the death of Maharashtra's (the state in which Mumbai is located) Chief Minister who died in mid-

2012 while he was awaiting a liver transplant created a minor surge of heightened public and government awareness. The Chief Minister's death could have been a focusing event to help create a policy window in which organ donation was pushed onto the government agenda, but like many issues in a country so fraught with disease, the issue faded away and more pressing concerns entered the government's policy agenda (Kingdon, 1995). As a result, no tangible action was taken on the part of the state government to take advantage of this fleeting focusing event.

The majority of key informants agree that campaigns to dispel commonly held myths surrounding organ donation, educate the public, and sensitize people to organ donation are the best way to increase the cadaver organ donation rate in Mumbai. Previous studies have indicated that public awareness campaigns that refute organ donation myths and perceived consequences of organ donation are effective in increasing intent to become an organ donor after death (Kopfman & Smith, 1996; Morgan & Miller, 2001). Media campaigns that dispel misbeliefs might be helpful in Mumbai where the population holds many myths surrounding organ donation. Morgan and Miller (2001) have also found that the more knowledgeable and positive an individual is about organ donation, the more willing he or she is to discuss organ donation with family. This is important to help increase families' post-mortem organ donation consent rate. Using public education to increase the donation rate is essential because researchers in India have declared that if the national deceased donor rate was increased to one donor per million population from the current 0.08 donor per million population, the demand for all livers, hearts, and lungs would be met, removing the need for transplants from living

donors (Abraham et al., 2010). This marginal increase can help save thousands of lives across the country.

Even if public awareness could be increased to a level where people are willing to donate their organs after death, infrastructure and transplant coordination within and between hospitals is costly. Therefore, although organ donation campaigns are relatively simple to implement, until the issue of organ donation experiences a prolonged presence on the government's policy agenda, policy change and increased funding are unlikely. That being said, education campaigns about organ donation are vital to begin shifting the perceptions of the public. Even if the supporting infrastructure is not yet in place, changing the inaccurate beliefs about organ donation can improve the likelihood that people will consent to post-mortem organ donation.

Values

The values held by policy actors and established institutions influence policy choices. In the Indian context, international organizations' and the central government's emphasis on improving population health through targeting communicable diseases affects the advancement of the organ transplant program. Larger population health issues often enter the government agenda, while organ donation does not gain priority on the agenda. This is further intensified by the legacy of private care in India, in which the responsibility for the payment of health services falls on the individual. These values of free market delivery in turn compete with the value of equity in the organ transplant wait list, affecting the ability of those who are unable to pay for transplant surgeries.

The Indian government struggles with balancing the international directives to improve overall population health with the need to improve individual health. In comparison to population-wide health initiatives that address communicable diseases that could positively affect millions of people, the beneficiaries of organ transplants are relatively few. Increasing the cadaver donor rate aims to improve individual health rather than overall population health. Realistically, however, the government should be concerned about improving both individual health and population health; these two concepts influence each other and are not mutually exclusive:

Health is not entirely individual; it is relative to the individual's context, which in turn is fashioned out of the interactions that exist between members of any defined collective whose health is defined by the health and context of its members. (Arah, 2009)

There needs to be a balance between appreciating the need for large-scale population-wide programs and smaller-scale initiatives that will aid in the betterment of quality of life for those who can afford the treatment. It may well be that the predominant role of the private sector in the delivery of individual health services has lessened the Indian government's sense of responsibility for delivering services deemed to be the purview of the private sector. Ultimately, the Indian government will need to find a way to balance between maximizing equality (population health) and optimizing individual well-being (through services such as a transplant program, especially as evidence is emerging that there will be increased need for transplants in the near future).

Within the Indian government, there is tension between the values of a free market health care delivery system and placing the responsibility of financing one's own health care on the individual versus the desire to increase the health status of the masses through public health initiatives. As deeply imbedded values are resistant to change, it is likely that the struggle between improving population and individual health statuses will persist into the future.

Similar to the concept of preventive medicine, in which the underlying causes of disease must first be addressed, the underlying values of the Indian system need to be adjusted so that equality and social welfare are increasingly valued in comparison to capitalistic gain: “the solution for satisfying the health needs of the people does not lie in the health policies and plans but is a question of structural changes in the political economy that can facilitate implementation of progressive health policies” (Gangolli, Duggal, & Shukla, 2005, p. 40). However, it is unlikely that the values of the present or future government in India will shift, as capitalism and private care are deeply rooted in Indian society. This means that organ donation will likely not gain priority on the policy agenda and transplant will remain accessible to the wealthy who are able to afford transplant surgeries in private hospitals.

