Should the United States Sign Off on Presumed Consent?

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Starting in December 2015, Wales will be the first nation in the United Kingdom to break away from convention and join the twenty-four European countries that have adopted presumed consent legislation to address the stagnant transplant rate and shortage of human organs. Hailed by many ministers in the National Assembly for Wales as the "most significant piece of legislation" since the United Kingdom was granted full lawmaking powers in 2011, the law hopes to alleviate the transplant list and save the lives of those who would normally die from waiting. [1] As is the case worldwide, there is a remarkable deficiency in donor organs, which fails to meet the demand for organ transplantation. In the United Kingdom, the active transplant waiting list has increased approximately eight percent each year, with the aging population and rising incidence of type-2 diabetes likely to worsen the strain on the transplantation system.[2],[3] Support for the legislation has stemmed from the rising donation rates of other European countries, especially Spain, which has the highest rate of donors per million population (pmp) in the world, attributing this trend to the adoption of presumed consent legislation. With Wales being the latest country to go down the road of presumed consent, the question will inevitably rise: Should the United States take a more critical look at its current system of explicit consent and "required referral" for organ donation? In light of all the available empirical data, should the United States follow suit of its European counterparts and adopt presumed consent? What are the ethical concerns regarding such a proposal; and how does the nation's previous attitudes toward presumed consent shape the conversation?

Opt-out vs. Opt-in

Presumed consent for organ donation is the systematic framework in which a deceased person's consent to be an organ donor is assumed. Those wishing not to be donors must express their objection in a national registry or a family member must object to organ donation after the person's death. Thus, presumed consent differentiates itself by being an "opt-out" system, whereas the majority of the world's organ donation systems

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are "opt-in", requiring an individual to register their intent as organ donors. Advocates of presumed consent often point to the successes of European nations such as Spain, Belgium, and Austria, highlighting how their donation rates significantly increased after the implementation of presumed consent. While Spain's donation rate of 34.8 pmp is certainly remarkable on a global scale, [2,3] it is necessary to undertake a systematic review of the empirical data in order to arrive at any assertive conclusion as to presumed consent's potential for use in the United States.

In addition to the umbrella terms "presumed consent" or "opt-out" system, legislation can vary between countries, leading to the use of additional terms such as "hard" and "soft" to characterize the degree of emphasis placed on the views of the decedent's relatives.[2] For instance, in Spain physicians must take active steps to make sure that the decedent's family does not object to the procurement of their organs. Therefore, the presumed consent law in Spain is "soft." This is in direct contrast with the case in Austria where procurement will proceed under all circumstances, barring evidence of the decedent's objection before death. The law in this case is relatively "hard" because the family is not consulted by doctors about their own objections to organ extraction. Irrespective of the "soft" or "hard" terminology, both forms of presumed consent have seemingly proven to be significant factors influencing the organ donation rate. Before the enactment of the legislation, the Austrian donation rate was 4.6 pmp. Within four years the rate increased to 10.1 pmp, and five years later the rate was 27.2 pmp. Three years after the adoption of presumed consent legislation, Belgium saw a rate increase from 18.9 to 41.3 pmp; and Singapore also saw an extraordinary increase from 4.7 to 31.3 pmp over a three-year period. In 1989, Spain's donation rate was similar to that of the United Kingdom – 14 pmp – and over the past twenty years the rate has climbed to its current levels. To further contrast the United Kingdom and Spain, the rate of families refusing to give consent to organ removal has dropped to 15 percent in Spain, while the refusal rate in the United Kingdom still sits at approximately 40 percent, which is an attributing factor to the lagging donation rate overall. [4],[5]

Learning from the Spanish Experience

Have these notable increases in the rate of deceased organ donation simply resulted from the implementation of a presumed consent law? Or are there other factors that are hiding behind the numbers? The facts tend to favor towards the latter. For example, the jump from 10.1 to 27.2 donors pmp found in Austria is not only because of the presumed consent law. Rather, the five years that reflect this increase was a time of focused improvement upon the country's transplantation infrastructure, which included the training of full-time transplant coordinators.[2,6] In addition, Spain's rate increase was only measured a full ten years after the Spanish government passed the presumed consent legislation. From 1979 to 1989, the donation and refusal rate did not change much relative to the other European nations.[2,4] It was in 1989 that Spain comprehensively reformed its organ procurement system, which included a number of innovations.

