

Would Presuming Consent to Organ Donation Gain Us Anything But Trouble?

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Organ donation is often in the news, ranging from the considerable media attention following the death and subsequent donation by Australian actress Natasha Richardson to the saga of Toronto baby Kaylee Wallace and the (ultimately moot) debate over whether to donate her organs to a fellow infant patient. Canada's first long-distance "kidney swap" also made national headlines in June 2009.

Reform of the donation system also has a way of capturing attention. Gordon Brown's attempts to implement presumed consent in Great Britain received consistent media coverage.¹ As the finishing touches are being added to this article, Wales is now considering the merits of changing its system to presumed consent.²

When organ donation is discussed, Canada's current donation system is often portrayed in less than favorable light. Often times, such articles include calls for reform of our organ donation system, sometimes focused on instigating presumed consent. For instance, a recent editorial in the *Calgary Herald* suggests the following after a discussion of Baby Kaylee's circumstances:

One solution may be to follow Spain's example and assume that the organs of anyone who dies will be transplanted unless otherwise specified in advance. This would provide a larger supply of donor organs and help reduce the possibility of a scenario like that at Sick Kids [Hospital] recurring.³

An older headline from the *Edmonton Journal* reading "Canada's organ-donation rate among world's worst"

provides less specific criticism in a much more direct manner.⁴

Is Canada's system of organ donation really that bad? Is changing our consent system necessary for boosting our donation levels? Do we really have an unacceptably low organ donation rate? I argue that the answer to all these questions is "no."

This paper will attempt to defend Canada's current donation organ consent system. While both live and cadaveric donation are important factors to consider in this context, this paper will only take issue with the consent system for post mortem cadaveric organ donation.⁵ Specifically, I intend to argue that (1) Canada's rate of organ donation is not as bad as portrayed, (2) presumptions regarding consent have limited impact on donation rates and (3) legal, political and practical factors in Canada favor the retention of our current explicit consent system.

What is Explicit Consent vs. Presumed Consent?

Canada's Current System of Explicit Consent to Cadaveric Organ Donation

Organ donation legislation is within provincial jurisdiction and, as a result, there are a variety of different legislative approaches. Despite differences, however, all provinces operate on an "express consent" (or "opt in") basis. In an express consent model, organ donation can only occur after a potential donor has expressly consented (through registration in a donor registry, oral direction



or written direction) to the removal of their organs after death. If the donor does not consent before their death, a surrogate decision maker is generally appointed by legislation to decide for the potential donor. Surrogate decision makers are selected in order of legislative priority, with non-estranged spouses at the top and a non-family member lawfully possessing a donor's corpse at the bottom. The key feature in an express consent system is that, without some positive consent (from the donor or surrogate decision maker), the donor will be presumed not to have consented and no organs will be removed.

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While a donor's consent to have their organs removed for transplant following death is legally binding and sufficient to authorize the harvesting of those organs,⁶ in practice a potential donor's family effectively possesses a veto. Hospitals or transplant agency staff will, if a potential donor has family, request the family's permission even if the donor has already recorded consent. This creates the somewhat curious possibility that a donor's family could overrule an otherwise valid donor consent. The status quo is summarized by Dr. Fady Moustarah, who writes

Under our current system, there is little incentive for anyone to sign a donor card. As a potential donor I have to foresee my death, realize the need for organs and sign my donor card as a goodwill gesture, all the time realizing that my family's wishes might be given precedence over mine.⁷

There are several reasons why a family's wishes continue to play such an important role. Arnold notes that convening with family is necessary to determine

if a previously given consent has ever been revoked (though he also notes that there is no obligation on a family to *prove* the existence of a revocation).⁸ There is also the prospect of malpractice suits or statutory and professional penalties for removing an organ where a family is not consenting.⁹

Perhaps most significant is the fear that removing over familial objections would draw significant negative attention and undermine the trust needed between the public and medical profession. This concern was made painfully clear after the Alder Hey and Royal Infirmary scandals in Great Britain.¹⁰ Though neither of these scandals related directly to organ donation or transplantation, it was accepted that these events had considerable impact on the debate surrounding a proper organ donation system in the United Kingdom.¹¹

The Alternative: A Presumed Consent System

A presumed consent system is conceptually simple, and is intended to specifically increase donors among those who have failed to leave instructions. Under a presumed consent system, all deceased patients are presumed to have consented to be organ donors in the absence of a specific *withdrawal* of consent (generally recorded in a national central registry). For this reason they are sometimes referred to as "opt out" systems, since one is automatically considered to be a donor unless a refusal of consent is recorded.