Conflicting values can also be found within the existing transplant program between basing health care provision on ability to pay and basing transplant wait list placement on medical need. In Mumbai, it seems that ability to pay prevails, as receipt of an organ is based on the patient's finances, not on his or her medically relevant criteria. According to key informants, the apparent transparency of the current transplant wait list procedure in

Mumbai is encouraging and can be regarded as a facilitator to improving the transplant program. However, in reality, it is typically the wealthier patients who are able to afford and therefore obtain transplant surgery in Mumbai. This is because although a poor person may appear before a wealthy person on the wait list and that sequence may be honoured, if the poor cannot afford the surgery at the time of organ availability, the organ is allocated to the next person on the wait list who has the money to pay for the transplant. Thus the system is technically fair but is actually ineffective in providing organs to the poor. The surface value of equal opportunity in placement on the wait list and organ allocation is practiced, but it is really the deeper value of providing services to those who are able to pay that persists. As India's present health system highly values ability to pay, and as long as there are wealthy patients willing to pay for transplants, the government will likely not implement policies that will enable the poor to access transplants.

Interests – Actors and Organizations

Those who have a stake in a certain issue or policy will usually work towards ensuring the development or effects of a policy will benefit themselves in some way. Policy actors are guided by ingrained values and the institutions surrounding them. Common interests can mobilize groups to attempt to influence policy makers, but it is typically the actors or organizations with more power and money who have greater influence on shaping policies; those who actually use the services and have more need for them may have very little power in policy decision making. Groups who have a vested interest in organ donation policies in Mumbai include the government, physicians, and

patients. Even within these groups there are divided interests based on the structures that surround them and the beliefs they hold. Additionally, groups are more likely to mobilize around a threat to their interests rather than a gain to the interests, especially if the benefits of the gain are concentrated.

Government

All levels of the Indian government are struggling with allocating resources between programs that will improve population health and those that will enhance individual health. While evidence suggests that the transplant program is advancing through continuous updates in legislation and the introduction of organ donor stickers on ID cards, key informant responses indicate that organ donation is not a priority for the government due to other health issues facing the country. This implies that organ donation is still on the government agenda, but is not a top priority.

Unsteady and wavering support from the central government indicates to state governments and organizations that organ donation may not be a priority for the country. In January 2012 the Ministry of Health and Family Welfare announced its plan to increase capacity of the country's National Organ Transplant Programme (NOTP) (Sinha, 2012). This included the implementation of a National Organ Procurement and Distribution Organization to increase the number of cadaver donors and to enhance organ retrieval capacity in hospitals. The Ministry also intended to establish new transplantation facilities and improve existing facilities across the country (Sinha, 2012). The expansion plan of the NOTP did not include the development of a donor registry. However, six months later in July 2012, the budget for the NOTP was cut by over 90%

and the Ministry renounced their support for new transplantation centres (Chatterjee, 2012).

The Director General of Health Services declared that “[Central government] cannot take responsibility of developing nationwide transplant programmes...,” and the onus is on individual states to improve the nation’s deceased organ donation (Chatterjee, 2012, para. 4). Both current and future governments will struggle with how to divide resources to support health initiatives that will enhance individual health and ameliorate population health. In a country besieged by epidemics, pandemics and a rise in non-communicable diseases, the National Organ Transplant Programme will mostly likely not be a priority for the current Indian government or their successors. The brief placement of organ donation on the policy agenda suggests that the government is somewhat aware of the need for improvements to the transplant program, but other health issues are more pressing at this time. Widespread population health issues are pushed onto the government agenda by international stakeholders, while organ donation is continually loses priority on the agenda.

In general, central and state governments contribute a comparatively small amount to health care (Ministry of Health and Family Welfare, 2009; WHO, 2013). The central government seems to rely on foreign investment and places responsibility for health care on the state governments, while state governments rely on the out-of-pocket payments from patients to fund the health system. Due to low government spending on programs to enhance individual health, the transplant program, including implementation of an organ donor registry, will most likely not be addressed.

Physicians and Transplant Coordinators

Physicians in private hospitals (where most organ transplants in Mumbai occur) may have more interest in improving their own transplant program rather than improving the city-wide transplant program. Some organ transplants do occur in municipal and government hospitals, but due to inadequate resources, medical staff prefer to focus on treating and saving patients as opposed to maintaining brain dead patients for transplant purposes. Thus, the organ transplant priorities of private hospitals are higher than transplant priorities within municipal and government hospitals, simply because private hospitals have more resources to focus on organ donation. At best, the development of a donor registry may help streamline the organ retrieval and transplant process, but it is unlikely that a registry will be considered a priority by physicians broadly, but may be by transplant surgeons and some specialists. Physicians who do support the development of a registry will most likely be those working in private hospitals, since their patients would benefit most from an increase in available organs.

