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Brief Communication

Preliminary Marked Increase in the National Organ Donation Rate in Israel Following Implementation of a New Organ Transplantation Law

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Israel's organ donation rate has always been among the lowest in Western countries. In 2008 two new laws relevant to organ transplantation were introduced. The Brain-Respiratory Death Law defines the precise circumstances and mechanisms to determine brain death. The Organ Transplantation Law bans reimbursing transplant tourism involving organ trade, grants prioritization in organ allocation to candidates who are registered donors and removes disincentives for living donation by providing modest insurance reimbursement and social supportive services. The preliminary impact of the gradual introduction and implementation of these laws has been witnessed in 2011. Compared to previous years, in 2011 there was a significant increase in the number of deceased organ donors directly related to an increase in organ donation rate (from 7.8 to 11.4 donors per million population), in parallel to a significant increase in the number of new registered donors. In addition the number of kidney transplantations from living donors significantly increased in parallel to a significant decrease in the number of kidney transplantations performed abroad (from 155 in 2006 to 35 in 2011). The new laws have significantly increased both deceased and living organ donation while sharply decreasing transplant tourism.

Key words: Brain death, Declaration of Istanbul, organ allocation, organ donation rate, organ shortage, registered donors, transplant tourism, waiting list mortality

Abbreviations: INTC, Israel National Transplant Center.

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Introduction

Deceased organ donation rate in Israel has traditionally been among the lowest in Western countries, ranging between 7 and 8 deceased donors per million population (1). The causes for this low donation rate have been multifactorial. One of the major causes has been the refusal of some particularly ultraorthodox religious groups to recognize brain death as a valid determination of death and subsequent objection to organ donation. This attitude has widespread consequences since during critical moments of life many of the Israeli population, mainly religious but also secular, seek comfort and advice from religious leaders and accept their judgments.

An accompanying cause of the low donation rate is the so-called "free-riding" behavior of those who reject brain death and thus organ donation yet do not abstain from being active candidates for organ transplantation themselves. This phenomenon arouses significant antagonism toward organ donation in many circles and has been repeatedly cited in public opinion surveys as one of the major reasons for the low consent rate for organ donation (2).

Another cause which has contributed to lowering the motivation for local organ donation, both from deceased and from living donors, has been generous reimbursement of transplant tourism by insurance agencies and sick funds. Motivated by the desire to help desperate patients overcome the local organ shortage, mixed with considerations of economic efficiency and lacking any legal restrains, Israeli insurance companies and sick funds have traditionally fully reimbursed transplant operations performed anywhere on the globe, regardless of the origin of organ donors or the legality of the operations by local laws, thereby providing a significant incentive for transplant tourism.

Finally, live organ donation has also been traditionally underutilized due to variety of disincentives which have all hampered the full utilization of this important organ source.

In a response to all of these obstacles to organ transplantation the Israeli Parliament passed into legislation two laws relevant to organ transplantation, aimed at bringing to a halt illegal transplant tourism while increasing local organ

donation both from deceased and from living donors. In this report we describe the preliminary impact of the gradual implementation of these unique new laws which has been witnessed in 2011.

Methods

In March 31, 2008 two new laws, prepared by the Israeli Ministry of Health, were accepted by the Israeli Parliament following a prolonged preparatory phase. The first law, the Brain-Respiratory Death Law (3), which represents a consensus between the medical community and the religious authorities, defines the circumstances and mechanisms for determining brain death. The law mandates the compulsory performance of an apnea test (no visual respiratory movement following an arterial blood pCO2 above 60 mmHg and oxygen saturation above 90%) in addition to one of the following ancillary brain imaging testing—transcranial Doppler, computed tomographic angiography, brain magnetic resonance imaging angiography, brainstem auditory evoked response or sensory evoked potential. It defines the precise qualifications of the physicians to be certified as members of brain death committees and specifies the mechanism for supervising these committees. In addition the law entitles relatives who object to brain death determination to request that the deceased not be disconnected from the mechanical ventilator while all other therapy except hydration is discontinued.