The theoretical advantage of a presumed consent system is simple. Given that many (if not most) citizens will fail to discuss their donation wishes with family or record their wishes in writing, presuming consent instead of non-consent should remove a barrier that would have otherwise barred such donations.

There are various types of presumed consent systems. A truly irrebuttable presumption of consent would be, in essence, conscription of organs. A "hard" presumed consent system allows donors to opt out (usually by registering a non-consent with a central registry), but, failing this, would allow no other factor to interfere with organ or tissue removal. Family vetoes would have no place in such a system. These systems exist more in theory than practice since, as I will discuss later, most systems, in practice, allow some (if not considerable) family involvement even if such involvement should be legally precluded. The more common "soft" presumed



consent systems will avoid retrieving organs if there is any objection to the procedure (like a family's refusal to allow the procedure). Indeed, "soft" presumed consent systems often look a great deal like Canada's express consent systems, since both often give the family a veto in practice.

While those opposed to presumed consent often suggest that practical, administrative or technological barriers will make a presumed consent expensive, unwieldy or unworkable, this paper will not address these criticisms.¹² Instead, this paper will argue that presumed consent is not compatible with Canadian health law, and will suggest that this is not a real concern since the actual effect of presumed consent on donation rates is overstated.

How Bad is Our Rate of Donation?

Before we can gauge the necessity of any reform, the status of Canada's current system warrants consideration. Undoubtedly Canada is, like all other developed nations, facing an organ shortage. The gross number of donations has remained reasonably consistent over the past ten years, though the actual cadaveric donation rate has declined (slightly) from close to 15 per million to about 13 per million.¹³ Most donations come from neurological deaths, though Canada has slowly begun accepting donations following cardiac death in very limited numbers. Our rate has consistently been below what is necessary to meet the demand for transplantable organs.¹⁴

Older data from the Urban Futures Institute suggests that, given the current declines in birth rate and rapidly aging population, organ shortfalls are likely to worsen in the near future. Assuming a constant or slowly increasing donation rate, the report estimates that by the year 2020, there will be 16,250 citizens whose transplant needs are unmet (a 199% increase over the year 2000), and by 2040, the report estimates this number will rise to 21,265 (a 291% increase over the year 2000).¹⁵

Canada's donation rate is often portrayed as frighteningly low by the media. While it is far from the world's worst, Canada's gross rate appears, superficially, to be significantly below that of the United States (approximately 20 per million) and Spain, whose rate of donation is the world's highest (approximately 32 per million).¹⁶

However, these statistics do not reveal the entire story. Compared to Canada, many countries with higher organ donation rates, including Spain and the United States, also have higher rates or significantly higher rates of traffic fatalities.¹⁷ Compared to other causes of death, MVA fatality victims tend to involve otherwise healthy people (with viable transplantable organs) who undergo a sudden and catastrophic trauma.¹⁸ As such, countries with higher traffic fatality rates have a greater pool of potential donors from which to draw. While the link between traffic fatalities and donation rates is debated, it remains largely accepted that a higher traffic fatality rate will feed a higher donation rate.¹⁹

Taken together, what emerges is the fact that Canada's rate of cadaveric donation may not be as bad as it may be portrayed.

Additionally, there have also been concerns raised that, due to differences in statistical collection, Spain's and the USA's rate of donation appears inflated compared to Canada's. Canada's rate reflects actual donors (situations where at least one solid organ is actually transplanted into a recipient). Spain and the United States count both actual transplants *and* situations where an organ is recovered but not transplanted.²⁰

Taken together, what emerges is the fact that Canada's rate of cadaveric donation may not be as bad as it may be portrayed. David Baxter of the Urban Futures succinctly sums up this situation, noting that "Canada cannot achieve Spain's, or the United States' cadaveric donation rates because it does not have the mortalities to start with."²¹ Clearly, Canada's lower rate of donation cannot be solely attributed to flaws in its system.

How strong is the correlation between presumed consent systems and donation rates?

Advocates of mandated choice point to Canada's donation rate of 14 per million and compare it to Spain's or that of other parts of Europe where presumed consent is the



rule, and suggest that boosting Canada's donation rate could be as simple as reversing this presumption. While there has been some empirical evidence that presumed consent may boost organ donation rates,²² other studies have concluded that such a finding is confounded by cultural, demographic or legislative/policy factors.²³ Kieran Healy argues that, while presumed consent countries do perform slightly better on average than explicit consent countries, this is not due to presumed consent *per se*, but primarily because "countries with presumed-consent laws are more likely to have paid close attention to the social organization of their transplant systems."²⁴ Healy supposes that cases like Spain and Italy owe their success to effective investment in transplant logistics, staffing, training, and administrative coordination.²⁵ I believe that a brief examination of two very different experiences with presumed consent validates Healy's supposition.

