Do Presumed Consent Laws Raise Organ Procurement Rates?

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Abstract: In Western countries, the legal procurement of cadaveric human organs is everywhere organized as a gift-exchange. Yet despite this basic similarity, donation rates vary widely, and this fact is often overlooked in debates about the merits of gift- versus market-based systems. I investigate the sources of variation in procurement rates using time-series data from seventeen OECD countries. I focus on the effect of laws that (at least in principle) allow for the consent of the donor to be presumed, and the wishes of the next-of-kin to be overridden. Countries with presumed consent laws are found to have higher procurement rates, but the effect is relatively weak. Evidence from two presumed-consent countries where procurement rates have grown rapidly (Spain and Italy) suggests that presumed consent laws are a marker for organizational practices that boost procurement rates rather than real causes of higher donation.

Gift-giving and voluntary donation are the standard ways of obtaining organs for transplant, particularly organs like hearts and lungs which must come from the dead.1 Yet this gift-exchange does not happen everywhere in the same way or to the same extent. Despite the universality of voluntary donation, there is considerable cross-national variation in donor procurement rates. Some countries do much better than others. This variability has not received the attention it deserves, partly because the dominant ethical and policy debates focus on the relative merits of voluntary versus market systems. This has had two consequences. First, these debates tend to draw a sharp contrast between gift- and market-based systems, encouraging us to think in terms of a clear choice between the two. The assumption is that once the overall exchange system is fixed, certain consequences for the volume and composition of the supply will tend to follow more or less directly. Second, there is a tendency for

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1Donation is also the main source of organs from living donors, a growing illegal trade in organ sales notwithstanding. See Scheper-Hughes (2000) and Cohen (1999) for accounts of the black market in organs.
debates about systems to become debates about motives: that is, arguments about gift versus market exchange shade over into discussion of altruistic versus selfish individuals. Of course, systems and motives are not unrelated: institutions may be characterized by the incentives they provide. They may attract different sorts of individuals to participate in them, or elicit different responses from the same kinds of individuals (Le Grand 2003, Frey 1997). But in general, too sharp a distinction between exchange systems will tend to mislead us, as will an overly narrow focus on individual motivations. The performance of actually-existing systems of organ procurement varies widely. I shall argue this variability has its roots in structural and organizational differences between systems rather than differences in individual dispositions to give.

This article presents a comparative study of rates of cadaveric organ procurement in seventeen OECD countries between 1990 and 2002. Although the experiences of other countries are sometimes drawn on in debates about transplant policy in the United States, this typically happens in a piecemeal or anecdotal way. Spain is the country most commonly cited in the English-speaking literature, because it has high rates of organ procurement and a different legal regime from the United States. In the “Spanish Model,” the story goes, “presumed consent” laws allow donor organs to be procured over the objections of the donor’s family or next-of-kin. Advocates of a presumed consent solution in the United States and Britain point to Spain’s high rate of donation as evidence that such a system works, and argue that other countries have also successfully implemented this model. While these arguments rely on claims about macro-level outcomes (such as differences in procurement rates), they quickly become bioethical disagreements over the autonomy of donors and the proper role of families. The ethical issues are difficult and important, but they should not lead us to forget the empirical questions that underlie them. Is it really true, for instance, that presumed consent laws make for more donors? Do they really work in the manner claimed by their advocates? By analyzing variation in procurement rates across countries and over time we can go some way towards answering these questions in terms of the particular experiences of different societies.

In the process, I hope to demonstrate the value of a broadly sociological approach to questions of organ procurement and donation. Modern debate about exchange in human goods begins with Richard Titmuss’s The Gift Relationship (Titmuss 1971), the classic study of the blood supply in Britain and the United States. Titmuss was concerned with the organizational and institutional conditions needed to ensure a safe and adequate blood supply. His argument emphasized the relationship between individual motives and the broader context of exchange, whether created by the state (in the U.K.) or by the presence of for-profit sales (in the U.S.). But the promise of Titmuss’s comparative approach was not realized in the debate that followed the book’s publication. Instead, The Gift Relationship became best known for its main
finding that altruistic donation was safer and more efficient than for-profit donation. The implicit idea that alternative ways of organizing the blood supply might lead to widely differing national outcomes — even when most systems were nominally gift-based — was not systematically pursued. We know, however, that rates of blood and organ procurement vary widely. It is also clear that neither form of donation (especially organ donation) could happen without an elaborate organizational and institutional apparatus, regardless of the general willingness of individuals to donate. We should therefore examine the social organization of exchange in organs, focusing on how procurement agencies systematically create opportunities to give and work to produce a public understanding of why donation is worthwhile. I develop, defend and apply this idea at greater length elsewhere (Healy 2006). Here I examine one aspect of it, namely the role of the legal environment in producing the organ supply. The law must obviously play some role: if market transfers are illegal, this will clearly affect the composition of the supply, and perhaps also its size. In the case of cadaveric organ donation, countries differ mainly in the way the law says the consent of donors must be obtained. How do these laws affect procurement rates?

THE SOCIAL ORGANIZATION OF PROCUREMENT

Cadaveric organ donation is generally thought of as a matter of individual altruism, but it can only happen in certain highly organized circumstances, subject to very tight logistical constraints. This makes it a distinctive kind of voluntary action. Despite the overwhelming emphasis on the motives and personal characteristics of individual donors and donor families, both in popular coverage of donation and the research literature, it makes more sense to treat donation as a procurement or resource-extraction problem faced by the organizations responsible for the organ supply. From this perspective, all organ procurement organizations face a similar set of constraints. Accident victims and other transplant candidates must be transported to hospitals quickly if they are not already there. Hospitals need to be able to deal with critically ill or brain-dead patients and quickly identify potential donors. Procedures need to be in place for stabilizing the condition of donor candidates and determining that brain death has occurred. Procurement teams must be available to confirm that donation is a possibility, obtain consent from the relevant individuals (most often the next-of-kin), and carry out the required surgery. Once procured, organs must be quickly distributed to patients awaiting transplants. All of this must happen in a very short period of time. These demands entail a complex infrastructure, which in turn presupposes a considerable amount of investment in personnel, equipment and organization.