The second law, the Organ Transplantation Law (4), which has been formulated following extensive preparations with leading ethical authorities, comprehensively defines all ethical, legal and organizational aspects of organ donation, allocation and transplantation in Israel. First, the law defines precisely the circumstances of organ trade and trafficking and declares it a criminal offence punishable by 3 years in jail together with a large fine. It clearly bans the performance and reimbursement of organ transplantation anywhere outside of Israel if the procurement of the organ and its transplantation have been performed contrary to the law of that country and if stipulations of the Israeli Law regarding organ trade are contravened.

A unique clause of the law grants prioritization in organ allocation to candidates who have either been registered as organ donors for at least 3 years prior to being listed as candidates, or have given their consent for actual organ donation of their deceased next-of-kin or have been nondesignated living kidney or liver-lobe donors (2). A recent Parliamentary amendment to this clause has broadened the prioritization to any living donor—designated and nondesignated alike—so that candidates who have previously donated an organ (kidney, liver lobe or lung lobe) which they are now in need of will be granted top priority in the allocation of these organs.

Finally, the law includes the following clauses aimed at removing disincentives to altruistic living donors who are approved by designated national ethics committees:

(a) Earning loss reimbursement of 40 days based on the donor's average income during the three months prior to donation. An unemployed donor will be reimbursed based upon the minimum salary in the market at the time of donation.
(b) A fixed sum transportation refund to cover all commuting to and from the hospital for the donor and his relatives for the entire hospitalization and follow-up period.
(c) Reimbursement for seven days of recovery in a recuperation facility within three months after donation.
(d) Five years reimbursement of medical, work capability loss and life insurances, all to be refunded upon submission of appropriate insurance policies and payment receipts.
(e) Reimbursement of five psychological consultations and treatments upon submission of appropriate receipts.

Banning reimbursement of illegal transplant tourism went into effect shortly after the new law has been legislated, in late 2008, while the Brain-Respiratory Death law went into effect on August 2009. Organs procurement and allocation in Israel are being conducted by the Israel National Transplant Center (INTC) which is supervised by a multidisciplinary ethics steering committee. It took the INTC 2 more years to prepare the multitude of new regulations and instructions inherent to the prioritization policy of the Organ Transplantation law. Following an intensive year-long multimedia and multilingual public campaign in 2011 which brought the new policy and its implications to the attention of the public (5) the law has been fully implemented as of April 2012.

Statistical Methods

Due to the short observation period of this report following the implementation of the new law, no estimation of variances of most variables of interest was feasible by a *t*-test and therefore the prediction intervals method has been chosen to test whether the litigation affected them (6). Using this method a linear regression of the variable was calculated excluding the 2011 data, estimating a time trend. This trend was used to predict the variable value for 2011 and construct a 95% prediction (or forecast) interval around this prediction which was then compared to the observed 2011 value to calculate a p value. The null hypothesis is that there was a change in the statistical distribution of the variable after the implementation of the new law. We interpret a change in the distribution to be the result of a change in the mean of the variable, as there is no reason to assume the law affects its variance. The standard two-sided t-test allowing for unequal variances was used for evaluating the impact of the new law on the numbers of new registered donors as monthly data of this variable was available. For the numbers of kidney transplantations performed abroad we have also used a standard two-sided t-test allowing for unequal variances as the law banning their reimbursement went into effect already in late 2008 and hence data of 3 years after the litigation is available. A p value of 0.05 was considered statistically significant. It should be noted that the Israeli population has increased since 2004 in a steady annual average rate of 1.9% from 6 869 500 to 7 836 600 in 2011 (7).