The Spanish Experience

Spain's rate of cadaveric donation is currently the highest in the world, and has been for some time. As a result, Spain is often viewed as the country to emulate in this field. Some attribute some of Spain's success to its adoption of presumed consent. Ironically, I would suggest that a close look at Spain's organ donation history illustrates that their adoption of presumed consent likely had a very limited effect on overall donation.

The Spanish government enacted a presumed consent law in 1979. While the new law did pay considerable dividends, the Spanish organ donation system floundered again through the mid 1980s, plagued with erratic donation rates, lack of infrastructure and administrative inefficiencies.²⁶ According to Carlos Gil-Díaz, the system was "perceived as being on the verge of collapse" during the mid 1980s.²⁷

The true turning point came in 1989, when the Spanish Ministry of Health set up the National Organization of Transplants (ONT). The ONT is a national body responsible for administering and coordinating Spain's system. Shortly after its creation, the ONT reorganized the Spanish system to allow more efficient and greater regional decision making. The ONT made extensive efforts to put infrastructure and training into place for transplant teams. These efforts bore tremendous

dividends – between 1989 and 2006, Spain's organ donation increased enormously and has remained at a sustained high level for years.

It is impossible to argue that Spain's hard presumed consent system was the sole, or, it appears, even major cause of this increase. Indeed, a 1993 Spanish poll found that up to 60% of Spanish citizens actually viewed the presumed consent law as an abuse of authority, and 7% believed that excluding the potential donor's family was insulting and disrespectful.²⁸

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Responding to this concern, the ONT actually began discouraging healthcare providers from mentioning the presumption of consent and absolutely respecting a family's refusal even if their deceased relative had not registered a non-consent. The ONT's primary fear was that trying to enforce the presumed consent law strictly would "increase grief and would taint the system as coercive, labeling the ONT as an organ hunting device protected by an abusive law."²⁹ This approach appears to have paid dividends – as Miranda *et al.* point out, Spain's rate of family refusal fell to 21.3% in 1998, representing a drop of almost 30% from refusal rates in the early 1990s.³⁰ The authors credit this to significant efforts to overcome various obstacles, including an earlier reluctance to approach grieving families.³¹

The Brazilian Experience

Far less needs to be written about Brazil's attempt at presumed consent. By way of background, the Brazilian law was passed in 1997, became effective in 1998 and immediately faced heavy criticism.³² Csillag notes that, in practice, almost all surgeons sought consent from family members, even with the presumed consent law in place, ultimately requiring another paragraph to be added to



the law legitimizing this practice.³³ Nevertheless, the law remained highly criticized and was ultimately repealed in 2005.

Certainly Brazilian healthcare has faced and continues to face many problems. Access to medical care and the quality of that care varies greatly for different social classes in Brazil.³⁴ Further, had donation rates increased, Brazil still lacked the necessary infrastructure and administrative effectiveness to take advantage of such a gain.³⁵ However the core problem with presumed consent in Brazil was widespread public distrust towards the medical profession. Csillag writes that

Popular imagination also played a part in the downfall of the law. Part of the population feared that their organs would be removed even before they were clinically dead. Many rushed to public offices to register themselves as non-donors, to avoid such a risk.³⁶

Apparently there were even difficulties registering as a non-donor in Brazil, further fueling the fear that the law was ultimately an attempt at exploitation.³⁷

There is no evidence that presumed consent in Canada would fail as spectacularly as it did in Brazil. Canada undoubtedly has a better resourced healthcare system and, hopefully, a greater level of trust towards the medical profession. Spain's and Brazil's experiences, however, demonstrate that the adoption of a presumed consent is, at best, one (arguably minor) part of a reform to boost donation. At worst it may even be painfully rejected by the populace. The following, and final, section of this paper will examine the Canadian context and consider whether presumed consent would be likely to have any positive effect in Canada.

Would Presumed Consent Work in Canada?