While the logistical constraints are universal, each of them opens up the possibility
of variation, because different organizations and health systems will produce different solutions. Medical systems will be more or less well-funded and well-managed; procedures will be more or less useful and followed to a greater or lesser degree; personnel will be trained in different ways or have different concerns.

Evidence of cross-national variation in donation rates is sometimes cited in public policy debates about transplantation in the United States and, recently, in Britain. Specifically, the fact that countries with high rates of organ procurement also have “presumed consent” laws is a common trope in debates about the future of organ donation. The distinction between presumed consent and informed consent is the most directly observable difference between national procurement systems. In the next section I describe these legal regimes and assess the extent of our knowledge about them. I then describe cross-national variation in procurement rates and the forces — including these laws — that might be responsible for differences between countries.

Presumed and informed consent laws

The idea of “presumed consent” is clear enough in principle. In the absence of a clear prior statement to the contrary from the potential donor, the law assumes that consent for procurement has already been given. Those who do not wish to be organ donors after their death must make a choice in advance to opt-out of the procurement process. This is done by signing on to a central registry of non-participants. Procurement coordinators check this registry when faced with a potential cadaveric donor in hospital. The main consequence of a presumed consent law is that there is no need to look for evidence that the donor supported the idea of organ donation: consent is assumed, absent a recorded decision to opt-out.

The most important implication of this view is that the donor’s next-of-kin should no longer play a role in the procurement decision. In its pure form, a presumed consent system works by taking the donor-to-be’s decision as sovereign and then switching the “default setting” for this decision to “yes.” The latter move can be justified on the utilitarian grounds that it should result in more donors. But supporters also point, in that public opinion surveys typically find a high degree of support for organ donation in principle. Where no recorded objection exists (and subject to some conditions like making the option to opt-out easy to pursue), it is therefore reasonable to assume that a potential donor supported the idea of donation.

In an “informed consent” system such as the United States, by contrast, neither of these assumptions is made. Donors must opt-in to the donation system and, absent a recorded decision, no assumptions are made about their views. More importantly,

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3Parliament in Britain recently held a debate about the possibility of introducing a presumed consent system. Supporters pointed to the experience of Spain and Belgium.
even when they do opt-in (for instance, by signing an organ donor card), this is generally not sufficient for procurement to take place. The consent of the next-of-kin or donor family is almost always required, assuming they can be found. Refusal of consent by donor families results in a substantial loss in donated organs (Siminoff et al. 2001). The possibility of removing the family from the decision process is therefore attractive to some transplant advocates. They argue that a presumed consent system would better respect the wishes of the donor, as it is not uncommon for grieving families to refuse consent to donate even when there is evidence that the candidate would have wanted to donate his or her organs.

It is important to note that the role of the next-of-kin complicates both presumed consent and informed consent systems. A fully-realized system of informed consent would employ a national “opt-in” register. Everyone would be required to make an informed decision about whether they wanted to become a donor if the circumstances ever arose — that is, after their deaths — and have it recorded and witnessed in a legally-binding way. Under such a system, the next of kin’s wishes should not play a role either, as the donor themselves would have made their own decision in advance. Signing a donor card (or a form on the back of a driver’s license) in the presence of a witness should provide enough information about the informed consent of potential donors. But in practice, the signature of the potential donor is not decisive. The United States is typical of informed consent countries in that the donor’s next-of-kin will make the final decision. Although procurement co-ordinators may point to any available evidence about what the potential donor would have wanted, in general they will not go against the wishes of the family — even if they would technically be within their rights to do so. They fear a violent backlash against transplantation led by families whose wishes were not followed.

The organizational obstacle to a fully-realized informed consent system is that it is impractical to require everyone to make their choice in advance and then efficiently keep track of their decisions. Most people do not consider it likely that they will be killed in a car crash or other sudden accident. For this reason it is difficult to get people to seriously think about the issue in advance. It also makes it difficult to assume that their consent is fully informed in some relevant sense, even if they fill out the paperwork quickly while in line at the DMV. The Netherlands comes closest to a full informed-consent system. Almost a third of the population are on the donor registry and their recorded wishes carry more weight than the family’s objections, although the latter are still considered. Supporters of presumed consent laws argue that the default decision needs to be shifted. This is partly because it is more convenient to put the burden on people to opt-out rather than to find a feasible way to make everyone opt-in; partly because it might better respect the weight of public opinion; and partly because removing the next-of-kin from the consent process might boost donation rates. Advocates for presumed consent argue that other
countries have successfully implemented this kind of policy. For example, the U.S.-based Presumed Consent Foundation claims that “Presumed Consent works well in other countries where it has been instituted — Austria, Spain, Portugal, Italy, Belgium, Bulgaria, France, Luxembourg, Norway, Denmark, Finland, Sweden, Switzerland, Latvia, Czech Republic, Slovak Republic, Hungary, Slovenia, Poland, Greece, and Singapore.”