Results

The number of deceased organ donors significantly increased in 2011 to 89, compared to 60 in 2010 or to any of the previous seven years (95% prediction interval 45.5–80.5, $p = 0.01$) (Figure 1A). Deceased organ donation rate per million population significantly increased in 2011 to 11.4 from 7.8 in 2010 (95% prediction interval 5.6–10.4, $p = 0.01$) (Figure 1B).

The monthly number of new registered donors has significantly risen from a mean number of 2889 in the years 1998–2010 to a monthly mean of 6273 in 2011, representing an increase in the total number of registered donors from 10% to 12% of the adult population (95% confidence interval for the difference between the means 1113–5654,

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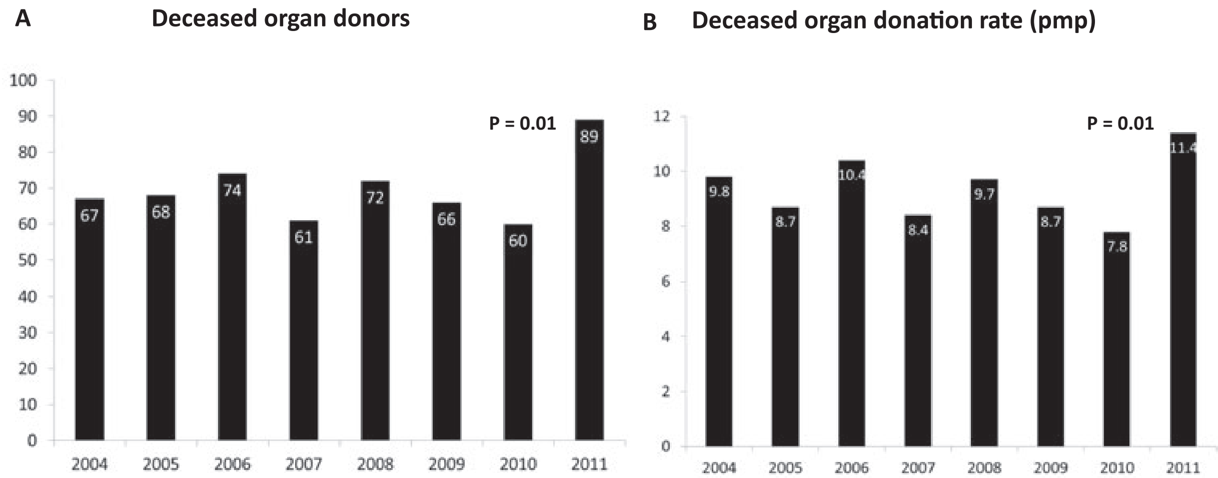

Figure 1: (A) Annual number of deceased organ donors. (B) Annual deceased organ donation rate (pmp—per million population).

p = 0.007) (Figure 2). The consent rate for organ donation from deceased donors has risen in 2011 to 54.9% from 49.2% in 2010, however the increase is not statistically significant (95% prediction interval 38.7–56.8, p = 0.11) (Figure 2).

The number of kidney transplantations from living donors has significantly risen from 71 in 2010 to 117 in 2011 (95% prediction interval 42.2–91.5, p = 0.003) (Figure 3). The annual number of patients who underwent kidney transplantation abroad has decreased from a peak of 155 in 2006 to an all-time low of 35 in 2011 (95% confidence interval for the difference between the means 6.6–121.6, p = 0.006) (Figure 3B).

The total number of candidates waiting for an organ transplant has decreased for the first time since 2006 from 1117 in January 2011 to 1041 in January 2012, though this decrease is not statistically significant (95% prediction interval 974.4–1282.0, p = 0.21) (Figure 4A). Similarly, the total number of candidates who died while waiting for transplants has decreased from 124 in 2010 to 105 in 2011 (95% prediction interval 66.8–168.8, p = 0.5) (Figure 4B).

Discussion

Preliminary results following implementation of the Organ Transplantation Law and the Brain-Respiratory Death Law have been very promising, showing a significant increase in both deceased and living organ donation.

