The Potential Implications of a Presumed Consent System on Organ Donation and Transplantation in Malaysia

Khaled Tafran Makmor Tumin
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Foreword

Organ transplantation is a therapy that offers patients with end-stage organ failure an opportunity to lead a healthy and productive life again. Not only is transplantation a viable therapy, it is also cost-effective and more compelling in granting patients quality years of life than almost all of the other alternative therapies.

Among the many organs that can be transplanted, kidney transplantation is the most commonly done worldwide. Since the very first successful kidney transplant performed by Dr. Joseph Murray in 1954, the demand for transplantation has grown tremendously. This was paralleled with the severe shortage in donated organs. To fill the gap between the supply and demand of transplantable organs, efforts have been made by countries worldwide to increase both living and deceased donation rates. The fact that transplantation is a long-term cost-saving treatment has amplified the efforts of governments to increase the number of donations in an attempt to optimise healthcare spending.

Even though living organ transplantation gives a better transplant outcome and patient survival, not all patients have suitable live donors. In addition, living donation is only limited to kidneys as well as part of the liver. Other organs such as the heart, pancreas, lungs, and intestines can only be procured from deceased donors. This has then further increased the demand for deceased organ transplantation worldwide.

It is a universal phenomenon to see a mismatch between the supply and demand for organs for the purpose of transplantation. Hence, increasing the number of deceased donors has become a pressing matter. Efforts to increase organ donation rates should focus on policy change, public education and awareness, better organisation of organ donation and the transplantation process, and engaging health professionals and religious leaders in organ donation promotion. Among all these approaches, a change in policy is expected to bring the most impact.

With the continuous of organ shortage, implementing a presumed consent system (or “opt-out” system) has been the foremost suggested policy for improving deceased donation rates in many countries. This system implies that everyone is deemed donors upon death, unless they
have made an objection during their lifetime. This system is the opposite of the informed consent system, a system used in many countries including Malaysia, in which donors are of those who have officially registered their willingness to donate during their lifetime.

Countries such as Spain, Croatia and Belgium have been applying the presumed consent system for decades, achieving very high deceased donation rates compared to other countries. Many researchers attribute the success of these countries to the presumed consent system per se. However, others argue that the presumed consent system has a marginal or no contribution to the higher donation rates achieved in these countries, crediting the success in these countries to their excellent organisation and management of the donation and transplantation process, respectively.

It is important to note that there are countries that have implemented the presumed consent system, but have failed to improve deceased donations. Such was in the case of Brazil, Chile and Singapore. The experiences of these three countries and the significant reported variations in deceased donation rates across countries applying the presumed consent system imply that the ability of the presumed consent system in improving donation could very well be contextual and country-specific. In other words, what works well for the donation rates in Spain and Croatia may not be the same for other countries. This highlights the importance of studying and understanding the potential implications of implementing this system in other countries.

Malaysia has one of the lowest deceased donation rates worldwide. The demand for transplantation in the country is rapidly increasing, where more than 21,000 kidney failure patients are currently wait-listed for kidney transplantation. Almost two patients die every day while waiting for a donated organ. The presumed consent system has been suggested as a policy change that may end or at least alleviate the organ shortage in the country. As highlighted earlier, studying and understanding the potential implications before implementing this system is imperative. This is to answer the many questions that could be encapsulated in one enquiry: will the presumed consent system improve deceased donation in Malaysia? Hence, this book is an attempt to provide a plausible answer.

This book examines the hypothesis of the superiority of the presumed consent system in achieving higher donations compared to the informed consent system using a cross-national approach. Data from 54 countries was used by the authors to test this hypothesis, which then builds a strong empirical ground before moving to discuss such plausibility in Malaysia. The book carefully extracted lessons which
could be learnt from the Singaporean experience with the presumed consent system, as well as lessons learnt based on the experiences of Brazil and Chile.

After thoroughly investigating the international scenario, the book moves on to discuss the Malaysian case in-depth. It first explores the potential public reaction towards the presumed consent system. It also gauges the percentage of the public who would oppose organ donation under the presumed consent system. The book then goes deeper in analysing the potential public potential attitude by exploring the demographic and socioeconomic characteristics of the opponents of organ donation under this system. In the same context, the public attitude under more complex policies was examined in which organ allocation priority is to be implemented, along with the presumed consent system.

Familial consent on their relatives' donation is required for the donation process in most countries, including Malaysia. Fortunately, the book explored the potential change in family consent rates which may be a result of implementing the presumed consent system.

It is well known that healthcare professionals are key players in determining the success or failure of policies aiming to improve organ donation. To address this, this book supported its conclusions further by investigating the Malaysian healthcare professionals' potential attitude towards the presumed consent system.

This book could serve as a critical document for policy makers as it provides important policy recommendations regarding the implementation of a presumed consent system in Malaysia. It considers and discusses the possible factors that may influence the success of such a system in Malaysia. It looks into the potential influence of each of these factors to derive an answer for the most important question: should Malaysia implement the presumed consent system?