Despite these claims, systematic comparative analysis of organ procurement rates is almost non-existent. It is not even clear whether presumed consent countries really do bypass the next-of-kin in the procurement process. On the question of presumed consent, then, three main questions need answering. First, which countries operate procurement systems where the law at least nominally implements presumed consent? Second, how do these laws work in practice? And third, how much of a country’s success in organ procurement is in fact attributable to its legal consent regime? It may be doing most of the work, or it might be that other features of a country’s institutions, the beliefs and attitudes of its population, or general environmental factors beyond the control of a procurement organization are responsible.

There is a stronger and a weaker sense in which a country might be said to have a “presumed consent” system. In the stronger option, doctors would be granted two powers. First, they could presume the consent of any donor who has not formally opted-out of the system in advance (by adding his or her name to a registry of non-participants, for instance). So no further checking into the wishes of the deceased is required. Second, once consent had been established in this way, they could procure organs even over the objections of the donor’s family or next-of-kin. In this case, the presumed consent law simplifies the procurement process by making putting the onus on potential donors to signal their unwillingness to participate, and by removing the family from the donation process. This sort of law is what advocates and critics generally have in mind in the United States when they discuss the possibility of introducing presumed consent legislation.

The second, weaker option would only grant the first of these powers. Consent is presumed only in the sense that the default option is moved from “No” (or perhaps “Ask”) to “Yes.” But the next-of-kin still participate in the process, and may decide to veto procurement if they wish. Veatch and Pitt (1995) argue that most “presumed consent” systems actually take this second form, and so should be called “Required Request” or “Routine Salvaging” systems instead. The available evidence supports this claim. Table 1 summarizes consent law and other available information about donor registration and procurement practice for seventeen OECD countries. The first column shows the nominal legal regime, as defined by each country’s law governing

\[^4\]See Roels and DeMeester (1996) and Gimbel et al. (2003) for rare exceptions.
organ donation and transplantation. The second and third columns show available information about donor registries. Both pure informed consent and presumed consent systems could have full donor registries, but this is not always (or even usually) the case. No country has a fully comprehensive registry of any kind, opt-in or opt-out. The fourth column shows information on whether “required request” laws exist, and the final column shows whether the wishes of the next of kin may, in practice, determine the outcome of the procurement process.

Table 1: Organ Procurement Regimes for selected OECD countries

<table>
<thead>
<tr>
<th>Country</th>
<th>Legal Regime</th>
<th>Registry Type</th>
<th>Population covered (%)</th>
<th>Required Request</th>
<th>Kin Veto</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Informed</td>
<td>Yes</td>
<td>24</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Austria</td>
<td>Presumed</td>
<td>Only No</td>
<td>0.05</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Belgium</td>
<td>Presumed</td>
<td>No and Yes</td>
<td>2</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Canada</td>
<td>Informed</td>
<td>Only Yes</td>
<td></td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Denmark</td>
<td>Informed</td>
<td>Yes and No</td>
<td>4.25</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Finland</td>
<td>Presumed</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>France</td>
<td>Presumed</td>
<td>Only No</td>
<td>0.05</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Germany</td>
<td>Informed</td>
<td>Pending</td>
<td></td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Ireland</td>
<td>Informed&lt;sup&gt;a&lt;/sup&gt;</td>
<td>None</td>
<td></td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Italy</td>
<td>Presumed</td>
<td>Yes and No</td>
<td></td>
<td>Yes</td>
<td>Yes&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>Netherlands</td>
<td>Informed</td>
<td>Yes and No</td>
<td>29</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Norway</td>
<td>Presumed</td>
<td>None</td>
<td></td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Spain</td>
<td>Presumed</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sweden</td>
<td>Presumed&lt;sup&gt;c&lt;/sup&gt;</td>
<td>Yes and No</td>
<td>13</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Switzerland</td>
<td>Presumed</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>U.K.</td>
<td>Informed</td>
<td>Only Yes</td>
<td>15</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>U.S.A.</td>
<td>Informed</td>
<td>Only Yes</td>
<td></td>
<td></td>
<td>Yes</td>
</tr>
</tbody>
</table>

Notes: Data from World Health Organization (1994), Gäbel (2003), Wolfsast (1999) and national organ donation agencies. <sup>a</sup>In practice, but no law. <sup>b</sup>If a donor is registered, the family’s wishes carry less weight. <sup>c</sup>National legislation is Informed Consent, but 15 of 23 Cantons have Presumed Consent laws. Blank entries mean information was not available.

All informed consent countries have an effective kin veto, regardless of their donor registry system. However, it turns out that the same is true of almost all presumed consent countries. They, too, generally allow the family to refuse consent. Austria is the only country with a strong-form presumed consent system, where family or next-of-kin have no involvement in the procurement decision (McCunn et al.

<sup>5</sup>Switzerland is the only case which is difficult to classify, as it has a national Informed Consent law but a majority of its Cantons (15 of 23) have presumed consent laws. Here I classify it with the presumed consent countries.
2003, Fitzgerald et al. 2002). After Austria, Belgium’s practices are the next strongest. It has a strong presumed consent system which nevertheless does allow the next-of-kin a role in the procurement process (Roels 1998, Roels and DeMeester 1996, Roels and Vanreunterghem 1996, Roels et al. 1991). In other countries — notably France, Norway, Sweden, and Italy — the de jure presumed consent system still nevertheless allows a de facto kin veto.

Table 1 shows right away that the most straightforward story about presumed consent cannot be true. If almost all presumed consent countries in fact allow the next-of-kin to refuse consent for donation, then any success in procurement cannot be due simply to a law that permits doctors to override the wishes of families during the donation process. With this in mind, we can still ask whether it is in fact the case that presumed consent countries do better than informed consent countries. Presumed consent laws may still play an important role, even if it is not the one advocates imagine.