While there are transplant surgeons across large cities in India who are advocating for the advancement of the transplant program, there has been no sign of a policy entrepreneur among them who has pushed organ donation onto the policy agenda or helped keep it there. Although health care providers and hospital administration may not be able to wield strong influence on government spending, they could foster more cooperation and communication between hospitals to facilitate transplants. It seems that the *policy stream*, in which experts analyze existing problems and offer resolutions, is beginning to affect organ donation in India, but with a very little audience receiving the

information. Organ donation has not reached the *problem stream*, in which the need for transplants is seen as a public issue that requires government intervention. Additionally, the *political stream*, where changes in administration or interest group pressure campaigns push an issue onto the government agenda, has not yet been affected by organ donation. Until the problem and political streams are present, and the three streams are coupled with a policy entrepreneur, it is not likely that organ donation will reach the agenda of the Indian government (Kingdon, 1995).

Transplant coordinators, on the other hand, may have a stronger interest in the development of an organ donor registry. The main role of the transplant coordinator is to encourage families to donate their relative's organs, and this process might be facilitated with proof that their loved one already joined the donor registry. As per findings from Sque et al. (2008), families who know of their relative's wish to become an organ donor are more likely to consent to post-mortem organ donation. However, as one key informant states, transplant coordinators in government hospitals may not be as committed to their role as transplant coordinators in private hospitals. Similar to physicians, transplant coordinators in private hospitals may show stronger support for the development of a registry, as more transplants are performed in private hospitals, and so patients in private hospitals would benefit more than patients in government hospitals.

Patients

In India, wealthier people in urban centres most likely have more influence on organ donation policy than do poor patients. This is because the wealthy are typically the ones who have more money and resources to demand transplants. Participants from this

study indicated that the poor often do not even bother placing their name on a transplant wait list because they will be unable to afford the surgery. If the wealthy continue to be the primary recipients of transplant surgeries, their needs will be met, while only minimal action will be taken to ensure the poor have access to transplants, further widening the inequity gap between those able to afford transplants and those who are unable to afford the surgery.

Despite India being the world's largest democracy, which would normally be associated with the opportunity for the public to effect change, it is unlikely that the general population will focus on the need to increase the organ donor rate. Rather, only people affected by transplants (wait-listed patients, recipients, and donor families) would see the greatest need and advocate to increase awareness about organ donation and to improve the donor rate. Transplant patients are a diffuse group spread across cities with millions of people afflicted by other health concerns. Although transplant patients would benefit most from an increased cadaver donor rate, it is unlikely that this small sub-population will mobilize to greatly affect donation policies in Mumbai. The number of people affected by organ transplants is relatively small, so it is difficult for patient groups in a city of over 12 million people to organize and effectively demonstrate any degree of power in influencing policies in Mumbai. Therefore, it is unlikely that a donor registry will gain the support of the government and public, as the population who receives the benefit is very small.

Institutions – Procedures and Rules

Institutions refer to the procedures for developing policies. These procedures can be considered the set of rules that guide processes and behaviour of policy decision makers. Policy legacies, in which governments are “predisposed towards policies with which they already have some favorable experience,” are strong influencers of subsequent policy decisions (Hall, 1989, p. 11). Path dependencies, in which previous political and social conditions affect subsequent conditions and therefore policies, limit the range of choices and actions of governments and policy makers (Howlett, Ramesh, & Perl, 2009). In India, path dependencies of private care and targeting communicable diseases affect the ability of other health issues, such as organ donation, to gain attention on the policy agenda. Thus, it is important to take into account India’s past policy decisions and structural constraints when analyzing policy making and current organ donation policies.

Fragmented Health Care System

The federalist government system in India (there are 28 states and seven union territories) has led to fragmented health care systems, making it difficult to develop a nationally coordinated organ donor registry or organ sharing network. Since individual states have jurisdiction over their health care, hospitals, and transplant programs, this creates a sense of proprietariness over limited resources and makes pooling or sharing resources and organs between states very difficult. Within the current transplant program, organs are contained to a specific city. This means that if there is an organ available from a deceased donor, but there is not a suitable recipient in Mumbai’s hospitals, the organ will be wasted. Furthermore, if there is a compatible recipient in Mumbai but the

recipient is not able to pay for the transplant surgery, the organ will most likely go to waste, even if there is a potential recipient in another state.