In Spain, the defining characteristic of the innovations is the placement of transplant coordinators at every procurement hospital—these coordinators have a unique educational profile that helps them quickly identify potential donors. Many coordinators are intensive care physicians that play increasingly active roles in the organ procurement process, such as approaching the potential donor's family and checking for potential donors in and out of the intensive care unit on a daily basis. Because transplant coordinators are not members

of the transplant team, but rather part of the in-house hospital staff, they can be placed throughout the country and especially in hospitals that have lower rates of deceased organ donation.[4]Moreover, the coordinators are trained and organized by a central agency, the Organización Nacional de Transplantes, which provides regular courses on the organ procurement process. This model has led to more than 11,000 medical professionals being trained as coordinators since 1991.[4] Thus, it was not the new presumed consent law by itself that triggered the rise and steady maintenance of a high donation rate but a widespread overhaul of how potential donors were identified in the places they are most likely to be found: the intensive care unit.

The systematic review of various studies conducted by Rithalia et al. also indicates that a number of other factors have a positive impact on the donation rate. The most obvious component of an increased donation rate is the availability of potential donors. Without a sizeable and renewable pool of donors from which to procure organs, the donation rate will remain stagnant and will fail to respond as the need increases. Interestingly, three studies conducted in Organization for Economic Cooperation and Development (OECD) countries considered the mortality rate from road traffic accidents and showed a significant correlation with donation rate.[2] Additional studies illustrated that wealth and healthcare expenditures, measured in gross domestic product (GDP) per capita and health expenditure per capita, were strong predictors of high donation rates.[2] A review of European countries by Gimbel et al. also discovered that the percentage of the population enrolled in third-tier education, used to assess the influence of social demographics on donation rates, had a significant positive association.[7]Finally, there was an overall favorable relationship between the percent of the population that identified themselves as Roman Catholic and the donation rate.[7,][8] This result is consistent with the popular suggestion that Catholicism tends to have more encouraging attitudes toward organ donation, recognizing it as a "service of life."[2] These statistics and correlations drive home the sentiment that presumed consent in and of itself cannot account for the rise in donation rates in European countries. Nor is the adoption of a presumed consent law a guarantee that the country will achieve high donation numbers.[9] This is further exhibited in Greece, where despite "presumed consent" legislation the donation rate remains at 6.9 pmp; thus supporting the argument that economic and social factors have influential roles to play.[10]

Conclusions such as these certainly make the case that presumed consent is not the sole predictor for improving the donation rate. Evaluating, understanding, and reforming the underlying economic and social circumstances hold great promise in changing the trend of organ donation. What presumed consent could provide, however, is a framework for expanding the availability of potential donors.[11] With a national survey finding a disparity between the number of Americans willing to donate organs and the number who are currently registered as donors,[12] the discussion concerning the adoption of presumed consent takes on a more significant role and scholars have urged for this change.[13],[14],[15]

In the United States, the donation rate is 26.1 pmp,[16],[17] placing it fourth worldwide.[9] Yet, the waiting list for organ transplants has exceeded 122,000 and is anticipated to grow roughly 10 percent each year, which results in thousands of people dying while waiting for an organ.[18]This is all despite the fact that more than 28,000 transplants are performed each year in the United States, more than any other country.[16] These facts are what drive the debate in the direction of presumed consent, for if the country is to save as many people as possible who are currently waiting on the transplant list, then legislators believe that presumed consent holds the key to reforming the decades-old "opt-in," explicit consent model.

