

Presumed Consent for Organ Donation

Perspectives of Health Policy Specialists



In contrast to the growing organ shortage in the U.S., other countries' use of a presumed consent policy has increased donation rates. There is currently a lack of research addressing the political feasibility of a presumed consent policy. This study mapped the terrain of opinions among health policy specialists regarding presumed consent as an organ donation policy. Fifteen health policy specialists from Congressional and Senatorial offices on committees that deal with legislation related to healthcare were interviewed. Analyses were conducted using the qualitative methodology of grounded theory and constant comparison. Study participants' responses were clustered in six categories: semantics of 'presumed consent;' semantics in policy making; 'specified refusal' as a replacement term; political feasibility of presumed consent; factors influencing the outcome of presumed consent; and objections to presumed consent. This study found that responses to 'presumed consent' as a label were negative, such that renaming the policy, perhaps to 'specified refusal,' should be considered. The findings also suggest that methods of public education and communication (especially the media response) may influence the feasibility of passing presumed consent legislation. The results of this study additionally indicate that a presumed consent policy may have more political feasibility on a state rather than federal level.

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Every day in the United States, 17 people die waiting for an organ transplant. The number of people on the waiting list for an organ has more than tripled over the last ten years and now exceeds 82,000 individuals; at the same time, the number of donors has remained relatively stagnant (OPTN, 2004). In 2001, 6,439 people died while waiting for a transplant, nearly double the 3,916 candidates who died while waiting just five years earlier in 1996 (OPTN, 2004; The Lewin Group, 2000; Wright, 1998). Neither the waiting list nor the number of patients who are dying each year is showing any sign of decrease – instead, there is only an increasing organ shortage crisis in the United States.

There has been much debate on the influence of policy on organ donation rates. While the United States operates under a system of 'expressed volunteerism,' with consent received from donors and their families, other countries such as Spain, Belgium, and Austria use an 'opt-out' policy frequently referred to as 'presumed consent.' Although the exact implementation varies, the general

concept is that individuals opposed to donating their organs may list their objection on a national registry, rendering them ineligible to donate. People who do not register are considered eligible to be donors unless their family specifically objects.

Organ donation rates in Spain, Belgium, and Austria suggest that presumed consent might have a positive effect on rates of organ donation. In 1999 Spain had an organ donation rate of 33.6 donors per million people (a 142% increase in ten years) while in the same year, the United States had 21.8 donors per million (Matesanz et al., 1996; Matesanz and Miranda, 2000). Spain's success was not necessarily the result of presumed consent, as its infrastructure and education systems greatly improved during that same time period, but the effect of Spain's policy change to presumed consent may have been an important factor. After Belgium passed presumed consent legislation in 1986, its donation rates also rose dramatically (Michielsen, 1996). A frequently cited example is that of two similar transplant

centers in Belgium – one in Leuven and one in Antwerp. Leuven switched to presumed consent with the passage of the law and in three years, its donation rate climbed from 15 to 40 donors per million, while Antwerp did not change its policy and only maintained previous levels (Kennedy et al., 1998). In Austria, presumed consent became law in 1982, and by 1990, the rates of donation had quadrupled, to the point where the number of patients awaiting kidneys nearly equaled the number of kidney transplants performed (Gnant et al., 1991). Implementation of presumed consent was followed by increased organ donation rates in these three countries.

Higher rates of organ donation not only result in saved lives, but frequently in saved financial resources. Spain estimates that its 10,000 renal transplants save approximately \$207 million every year (López-Navidad et al., 2002). Compared to dialysis, transplanting a kidney is beneficial both in quality of life for the patient and in money spent. In the United States, there are currently over 50,000 people on the waiting list

for kidney transplants, which potentially represents a large savings in healthcare expenditures.

Although studies have discussed both the ethics and the merits of presumed consent in the United States, there is a lack of research addressing the political feasibility of the policy (political feasibility being the possibility of a policy proposal actually becoming law). Efficacy alone will not determine if presumed consent can be adopted in the United States. Understanding the cultural, societal, and political climate is also necessary to determine a solution to the rising shortage of organs.

This study mapped the terrain of opinions among health policy specialists in Washington, D.C. regarding presumed consent as an organ donation policy. Study of the perspectives of members of this community can lead to a better understanding of the political feasibility of an 'opt-out' organ donation policy for the U.S.

Methods

Participants and Procedures

A staff member involved with health legislation from the office of each Member of Congress from the Subcommittee on Health and the Environment (part of the Energy and Commerce Committee, 31 offices total) and from the office of each Senator from the Health, Education, Labor and Pensions Committee (21 offices total) was contacted requesting participation in the study. Of the 52 offices contacted, 14 did not respond and 18 declined participation. The remaining 20 offices agreed to be interviewed, though at the time of interview, five did not consent to the informed consent sheet and were not interviewed. Two reasons were given for declining participation: an office policy not to participate in any form of research (22 offices); and a lack of a staff member focused on health issues (one office).

