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# *The Political Economy of Presumed Consent*

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*Abstract:* The legal procurement of cadaveric human organs in Western countries is institutionalized in different ways, and donation rates vary widely. In particular, law in some countries allows for the consent of the donor to be presumed, and thus — in principle — the wishes of the next-of-kin to be overridden. I investigate the sources of variation in procurement rates using time-series data from seventeen OECD countries. 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 the legal regime is a marker for other organizational practices rather than a causal mechanism in itself. More broadly, donor procurement takes place within societies that have institutionalized different relationships between the individual, the market and the state. The social organization of organ procurement may reflect aspects of these broader features of society: states with corporatist or conservative welfare regimes are likely to have adopted presumed consent laws, while liberal regimes always have informed consent rules.

There is no formal production market for human organs. In most parts of the world, including all of the advanced capitalist democracies, it is illegal to sell one's own organs (or those of a dead relative). The agencies in charge of collecting organs cannot offer financial incentives for them. When they can be collected from living sellers, some human tissues *are* commercially marketed. Sperm and eggs are the most notable examples, along with plasma in the United States. But the majority of tissue must be collected from the dead and, once again, the donor or their next-of-kin cannot be paid or otherwise reimbursed for them. In addition to the major solid organs, tissues in wide demand include skin and skin products, bone and bone chips, tendons and cartilage, corneas, veins and heart valves. Despite the absence

of a production market, and the strong emphasis on the altruistic virtues of organ donation, the secondary markets for these goods are extensive and lucrative. Organ transplants are expensive and the commercial demand for processed tissue — which is used in trauma, reconstructive and cosmetic surgery — is large and increasing.

All of these raw materials must come from donors. This fact has provoked a long-running debate among ethicists, medical professionals, economists and other social scientists. At its core are questions about the moral and economic implications of donation, and the potential benefits — or possible exploitation — that might result from the commodification of these goods.<sup>1</sup> Because the debate is centered on the different effects of giving and selling, the tendency has been to neglect heterogeneity within these categories in favor of a sharp contrast between them. A further consequence has been a notable lack of attention to variation across actually-existing organ procurement systems in favor of an analysis of the supposed effects of hypothetical commercial systems.

Gift-giving and voluntary donation are the standard ways of collecting organs, particularly organs like hearts and lungs which must come from the dead.<sup>2</sup> Yet this does not happen everywhere in the same way or to the same extent. There is a considerable variation in donation rates cross-nationally. Despite the use of particular countries as examples in a stylized or anecdotal way in policy debates, this variety has not received the sustained attention it deserves. Yet its implications are striking. If donation simply involves individuals coming forward to give, in much the same way everywhere, why do countries differ? Can we relate this variation to differences in the social organization of organ donation and transplantation systems, and perhaps also to broader features of national societies? I address these questions in this paper through a comparative analysis of rates of cadaveric organ donation in seventeen OECD countries between 1990 and 2002.

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<sup>1</sup>Arguments about the problem of commodification are thriving in many fields, including philosophy, law, economics, sociology, anthropology and public health. Notable contributions include Anderson (1993), Radin (1996), Nussbaum (1998), Sunstein (1997), Nelson (1998), Ubel (2000) and Scheper-Hughes and Waquant (2002), among others. This work continues (though not always directly) an earlier wave of debate that began in the 1970s. See especially Titmuss (1971), Arrow (1972), Singer (1973), Landes and Posner (1978) and Walzer (1983). The goal throughout has been to determine exactly what commodification is, what it does to people and goods, and which things — if any — should be kept from the market.

<sup>2</sup>Donation 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 an account of the black market in organs.

## THE SOCIAL ORGANIZATION OF PROCUREMENT

Although generally thought of as a matter of private altruism, cadaveric organ donation 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 from the point of view of transplant organizations. From this perspective, organ procurement is a quite local and specific phenomenon that, in key respects, is the same everywhere — at least in terms of the main conditions that need to be fulfilled on the organizational side. Accident victims and other transplant candidates must be transported to hospitals quickly. Hospitals need to be able to deal with critically ill and brain-dead patients. 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 identify potential donors, obtain consent from the relevant individuals (most often the next-of-kin) and carry out the required surgery and quickly distribute the organs 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.

These logistical constraints are universal, but each of them opens up the possibility of variation. Medical systems will be more or less well-funded; procedures specified and followed to a greater or lesser degree; personnel will be trained in different ways or have different concerns. Pulling back the focus a little further, organ procurement and transplant systems evolve and operate in countries with differing degrees of wealth and inequality, different conceptions of public health and social welfare, and distinctive institutional solutions to social questions. In Western countries, organ donation happens as gift-giving, and the contrast between gifts and with sales for profit might lead us to think that gifts are more or less the same everywhere. But this is a mistake. In the same way that societies struggle over social bargains in the formal economy — in the labor market, for instance — basic similarities go hand-in-hand with substantial variation in particulars, which in turn affects outcomes like the rate of donation.