Presumed Consent is not strongly supported in Canada

From a legal perspective, the ability to give or withhold consent to actions towards one's own body is grounded in well established legal tradition. The general common law rule was stated succinctly in 1914 by the celebrated jurist Benjamin Cardozo who wrote "[e]very human being of adult years and sound mind has a right to determine

what shall be done with his own body."³⁸ While there are some exceptions to this principle, Picard & Robertson note that, "the right to refuse medical treatment is so fundamental, it is protected not only by the common law but also the Constitution, falling within the right to liberty and security of the person under section 7 of the *Canadian Charter of Rights and Freedoms*."³⁹ There can be no debate that autonomy in decision-making is a central feature of Canada's medical law.

While a presumed consent reform would not likely fail due to legal challenge, there is legitimate reason to be concerned that presumed consent does not fit neatly in Canada's system. The Committee on Increasing Rates of Organ Donation argues that presumed consent may be unacceptable in nations where personal autonomy is highly-prized.⁴⁰ While they accede that an ideal long-term goal may be a society so committed to organ donation that presumed consent is acceptable, they state that the United States (and, I would argue, Canada), is not yet there. The Kidney Foundation of Canada has likewise stated that it does not support a presumed consent system on the grounds that it "is inconsistent with free and informed decision making."⁴¹ Frank Markel, CEO of Ontario's Trillium Gift of Life Network, stated in 2006 that he believes Ontario is not ready for presumed consent, and has indicated that presumed consent should not be viewed as a panacea to organ donation difficulties.⁴²

There is also some very recent evidence that the Canadian public would approach presumed consent with some trepidation. In 2008, Ontario attempted to reform its organ donation system, with several bills simultaneously being considered to accomplish this. One (proposed by MP Peter Kormos) would have, if passed, made Ontario the first jurisdiction in Canada to operate on a presumed consent to donation basis.

The dissolution of the provincial parliament prevented any of these initiatives from reaching fruition. However, in the wake of these bills, the Ontario government sponsored a citizens committee to consider possible reforms to its organ donation system. After hearing expert testimony on organ donation and transplantation policy, the committee did not recommend the enactment of a presumed consent system.⁴³ Participants felt that presuming consent after death was a violation of civil rights and expressed concern that the government would fail to adequately inform all residents of Ontario



(particularly new immigrants or those lacking capacity) of their rights and responsibilities under presumed consent. Interestingly, the panel's report points out that the topic of presumed consent often generated the most heated debates.⁴⁴

Another paper in this issue also found that recent immigrants to Canada have negative views of presumed consent and actually view it as "un-Canadian."⁴⁵

While it is undeniable that Canadians consistently report high levels of support for organ donation *in general*,⁴⁶ this does not necessarily translate to support for presumed consent. Repeated studies show that two thirds of Swedish citizens are in support of organ donation, yet only about 40% would consider donating a loved one's organs if their wishes were not known.⁴⁷ In short, there is no evidence that presumed consent enjoys any popular support in Canada at this time.

Family Wishes are Ultimately Still Determinative in Canada

Given that Canada's system and many presumed consent systems allow a family veto in relation to donation, there is also the legitimate concern that moving from an express to presumed consent system will have little practical effect. Studies of European countries comparing different consent systems have, in fact, found that there is very little practical variation between consent systems.⁴⁸ In other words, even if Canada were to presume consent, the family veto would probably still be determinative. While Abadie & Gay suggest that modifying the legislative default for donation may affect family behavior,⁴⁹ this is not backed by evidence in the Canadian context.

At the outset, I fully concede that the family veto is not supported by legislation and can potentially lead to the odd situation in which a donor's genuine wishes are thwarted by the wishes of their family. Indeed, all but two provinces specifically state within their legislation that a valid consent before death is valid and binding on healthcare providers and protect healthcare professionals from good-faith mistakes. Despite these measures, the practice of asking families for their permission prior to organ removal has remained firmly intact in Canada. So long as this is the case, a move to presumed consent will be a reform in name only.

Is the Family Veto the Real Problem?

Given the criticism the family veto often receives, it may be reasonable to pause and question whether this veto is the true problem with the Canadian organ donation system, since this issue often arises alongside debate over the consent system. While I accept that the family veto has no support in law, I would suggest that it has very limited practical impact.

There appears to be an unproven concern behind the criticism of the family veto; namely, that distraught families will routinely override their loved one's otherwise valid consent. While there is no comprehensive data on this subject, what data does exist appears to go the other way. A recent survey carried out by the Canadian Council for Donation and Transplant found that the overwhelming majority of Canadians surveyed are "very likely" or "somewhat likely" to consent to organ donation on behalf of a loved one if that loved one has filled out a donor card, discussed their wishes, or both.⁵⁰ The Council of Donation and Transplantation has found that 80% of healthcare providers⁵¹ and 89% of the public⁵² felt that a deceased's recorded wishes should take precedence over that of the family in the event of a conflict. While fewer respondents in both groups believed this actually happens, it appears that most Canadians are willing to follow their deceased relative's wishes, if given the opportunity.