These offices were selected because they work with the committees where legislation relating to organ donation

would likely be submitted and reviewed. These offices were also likely to have staff members who focus on health policy. Participating staff members had the title of Legislative Director (1), Legislative Aide (13), or Legislative Correspondent (1). All focused on health issues alone or healthcare along with one or two other topics.

Semi-structured interviews were conducted with each participant following a field guide, and participants were encouraged to comment freely about their opinions. Interviews lasted between 30 and 90 minutes, and field notes were written during the interview and immediately afterwards. Confidentiality was assured. This study was approved by Stanford University's Institutional Review Board.

Analyses

Transcripts of field notes from the fifteen interviews were read and reread. Statements pertaining to presumed consent were excerpted. These statements were analyzed together using hard-copy analysis¹ and NVivo qualitative analysis software and hard-copy analysis. An experienced team of qualitative researchers used a constant comparative methodology. This grounded approach sought to 'map the terrain' of study participants' perspectives on presumed consent as an organ donation policy. Study participants' statements about presumed consent clustered in six categories.

Results

The six categories that the excerpted statements reflect specific issues repeatedly mentioned in the interviews. For each category, citations are listed to give a sense of the nature and range of participants' stated perspectives.

Terminology of 'Presumed Consent'

The most striking theme that emerged was how these staff members who work with health policy responded

negatively to 'presumed consent' as a term. Some informants considered the term to be a major barrier to the policy's acceptance by the public. The term was associated with assuming an individual's choice and the taking away of rights.

Citations:

'Presumed consent seems coercive.' 'It sounds like it takes away a patient's rights, period.' 'Presumed consent has negative connotations. It sounds like something is being taken away. It sounds like the opposite of informed consent.' 'Presumed consent sounds like you're thinking something about me without asking me.' 'I wouldn't use it in my media.' 'Presumed consent is a dicey term on the continuum of stem cells.'

Importance of Semantics in Policy Making

Related to the previous category, informants indicated that semantics play a large role in the passing of legislation. All responding participants agreed that how a policy is perceived is critical. Other examples of recent issues where naming has mattered were mentioned, such as the stem cell debate and medical liability reform.

Citations:

'If you are going to try to get a [bill] passed don't call it presumed consent. Words definitely matter.' 'Names [do] matter on the Hill. Washington, D.C. is all about semantics.' 'Terms matter in a debate.' 'The worst outcome would be if [presumed consent] were villainized; it could go the way of cloning in a debate.'

Specified Refusal as a Replacement Term

Informants were asked if the term 'specified refusal' would be better than 'presumed consent.' While the policy specialists thought the term accurately described the organ donation policy, responses varied significantly among interviewees as to whether the term "specified refusal" would be better.

Citations

'Specified refusal is too cold. It needs something more.' 'It sounds more clean and less hairy.' 'It doesn't draw the same immediate suspicions, but it is splitting hairs.' 'Presumed consent is lost on the public, but it is probably as good as it can get.'

Political Feasibility of Presumed Consent

Interviewees' comments cast doubt on the chances of presumed consent legislation being passed at the federal level. Most informants indicated that federal legislation is not currently a possibility, and suggested that this issue may be better addressed as a state ballot measure. Some thought that organ donation policy is a state issue and should not be legislated by the federal government.

Citations:

'It is theoretically a good idea... but half the people in Congress wouldn't go for it.' 'It has no political feasibility federally. It should be done state-by-state, but organs fly all over the U.S., so it would be complicated.' 'It should be done as a ballot measure.' '[Legislation would] bring donation to the national forefront and help to educate the population, even if the legislation isn't passed.' 'It is worth doing in a state ballot. It can't go zero to 100 percent on the federal level.... For it to work on the federal level you would need a crisis beforehand.' 'No, it isn't politically feasible on the federal level. Organ donation is more of a state issue. It might be feasible on the state level.' 'I can't imagine it going through federally; it is too big a step. If a state were to pass a bill first, then federally we could look at it again.' 'I also see this as a States' Rights issue.'

Factors Influencing the Outcome of Presumed Consent

Many interviewee comments dealt with factors that might alter presumed consent's political feasibility and its acceptability by the public. These

statements fit into two subcategories: education and communication.

Education and Knowledge of Presumed Consent

There was disagreement between informants regarding the effects of education and public knowledge of presumed consent on the policy's acceptability and effectiveness at increasing donation rates. While some felt that presumed consent would only raise donation rates if the public were uninformed, others believed education is critical to avoid a backlash by the public against the policy. Also mentioned was the possibility that public outcry and media attention itself would actually lead to greater awareness and higher donation rates as the public learns about the organ shortage.

Citations:

'Without education there would be public outcry and a backlash.' 'Some people would object but the outcry would provoke discussion and raise awareness.' '[Presumed consent] would increase donation if people don't know about it, but the numbers would stay the same if people are knowledgeable.' 'Maybe we should go into schools to educate people about organ donation. Presumed consent could backfire without education.'