Evidence of cross-national variation is sometimes cited in public policy debates about transplantation in the United States and, recently, in Britain.<sup>3</sup> Specifically, the fact that countries with high rates of organ procurement also have “presumed

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<sup>3</sup>Parliament in Britain recently held a debate about the possibility of introducing a presumed consent system. Supporters pointed to the experience of Spain and Belgium.

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 go on to discuss 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: he or she is assumed to have, absent a recorded decision to opt out.

The most important implication of this approach is that the donor’s next-of-kin should no longer play a role in the procurement decision. In the United States, by contrast, the consent of the next-of-kin or donor family is always required, assuming they can be found. Refusal of consent by donor families results in a substantial loss in donated organs, so the possibility of removing the family from the decision process is attractive to some transplant advocates. It is important to note, however, that the role of the next-of-kin complicates *both* presumed consent and informed consent systems. A fully-realized system of informed consent would have with a national “opt-in” register. Everyone would make an informed advance 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 evidence about what the potential donor would have wanted, such as a signature on a donor card, 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 public backlash led by families whose wishes were not followed.

The organizational difficulty with a fully-realized informed consent system is getting everyone to make their choices and then keeping track of the decisions. Most people do not consider it likely that they will be killed in a car accident or other sudden accident and so become a candidate organ donor. 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 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. But, more importantly, the goal of a presumed consent system is generally thought to be the removal of next-of-kin from the decision process. This boosts procurement rates because the decision is not in the hands of grieving families. Advocates argue that the generally strong public support for organ donation found in opinion poll data is evidence that a large majority of people have a default position of "Agree" to donation and would therefore be happy with a presumed consent system. They 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."<sup>4</sup>

In fact, we know little about the empirical effects of presumed consent laws on procurement rates, or about cross-national variation in organ procurement more generally. Systematic comparative analysis is almost non-existent.<sup>5</sup> On the question of presumed consent, 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, as opposed to other features of the system's social organization, the beliefs and attitudes of its population, or general environmental factors beyond the control

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<sup>4</sup><http://www.presumedconsent.org/solutions.htm>, visited February 2nd, 2005.

<sup>5</sup>See Roels and DeMeester (1996) and Gimbel et al. (2003) for rare exceptions.

Table 1: Organ Procurement Regimes for selected OECD countries

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

Notes: Data from World Health Organization (1994), Gäbel (2003), Wolfslast (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.

of a procurement organization?

The practical meaning of the category of “Presumed Consent Country” needs clarifying. Veatch and Pitt (1995) argue that most of the countries alleged to have presumed consent laws in fact have something like “Required Request” or “Routine Salvaging” systems instead. The available evidence supports this claim. Table 1 summarizes consent laws and available information about donor registration for seventeen OECD countries. The first column shows the nominal legal regime, as defined by each country’s law governing organ donation and transplantation. 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. 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.

All informed consent countries have an effective kin veto, regardless of their donor registry system. Surprisingly, however, it turns out that the same is true of almost all presumed consent countries. They, too, generally allow the family to refuse consent. Only Austria seems unequivocally to presume consent to the exclusion of family involvement in the decision (McCunn et al. 2003, Fitzgerald et al. 2002). The next most consistent country is Belgium, which has a strong presumed consent system that nevertheless does seem to allow for families to object (Roels 1998, Roels and DeMeester 1996, Roels and Vanrenterghem 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.

With this information about the basic distinctions between countries and systems, we can now examine cross-national variation in procurement rates before returning below to the question of the possible effects of presumed consent legislation on donation.

#### *Cross-national variation and longitudinal trends*

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.