In 2010, the first year following implementation of the new Brain-Respiratory Death Law, a significant decrease in the number of brain death determinations was evident

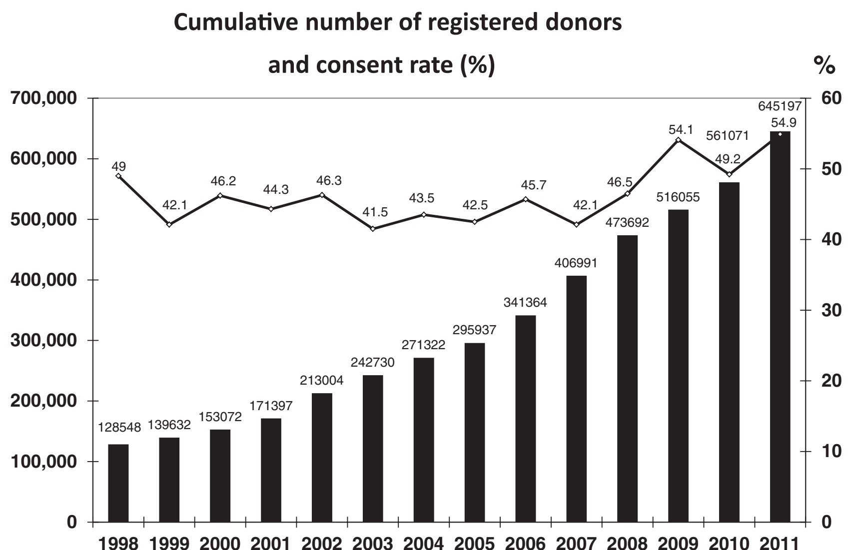

Figure 2: Cumulative number of registered donors by the end of each year and the annual consent rate for deceased organ donation (in percent).

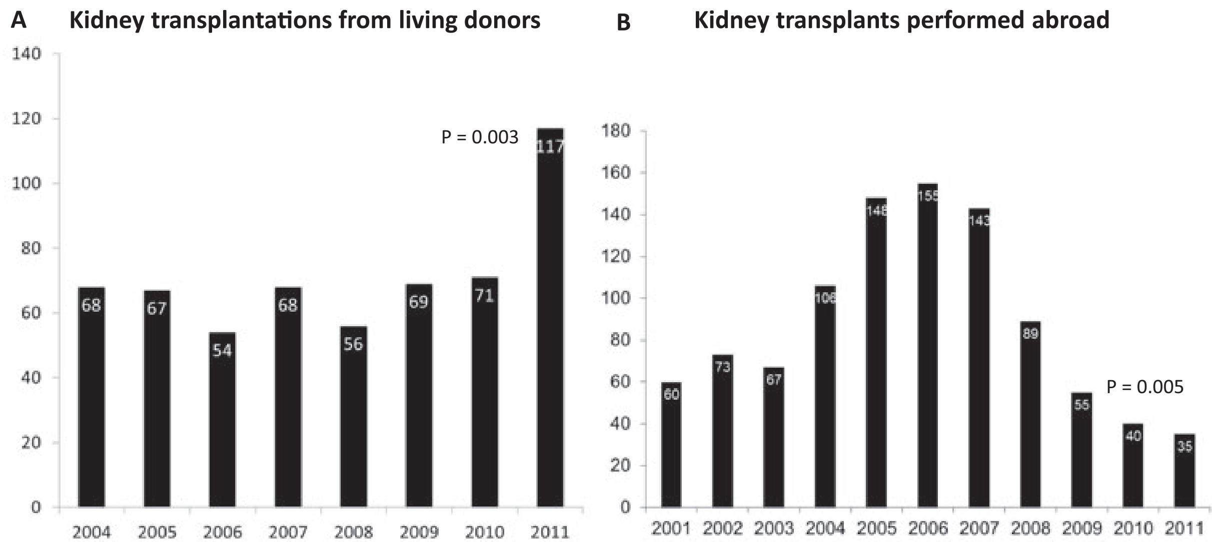

Figure 3: (A) Annual number of kidney transplantations from living donors. (B) Annual number of kidney transplantations performed abroad.