Philosophical Arguments

Promoters shape their arguments around the need to fundamentally change the American assumption that "absent specific notification to the contrary, decedents are best protected if we act as though they had autonomously willed that their organs not be donated for transplantation."[14] This is precisely the principle governing explicit consent for organ donation, in which a person during their lifetime, or a family member after their death, must clearly express the will to donate the organs. Cohen argues that this ideology should be reformed and replaced with the notion that the best way to protect the autonomous wishes of the deceased would be to assume that they would have willed for their organs to be used for "beneficial medical uses." Furthermore, he espouses the "hard" form of presumed consent, stating that no permission should be sought from anyone in the absence of express refusal from the deceased. The basis for Cohen's reasoning lies in his appeal to the moral argument: it is morally just—not only for the decedent, but also for the members of society who need organs—to remove the organs from the majority of individuals who would have wanted to donate their organs but left behind no indication of that wish. It is therefore morally unjust to violate their wishes and bury them with all their organs intact inside their bodies. Cohen characterizes this as a breach of autonomy; a breach that only a presumed consent policy would rectify, resulting in an increase in the number of decedents whose wishes are respected.

Veatch and Pitt counter Cohen's claims by asserting that presumed consent is morally unacceptable because it results in the violation of a person's fundamental right to be able to autonomously choose what happens to his or her body after death.[19] Whereas Cohen's majority would have wished to have their organs removed, Veatch and Pitt's minority prefer not to have their organs removed after death. If presumed consent were instated, then it would be easy to assume that many in the minority would fail to properly indicate their desire *not* to donate, much like the many in the majority who fail to properly indicate their desire *to* donate. What would result are instances in which individuals who wished to be buried with all their organs inside their body would have their organs removed. Veatch and Pitt posit this as a far more egregious violation of autonomy than the one found in Cohen's argument. The current system of explicit consent, therefore, is in a better position to protect autonomy and respect the wishes of those who do not wish to donate.

Michael Gill attempts to reconcile the two sides of this debate, ultimately reaching the conclusion that presumed consent provides the most morally acceptable solution. He starts by acknowledging that mistakes will be made in either consent scheme. Regardless of how well explicit consent is instituted, there will be cases where those who wished to donate their organs will be buried with their organs intact. Similarly, regardless of how well presumed consent is instituted, there will be cases where those who did not wish to donate are buried with their organs removed. Gill emphasizes the moral duty to respect a person's wishes concerning his or her body, but asserts that violating this duty by either mistakenly removing or not removing organs is equal. Both of these mistakes fail to bring about the "state of affairs the individual desired." With the moral gravity of these mistakes being equal in Gill's view, the moral question then becomes: Which consent scheme minimizes the moral harms and maximizes the moral benefits? It becomes easy to see from this line of thinking that the ethical fortitude sides with presumed consent, which is prone to make fewer mistakes than explicit consent.

How Does the United States Fit In?

Although Gill's conclusion would certainly appease those fighting for the implementation of presumed consent, his notion is meant for a country with a stronger communitarian ethic; one in which the tenets of utilitarian moralism outweigh those of individual autonomy. Such a policy, however, goes "against the grain of American individualism."[13] As Orentlicher states, the United States has actually tried presumed consent on a limited basis for the past forty years, and it failed because it went either too far or not far enough. In allowing family members to overrule the presumption that the decedent would have preferred donation, presumed consent did not go far enough. This deference to the family in regard to organ donation never allowed presumed consent to surpass the real reason why decedents do not become organ donors, namely the refusal of family members to give consent.[13] This is akin to the kind of "soft" presumed consent found in Spain. Spain places great importance upon the fact that death is not an isolated event involving the deceased, but instead engages the whole family. Spain realizes that any organ procurement system relies on the trust that exists between the patient's family and the physicians or transplant coordinators. Undermining that trust would completely damage the entire organ donation process. This serves to highlight Spain's accomplishment in keeping the refusal rate so low at 15 percent; which is achieved mainly through its extensive training of transplant coordinators, lack of donor registry , and enhanced capacity to identify potential donors.[4] In essence, the Spanish model succeeds without much need for presumed consent.