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 *average rate* from state to state. Larger countries (the United States, Britain, Germany) show less volatility from year to year than smaller countries (Ireland, Belgium). This is because potential donors come, in large part, from deaths caused by violent accidents, and so countries with smaller populations will have a more variable incidence of such events than larger ones. 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. 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



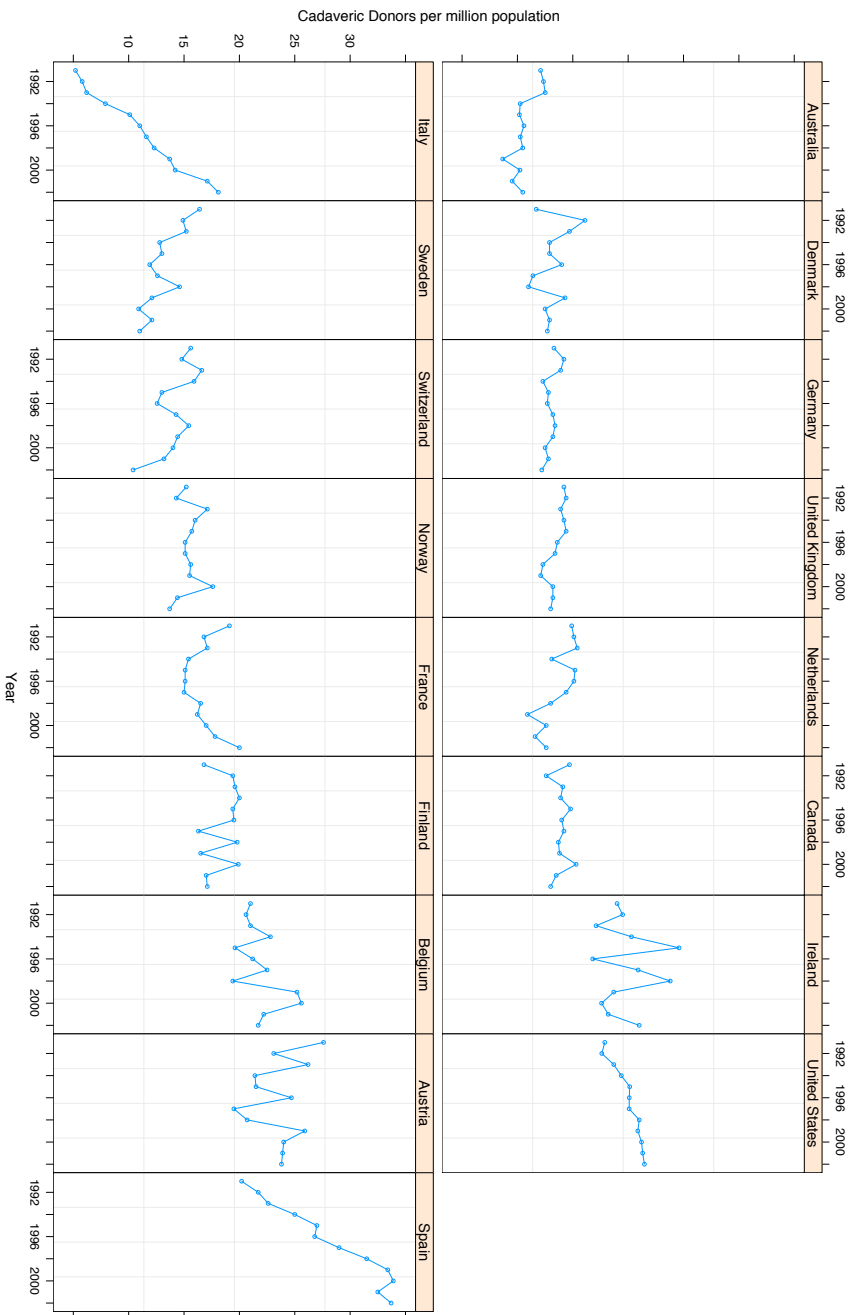


Figure 1: Procurement Rates per Million Population, 1990-2002, for seventeen OECD countries. Informed Consent countries are shown in the top row; Presumed Consent in the bottom row. Rows are ordered from lowest to highest median procurement rates.

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 begins the period 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 higher in countries with presumed consent legislation than in those with informed consent rules. What might explain this difference, and what factors predict procurement rates more generally?

*What explains variation in procurement rates?*

On the supply side, procurement rates will be affected by forces outside the control of procurement organizations. Cadaveric organ procurement is naturally limited by the supply of potential donors. Potential donors are people who die in circumstances and from causes that make procurement possible in principle. Not all causes or circumstances of death yield a potential donor. Many diseases rule candidates out of consideration, for instance. Potential donors come most often from deaths caused by cerebro-vascular diseases (like strokes), 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 cerebro-vascular disease, we should expect the procurement rate to vary accordingly, all other things being equal.

Once a potential donor is available, the next step is to acquire consent to procure from whomever is responsible. Presumed and informed consent laws govern this process. There are three ways that presumed consent laws might be associated with higher procurement rates, each weaker than the previous one. First, and strongest, presumed consent laws allow for the next-of-kin's wishes to be ignored in the procurement process. But we have already seen that almost all countries with presumed consent laws allow in practice for the next-of-kin to be consulted and have a deciding say. Austria is the only exception. Outside this case, the standard interpretation of presumed consent laws is not responsible for any difference between presumed and informed consent countries.