When the health system is as fragmented as it is in India, an inter-state or national organ sharing program cannot easily succeed. Additionally, state governments cannot afford to focus on organ donation without the steady support (financing or prioritization) of the central government. If cities and hospitals worked together to ensure that hospital infrastructure is increased and an organ sharing program is implemented, there is potential for less organ wastage and there would be greater possibility for a wait-listed patient to receive an organ. However, it is still likely that only wealthy patients in private hospitals would be able to afford and obtain transplants.

Policy Legacies – Private Care

For at least the past 70 years, reports have recommended that India adopt universal health care and that individuals should not fail to benefit from health care because of ability to pay. However, the Indian government has decided not to implement coverage for even a limited basket of services on a universal basis. Despite acknowledging that the present health system falls short and does not provide care to large parts of the population, the government still has not acted to remedy the situation. The Bhole Committee, formed in 1943, proposed a National Health Service that would provide universal health coverage to the entire Indian population (Gangolli et al., 2005). One objective of the Committee was that “no individual should fail to secure adequate medical care, curative and preventive, because of inability to pay for it” (Gangolli et al., 2005 p. 25). The Indian government did not adopt the Committee’s recommendations for a

comprehensive health system and instead chose to focus on developing the private health sector.

In only very few instances since 1943 has the central government recommended universal comprehensive health care: the National Health Policy of 1983 was the first time since in 40 years that the government mentioned universal primary health care (Gangolli et al., 2005). This legacy of private health care in India contributes to the hindrance of the advancement of accessible health care in the country, as private care is entrenched in the values of the Indian government. The transplant program in private hospitals will be accessible to most wealthy patients, but transplant surgeries in municipal and government hospitals will continue to be far too expensive for poor patients, at least in the foreseeable future.

Extending as far back as the colonial period in India, the majority (77%) of physicians were in private practice (Gangolli et al., 2005). This deep-rooted practice of private health care has become part of the Indian fabric and is still valued in present-day India. The growing private health sector can be attributed to the broader capitalist economic policy in India, in which businesses have vested interests in owning and controlling goods and services. The Indian government seems to favour expansion of the private sector through alliances with international foundations and businesses to help fund the health system (Sengupta & Nundy, 2005). The government values providing private services, including health care, instead of providing comprehensive care to all, and as a result, policies that promote increasing the role of the public health sector may be resisted.

Mistrust of both central and state governments has also played into the emphasis on a private health care system. Corruption within the Indian government has been an issue for decades. According to a 2012 Corruption Perceptions Index, which ranks countries based on the perceived corruptness of the public sector, India ranked 94th out of 176 countries on the Index (Transparency International, 2013). One study has found that as many as 30% of patients have experienced corruption in government hospitals when they had to pay ‘under the table’ for faster treatment and appointments with senior physicians, as well as for clean bed linens and better hospital food (Jilani, Azhar, Jilani, & Siddiqui, 2008). This concern of corruption in the public sector leads to further attention to strengthening the private health system. However, corruption within private health care is also very prevalent: in a study of the health sector in India, 20% of respondents admitted to irregular hospital admission processes and 15% reported corruption after admission; doctors and hospital staff were the most common offenders (Balarajan et al., 2011). It is likely that most corruption in health care takes the form of bribes being taken in return for proper treatment during admission (Balarajan et al., 2011).

Most transplant procedures are completed in private urban hospitals, and many people of lower socioeconomic status simply do not have access to these services. Most cadaver organs are used by private hospitals whose patients can afford to fund the transplant surgery and few people from the poorer segment of society are able to receive organs (Mathiharan, 2011). Even if a transplant is performed in a municipal or government hospital, the poor patients often have to sell their belongings to pay for the surgery and necessary immuno-suppressive drugs. Mathiharan (2011) states that “the

present [transplant] system [in India] is heavily tilted to benefit rich recipients and corporate hospitals and [is] not at all helpful to the economically weaker section that supplied most of the unrelated donors” (p. 138). This trend is present in Mumbai as well, with most transplants occurring at private hospitals.

Without attention being paid to improving and strengthening public health facilities, the public system will only become weaker, leaving hundreds of millions of people without access to adequate health care. The private sector will continue to grow, and the transplant program will most likely advance in private care centres but will not develop at the same pace in public facilities. This could increase the disparity in health equity between those who can access and afford transplants and those who cannot.

