INTRODUCTION

A persistent shortage of transplantable organs is one of the most pressing health problems worldwide [1,2]. There is a policy debate in many countries around addressing the organ shortage for transplantation [3-7]. Broadly, there are two different systems: explicit consent (“opt-in” system) and presumed consent (“opt-out” system) [6]. In the explicit consent system, the default condition is that nobody is a donor. In the presumed consent system, every adult citizen is regarded, by default, as an organ donor unless he or she chooses to opt-out of the system. Both systems have critical drawbacks. In the opt-in system, the opportunity for discussion with family members about the organ donation of the patient is difficult. In the opt-out system, the default choice about organ donation depends on social promise and agreement, rather than the patient’s own decision. One form of organ donation...
A mathematical model was used to predict ethical legitimacy and potential efficacy of current opt-in system and mandatory choice system for organ donation after brain death in this study.

Even if the total number of donors slightly decreases in the mandatory choice system, the mandatory choice system can improve the ethical limitation of the current system by increasing achievement of autonomy in the decision for organ donation in Korea.

In the mandatory choice system, achieving of negative autonomy was more prominent than that of positive autonomy.

The mandatory choice system is needed for ethical justification rather than promoting organ donation.

In Korea, the consent from all family members is needed for organ donation in principle. However, if there is disagreement among family members, the priority of the decision making is given, in the order, to the spouse, descendant, parents, and then siblings. After sufficient discussion, the family member with the highest priority signs the consent document.

To consider Korea's consent system and simplify the mathematical model for family decision, we assumed that the family decision would be made by the spouse. To predict the efficacy and the extent of autonomy under each system (current opt-in and mandatory choice), 100 couples (200 people) were included in the mathematical model assuming that these were family groups facing the decision to donate an organ [11]. All these couples were in a legally established marital relationship. Autonomy was defined as the achievement of one's decision regarding organ donation after the consideration of the family decision in each social system [11]. A structured questionnaire was designed to investigate the decision on organ donation and family consent after brain death in each system. The survey was conducted between December 2017 and January 2018, and a professional surveyor conducted face-to-face interviews.

The participants of this study were recruited with the help of Korean Policy & Research Groups (https://www.kprg.re.kr), which is a professional survey agency. They joined this survey voluntarily after the announcement of the survey agency. Participants were neither actual family members of a brain death patient nor were they exposed to the organ donation process. Participants were free to respond according to their own opinions and could withdraw participation at any time for whatever reason. The questionnaire constituted eight questions pertaining to the decisions on one's own and one's spouse's organ donation after brain death according to the two systems. The detailed questionnaire is shown in Supplementary Fig. 1. Questions 1–4 were about opinions and decisions on organ donation in the current opt-in system, and ques-
tions 5–8 were about the opinions and decisions on organ donation under a supposed mandatory choice system. Questionnaires were designed, and the survey was performed with the help of Korean Policy & Research Groups, and IBM SPSS ver. 21.0 (IBM Corp., Armonk, NY, USA) was used for statistical analysis.

RESULTS

All of the participants completed the survey without dropping out. The mean age was 39.5 years (standard deviation, 11.0), and sex distribution was even. Of these participants, 48% were religious (Christian, 31%; Catholic, 10.5%; Buddhist, 6.5%), and 56.5% of all participants were college graduates. Table 1 summarizes the characteristics of the participants.

The responses to the survey questions are shown in Table 2, and the results of the final decision on organ donation under the current and mandatory choice systems are illustrated in Fig. 1. Under the current system, 31 of the total 200 participants surveyed answered that they were registered organ donation applicants. Of the 169 people not registered as organ donors, the numbers of persons who wanted to donate their organs were 82, while the people who did not were 87. In this situation, the final donation decision was made considering the consent of the family (spouse), and finally, 102 persons (51%) were able to donate (Fig. 1A). Of the participants, 48% were positive about the implementation of a mandatory choice system, and 20.5% were negative (Table 2). When in a hypothetical mandatory choice system, 109 of the 200 surveyed registered as applicants for organ donation on their driver's licenses, and 91 registered as not-wanting organ donation. In each situation, the consent for a donation of family members (spouses) was considered. Among 109 registered applicants, 69 spouses (63.3%) agreed to donate, and among the 91 who were not registered applicants, 24 spouses (26.4%) agreed to donate. Finally, 93 people (46.5%) were able to donate (Fig. 1B).

In a comparison of achieving autonomy (consistency between a patient's own wish and the final family decision) between the two systems, the rate of achieving autonomy was increased from 62.5% (125/200) in the current system to 68.0% (136/200) in the mandatory choice system (P=0.248). Additionally, we defined the achievement of “positive” autonomy as the percentage of final family consent given among those who wished to donate, and achievement of “negative” autonomy as the percentage of final family refusal among those who did not wish to donate. In comparing these, the achievement of positive autonomy was similar between the two systems (63.3% [69/109] vs. 61.9% [70/113], P=0.835); however, the achievement of negative autonomy was higher.
in the mandatory choice system (73.6% [67/91] vs. 63.2% [55/87], P=0.135). The total number of donors and results on autonomy are shown in Table 3.