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 might mean, in effect, that the question put to donor families is assumed to be something like “Do you have any reason to think the donor would have objected?” rather than something like “Can we have your permission to go ahead?” Presumed consent laws would therefore express a social norm or collective expectation about the default course of action; one where donation is assumed to be the standard option, rather than a special decision for which consent must be specially sought. This allows the kin veto to be retained, but its role in the decision process is somewhat different. Some philosophers have argued for this interpretation of presumed consent while arguing for reform in the U.S. case (Gill 2004).<sup>6</sup>

The third possibility is related to the second, but is weaker again. Rather than being a active signaling device or a formal expression of a general 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 overhaul 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 materially 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.

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<sup>6</sup>This interpretation also makes the “presumed consent” label somewhat misleading for policy making. But it does articulate an important position that is missing in the U.S. debate. The strong form of presumed consent says doctors can override the wishes of the next of kin. A much weaker version is the claim that presumed consent countries really just have “required request” or “routine salvaging” rules, where procurement co-ordinators are obliged to follow up on every potential donor. But Gill’s (2004) point is that there ought to be a presumption *on everyone’s part* that organs should be donated, even if the family still has the right to object. This is stronger than the “required request” position, because one can believe that all potential donor families should be asked their permission while not having any expectation that they should be expected to consent.

Organ procurement organizations and transplant centers are part of wider systems of health care. Should a country's system of health-care have an effect on procurement rates? There are two opposing possibilities. The first is that an inclusive public health care system is a prerequisite for high procurement rates. The idea here 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*, the classic study of blood donation in Britain and the United States.

Alternatively, it might be that a strong commitment to publicly-funded health care makes organ donation *less* widespread, given the expensive and selective nature of the practice. 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. Limiting 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).

One possibility of interest is whether laws governing transplantation fit with broader social and political bargains of the kind identified in the comparative literature on welfare provision (Esping-Andersen 1999, Goodin et al. 1999). As is well known, this tradition makes a basic threefold distinction between kinds of ideal-typical welfare regimes, each of which can be thought of as representing a distinctive conception of the relationship between the individual, the state and the market within society:

The classically *liberal welfare regime* is rooted in capitalist economic premises and confines the state to a merely residual social welfare role.

The classically *social democratic welfare regime* is rooted in socialist economic premises and assigns the welfare state a powerful redistributive role. The classically *corporatist welfare regime* is rooted in a communitarian ‘social market’ economics and sees the welfare regime as primarily a facilitator of group-based mutual aid and risk-pooling (Goodin et al. 1999, 39).

In its original formulation, these “three worlds of welfare capitalism” were defined in terms of differences in welfare-state support for workers via income maintenance programs (Esping-Andersen 1990). Subsequent scholarship has sought to broaden the scope of the idea. Is there reason to expect organ procurement to fit with comparative welfare regimes, broadly construed? If we think of the connection as being directly through the health care system, the answer is probably not. The details of health-care financing are complex, and useful generalization about them is difficult. The OECD has identified eight types across seventeen countries, for instance (Organization for Economic Cooperation and Development 1994), and more complex formulations have also been suggested. (This is one of the reasons that the comparative analysis of health policy is not well-integrated with the welfare state literature, despite the high levels of public health-care spending in most countries.) On the other hand, although the details of financing vary, basic levels of health coverage are fairly similar across most of the advanced capitalist countries, with the notable exception of the United States (White 1995). A useful typology distinguishes between the financing source for the system (single payer vs multi-payer), on the one hand, and the ownership of medical facilities (public vs private), on the other (Hacker 2004). But these structural distinctions are difficult to parse into clear implications for the organ procurement rates.

A more promising route is to consider the relationship between the state and the individual that the worlds of welfare capitalism are meant to capture. The key question of consent in organ procurement is essentially one about the source and degree of authority over the dead: Who, in principle, controls the decision to procure? There are three candidates. The first is the donor herself, in advance via a decision to opt-in or opt-out of the system. The second is the next-of-kin or family, just prior to the time the procurement must take place. And the third is the doctor or medical officer in charge of declaring that the patient has died and is a candidate for organ procurement. Liberal regimes ought to be the least likely to delegate authority to the state, consistent with a general orientation to individual sovereignty. Corporatist (or conservative) regimes should be much more likely to allow the state or its representatives — in the form of medical officials — to decide, consistent with a communitarian

commitment to the collective good. Liberal regimes should therefore tend to have informed-consent systems, with corporatist countries tending to presumed consent. The prediction for Social Democracies is less clear-cut, but the expectation would be that these countries would also tend toward presumed consent regimes.