Policy Legacies – Communicable Disease

In the 1950s and 1960s, India’s whole health sector was engrossed in eradicating communicable diseases; still functioning under the colonial school of thought that believed that diseases could be eradicated if the causing germs were eliminated, there was no focus on the most basic determinants of health – nutrition, sanitation, and a safe environment (Gangolli et al., 2005). The long-standing focus on infectious diseases, without very much attention being paid to burgeoning health issues (such as the various chronic diseases now afflicting India’s population), has led to the present-day health system still being very much focused on communicable disease initiatives. The emphasis on providing short-term solutions to infectious diseases rather than addressing the underlying causes of diseases is further exacerbated by the increasing role of private actors in health policy, who financially support large-scale public health initiatives to

eliminate infectious diseases. Under this stance, it is unlikely that an organ donor registry will come to fruition, as it does not advance the established efforts of communicable disease eradication.

Foreign Actors

External aid agencies and foundations provide significant financing, for which India must comply with guidelines and work towards the external funders' priorities, almost singularly focused on infectious diseases and decreasing the global burden of disease. Near the end of the 20th century, there was a shift in health policy making in which public-private partnerships gained momentum, taking over the role of United Nations agencies. International organizations began not only funding health programs, but also setting health policies (Ollila, 2005). The formation of public-private partnerships can be beneficial by promoting collaboration between organizations and governments and allowing the public sector to tap into resources and expertise that would not normally be available (WHO, 2012).

However, these external actors are not only influencing global health priorities, they are also guiding policies and priorities of national governments, and may have a more influential role in setting national health policies than do the countries' own politicians. It is in India's best interests to follow the directives of these funding agencies in order to continue receiving financing and eliminate deadly communicable diseases, rather than focus on improving cadaver organ donation rates, which has very little to no international or national government funding support. As long as large international agencies are

channeling vast sums of money into Indian health programs, the interests of these influential actors will take precedence over organ donation in India.

It seems that the Indian government values population health initiatives, such as the eradication of infectious diseases, rather than focusing on programs that may help increase the deceased organ donor rate. It is possible that, to some degree, the government feels compelled to set policy priorities in keeping with the expectations of international organizations. In 2001, the Millennium Development Goals were developed by the United Nations and several international agencies, and they too had an impact on India's policy making. These goals aim to improve the lives of the world's poorest populations by improving health, poverty, education, and women's empowerment. The Millennium Project was subsequently created to ensure that developing countries are reaching the Development Goals (Ollila, 2005). Additionally, the 2001 report of the Commission of Macroeconomics and Health stated that public health resources should be concentrated on communicable diseases, malnutrition, and maternal mortality (Ollila, 2005). While the Goals and Commission are noble and worthwhile, they represent a top-down approach to policy setting, whereby supranational organizations design policies to implement at the national level. This is not optimal because national governments often do not have a voice in formulating policies, but are forced to implement them under the directive of international organizations, especially if the country relies heavily on foreign aid. This global emphasis on infectious diseases detracts from helping countries such as India develop their health systems, including improving hospital infrastructure which could help increase the cadaver donor rate.

Family Consent

Abadie and Gay (2006) have indicated that not considering the family's preference for organ donation can increase deceased donor rates. In India, the organ donation preference of the family outweighs the preference of the individual. This is due to India's collectivist society, in which there is a tendency towards strong family orientation (Verma & Triandis, 1999). It is thus important to encourage people to discuss organ donation with their family to ensure that families are more likely to agree to organ donation. Though, as key informants indicated, discussing organ donation after death is not a conversation that many families in Mumbai have. Byrne and Thompson (2001) have noted that in societies where death-related issues are rarely discussed and the ultimate decision to donate is left to the family, "donor registration is nothing more than a signaling device" (p. 74). Implementing a registry in Mumbai may serve to help transplant coordinators convince families that organ donation was their relative's last wish. The existing literature indicates that families are more likely and willing to consent to organ donation if they are aware of their relative's desire to become a donor (Lange, 1992). Families of brain dead patients play a crucial role in influencing organ donation rates in Mumbai, and their support is required to increase the deceased donor rate.

Summary of Implications

This analysis has revealed that the feasibility of implementing an organ donor registry in Mumbai is extremely low, as the barriers, identified through the ideas, interests, and institutions lens, may be too difficult to overcome in India's current political and social environment.

Strengthening support for organ donation is a two-part process: transferring evidence to governments to invest in infrastructure and educating the public to increase the organ donation rate. Right now, there is insufficient knowledge exchange about the benefits of focusing on organ donation programs. Research evidence for the government needs to be prepared in a way that allows policy makers to understand the long-term economic and health benefits of investing in a transplant program. This evidence can be used to positively influence public beliefs surrounding organ donation. Although there have been brief focusing events in which the necessity of organ donation is highlighted to the government and public, there have been no sustained focusing events, meaning that even if organ donation earns the attention of policy makers, its place on the issue attention cycle is quickly lost. It would be especially beneficial if there was a policy entrepreneur who pushed organ donation onto the government agenda, but right now there does not seem to be any major drive from an individual or group to advance the cause of organ donation in India. However, in addition to a policy entrepreneur, there also needs to be recognition of the need for an improved transplant program and favourable political structures, such as a focusing event that pushes organ donation onto the government agenda and increased uptake of research evidence, to effect change in organ donation policies in India.