**DISCUSSION**

How can a country raise the number of registered organ donors? This has been the question at the forefront of health policy debates for transplantation, and the transplantation industry has made various efforts to establish social systems to promote and increase organ donation. However, simply increasing donation is not the sole issue. Despite the recommended amount of organ donation by social needs, whether a system can protect an individual's autonomy or not should be considered. The effort to minimize the possibility of discrepancy between the actual donation and the patients' wish should be included in the ethical justification of a given system. Autonomy must be preserved in any legislation concerning organ donation, but how it is defined and viewed is hard to specify, and how much autonomy can be achieved in a given system is hard to quantify. The current system for organ procurement in the United States, as well as most of Europe, is presumed refusal, which is also known as the opt-in system [4,6,12]. The mandatory choice system is a prime example of how to transform the ineffectiveness of an opt-in system while simultaneously avoiding much ethical controversy [8-10]. If every individual could explicitly...
state his or her wishes prior to their death, it could remove the barrier of presumption.

Regardless of social systems, the decision of family members is another value that should be considered and is a prominent factor in most countries [13-19]. Even under a mandatory choice system, discrepancies between the patient’s status on a document and the family’s decision frequently occur. Ideally, if the patients’ declaration of their wishes exist, they would be respected more than the family’s decision; however, most countries still grant authority of the final decision to families. In this study, we identified the percentage of achieving autonomy considering the family decision in each system. Notably, the relatively low percentages of achieving autonomy in both systems show how ethically incomplete the Korean organ donation system is. However, the increase in achieving autonomy in the mandatory choice system (from 62.5% to 68.0%) is an important factor to justify this system. In addition, we have to note the achievement of negative autonomy. This comes down to respecting the choice of those who do not want to donate their own organs. When a social system for organ donation is selected, the opinions of those who do not want to donate should be respected as it is a voluntary decision. In the mandatory choice system, achieving of negative autonomy was more prominent than that of positive autonomy. Even though the consent rate of individuals in the community is high, that rate must not be applied to each individual.

In the current system, not achieving autonomy is caused by the lack of information about the patient’s desire or perspective; the patient’s wish should be considered to be the most fundamental factor for ethical justification. The discrepancy between the patient’s wish and the family’s decision in the mandatory system is caused by the naivety or negative perception of the family members. In this study, under the mandatory system, 92 spouses (46%) chose “do not donate” even though patients were registered as donors on their driver’s licenses (question 7). In addition, 72 spouses (36%) chose “donate” even though the patients were not registered as donors on their driver’s licenses (question 8). With these figures, we can specify how family members respond considering the declared opinion of patients. The authority of the declared status on the donor card must be emphasized and people need to be educated on the ethical justification of the mandatory choice system.

In this study, the decrease in the total number of donors in the mandatory choice system is an unexpected finding. However, the sole value is not the increase in organ donors; the ethical legitimacy of this event must be considered, and some proponents of the opt-out system overlook this [12,20]. The choice between the legitimacy of the process and the resulting gains is an abstruse problem in the choice of the social system. It would be ideal to promote these two values at the same time. Mandatory choice systems are generally expected to help increase donations, however, the results of this study were unfortunately reversed. This may be due to public awareness of this topic as still negative in Korea, and educational interventions that encourage donations are not generalized. The number of organ donations per 1.0 million people in Korea remains between five and 10, which is significantly lower than in the West. The negative public perception is also evident in the results: 46% of the spouses of those who declared own organ donation objected to donation (question 7). This shows that, unless the public’s perception is changed, ultimately, Korea will not be able to achieve the resultant efficiency. The mandatory system will, at least, be able to solve the ethical legitimacy problem and may improve efficiency if awareness is changed in the future.

This study had many limitations. First, owing to the small number of participants, the scope for generalization of the results of this study is limited. Second, it was assumed that the problem of family motivation would be simplified by the decision of the spouse. Realistically, this may be oversimplified; there is a dynamic relationship between various families. Third, the hypothetical mathematical model used to predict the outcomes has a limited value. In real situations where such families have to make a decision about organ donation, the state of emotional shock they may be in profoundly affects the decision [21]. Despite these limitations, we believe that the findings of this study can be used as an important reference to adopt a new system and persuade politicians and lawmakers.

Even if the total number of donors slightly decreases in a mandatory choice system, this system can improve the ethical limits of the current system in Korea by increasing achievement of autonomy in the decision for organ donation. This system is needed for ethical justification rather than promoting organ donation.
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Conflict of Interest
No potential conflict of interest relevant to this article was reported.

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Supplementary Material
Supplementary Material is available on the electronic version of this paper at the KJT website, http://www.ekjt.org.

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