According to Orentlicher, presumed consent in the United States went too far in regard to the fact that public officials attempted to bypass family members in an effort to avoid the possibility of family refusal. Such attempts only exacerbated concerns and fears that physicians would harvest organs from those who would not have wished for their removal. Starting in the late 1960s, state legislatures passed measures that authorized the removal of corneas, pituitary glands, and sometimes even hearts, lungs, kidneys, and livers if the decedent's body came under the custody of a medical examiner or coroner. The lawmakers' reasoning was rather simple – since the body of these individuals would already be subjected to a major intrusion in the form of an autopsy, then removal of an organ for the benefit of living persons was acceptable. This practice was supported and reinforced by the 1987 Uniform Anatomical Gift Act, but has since been discarded since the document's 2006 revision and adoption by a vast majority of states.[13] Therefore, the largest hurdle for presumed consent to conquer is that of public perception and attitudes against it. Because the registration process varies from state to state, many state legislatures have tried to bring up the issue of presumed consent, proposing opt-out systems. These have never gotten very far due to concerns about individual rights—another testament to the importance of autonomy, which is present in American minds. For example, Colorado tried to pass an opt-out law in 2011, but the lawmaker who introduced the bill was forced to pull it due to negative reactions from the public.[10]

There has been abundant skepticism about the possibility of presumed consent as a solution to close the organ gap that exists in the United States.[11,][20] Researchers have concluded that despite the substantive differences in the laws themselves, presumed consent, in countries like Spain, does not differ dramatically from the application of explicit consent in the United States. In both the United States and Spain, primacy is given to respecting the wishes of the individual and the family. If anything, the experience in Spain has shown that

what can truly improve the donation rate is diligent attention to the infrastructure of the organ transplantation system, using it to quickly and efficiently identify patients in the intensive care unit who are potential donors and taking the necessary steps to ensure that the organs are procured ethically and respectfully once death occurs. With respect to the procurement system currently in place in the United States, legislation was introduced by the Surgeon General that legally requires all hospitals to identify and refer potential donors to an organ donor organization.[3] Potential donors are identified using clinical markers that are present in patients likely to be diagnosed as brain dead, and organ donor organizations are well-staffed with an extensive network of trained organ coordinators.

Alternatives to Presumed Consent

Comparatively, the transplantation environment of Spain and the United States is very similar. What is lacking, then, in the United States is not the adoption of presumed consent, but a method of improving the family refusal rate. This can be achieved through public policy that aims to increase the likelihood that individuals will document their wishes. Family members who are aware and confident in the decedent's wish to donate his or her organs after death are more likely to respect these wishes and consent to organ procurement upon request. Orentlicher suggests that if everyone willing to donate were to officially register, then organ donation rates could increase by as much as 50 percent.[13] Efforts such as the Hero Act in New Jersey have taken the initiative by mandating that New Jersey public schools provide information about organ and tissue donation and that material be included in the state's Core Curriculum Content Standards for Comprehensive Health and Physical Education for grades 9–12.[21] The goal is to ensure that all residents have the "fundamental responsibility to choose whether to help save another's life."

Overcoming high refusal rates can also be done by combating the misconceptions that seem to be at the root of the refusals,[13] such as the notion that organ donation violates certain religious ideals or that donation would affect the body's appearance at an open casket funeral. Motivated physicians dedicated to the cause of organ donation have been the key for success in Spain,[4]and as such, physicians in the United States must develop the skills to delicately approach families. Gortmaker has found that this is best realized when the discussion about the patient's death is separated from the discussion about organ donation, when organ procurement professionals join with hospital staff in the donation discussion, and when the request for donation takes place in a quiet, private setting.[22] Procurement professionals have also begun utilizing a "presumptive approach" when discussing organ donation with families, which is an approach that takes on a more value-positive tone and strives to encourage the family to consent to donation.[23] Application of strategies such as these may see refusal rate in the United States drop significantly, altering the transplantation landscape in ways that presumed consent legislation simply could not.

In all, the talk about presumed consent seems to have taken a back seat since its abandonment in the latest version of the Uniform Anatomical Gift Act and public sentiment has proven to be a difficult obstacle to clear in recent years. Although it may always seem like an attractive solution to an issue that is at the forefront of medicine, the data illustrates that presumed consent is not what the United States is clamoring for. It begs for a solution that makes use of the current organ procurement infrastructure, expands the base of information available to potential donor registrants, and continues to build upon the trust between families and hospitals.

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