Various interests in India are extremely fragmented with a low probability of individuals with common interests (physicians, organ donation organizations such as the ZTCC, and the public) forming groups of sufficient size and resources to have any substantive influence on getting organ donation onto the government's policy agenda.

Even if organ donation makes it to the government's internal policy agenda, with the overwhelming amounts of money contributed by international organizations, the priorities of the wealthy agencies may take precedence, pushing organ donation lower on the priority list. It is more probable that organizations with power and money (foreign agencies, government) will be successful in advocating for their interests, including the eradication of communicable diseases.

Politicians may see very little benefit of focusing on organ donation in the face of a host of other pressing health issues. At the same time, institutional structures typically reinforce the status quo rather than effect policy change. In this instance, embedded policy legacies of focus on communicable diseases and a fragmented health system with division between private and public facilities further reduce the likelihood of an organ donor registry being adopted.

Policy change is most likely to occur when ideas, interests, and institutions align, providing a political and social environment conducive to change. Given the current situation in India of powerful policy legacies, fragmented bureaucratic structures, little substantive research evidence, and lack of strong political advocates for organ donation, it is unlikely that an organ donor registry will be implemented, the city's deceased donor rate will greatly increase, or that organ donation will even make it to the top of the government agenda.

Study Limitations

This study has three main limitations that should be acknowledged. First, this study focused only on Mumbai; results cannot be generalized to the state of Maharashtra or to

the whole of India. As the largest city in India, it is more likely that Mumbai is closer to having the infrastructure required to successfully execute a transplant program. However, because of Mumbai's size and urban resources, study findings may not be relevant to extrapolate to smaller cities, which may not have the human resources, hospital and technical capacity, or financial means to perform organ transplants and develop a donor registry. Second, because only participants from Mumbai were interviewed, their perspectives cannot be generalized to health care providers in other towns and cities. Physicians and transplant coordinators who work in Mumbai, India's most cosmopolitan city, may be more liberal-minded and open to changes in organ donation procedures. A large-scale study with participants from a mix of both large and smaller cities needs to be conducted. Lastly, key informants were selected based on purposive sampling, which may lead to volunteer bias. This can affect the reliability of the study, as results may not be consistently reproduced, as well as the validity of the study, as participants who agreed to participate in the study may be more open and willing to talk about organ donation than the general population.

CONCLUSION

Like many countries around the world, the demand for organs in India far outstrips the supply. This study provided insight into the current state of cadaver organ donation in Mumbai, framed within the health care policy setting in India, as well as explored the likelihood of a donor registry being implemented. Using the 3-I framework, this study specifically analyzed the role and impact of ideas, interests, and institutions on the feasibility of implementing an organ donor registry in Mumbai. The likelihood of any new policy being adopted by any level of Indian government is related to and affected by the complex interplay among numerous actors and organizations; the range of more widespread health issues competing for scarce resources and government attention; and the broader political environment within which health policies are considered. In the case of the feasibility of implementing a donor registry in Mumbai, there is intense competition for health care resources and both domestic and international pressures to pursue population health initiatives. In the current political arena, it is unlikely that organ donation will make it to the top of the government policy agenda.

At present, a registry would require infrastructure and resources that are currently not available, especially when there is not widespread support for organ donation. However, given the current situation of cadaver organ donation in Mumbai within the context of overwhelming health issues, even if a registry is implemented, a registry alone is unlikely to have a major impact on increasing the city's cadaver donor rate. Even if the general public were to become aware of the registry and were willing to donate their organs, due to illiteracy and lack of access to technology, many in Mumbai would not be

able to register. An effective registry would have to be woven into the intricate tapestry of other organ donation issues, such as awareness, accessibility, funding, and infrastructure. At best, implementing a registry without addressing other organ donation issues could make the donation process more efficient by determining who is a potential donor prior to the family being approached by a transplant coordinator.