Cross-national trends in procurement rates

Procurement rates show substantial cross-national and longitudinal variation. Figure 1 shows the number of cadaveric donors per million population for seventeen advanced capitalist democracies between 1990 and 2002. Countries with informed consent laws are shown in the top row and presumed consent countries are on the bottom. Countries are organized by average procurement rate in each row, from lowest to highest reading left to right. The scale of each panel in the figure is the same, so trends are directly comparable across countries.

National procurement rates vary in the volatility of the time trend (its tendency to bounce around from year to year), the pattern of relative growth or decline over time and the overall average rate observed. Larger countries (the United States, Britain, Germany) show less volatility from year to year than smaller countries (Ireland, Belgium). Between one third and one half of the countries show a relatively flat profile or a slight decline over the period: Australia, Germany, the U.K, and Canada are most clearly in this category, with Denmark, Ireland and Finland showing more volatility from year to year around a more or less unchanging mean. Procurement rates in the Netherlands, Sweden, Switzerland and Norway tend to decline over time, though each of the latter three cases experiences a short period of growth in the late 1990s that does not seem to have been sustained in more recent years. By 2002, the procurement rate in each of these countries had fallen to back to or below the starting point in 1990. In France, rates decline until 1997 and then steadily increase thereafter. The United States shows slow but consistent growth over the whole time period. The two most striking cases are clearly Italy and Spain. Both these countries show continuous, rapid growth over the whole period. The main difference between them is that Spain
Figure 1: Procurement Rates per Million Population, 1990-2002, for seventeen OECD countries. Informed Consent countries are shown in the top row; Presumed Consent in the bottom row. Rows are ordered from lowest to highest median procurement rates.
begins with the highest procurement rate (by far) while Italy is initially the poorest performer after Australia.

Comparing the top and bottom rows of Figure 1 suggests that average procurement rates tend to be a little higher in countries with presumed consent legislation than in those with informed consent rules. What might explain this difference? And what other factors should predict national procurement rates?

*How might presumed consent laws affect procurement rates?*

There are three ways that presumed consent laws might be associated with higher procurement rates. First, and strongest, presumed consent laws may allow for the next-of-kin’s wishes to simply be ignored in the procurement process, and so all potential donors become actual donors, with no loss due to refusals by the next-of-kin. We now know, however, that this cannot be the right explanation. Almost all countries with presumed consent laws allow for the next-of-kin to be consulted and even have a deciding say. Austria is the only true exception, and perhaps also Belgium to a lesser degree. Outside of this one case, any effect presumed consent laws have cannot be due to them removing families from the procurement process.

This does not mean these laws have no effect. A second possibility is that presumed consent laws function as a signaling device to the population at large and next-of-kin in particular. Having a presumed consent law shifts the question facing donors and especially their families. Rather than being asked “Can we have your permission to go ahead?,” families are instead asked something like “Do you have any reason to think the donor would have objected?” This is a small but significant shift. With respect to public opinion, in such a system presumed consent laws would express a social norm or collective expectation about the default course of action. Donation is still a choice, but saying “yes” is assumed to be the standard option, rather than a special decision for which consent must be specially sought. In the context of actual procurement requests, this means that the next-of-kin retain the right to object, but their role in the decision process is somewhat different. They must actively throw up an objection rather than be approached as a sole arbiters of the outcome.

In the United States, the phrase “presumed consent” strongly connotes that the next-of-kin’s wishes can be ignored or overridden, and so this weaker interpretation might not seem to qualify as presumed consent system at all. But, as Gill (2004) argues, it does articulate an important position, neglected in the U.S. debate, that falls between strong-form presumed consent and the much weaker notion of a “required request” rule. A “required request” system simply obliges procurement co-ordinators to follow up on every potential donor. From the next-of-kin’s point of view, the burden of expectation is not shifted in any way. Gill (2004) argues that there ought

*Indeed, required request laws were instituted in the U.S. in the 1980s to overcome reluctance on
to be a presumption on everyone’s part (a social norm, in other words) that organs should be donated, even if the family still has the right to object. This does indeed shift the burden of expectation on families and may make consent easier to obtain from families as a result.

A third way that presumed consent laws might be empirically associated with higher procurement rates is weaker again. Rather than being the formal expression of a real norm, it might be that presumed consent laws are simply a marker for other practices that make organ procurement more efficient. We know from the U.S. case that procurement organizations with more resources and wider reach have higher procurement rates (Healy 2004). The historical development of transplant programs is often associated with the work of organizational entrepreneurs (usually the transplant surgeons) who mobilize resources in an effort to secure as many organ donors as possible for the transplants they want to perform (Simmons et al. 1977). When transplant advocates reorganize or expand a transplant system, they are likely to invest in its infrastructure and personnel — providing new facilities, more training, and so on — while also organizing publicity campaigns and public policy initiatives. Presumed consent legislation might be a byproduct of such efforts, and might be the most visible external marker of them, without itself contributing much to any subsequent increase in procurement rates. In such circumstances, we would still expect presumed consent countries to do better than informed consent countries, but not because the law is directly intervening in decision-making by donors. Rather, it is a proxy for other factors that do make a difference.