My argument here is not that there is a tight connection between organ procurement policies and the specific income-replacement or social-insurance programs classically associated with each system in the welfare-state literature. Rather, it is that these distinctions capture broader categories of welfare regimes, broadly understood.<sup>7</sup> Each regime tends to have a logic of action that identifies relevant actors and provides models for good institutional design that will tend to be found across a wide variety of contexts (Dobbin 1994, Schofer and Fourcade-Gourinchas 2001). From this point of view, the connection between organ donation and conceptions of welfare provision is more direct. It is at least plausible that standards for the appropriate use of the body after death, and conceptions of authority to make decisions about it, should vary with broader conceptions of the common good. The increasing pressure of demand on procurement systems over the past ten years, together with the expansion of markets for solid organs and (especially) processed human tissues suggests that these standards would be very much to the fore in this area.

## 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. Summary statistics for the dataset as a whole and for each country can be found in Table 2.

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

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<sup>7</sup>It is more helpful to speak in terms of “welfare *regimes*, not welfare *states* nor individual social policies” (Esping-Andersen 1999, 72).

Table 2: Summary statistics by country. Countries are ordered by donation rate within legal regime.

	Donors		GDP		Health		Roads		C/Vasc		Law
	MEAN	SD	MEAN	SD	MEAN	SD	MEAN	SD	MEAN	SD	
Overall	16.42	5.12	23447.25	4571.85	6.22	0.90	109.34	33.63	600.03	139.81	—
Australia	10.64	1.14	22629	3770.63	5.75	0.35	102.23	11.17	547.33	77.06	Informed
Germany	13.04	0.61	22314	2550.48	8.28	0.40	107.64	18.86	695.17	124.18	Informed
Denmark	13.09	1.47	24175	3693.83	6.98	0.16	99.83	11.04	635.83	44.73	Informed
United Kingdom	13.49	0.78	21787	3775.12	5.83	0.28	65.73	7.12	695.42	85.47	Informed
Netherlands	13.66	1.55	23455	3568.16	5.73	0.31	74.77	9.09	579.58	50.71	Informed
Canada	13.97	0.75	24100	3874.61	6.67	0.41	106.44	15.11	417.92	36.48	Informed
Ireland	19.79	2.48	21483	6509.17	4.92	0.26	116.25	9.67	694.67	82.89	Informed
United States	19.98	1.33	29726	4363.63	5.87	0.34	153.21	4.66	441.92	13.95	Informed
Italy	11.10	4.28	21898	2600.74	5.95	0.45	121.62	10.54	697.67	110.55	Presumed
Sweden	13.12	1.75	22728	3142.64	7.30	0.23	70.12	11.00	589.17	46.46	Presumed
Switzerland	14.18	1.71	27448	2097.82	5.52	0.52	92.57	17.54	413.42	66.03	Presumed
Norway	15.44	1.11	27160	6227.72	6.87	0.29	69.31	6.47	648.75	92.98	Presumed
France	16.76	1.60	22973	3107.09	7.12	0.18	152.69	16.39	424.67	48.28	Presumed
Finland	18.44	1.53	21268	3713.96	5.83	0.75	90.53	16.19	755.92	130.10	Presumed
Belgium	22.24	2.15	24057	2447.36	6.19	0.20	143.84	10.12	562.78	30.55	Presumed
Austria	23.53	2.42	24289	3125.08	5.52	0.26	145.44	26.89	753.50	110.80	Presumed
Spain	28.11	4.96	17263	2748.63	5.47	0.14	155.17	29.22	637.50	129.39	Presumed

Units: (1) Donors per million population. (2) US Dollar PPPs. (3) Public Health Spending as a percentage of GDP. (4) Road deaths per million population. (5) Cerebrovascular Deaths per million population. See main text and Appendix for further detail on legal regimes.