(from a mean of 160 per year in the years 2007–2009 to 122 in 2010, $p < 0.001$) (8). This decrease was related to unforeseen consequences of the new law such as family refusal to disconnect the deceased from the mechanical ventilator, inability to perform the standard apnea test in some cases and inability to perform the mandatory ancillary imaging testing due to lack of appropriate resources in all hospitals. During 2011 most of these obstacles were successfully overcome and the number of brain death determinations ($n = 160$) returned to that seen in previous years following the introduction of an alternate apnea testing, in which the patient remains connected to the mechanical ventilator with a gas mixture comprising 97% oxygen and 3% carbon dioxide and which decreases apnea time and thus avoids the consequences of prolonged disconnection (9), and additional ancillary brain imaging tests such as radionuclide angiography using hexamethylpropylene amine-oxime single photon emission computed tomography (SPECT). The law is now fully implemented country wide and has been largely accepted by large elements among the religious population including the Chief Rabbinate (8).

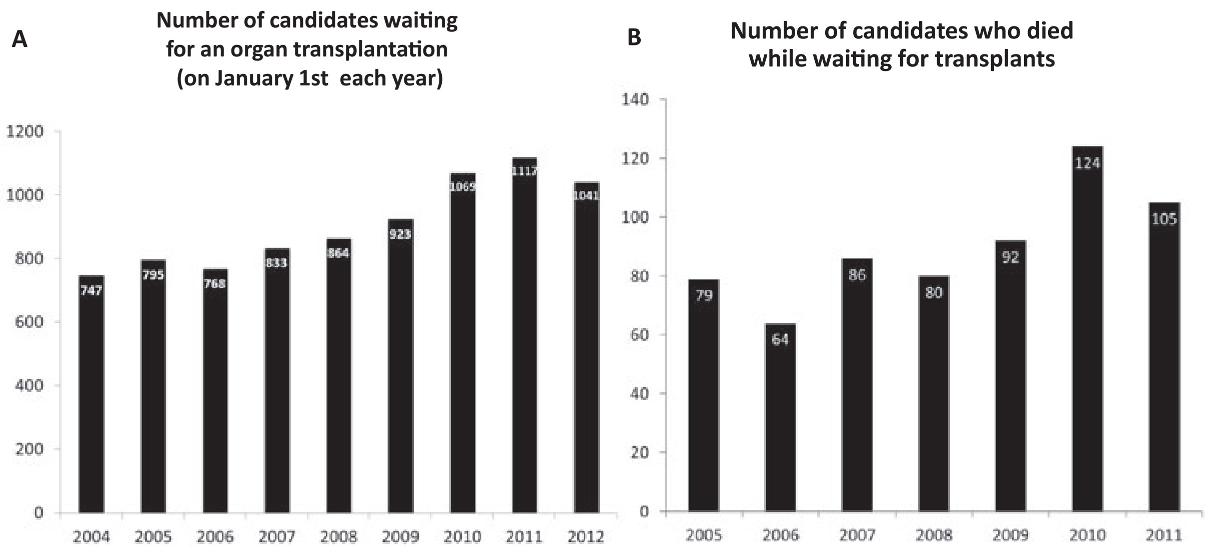

Figure 4: (A) Annual number of candidates waiting for organ transplantation on January 1 each year. (B) Annual number of candidates who died while waiting for transplants.