Media and Communication Affecting Presumed Consent Acceptance

Considering the extent of media coverage in politics and healthcare, it is not surprising that informants repeatedly suggested that the nature of presumed consent's media coverage would be important to how the public responds. Additionally, it was suggested that healthcare policy requires good publicity and marketing.

Citations:

'Where I'm from, people don't like big government. But whether or not presumed consent would work would depend on the publicity.' '[Political feasibility] would depend on the com-

munication campaign.' 'Presumed consent would have to go through a lot and would need media and public support.' 'It would need good media coverage.'

Objections to Presumed Consent

Respondents frequently suggested problems they had with presumed consent, and the responses were quite varied. Objections ranged from concerns about exploiting minorities, to respecting religious and cultural beliefs, to issues of spending and individuals' inherent rights.

Citations:

'I don't want a system that leaves out the exception to the rule. Presumed consent is fine if opposition is allowed, but what if English is not the first language?' 'I don't think that's right; it's unethical. People have religious, cultural, and ideological beliefs.' 'There are rights you are entitled [to] regardless of registry. People in our district don't even pay their federal taxes and don't think the government should know their income.' 'Why not just spend the money to educate people about the current system?'

Discussion

Methodological issues

The informants were selected because they worked for committees that would be the first to deal with legislation related to organ donation policy. Many offices chose not to participate in this study, frequently due to office policy against participating in research. Because of this policy, the number of respondents was reduced, and it is unsure if the responding offices have differences that result in biased results. Republican and Democratic offices were represented from both the House and Senate committees.

The interviews were conducted by a single interviewer who followed a semi-structured interview field guide. The analyses of the interviews were conducted primarily by the author, who

conducted the interviews, but the categories were determined by a team of researchers using a constant comparative methodology. There is still a certain risk that some phenomena were exaggerated and others overlooked, though working within an analysis team should have minimized this possibility.

Terminological Issues in Organ Donation Policy

The results indicated that health policy specialists in Washington, D.C. had significant problems with 'presumed consent' as a term. Informants indicated the term had negative connotations, sounded coercive, and would be difficult for the public to understand. 'Specified refusal' received mixed responses as an alternative to 'presumed consent'. Some considered this terminology such a problem that continuing to name this 'opt-out' policy presumed consent might prevent its adoption as policy.

Without exception, participants believed that 'words matter' in the context of policymaking. Additionally, positive media coverage and the right public education were labeled as factors influencing whether or not presumed consent would be accepted and passed into law. These findings suggest a significant change in how addressing the organ shortage from a policy standpoint

should be approached.

Having a policy that can potentially increase rates of organ donation is not enough in and of itself. These informants, who are involved in the creation of health policy, suggest that semantics and marketing are just as important as efficacy in influencing political feasibility.

Federal Political Feasibility of Specified Refusal

Many of the responses suggest that an 'opt-out' organ donation policy would not be passed as federal legislation. Some respondents felt it would be too great a step, while others were concerned that organ donation policy is not the responsibility of the federal government. However, many suggested that such a policy would be much more acceptable at the state level, and more specifically as a state ballot initiative that the public itself would vote on. Informants felt that regardless of such a bill's passage, the discussion that such a vote would generate could broadly increase awareness and donation rates.

Implications of this Study

This study has identified several issues for consideration by those seeking to increase organ donation rates

through policy changes, particularly through any form of presumed consent. The terminology describing this organ donation policy may need reevaluation. This study's results indicate potential negative consequences of using the term 'presumed consent;' a different label and a change of title, perhaps to 'specified refusal,' needs to be considered. Also, although literature exists on the effectiveness of an 'opt-out' policy, research is needed regarding how best to educate the public about new organ donation policy and how to communicate effectively with the media. Informants in this study felt that both education and communication could strongly affect the outcome of presumed consent legislation. Beyond efficacy, several factors may contribute to a policy's success, and their importance should not be ignored. Another potential implication is that new types of organ donation policy should first be tried on the state level. Informants expressed resistance to any sudden change, and many suggested that first passing legislation in a state would increase the chance of federal legislation.

Author Notes

* The key features of the data analysis and coding process are (1) Explicitly stating what each excerpt conveys (and convincing other member/s of the coding team that your characterization is correct). (2) Explicitly justifying why a particular excerpt is being placed in a particular category/cluster (and convincing the other member/s of the coding team that your categorization of this item is correct).

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Kenneth Gundle is a junior majoring in Human Biology with an Area of Concentration in "Biological and Social Issues in Organ Transplantation." He first became interested in organ donation policy during a class entitled "The Nation's Health." The research presented here was supported by a Chappell-Lougee Scholarship and a Haas Summer Fellowship. Readers interested in learning more about presumed consent should contact the author or visit www.presumedconsent.org. Kenneth would like to thank his mentors for their insight and encouragement throughout his research, and his family for their constant support. He would like to thank his mentors Linda Hogle, Stan Wanat, Philip Lee, Geoffery Heller, and Barbara Koenig