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. Because consent laws do not vary within countries over the observed time period, a fixed-effects formulation is not applicable. Because there are likely to be unobserved factors affecting the donation rate within each country, a hierarchical linear or mixed-effects model with a random effect for each country is a natural specification. This model takes the following form:

$$\mathbf{y}_i = \mathbf{X}_i\beta + \mathbf{Z}_i\mathbf{b}_i + \epsilon_i, i = 1, \dots, M, \quad (1)$$

where  $\mathbf{y}_i$  is the  $n_i \times 1$  vector of donation rates in the  $i$ th country,  $\mathbf{X}_i$  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,  $\mathbf{Z}_i$  is the  $n_i \times q$  model matrix of random-effects for 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

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

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

$$\epsilon_i \sim \mathcal{N}_{n_i}(\mathbf{0}, \sigma^2 \mathbf{\Lambda}_i), i = 1, \dots, M, \quad (3)$$

where  $\sigma^2 \mathbf{\Lambda}_i$ , 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):

$$\epsilon_t = \phi\epsilon_{t-1} + a_t, \quad (4)$$

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 formulations — notably pooled time series or generalized least squares approaches — are also plausible, but are not presented here. In a generalized least squares model, for example, the autocorrelated nature of the data can be incorporated in to the error structure of the model, without specifying a country-level random effect. This will give overly-optimistic estimates of the fixed-effects that have much



smaller standard errors. Exploratory analysis suggested a high degree of country-specific variation. Because there is so little existing research on the cross-national determinants of organ donation, it is best to incorporate the likely presence of country-specific factors into the model as directly as possible. The random effects approach allows for this better than alternative specifications, and consequently produces more conservative estimates of the fixed effects.

The models were fit using restricted maximum likelihood using the nlme library in R (Pinheiro et al. 2004, Pinheiro and Bates 2000, R Development Core Team 2004). Graphics and tables were produced with the lattice (Sarkar 2004) and Hmisc (Harrell 2004) libraries for R.

## RESULTS

Fixed-effects coefficients for the linear mixed-effects model are presented in Table 3. Although the signs of the coefficients are in the expected direction (with the exception of cerebrovascular deaths), none are significant at conventional levels. 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 for a specific reason. A diagnostic plot of the standardized residuals by country (the left-hand panel of Figure 2) shows that the model fits the data from Spain and Italy quite poorly. 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 very different from other countries in the dataset — particularly the larger ones, which show comparatively modest patterns of growth or decline. Our country-level predictors of procurement, then, do poorly as a consequence. This suggests that it is worth treating the outlying cases separately, and examining their procurement systems a little more closely. At the same time, we can look again at the country-level predictors with Spain and Italy dropped from the dataset.

Table 4 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 stronger: GDP, road fatalities and cerebrovascular deaths all have positive and significant effects on the procurement rate, as predicted. The effect of the legal regime is also stronger. 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 2 confirms that the model fits the data much better with Spain and Italy excluded.

This analysis suggests, first, that when all of the available data is taken into ac-

Table 3: Fixed-effects coefficients from a linear mixed-effects model of donor procurement.

	Value	Std.Error	DF	t-value	p-value
(Intercept)	14.729	1.45	180	10.13	0.00
GDP	0.007	0.00	180	0.52	0.60
Health	-0.602	0.54	180	-1.11	0.27
Roads	0.016	0.02	180	1.04	0.30
C/Vasc	-0.003	0.00	180	-0.64	0.53
Presumed Consent	3.316	2.01	15	1.65	0.12

AIC: 895.6. BIC: 925. Log-likelihood: -438.8. Country-level random effects fitted but not shown. Variables are centered on their means. GDP coefficient is multiplied by 100.

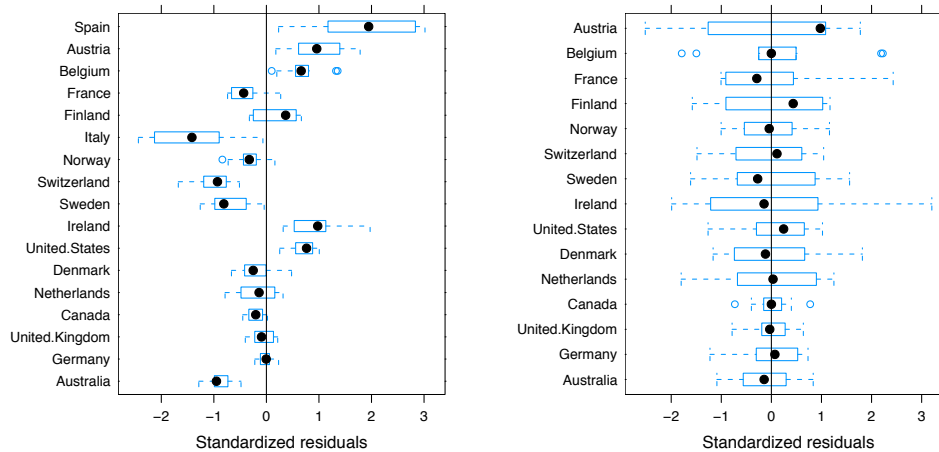


Figure 2: Distribution of standardized residuals by country for a model including Spain and Italy (left) and the same model excluding Spain and Italy (right). Residuals ought to be evenly distributed around zero.