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The rationale behind the Organ Transplantation Law prioritizing candidates who are registered donors in organ allocation lay in the fact that a higher number of registered donors in the population would increase the consent rate for organ donation by the donors' next of kin, since traditionally signed donor cards are interpreted as representing the donor's written will (2). We also hypothesized that implementing the ethical rule of reciprocal altruism (10), whereby those in the society who are willing to help others will in turn be helped, would be an incentive for many to become registered donors (2). The new Israeli Organ Allocation policy has been previously suggested but not yet implemented anywhere on a national level, except for the United Network for Organ Sharing policy to give living donors of organs priority to receive a transplant from a deceased donor should they ever need one (11) and Singapore's Human Organ Transplant Act which grants a person who has not registered any objection in respect of organ donation a priority in organ allocation over a person who has registered such objection (12). Our preliminary results have indeed shown that in parallel to the significant increase in the annual number of new registered donors there has been an increase in the consent rate for organ donation from deceased donors but no causative relationship between the two can yet be claimed. It should be noted that the new prioritization in organ allocation policy was only implemented in April 2012, so that the increase in organ donation observed in 2011 could be cautiously attributed to the year-long public campaign which preceded it. So far the implementation of the new law has been well accepted by the public in general and has not been challenged in court. We can only hope that once the effects of the new prioritization policy are more extensively publicized and fully comprehended by the public, its impact on consent rate for organ donation will be further enhanced.

The banning of reimbursement for organ transplantation in countries where the procurement of such organs has either been performed against local law or where organ trade has been involved has resulted in an abrupt decrease in the number of patients undergoing kidney transplantation abroad. Most Israeli patients will not seek transplantation abroad once it is not reimbursed by law. Most of the few kidney transplantations performed abroad in 2011 were privately funded by the patients. Travel of Israeli candidates for deceased donors' organs, in particular for heart or liver transplantation, to traditional venues such as China has stopped completely since the new law has taken effect (13).

In parallel to the significant decrease of transplant tourism from Israel, local living kidney donation has significantly increased. It is hard to ascertain whether this was the result of the dwindling opportunities to receive a kidney abroad or due to the removal of disincentives for local living donation. Regardless, the end result was a marked increase in the number of living kidney donations from 71 in 2010 to 117 in 2011. It should be emphasized that the various reimbursements to authorized living donors provided by the new law do not constitute any financial incentives for living donation by themselves but merely serve as removing disincentives to those considering altruistic living donation. In addition, Israel's National Health Insurance Law grants every Israeli citizen the performance of organ transplantation from approved living or deceased donor free of charge.

Overall, the significant increase in 2011 in organ transplantations, both from deceased and living donors, has resulted for the first time since 2006 in a preliminary decrease in the number of candidates awaiting organ transplantation and in the number of potential recipients who died on the waiting list. These were not yet found to be statistically significant and should be cautiously observed over a longer follow-up period.

The new Israeli Organ Transplantation Law was approved by the Israeli Parliament one month before the Declaration of Istanbul was formalized and signed by the representatives of 78 countries around the world, yet it follows its principles almost to the word. The fundamental idea of the Declaration of 'striving to achieve self-sufficiency in organ donation by providing a sufficient number of organs for residents in need from within the country' (14), while blocking transplant tourism by banning its reimbursement, has been incorporated into the Israeli law and seems to be bearing fruit.

Changing national attitudes toward organ donation is a formidable task which undoubtedly cannot be achieved overnight. The two new Israeli laws have been formulated in response to a variety of major obstacles which were identified as being responsible for the low local organ donation rate. The preliminary results of their implementation appear promising and suggest that appropriate responses were implemented to overcome these obstacles; however only time will tell whether our expectations of increasing the organ donation rate in Israel to that achieved in most Western countries will be realized. The INTC will continue to monitor and report the impacts of the new laws on the annual donation results. Meanwhile, in the spirit of the recent call for governments' accountability to achieve national self-sufficiency in organ donation and transplantation (15), we suggest that some of the measures we have taken may have more universal application.

Disclosure

The authors of this manuscript have no conflicts of interest to disclose as described by the *American Journal of Transplantation.*

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