Other factors affecting procurement rates

Procurement rates are influenced by structural and organizational forces other than the law. On the supply side, cadaveric organ procurement is naturally limited by the supply of potential donors. Potential donors are people who die in circumstances that make donation possible in principle. Not all causes or circumstances of death yield a potential donor. Many diseases rule candidates out of consideration. Potential donors come most often from deaths caused by cerebrovascular diseases (such as strokes or aneurysms), or from deaths in road accidents. Other trauma cases, such as deaths due to falls, drowning or assault, are also a source of potential donors. Procurement organizations do have some leeway at the margins: better-resourced systems will be better able to locate road accident victims in time and stabilize them in hospital, for instance. But if a country simply has a lower rate of road accident fatalities than average, or a higher rate of deaths from cerebrovascular diseases, we should expect the procurement rate to vary accordingly, all other things being equal.

the part of medical staff to ask about procurement, not to better encourage next-of-kin to say yes.
In addition to these exogenous effects, organ procurement organizations and transplant centers are part of wider systems of health care. Features at both the organizational and macro-institutional levels should affect procurement rates. The structure, staffing and resources of procurement organizations are vitally important aspects of the transplant system, and evidence from the U.S. case suggests these features may be the most important determinants of the procurement rate (Healy 2004, 2006). We cannot easily measure these variables across countries or over time. We can, however, control for some broader features of each society that might be correlated with procurement. Most simply, a country’s per capita GDP ought to be positively associated with the procurement rate. Transplantation is carried on mainly in wealthy countries, and the necessary infrastructure is expensive to support. More specifically, we might also expect a country’s system of healthcare and its level of healthcare spending to affect procurement rates. But the direction of the relationship is not clear. Two opposing possibilities suggest themselves. The first is that an inclusive public health care system is a prerequisite for high procurement rates. The idea is that the ultimate reliance of transplant systems on the gifts of donors is more likely to be successful where there is a strong collective commitment to public health. The generalized reciprocity that donation depends on (gifts from anonymous donors to unknown recipients) might be more easily sustained in the context of a national health service of some kind. This was a key part of Richard Titmuss’s (1971) argument in *The Gift Relationship*.

Alternatively, it might be that a strong commitment to publicly-funded health care is associated with lower rates of organ procurement, given the expensive and selective nature of donation. Organ transplantation has become quite widespread in the past twenty years, and looks set for continued growth (or at least increasing demand). But the cost and difficulty of the operation, and the life-long post-transplant care needed by recipients, means that it is not by any measure a form of basic health care. This suggests that while wealthier countries should have higher procurement rates, high levels of public spending on health care might be negatively associated with higher procurement rates.

As this last point implies, the organizational and legal details of organ procurement are embedded in broader institutional and cultural features of societies, not just the health care system. The form and extent of logistical support for donation will have evolved within particular systems of health care provision. Similarly, legal regimes governing transplants will not have emerged in a vacuum. Cases like Japan, where transplants were taboo for many years (Lock 1996), show that cultural context can matter a great deal. Historical legacies in Germany have also made transplantation a complex public issue (Hogle 1999). I will not pursue this question further here, though it certainly merits closer analysis. For present purposes, our goal is to estimate the contribution of a country’s legal regime to its procurement rate. We will do this
while controlling for two of the major inputs to the supply of potential donors (death rates from road accidents and cerebrovascular diseases), on the one hand, and two measures capturing the overall wealth and commitment to public health spending for each country, on the other.

DATA AND METHODS

The dependent variable for the quantitative analysis is the number of cadaveric donors procured per million population for each of seventeen OECD countries between 1990 and 2002. These data were provided by Transplant Procurement Management (2004) and national organ procurement agencies. The independent variables — covering the same countries and time period — are the per capita GDP (measured in US$ Purchasing Power Parity), public health expenditure as a percentage of GDP, the road accident fatality rate (per million population), the death rate from cerebrovascular disease (per million population), and the country’s classification as a presumed consent or informed consent regime. Figure 2 provides summary information about the distribution of these variables.

Most countries can be unproblematically assigned to a legal regime, having passed the relevant legislation prior to the period under analysis. Some countries passed new legislation between 1990 and 2002 that reaffirmed or expanded the existing legal status of transplantation: France and Italy passed new presumed consent laws in 1990 and 1999, respectively, superseding older presumed consent laws dating from the mid-1970s. Similarly, Germany passed new informed consent legislation in 1997 which continued its existing practices. As noted above, Switzerland is classified as a presumed consent country.

The cross-sectional, time-series structure of the data makes regular OLS methods inappropriate due to the clustering of observations at the country-level and the serial correlation of within-country observations over time. Consent laws do not vary within countries over the observed time period, so a fixed-effects formulation is not applicable. In addition, there are likely to be unobserved factors affecting the donation rate within each country. Both of these features make a hierarchical (or mixed-effects) model the natural specification, with a random effect for each country. This model takes the following form:

$$ y_i = X_i \beta + Z_i b_i + \epsilon_i, \quad i = 1, \ldots, M, $$

where $y_i$ is the $n_i \times 1$ vector of donation rates in the $i$th country, $X_i$ is the $n_i \times p$ model matrix for the fixed-effects for observations in country $i$, $\beta$ is the vector of fixed-effect coefficients, $Z_i$ is the $n_i \times q$ model matrix of random-effects for
Figure 2: Summary information about the dataset. The distribution of country-year observations for 1990 to 2003 is shown for each variable. For continuous variables, observations are represented by tick marks above the scale line. Triangles below the line indicate the values of the 10th, 25th, 50th, 75th and 90th percentiles.

observations in country $i$, and $\mathbf{b}_i$ is the $q \times 1$ vector of random-effect coefficients for country $i$. The random-effects coefficients are assumed to be distributed as

$$\mathbf{b}_i \sim \mathcal{N}_q(\mathbf{0}, \Psi),$$  (2)

where $\Psi$ is the variance-covariance matrix for the random effects. The error term in equation (1), $\epsilon_i$, is characterized as

$$\epsilon_i \sim \mathcal{N}_{n_i}(0, \sigma^2 \Lambda_i), i = 1, \ldots, M,$$  (3)

where $\sigma^2 \Lambda_i$, is the covariance matrix for the errors in country $i$. Because the within-country observations are an annual time series, the error structure is given by the first-order autoregressive process, AR(1):
\[ \epsilon_t = \phi \epsilon_{t-1} + a_t, \]

where the current observation’s error term is a linear function of the previous observation, \( \phi \epsilon_{t-1} \), plus a normally distributed noise term, \( a_t \).