Table 4: Fixed-effects coefficients from a linear mixed-effects model of donor procurement, excluding Italy and Spain.

	Value	Std.Error	DF	t-value	p-value
(Intercept)	15.101	0.93	158	16.22	0.00
GDP	0.012	0.00	158	1.99	0.05
Health	-0.553	0.34	158	-1.62	0.11
Roads	0.033	0.01	158	2.88	0.00
C/Vasc	0.006	0.00	158	1.85	0.07
Presumed Consent	2.719	1.36	13	2.00	0.07

AIC: 745.3. BIC: 773.6. Log-likelihood: -363.7. Country-level random effects fitted but not shown. Variables are centered on their means. GDP coefficient is multiplied by 100.

count, a presumed consent regime has a positive effect on procurement rates, but that it is not significant at conventional levels. Other variables expected to be positively associated with the procurement rate have no measurable effects. But these results are due mainly to the presence of two high-growth countries in the data set. If Spain and Italy are removed, our model does 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, though this effect is only marginally significant. The effect of presumed consent laws is positive and significant, though perhaps not to the degree that its strongest advocates would suggest.

### *Spain and Italy*

The distinctive status of Spain and Italy can be seen from Figure 3, which shows the relative change in the procurement rate for each country from its 1990-94 mean to its 1998-2002 mean. Countries with zero net growth or decline would score a one in this Figure. Net-growth countries score above one and net-loss countries below one. Stable and net-loss countries are split more or less evenly between presumed and informed consent regimes. The biggest losers are Switzerland and Sweden among presumed consent countries, and Australia and the Netherlands among informed consent countries. Belgium and the United States show fairly steady growth. But Spain and especially Italy are clearly far ahead of everyone. Spain has long been

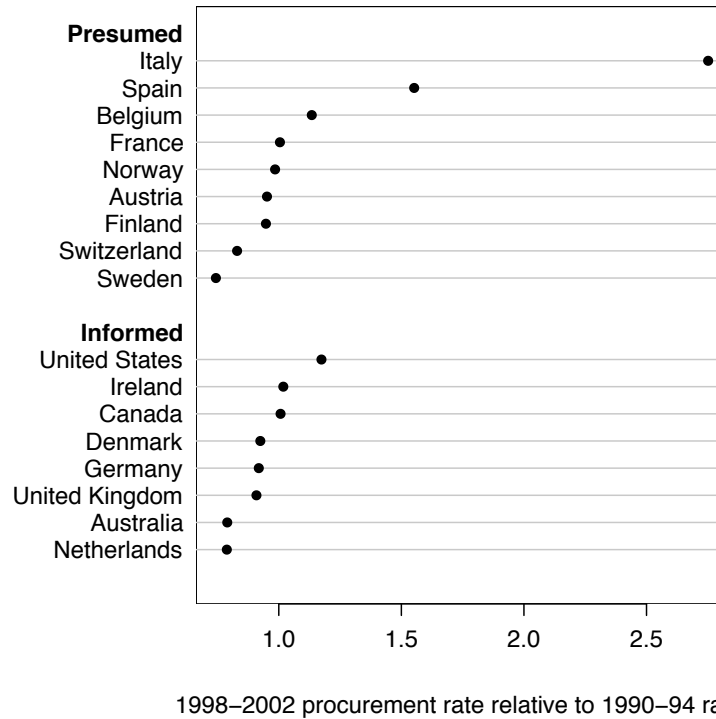


Figure 3: Relative change in average procurement rates for seventeen OECD countries, by type of consent law.

known for its successful programs. Italy's growth has been much more recent and quite remarkable by international standards.

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) 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).

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

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) notes, in summary, that

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.

In summary, the Spanish case strongly suggests 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.

The Italian case 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. Simini (2000) 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.”

Similarly, 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."

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. While 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), the dynamic growth observed in Italy and Spain springs mainly from meso-level organizational investment and expansion.

#### *Organ procurement and welfare regimes*

A final consideration is whether the legal arrangements governing procurement and transplantation fit with welfare regimes more broadly. Table 5 cross-classifies informed and presumed consent countries with corporatist, liberal and social-democratic welfare regimes. Spain is classified as corporatist in this table, though its place within welfare-regime typologies is less clear than most other countries. The table shows a clear preference for informed consent laws in liberal polities and a corresponding preference for presumed consent laws in corporatist polities. Denmark is the only corporatist state with informed consent laws, and no liberal states have presumed consent laws. Among the corporatist or conservative regimes, only in Austria does the state in fact control the procurement of organs from potential donors. Some commentators have pointed in passing to "an old tradition, well accepted by society, that disposal of the body is the responsibility of state" (Matesanz and Miranda 2002, 27), but more information on the Austrian case is needed. Social democracies are split about evenly.

