

## Mandated Consent – Not a Viable Solution for Organ Transplant in Singapore

Jing Jih Chin,<sup>1,2</sup> MBBS, FRCP(Edin), FAMS

The last decade has seen an alarming increase in the prevalence of end-stage renal failure in Singapore, attributed to factors such as dietary and environmental triggers, improved healthcare accessibility and a rapidly ageing population. This, in turn, has contributed to a relentless increase in demand for renal transplant. As in many first world countries, this demand is not matched by kidneys available, leading to long waiting time for renal transplant.

Singapore stands out among many Asian countries as one which has since 1987 legislated an “opt-out” presumed consent model in its national organ donation scheme. Under the Human Organ Transplant Act (HOTA), a citizen or permanent resident is presumed to have given his or her consent to the removal of specified organs for purpose of transplantation upon death, unless an objection form (HOTA opt-out form) has been actively filled to indicate an objection to the removal of some or all of the specified organs. Observers have noted that despite the amendment of HOTA in 2004, 2008 and 2009 to widen the deceased donor pool, the incident of deceased or cadaveric renal transplant rate has remained relatively static.<sup>1</sup> The statistics reflect that despite a high percentage of potential donors among the population as a result of the default donor system adopted by HOTA, the number of actual organ transplants has not risen correspondingly.<sup>2</sup>

Presumed consent is intended to be ethically equivalent to a valid informed consent, with the qualifying criteria of an informed consent all assumed to be present. Individuals who do not actively register an objection will automatically be presumed to have received and understood the information provided, and made the decision without being coerced. The absence of an objection is presumed to be a positive expression of agreement to donate the organs for transplantation in the event of brain death. Critics of presumed consent contend that it is more accurately a “presumed lack of objection”, and one cannot dispel the possibility that the failure to formally register a refusal represents either ignorance or a failure on the part of the deceased donor to overcome the inertia to confront the decision, rather than an active expression of his genuine willingness to opt-in as a future organ donor.<sup>3</sup> In many of

the organ donation systems based on presumed consent, there is also no requirement to ascertain that a donor’s family is unaware of any objection (on the part of the deceased patient) to donating as a criteria for validating the presumed consent. This frequently becomes the flash point for family members to object strongly to organ donation, arguing vehemently that the deceased either did not receive or had never comprehended the relevant and critical information needed to make the decision. Some have even insisted that the deceased had consistently been against organ donation, but just did not get down to executing his refusal in accordance to the prescribed legal procedures. The conflict between the family of the deceased and hospital staff—perceived in these conflicts as agents executing the “unjust” system of presumed consent—can be highly emotional and antagonistic, and may potentially lead to a failure to actualise the organ donation.<sup>4</sup>

This dissatisfaction with presumed consent has led to the call for an alternative system of “mandated consent”,<sup>5</sup> a plea similarly echoed by some in Singapore.<sup>2,6</sup> In mandated consent, a competent adult is required by law to explicitly indicate a choice regarding his wishes to donate his organs after his death through various registration mechanisms.<sup>5</sup> This choice generally includes whether or not to donate and which organs to donate. It is mandatory as individuals must register a decision; failure to make a choice is not legally permitted. One commonly employed approach is to make it compulsory for an individual to declare his (or her) preferences regarding organ donation when performing a state-regulated task, such as obtaining or renewing his driver’s license, or filling a tax return.

Mandated consent is perceived by its proponents as a more ethical and enforceable form of consent as it represents an enhancement of a person’s autonomy—expressed as a clear and explicit decision towards organ donation—rather than a permission that has been presumed via an overt absence of objection. The clear indication provides a strong and unambiguous directive from the donor to supersede any future objection from family members, thereby having the potential to increase the number of organ transplant actualised in hospitals, particularly those which tend to

<sup>1</sup>Department of Continuing & Community Care, Tan Tock Seng Hospital, Singapore

<sup>2</sup>Geriatric Medicine Department, Tan Tock Seng Hospital, Singapore

Address for Correspondence: A/Prof Chin Jing Jih, Geriatric Medicine Department, 11 Jalan Tan Tock Seng, Singapore 308433.

Email: [jing\\_jih\\_chin@ttsh.com.sg](mailto:jing_jih_chin@ttsh.com.sg)

submit to pressures from the deceased's family. Critics of presumed consent argue further that a system of mandated choice helps to distinguish the "true donors" from those who are in the donor registry simply because of procrastination in their act of formally filing a refusal. Acknowledging organ donation as an act of social good and which saves lives—a "modified mandated consent"—where processes and communication materials are deliberately directed towards and biased in favour of organ donation help to balance the ethical imperatives of beneficence and autonomy.<sup>7</sup>

Mandated consent, however, is not without its detractors. One of the most frequently cited ethical flaw is the potential coercion associated with its execution. As its name suggests, mandated consent inevitably involves giving individuals—including those who do not wish to think about death and organ donation—no choice but to deliberate and decide on such issues against their own free will. It remains questionable whether it should be framed as a form of statutory living will, as forcing a decision to donate one's organs well in advance of death is arguably very different from making end-of-life choices nearer or at the time of death.