More importantly, this study revealed ethical issues relating to the need to improve individual health while also advancing population health in a country rife with poverty and inequality. Governments need to develop both individual and population health improvement programs simultaneously. Under the current fee-for-service payment system in India, improving deceased organ donation rates in Mumbai will not help to reduce the health inequality gap. Any resulting increase in the number of organs (regardless of their origins) will benefit only the middle and upper classes, but will not provide any initial additional benefit for the poor. Because health care relies on direct payment from the patient, it is usually only middle and upper class patients who are able to afford quality care. Improvements to the wider health care system are needed so that the poor are able to access transplant surgeries.

While the present study did not find evidence that implementing an organ donor registry in Mumbai is likely or feasible, it did shed light on the current organ donation procedures in the city. Key informants stressed that technically the organ allocation system is fair and transparent, but in reality it favours the rich. Under the current transplant system in Mumbai, patients are able to place their name on multiple hospital wait lists (if they have the ability to pay). These multiple lists across the city lead to gross

inefficiencies in use of time and resources. With one central city-wide organ wait list and eventually one central organ donor list, the transplant process in Mumbai can become much more efficient and save time and resources for physicians and hospitals.

Taken together, this assessment of ideas, interests, and institutions strongly support the contention that there will be no political appetite for any government-sponsored organ donation policy initiatives despite the demonstrated need. Given the current situation in India of powerful policy legacies, strong political actors, and lack of substantive research evidence, it is unlikely that an organ donor registry will be implemented. In the absence of a focusing event or a high profile policy entrepreneur who is able to push the issue of availability of organs for transplant onto the policy agenda, government may have little incentive to take up the cause in more than a superficial way. This suggests that efforts for enhancing organ availability will only proceed in an incremental fashion and successes are most likely to take place at the margins within the existing policy environment.

In the instance of organ donation, the more public education and knowledge translation that occurs, the more likely it is that unfounded beliefs will begin to shift. Eventually, resistance to organ donation that is based on misconceptions will be overcome and the willingness towards and acceptance of deceased organ donation will increase. With development and implementation of proper infrastructure combined with increased public acceptance of organ donation, the number of organs harvested from cadaver donors can be increased, potentially meeting Mumbai's organ transplant needs. When expanding the transplant program, it is also necessary to take into account India's

vast population and complex circumstances of poverty that so severely affect literacy, education, comprehension, and access. Increasing the cadaver donor rate will take time, commitment from the government, and widespread public acceptance, but it is an important endeavour to save many lives in India.

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APPENDICES

Appendix A – Letter of Information and Consent Form

Principal Researcher:

Diana Vania, MSc Candidate (2013), Global Health, Faculty of Health Sciences, McMaster University, Canada

Faculty Supervisor:

Dr. Glen Randall, Health and Policy Management, DeGroote School of Business, McMaster University, Canada

Purpose of the Study

The purpose of this research project is to determine the barriers to formulation and implementation of an organ donor registry in Mumbai, India. Through participant interviews, data will be collected to assess the current organ donation policies and processes in Mumbai; identify barriers to implementing an organ donor registry; and determine to what extent organ donation is a priority within the government. This student research is being conducted as part of a Master's thesis.

What will happen during the study?

Information will be collected through one-on-one interviews with approximately 15 to 20 participants, including health care providers, hospital administrators, government officials, and organ donation advocacy groups. Participants will be selected so as to gain maximum representation of the views from identified groups.

You are assured full anonymity and study results will not allow you to be identified. You will be asked questions related to policies in India, hospital policies, and health priorities in Mumbai. You will not be asked for personal information. With permission, the interview will be tape recorded and transcribed. It is anticipated that the interview will last approximately 30 minutes.

Are there any risks to doing this study?

Risks anticipated from participating in this study are minimal. However, there is psychological risk of feeling embarrassed if you reveal an answer you did not intend to. If interview responses are linked to you, efforts will be made to minimize the risk to you and to protect your confidentiality. If you have questions or concerns, either before or after participation, you may contact Diana Vania (Principal Researcher).

Are there any benefits to doing this study?

This research will not benefit you directly. However, contributions made to the study will lead to a better understanding of the transferability of policies and potential barriers to policy formulation and implementation. This research aims to fill some of the gaps in current organ donation literature.

Who will know what I said or did in the study?

Your responses will be recorded during the interview; however any identifying information will be removed and will not be included in data analysis or reporting. All participants will be kept confidential and anonymous. Only the researchers on this project will have access to the information provided. Responses and data will not be used outside of the research context. Interview recordings will be erased once data analysis is complete (estimated to be July 2013).

Every effort will be made to protect your confidentiality and privacy; I will not use participant names or any information that would allow any participant to be identified.

What if I change my mind about being in the study?