Alternative model formulations (notably pooled time series or generalized least squares approaches) are also plausible, but are not presented here. In a generalized least squares model, no country-level random effect would be specified. Instead, the serial correlation of the data and the within-country variance would be incorporated into the error structure of the model. This approach gives what seem like overly-optimistic estimates of the fixed-effects. Exploratory analysis suggests that there is a high degree of within-country variation that is not explained by our measures of death rates, GDP or spending. As we have seen, there is little existing research on the cross-national determinants of organ donation, and such research as is available suggests that subnational and organizational-level factors will matter a great deal. The best methodological strategy is to incorporate the likely presence of country-specific factors into the model as directly as possible. The mixed-effects approach allows us to do this in a convenient way. It may produce more conservative estimates of the fixed-effects we are interested in (such as the presence of presumed consent laws) than other specifications, but it better reflects the nested process that generates the data we observe. The models were fit using restricted maximum likelihood with the \texttt{nlme} library in R (Pinheiro et al. 2004, Pinheiro and Bates 2000, R Development Core Team 2004). Figures were produced with the \texttt{lattice} (Sarkar 2004) and \texttt{Hmisc} (Harrell 2004) libraries for R.

RESULTS

Fixed-effects coefficients for a linear mixed-effects model are presented in Table 2. Although the signs of the coefficients are in the expected direction (with the exception of cerebrovascular deaths), none are statistically significant. The effect of presumed consent laws is relatively large in magnitude, but is not statistically significant. These weak results are somewhat surprising. Further exploration of the model reveals that it does not fit the data well, and for a specific reason. By examining a plot of the standardized residuals by country (the left-hand panel of Figure 3), we can see that the observed data from Spain and Italy are poorly explained by the model.\(^7\) These are, of course, the only two countries that have shown sustained, rapid growth in their procurement rates through the 1990s. This makes their profile quite different from other

\(^7\)The residuals can be thought of as reflecting the difference between what the model predicts and what we actually observed. Standardized residuals ought to be evenly distributed around zero for each country. If they are not, this is evidence that the model does not fit the data for that country very well.
Table 2: Fixed-effects coefficients from a linear mixed-effects model of donor procurement.

<table>
<thead>
<tr>
<th></th>
<th>Value</th>
<th>Std.Error</th>
<th>DF</th>
<th>t-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Intercept)</td>
<td>14.706</td>
<td>1.42</td>
<td>180</td>
<td>10.33</td>
</tr>
<tr>
<td>GDP</td>
<td>0.005</td>
<td>0.00</td>
<td>180</td>
<td>0.40</td>
</tr>
<tr>
<td>Health</td>
<td>-0.683</td>
<td>0.53</td>
<td>180</td>
<td>-1.29</td>
</tr>
<tr>
<td>Roads</td>
<td>0.018</td>
<td>0.02</td>
<td>180</td>
<td>1.17</td>
</tr>
<tr>
<td>C/Vasc</td>
<td>-0.004</td>
<td>0.00</td>
<td>180</td>
<td>-0.79</td>
</tr>
<tr>
<td>Presumed Consent</td>
<td>3.185</td>
<td>1.97</td>
<td>15</td>
<td>1.62</td>
</tr>
</tbody>
</table>

AIC: 885.5. BIC: 914.9. Log-likelihood: -433.7. Country-level random effects fitted but not shown. Variables are centered on their means. GDP coefficient is multiplied by 100.

Figure 3: Distribution of standardized residuals by country for a model including Spain and Italy (left) and the same model excluding Spain and Italy (right). Residuals ought to be evenly distributed around zero.

countries in the dataset — particularly the larger ones, which show comparatively modest patterns of growth or decline. Our country-level predictors of procurement do poorly as a consequence. This suggests that it is worth treating the outlying cases separately. Before we examine these two cases in more detail, we can look again at our model with Spain and Italy excluded from the dataset.

Table 3 shows the fixed-effects coefficients for a the same model as before, this time excluding data from Spain and Italy. The results are a good deal better: GDP, road fatalities and cerebrovascular deaths all have positive and significant effects on
Table 3: Fixed-effects coefficients from a linear mixed-effects model of donor procurement, Italy and Spain excluded.

<table>
<thead>
<tr>
<th></th>
<th>Value</th>
<th>Std.Error</th>
<th>DF</th>
<th>t-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Intercept)</td>
<td>15.131</td>
<td>0.89</td>
<td>158</td>
<td>16.92</td>
</tr>
<tr>
<td>GDP</td>
<td>0.012</td>
<td>0.00</td>
<td>158</td>
<td>2.03</td>
</tr>
<tr>
<td>Health</td>
<td>-0.590</td>
<td>0.33</td>
<td>158</td>
<td>-1.79</td>
</tr>
<tr>
<td>Roads</td>
<td>0.036</td>
<td>0.01</td>
<td>158</td>
<td>3.19</td>
</tr>
<tr>
<td>C/Vasc</td>
<td>0.006</td>
<td>0.00</td>
<td>158</td>
<td>2.03</td>
</tr>
<tr>
<td>Presumed Consent</td>
<td>2.516</td>
<td>1.31</td>
<td>13</td>
<td>1.93</td>
</tr>
</tbody>
</table>