The preference of liberal regimes for informed consent law is consistent with their general orientation toward the individual rather than the state. These regimes are also associated with market rather than state solutions to collective problems. The archetypal liberal regime is the United States, and it is not a coincidence that proposals to commodify the supply of organs (both living and cadaveric) have received the most public discussion there. The persistence of voluntary donation in the U.S. is not a paradox: we can think of it as a manifestation of the liberal outlook, expressed in this case through a very strong emphasis on the moral worth of the "gift of life" and the sovereignty of the individual choice behind this gift.

Table 5: Consent Laws and Welfare Regimes

	Informed	Presumed
Corporatist	1	6
Liberal	5	0
Social-Democratic	2	3

Besides the welfare-regime, there are other national characteristics that might be tied to the presence of one legal regime rather than another. Catholic countries may be more likely than not to have presumed consent systems (though Ireland is an exception here). Countries based on civil law rather than common law also seem more likely to have presumed consent systems.

## DISCUSSION

National welfare regimes are usually thought of in terms of particular social programs or, more generally, in connection with effect their institutions have on economic growth or other measures of success in the formal economy (Kenworthy 2004, Western and Healy 1999). Organ donation appears to be doubly removed from these concerns first because we associate it with the particular altruism of individual donors and, second, because it is institutionalized as a gift relationship rather than a transaction measurable in the formal economy. But organ donation is also organ procurement, and the organizations responsible for securing the supply are embedded in particular health systems and, more generally again, in national contexts with differing conceptions of public welfare and the common good. As secondary markets in human tissue proliferate, and the demand for organ transplants continues to rise, procurement systems are becoming increasingly important. The role of the altruistic donor as a source of “bio-value” (Waldby and Mitchell 2006) is increasingly contested in public debate. The growing prominence of procurement systems in the public sphere also brings distinctive conceptions of the exchange to the fore, and makes the connection between transplantation and welfare clearer.

As it happens, we do not have to go too far back to find an explicit connection between conceptions of welfare capitalism and ideas about the social organization of the gift relationship. Richard Titmuss is the originator of the dominant typologies in both areas. His distinctions between kinds of welfare state in “The Social Division



of Welfare” (Titmuss 1958) are the prototypes for Esping-Andersen’s typology of welfare state regimes. And his contrast between the U.S. and British blood donation systems in *The Gift Relationship* (Titmuss 1971) is the foundation for subsequent work on the blood and organ supply. The former literature has thrived considerably better than the latter, but the animating concern with collective conceptions of social responsibility is shared by both.

From an organizational point of view, organ donation is a very difficult process to manage. The formal and informal organization of a procurement system must overcome numerous obstacles even to locate potential donors in time, let alone successfully orchestrate the donation. A legal solution like presumed consent is attractive as it seems, in principle, to reduce the problem to directly regulating individual choices by eliminating the possibility that families can refuse consent. In practice, presumed consent systems generally do not work this way and the family’s right of refusal is retained almost everywhere. Moreover, the evidence is that organizational factors drive much of the most striking variation in procurement rates.

At the same time, background social conditions do matter. At a minimum, they can affect the supply-side constraints on procurement rates. Comparativists used to seeing social democratic states score highly on measures of the common good might be surprised to see that Scandinavian rates of donation are not that good, for example. They are clustered in the middle of the distribution, and do not show much in the way of growth. (Between the three welfare regimes, social democracies show the narrowest range of variation in procurement rates.) The reason for this is that these countries have been notably successful in another area: road safety. Safe Scandinavian roads and vehicles reduce the number of accident fatalities and hence the number of potential donors. This is a slightly perverse way to find collective welfare priorities at work.

More generally, it seems that even if the legal regime is not a direct cause of higher procurement rates, its incidence does tend to line up with welfare regimes in general, particularly for liberal and corporatist or conservative polities. This suggests that presumed consent laws may well have some signaling effect, in the sense that they tend to reflect the polity’s default position on how potential donors should be treated, and that this position is consistent with broader conceptions of the relationship between the individual and the state. Presumed consent systems do better than informed consent systems on the average, but not by an enormous margin and not because they organize the procurement process in a way that excludes families from the decision. In cases where procurement rates are high and growing fast, it is investment in the organizational layer that has mattered most. This suggests that rates of organ donation are not ultimately constrained by fixed institutions, but rather by relatively malleable

middle-range organizational practices.

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