Associate Professor Dr. Lim Soo Kun
MBBS(MAL), MRCP(UK), FRCP(Edin), AM(MAL)
Consultant Nephrologist & Head Renal Division
Department of Medicine
University of Malaya
The advancement in medicine, specifically in transplantation, has reached a sophisticated level and increased the demand for transplantation as treatment for organ failure. However, there is an inadequate supply of human organs for transplantation. As a result, many patients die before an opportunity for transplantation arises.

In 2015, more than 370,000 patients awaited organ transplantation across the world; more than 20,000 of them died that year, unable to undergo transplantation (European Directorate for the Quality of Medicine 2016). The highest number of patients awaiting organ transplantation in 2015 was recorded in the US, with more than 139,000 patients registered on the waiting list (see Table A1 in the Appendices for a full list of countries). When controlling for population, Malaysia has the highest global concentration of patients awaiting organ transplantation. As shown in Figure 1.1, for each million population, there are roughly 537 patients awaiting organ transplantation. This figure suggests that the Malaysian human organ shortage is most severe compared with other countries across the globe.

Perhaps, it is useful for readers to get some insight on organ transplantation activities in Malaysia during the past years. For this purpose we provided full statistics on the number of kidney, heart and liver transplantations in the appendices, Tables A2, A3, and A4.
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Figure 1.1: Patients on the Waiting List for Organ Transplantation (per million population), by Country, 2015.

Abbreviations: PMP = Per Million Population.

Notes: The crude number of patients on the waiting list can be found in Table A1.

Sources: The author calculated the numbers and arrived at the figure. Data on the number of patients on the waiting list was compiled from the Transplantation Newsletter (2015) published by the European Directorate for the Quality of Medicine (EDQM). Data on population size was obtained from the World Development Indicators Database of the World Bank (World Bank 2016).

Figure 1.2: Deceased Organ Donations in Malaysia, 2001-2015.

Abbreviations: PMP = Per Million Population.

Sources: International Registry of Organ Donation and Transplantation (IRODaT, 2016) and the 12th report of the Malaysian National Transplant Registry (LS & Mansor 2018).
The prime reason behind the escalating number of Malaysians registered on the waiting list is the lack of deceased organ donations. The deceased donation rate, which is normally defined as the annual number of deceased organ donors per million population of a country in a single year, has never exceeded one donation per million population in Malaysia (Figure 1.2). To fathom how low this donation rate really is, we should consider the following: A single donor may save up to 10 lives; thus, in Malaysia, there is only one donor (10 donated organs) for every 537 patients. Another way to contextualise the low deceased donation rate in Malaysia is to compare it with the donation rates of other countries. Again, Malaysia appears to have one of the worst figures globally (Figure 1.3). While countries such as Spain and Croatia are close to 40 donations per million population, Malaysia reported only one deceased donation per million population in 2015.

Two main legislations govern deceased donation in the world. The first is the presumed consent system or opt-out system, which can be defined as a legal system which allows the procurement of organs from any potential donor, unless he had officially signed an objection to donate organs after death. The second is the informed consent system or opt-in system which can be defined as a legal system that forbids procurement of organs from a potential deceased donor, unless he officially had chosen to donate organs during his lifetime.

Some countries such as Spain, Croatia and Sweden use the presumed consent system, while others, such as Malaysia, the UK and US apply the informed consent system. Current statistics and academic studies show that countries with the presumed consent system produce higher deceased donation rates than countries with the informed consent system. Accordingly, some believe a shift from the informed consent system to the presumed consent system can increase deceased donation rates, especially in countries suffering from chronic shortages in human organs for transplantation (Abadie & Gay: 2006; Gimbel, Strosberg, Lehrman, Gefenas, & Taft: 2003; Shepherd, O’Carroll, & Ferguson: 2014). Others, however, argue that this system is unnecessary and an ineffective policy option in increasing the deceased donation rate (Dominguez & Rojas 2013; Fabre 2014).

This debate leads us to an imperative question: should Malaysia shift from the currently applied informed consent system to the presumed consent system to improve the deceased donation rate? In order to answer this complex question, we attempt a thorough investigation of several issues that might influence the success of such a policy change.
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More than 21,000 patients are in the waiting list for organs in Malaysia, and around two of them die every day while waiting. The extremely low number of deceased donors is the prime reason behind this dilemma. However, the case is not exclusive only to Malaysia, as most countries also suffer from organ shortage. However, countries like Spain and Croatia have been reporting the highest number of donors. Some scholars argue that the success of these countries is attributed by the implementation of the presumed consent policy, in which everyone is deemed as a deceased donor unless he or she stated otherwise during his or her lifetime. Therefore, implementing the presumed consent system is suggested to be the solution for organ shortage. However, other scholars argue that the presumed consent system is not a magical solution for the organ shortage, citing the low number of donations achieved in Chile and Brazil after the implementation of a similar system.

Malaysia applies the informed consent system, wherein organs can be procured from a deceased if he or she has registered his or her will to donate during his or her lifetime. Some argue that the implementation of a presumed consent system in Malaysia will enhance the number of donors, while others argue that such implementation may worsen the problem. Therefore, studying and understanding the potential implications before implementing this system is imperative. This is to answer the many questions that could be encapsulated in one enquiry: will the presumed consent system improve deceased donation in Malaysia? This book is the first of its kind to attempt to provide a plausible answer for this question.