AIC: 736. BIC: 764.3. Log-likelihood: -359. Country-level random effects fitted but not shown. Variables are centered on their means. GDP coefficient is multiplied by 100.

the procurement rate, as predicted. Road fatalities make a much larger contribution to the procurement rate than do deaths from cerebrovascular diseases. This may be because road accident victims are converted into donors more efficiently. Although not quite significant at conventional levels, the negative effect of health spending is quite large: a two point change in health spending as a percentage of GDP is associated with roughly a one point drop in the procurement rate. The effect of the legal regime is also large. A presumed consent regime is worth an additional 2.7 donors per million population, when other variables are at their mean values. The right-hand panel of Figure 3 confirms that the model fits the data better with Spain and Italy excluded.

This analysis suggests, first, that when all of the available data is taken into account, the presence of presumed consent laws does not make a material difference to the procurement rate one way or the other. But it is not unique in this regard: other variables expected to be positively associated with the procurement rate have no measurable effects, either. On the other hand, the presence of two countries with rapidly growing procurement rates makes the statistical model fit quite poorly. If Spain and Italy are set aside, our model does rather better. The “supply-side” measures of the death rate are positive and significant (particularly the road fatality rate). Richer countries procure more donors, in line with our expectations. Countries with a higher share of public health spending seem to procure fewer donors; and the effect of presumed consent laws is positive — though neither of these effects is strongly significant at conventional levels.

Spain and Italy

If we focus on the overall percentage change in the procurement rate over the past twelve years, the distinctive status of Spain and Italy becomes very clear. Figure 4
shows the percentage change in the procurement rate for each country from taking the mean procurement rate from 1990-94 as the start point and the 1998-2002 mean rate as the end point. Countries with zero net change score a zero in this Figure. The median change across all countries was a decline in the average procurement rate of about 4.75 percent. Half the countries fall somewhere between a decline of about 15 percent and an increase of about two percent. Countries showing only modest growth or a net decline are split more or less evenly between presumed and informed consent regimes. As the more formal model confirms, presumed consent countries may do slightly better on the average, but in general the differences are small. The biggest losers are Switzerland and Sweden among presumed consent countries, and Australia and the Netherlands among informed consent countries. Procurement rates in all four of these countries declined by about twenty percent from the early 1990s to the early 2000s. By contrast, Belgium (presumed consent) and the United States (informed consent) show fairly steady growth. But it is the cases of Spain and especially Italy that stand out here, with growth rates far greater than any other countries. Spain has long been known for its successful organ procurement program. Already a leader at the beginning of the 1990s, it procured 55 percent more organs at the end of the period than it did at the beginning. Italy’s growth — about 175 percent over the period — has been astonishing. Unlike Spain, it began the 1990s as one of the poorest-performing countries, but by 2002 had moved to the upper half of the distribution.

Spain successfully re-organized its procurement system in the early 1990s and has seen a substantial increase in donation rates since then. It is the country most frequently cited as the exemplary “presumed consent” regime — the “Spanish model.” Its continued growth is not easily explained in terms of the unchanging laws governing donation. The evidence strongly suggests that other factors are responsible for this success and shows decisively that the strongest form of presumed consent (with no next-of-kin veto) is not practiced. Instead, investment in hospitals and procurement organizations is responsible for the sustained growth. (Matesanz et al. 1994, 281) discuss the overhaul of the Spanish system:

In each potential donor hospital there is a transplant coordination team that is responsible for the whole process of organ procurement, from the detection of the donor to the organ grafting or tissue banking. Annual rate of cadaveric donors rose from 14.3 per million population (pmp) in 1989 to 21.7 donors pmp in 1992. Organ retrieval rate increased by 81% during the same period. Renal, liver and cardiac transplants increased by 44%, 175% and 162% respectively. We conclude that this particular approach to the problem has been successful in Spain, overcoming obstacles such as untrained or undertrained requesting staff,
unidentified donors, and reluctance to approach grieving families.

A more recent account by the same lead author confirms this view, emphasizing the positive effect of training and organizational innovation in improving the consent rate:

A proactive donor detection program performed by well trained transplant coordinators, the introduction of systematic death audits in hospitals and the combination of a positive social atmosphere with adequate economic reimbursement for the hospitals have accounted for this success (Matesanz and Miranda 2002, 22).

Similarly, (Chang et al. 2003, 1259) describe the success of the “Spanish Model” not in terms of presumed consent laws but as a matter of organizational innovation:

![Percentage change diagram](image)
The so-called ‘Spanish Model’ has been outlined as a structure of national, regional, and local or in-hospital efforts to increase organ donation. The management structure consists of a front-line in-hospital transplant coordinator who is fully involved and accountable for the donor recruitment effort. Furthermore, transplant donor coordination has been ‘professionalized’ and most coordinators are qualified doctors, mainly intensive care specialists and nephrologists, who have dedicated time allocated to transplant coordination. Moreover, the Spanish system adheres to the principles of decentralization of the donor coordination effort through the use of regional coordinators and the establishment of organ procurement as the main priority for national, regional, and hospital coordinators.