The tying of the execution of a mandated choice policy to a state-regulated task like registering or renewing of driver's license gives rise intrinsically to several issues. Firstly, it is conceivable that the quality and quantity of communication related to organ donation would be compromised in order to sustain the usual efficiency of the task it is paired with. The misgiving for the quality, and hence validity, of the mandated consent inevitably raises ethical questions similar to those hurled at a presumed consent policy. Secondly, the desire to complete the state-regulated task without delays—usually of greater contemporaneous social relevance to the applicant—for instance registering or renewing one's driving license, can constitute an inducement that would result in a hurried decision that lacks both altruism and careful consideration. Again, this casts a shadow of doubt on the validity of mandated consent. Thirdly, there are very few state-regulated tasks that have been tested and shown to involve a convincing proportion of the eligible population. In fact, many were left out due to lack of relevance of the twinned task, and consequently their choices remained unregistered.

Given that attempts at adopting mandated consent in several Western countries have seen varying outcomes—and the policy has even been abandoned with a reversal back to an "opt-in" consent model in Australia and in Texas—one cannot help but ask if it will be relevant and effective in Singapore. A reasonable question that should be answered before deciding on implementation would therefore be whether a mandated choice system will succeed in making a significant impact in enhancing the rate of organ transplant

in Singapore, given the small country's unique political, social and cultural environment.<sup>6</sup>

Some of the pros and cons of a mandated consent policy discussed above are applicable to varying extents in Singapore. On one hand, one can argue that the much-admired efficiency of Singapore's state-run agencies puts the country in a good position to execute this twinning of task adeptly and reliably. However, this can cut both ways, possibly inviting accusations of bullying and coercing the public into making a choice to donate their organs even when they are not willing or ready.

But perhaps an even more pertinent question is whether the number of organ transplants will increase significantly with a switch from presumed to mandated consent. For organs to be suitable for cadaveric transplant, organ donors need to deteriorate to brain death. Typically, these are patients who have suffered catastrophic intracranial injuries. Furthermore, organ donors who decline to the point of brain death need to have their cardiopulmonary functions artificially supported to keep the organs viable for transplant. Invariably, this can only take place in intensive care units of acute hospitals. Taken in combination, these requirements will inevitably limit the number of potential donors in Singapore. This was indirectly affirmed in a study looking at patients admitted to Singapore's largest neuro-intensive care unit from 2004 to 2011, which found only 365 cases of severe traumatic brain injury (TBI) over a period of 7 years. Of these, 180 (49.3%) died in hospital, giving an annual figure of approximately 26 in-hospital deaths from severe TBI.<sup>8</sup> Of note, a majority (76.7%) of these fatalities were cases above 60 years old,<sup>8</sup> and many of these older patients tend to have pre-existing chronic multisystem pathologies that render their organs unsuitable for transplant. Therefore, contrary to the views of some advocates of mandated consent,<sup>2,6</sup> the rates of organ donation converted into actual organ transplant is unlikely to increase in any impactful way via a policy switch from presumed to mandated consent.

Another challenge to Singapore lies in selecting the appropriate state-regulated task for twinning with the registration of the mandated choice. This task should cover a sizable proportion of eligible donors. Otherwise, the mandated consent system will have a serious inclusion issue, and will expectedly lead to a large number of citizens and residents who never had an opportunity, thus leaving their choices unregistered. For example, in Singapore, not everyone has a driver's license, and an even smaller number pay taxes. Overall, this will cause a reduction in number of potential donors.

Take registration and renewal of driving license as an example of a state-regulated task twinned to mandated consent. In 2016, there were only 1,967,619 persons holding

valid driving licenses in Singapore. The actual number would probably be lower if those below the statutory age for pledging organs for donation (of 21 years) are excluded. Using the population above the age of 21 years as a denominator, this makes up only about 55% to 56% of the population eligible for organ donation.<sup>9,10,11</sup> Tax filing suffers from the same issue. In 2016, there were only 1,728,499 tax residents,<sup>12</sup> though the real number covered statutorily under the provisions of HOTA is smaller due to the exclusion of foreign tax residents. This constitutes lower than 50% of the population above the age 21 years. These statistics reflect the restricted reach in Singapore of these 2 commonly employed mechanisms in mandated choice systems.

In addition, a hypothetical choice experiment seems to suggest that a mandated choice policy which fails to cover many individuals, thereby leaving their choices unregistered, may independently make it more challenging for hospitals to obtain permission from their next-of-kin for organ donation.<sup>13</sup> This will further reduce the number of organ donors.

Lessons from early pilots and movers elsewhere have indicated that an effective mandated consent system must include the presence of several elements. Registrations must be made legally binding, and enforcement must therefore be consistent. A third option of designating the decision to a family member is considered by many to be helpful.<sup>14,15</sup> The task chosen should be inclusive in order to reach a maximum number of potential donors. The process must fulfill the requirements of informed consent, where individuals must be able to register their choice in an environment conducive to communication and contemplation. It should also include a user-friendly method to change one's choice. There needs to be adequate design-thinking applied to the operating model as negative experience resulting from cumbersome and difficult methods of registration have been shown to result in lower rates of organ donation.<sup>14</sup> The failure to address even one of these elements will prevent mandated consent from being the magic bullet for meeting organ transplant needs.

While there is no denying the ethical value of a properly administered mandated consent policy, the practical solution for Singapore's low rate of cadaveric organ transplant in the immediate and near future is unlikely to be found in such a system. What is critical to sustaining organ transplantation as a collective societal institution is to step up the efforts to change mindsets through sharing of knowledge and promotion of altruism and social compact between

citizens. Ultimately, we need to negotiate an appropriate and sustainable balance between an individual's right of autonomy and his obligation towards communal interests.

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