Participation in this research project is completely voluntary. During the interview you are not obligated to answer any questions that make you feel uncomfortable. You may withdraw from the project at any time with no consequences before, during, or after the interview, up until July 2013 when I expect to be finalizing my research. If you withdraw from the study, your responses will not be used.

Questions about the Study

If you have questions or need more information about the study itself, please contact Diana Vania (Principal Researcher) at vaniadk@mcmaster.ca

This study has been reviewed by the Hamilton Health Sciences/McMaster Faculty of Health Sciences Research Ethics Board (HHS/FHS REB). The REB is responsible for ensuring that participants are informed of the risks associated with the research, and that participants are free to decide if participation is right for them. If you have any questions about your rights as a research participant, please call The Office of the Chair, HHS/FHS REB at 001-905-521-2100 extension 42013.

CONSENT

- I have read the information presented in the information letter about a study being conducted by Diana Vania of McMaster University.
- I have had the opportunity to ask questions about my involvement in this study and to receive additional details if requested.
- I understand that if I agree to participate in this study, I may withdraw from the study at any time until approximately July 2013.
- I have been given a copy of this form.
- I agree to participate in the study.

Name of Participant (Printed) _____

Signature: _____

Person Obtaining Consent: _____

Signature: _____

Appendix B – Interview Guide

1. Currently, what is the procedure to receive an organ in Mumbai if someone is in need?
 - a. What works and what does not work in this process? What changes are needed?
2. What is the current number of organs needed versus organs available?
3. What are the factors that influence a patient's position on the organ transplant wait list?
 - a. Is the rank in wait list adhered to?
4. What is the procedure to ask families about donating their relative's organs after death?
 - a. What steps are taken to convince families to consent to donation?
 - b. Are families usually agreeable to consenting to donation?
5. How is information shared between hospitals about organs available for transplantation?
6. Is there priority for organs to go to the wealthy or those who are able to pay?
7. Do patients in private hospitals have higher priority for receiving an organ?
8. What efforts have been made to increase awareness about organ donation, both among the public and within the government?
 - a. Have governments, health care providers, and the public been receptive to these messages?
9. What is the government doing to minimize illegal organ donation?
10. How does medical tourism affect the Indian economy?
11. Who has jurisdiction over the health system? (National, state, municipal)
 - a. How does this affect organ transplants?
12. Is organ donation a priority for the government?
13. Is organ donation a priority for your organization?
14. What might some barriers be to developing an organ donor registry? (*I.e. religious, political, cultural*)

15. Do you think that religious beliefs would be a barrier to garnering support for organ donation?
16. What resources would be needed to implement and make use of an organ donor registry in your organization? (*I.e. time, money, personnel, technology*)
 - a. Does your organization have the resources that are needed?
17. What kind of donor registry would work best in Mumbai (opt-in or opt-out)?

Appendix C – Components of Ideas, Interests, and Institutions Found in Research

<p>Ideas</p>	<ul style="list-style-type: none"> - Lack of research on organ donation in India – inhibits advancements in transplant program due to lack of knowledge and evidence - Religious beliefs (perceptions vs. actuality) – hinders increasing public support for deceased organ donation - Population versus individual health – need to allocate resources to maximize both equality and well-being - Transplant wait list priority and allocation – equity versus ability to pay
<p>Interests</p>	<ul style="list-style-type: none"> - Central and state governments – wavering central government support for organ donation indicates that organ donation is not a top priority - Physicians and transplant coordinators – most transplants are performed by surgeons in private hospitals who may have more interest in enhancing their own transplant program rather than the city-wide transplant program; municipal/government hospitals prefer to focus resources on saving a patient than on maintaining a brain dead potential donor - Wealthy and poor patients – services provided to wealthy patients in private hospitals are more profitable than are public services; wealthy patients generally have greater access to and ability to obtain transplants; little chance of interest group mobilization from patients
<p>Institutions</p>	<ul style="list-style-type: none"> - State jurisdiction over health care, hospitals, and transplant programs – makes initiatives very fragmented, creating difficulties in establishing an inter-city organ sharing program - Legacy of private health care – high out-of-pocket payments by patients, low government contribution to health care; no efforts being made to transition to a universal comprehensive health care system - Legacy of focusing on communicable diseases – little focus on the rising incidence of chronic diseases, many of which will lead to an increased need in transplants; can be attributed to the lack of research evidence on the increasing burden of chronic diseases in India - International aid agencies and foundations – provide financial aid to India mostly for eradication of communicable diseases; strong role in setting international and national health policies - Family consent – due to India’s collectivist culture, the family’s preference for organ donation is always considered when a patient has died; it is important that patients discuss their post-mortem organ donation wishes with their family to maximize familial consent