Chang et al. find that a substantial portion of the improvement in donation rates in Spain is due to increases in the use of older donors, who previously would not have been considered viable candidates for procurement. A study by Rosel et al. (1999) tried to identify “variables [that] influenced a family’s decision to donate.” (Similar studies have been carried out in the U.S., for example Siminoff et al. 2001.) They found that, for 71 cases in hospital in Malaga, the “the manners and approach of the doctors” to the donor families played a significant role in obtaining consent from donor families. Matesanz (2004, 740) describes the system in further detail:

The Spanish Model also includes a great effort in continuous medical training and education for new and old transplant coordinators financed and directed by the central Health Administration, including various training programs for health professionals, specifically dedicated to every step of the process (donor detection and management, legal aspects, family approach, organizational aspects, management of resources, and so on) ...Spain has a theoretical presumed consent law, but, from a practical point of view, family consent is always requested and the wishes of the relatives are always respected, as happens in practically all European Union countries. In fact, family refusal rates have remained stable between 20% and 25% during the last few years. What is clear is that the increased organ donation during the 1990s cannot be attributed to any change in Spanish legislation, which has remained unmodified since 1979.

Reports of the Spanish case strongly suggest that improved donation rates are due to substantial investment in the logistics of organ procurement — better training, clear delegation of responsibility, a strong presence in hospitals — rather than a change
in the legal definition of donation or an unprompted sea-change in public opinion. Consent laws are not responsible for Spain’s high rate of organ donation.

Italy’s experience is less well-documented, in part because the rapid rise in its procurement rate has been a more recent phenomenon than Spain’s. However, the available sources make it clear that regional transplant authorities in Italy have explicitly copied the Spanish approach to procurement, with similar results. Matesanz (2004, 741) argues that “Italy has probably been the country that has adopted more elements of the Spanish Model and worked more seriously in this direction” than any other. Simini (2000, 476) reports that

Tuscany alone doubled its organ donation rate to 26dpmi in the space of just one year. “Tuscany”, said [transplant director Alessandro] Nannicosta, “achieved in one year what northern regions achieved in 4 or 5 years, after adopting the Spanish model for organ donation.” This model relies upon “local transplant co-ordinators and excellent training of all staff involved.”

Data on regional trends within Italy bear out these reports. Growth in the procurement rate since 1999 has been unevenly distributed within the country. Southern regions have performed very much worse than northern ones on the average. Procurement rates in northern provinces such as Piemonte or Emilia–Romagna are typically twice or even three times as high as those in Calabria or Sicily. Amongst the central regions, Tuscany, Marche and also Sardinia increased their procurement rates rapidly between 2000 and 2003. The results of the quantitative analysis together with more detailed reports about individual countries suggest that overall average levels of organ donation are partly explained by supply-side considerations and stable structural features of societies (perhaps including the nominal legal regime governing procurement). At the same time, dynamic growth in procurement rates depends mainly on “middle-range” changes, notably infrastructural investment and organizational reform.

SUMMARY

Cadaveric organ procurement is a complicated kind of gift, because the next-of-kin or family are the de facto givers. Faced with this fact, presumed consent laws have

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8Similarly, Bozzi et al. (2004, 424) describe part of Tuscany’s pilot program as “based on a database elaborated by the Transplant Coordination Office of the Pisa University, according to the Spanish program of the National Transplant Organization.”

9Regional data obtained from the Associazione Italiana per la Donazione di Organi, Tissuti e Cellule, http://www.aido.it, October 2005.
seemed like an attractive solution to some because they promise to remove the next-of-kin from the decision and so guarantee a boost in the procurement rate. There has been considerable debate about the ethics of this policy, speculation about a possible backlash in public opinion should it be implemented, and anecdotal evidence about its success in other countries. Yet there has been virtually no research on whether these laws work as advertised. As this article has shown, presumed consent laws typically do not remove the next-of-kin from the procurement process. In all but one or perhaps two cases in western countries, the family’s right of refusal is retained. This fact alone vitiates the standard case for presumed consent, at least insofar as it credits higher procurement rates to the elimination of the next-of-kin’s veto. Yet there is more to the problem than this. Presumed-consent countries do in fact perform a little better on average than informed-consent countries. I have argued that this is not because of any direct effect of the law on individual choices. Rather, countries with presumed-consent laws are also more likely to have paid close attention to the social organization of their transplant systems. High-yield cases like Spain and Italy stand out not because their legal systems mandate a different kind of choice for donors, nor because they offer some special incentives for donor families or next-of-kin. Instead, they have invested effectively in the logistics of the transplant system: they put more staff on the ground, trained them better (especially in the crucial process of requesting consent from families), and improved co-ordination between the different actors and agencies in the procurement process. Recent research shows that similar reforms may boost donation rates in U.S. organ procurement organizations, also (Sade et al. 2002). This result is encouraging: it suggests that there is room for programs to improve their performance. Organizations are easier to change than baseline death rates, the entire health-care system, or the cultural traditions of a whole country.

The organizational underpinnings of donor procurement have been neglected in debates about the future of organ and tissue donation. This is unfortunate but perhaps not surprising. In the United States and elsewhere, these debates are dominated by the division between market- and gift-based exchange. Our stylized images of how these institutions ought to look (and how they should differ) leads us to assume more than we really know about the empirical cases. As a consequence, variation amongst actually-existing procurement systems is not well-understood, or simply not investigated at all. Instead, countries are classified as all being of the same gift-based type, and then contrasted with the supposed (usually hypothetical) commercial alternative. Thus, substantial differences in performance between countries are masked. Arguments about altruism vs self-interest and disputes over presumed and informed consent together constitute a good portion of the public discussion about organ donation. Yet neither debate helps us explain why some countries have many more organ donors than others. As best we can tell, countries with high procurement rates do not owe their success to any distinctive legal conception of consent, nor to any spe-
cial way of institutionalizing exchange in human goods. Rather, more fine-grained organizational differences — specifically in logistics and process management — are responsible for their success.

REFERENCES