The real problem appears to arise where donors have not made their wishes known. Data from the Trillium Gift of Life Network suggests that only half of Ontarians have signed their donor card and less than half have discussed their wish to donate with family despite the overwhelming majority of Ontarians believing these steps are important.⁵³ Further, a vast majority of Ontarians very strongly supports organ donation in general.⁵⁴ Similar trends exist in Canada as a whole, with some estimates finding that only 54% of Canadians have signed their organ donation card, only 17% have placed their name on a donor registry (if one exists in their province) and only 58% have discussed the wish to donate with their family.⁵⁵

Where a potential donor does not discuss their wishes, complete their donor card or add their name to a registry, relatives are far less likely to consent on their behalf. In the study of the public mentioned above, 49% of respondents would be not at all likely or somewhat unlikely to agree to donation without guidance from



a donor card or explicit wishes.⁵⁶ This is consistent with other data suggesting that, in the absence of any authorization, family members tend, for a variety of reasons, to default to refusing consent.⁵⁷ The problem is not the family veto, it seems. The problem is that too often family members have insufficient information to feel comfortable consenting to donation.

A family veto need not preclude a successful donation system. Spain's system is functioning admirably and contains a well-established practice of involving grieving families in the decision making process. R. Matesanz, founder and former director of Spain's national organ

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procurement agency, notes that 78% of Spanish families who initially refused consent changed their mind after speaking with a transplant coordinator.⁵⁸ Belgium has Europe's second highest rate of cadaveric donation (almost 28 per million).⁵⁹ Although Belgium uses a presumed consent system and families are not generally asked for consent, families are included and their resistance can stop a donation in some circumstances.⁶⁰ In Austria, consent is presumed and family members do not even have a legal right to know if doctors envision a possible donation from their deceased relative. Nevertheless, in practice the next of kin are usually contacted and asked whether they can agree to donation on behalf of their deceased relative.⁶¹ Austria's rate of cadaveric donation is high (about 18.8 per million).⁶²

Like Canada's explicit consent system, the family veto receives considerable criticism but likely has a far more limited practical effect. Dialogue with family will always be necessary for inquiring about a potential donor's wishes, their health status or to rule out any medical conditions precluding donation. Interaction and building consensus with a grieving family are also crucial for maintaining the positive public image

and trust necessary for the continued success of organ donation organizations.⁶³ Abandoning the practice of seeking familial consent to donation could alienate grieving relatives and, ironically, impair donations. It will also do nothing to address the real problem: the fact that most Canadians do not take adequate steps to make their wishes regarding donation known.

Conclusion

Laws, customs and public sentiments can change with time. Indeed, perhaps there will be a time in the future when Canadians do support a presumed consent system and a legislative change to that effect may be in order. That time is not here yet.

In the meantime, Canada's system of donation is working. Studies show that Canadians are both highly supportive of donation and generally very willing to follow the explicit instructions of a relative wishing to donate. Canadians could do a far better job filling out their organ donation cards or discussing their wishes with their loved ones, but there is little reason to believe that presumed consent will do anything to remedy this deficit. Changes at the organizational level may also pay significant dividends, as has occurred in Spain. After all, as Healy aptly notes, "Organizations are easier to change than baseline death rates, the entire healthcare system, or the cultural traditions of a whole country."⁶⁴

Ontario's Citizen's Panel on organ donation recommended introducing a "mandated choice" model, which basically involves having citizens fill out their donation preference during routine renewal of government forms (like renewing a driver's license).⁶⁵ Such a reform is untested in Canada, but could at least prompt people to consider recording their wishes or discussing this important topic with family or friends beforehand. A mandated choice model has been introduced in New Jersey and its effect should be closely observed.⁶⁶

Presumed consent may seem like a logical way to improve donation rates, but its effects are exaggerated and it is not supported by Canadian citizens. In short, presumed consent is a reform whose time has not yet come in Canada.

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Endnotes

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- 17 Norris, *supra* note 5.
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- 21 Baxter, *ibid.* at 31.
- 22 Alberto Abadie & Sebastien Gay, *The Impact of Presumed Consent Legislation on Cadaveric Organ Donation: A Cross Country Study* (Cambridge, Mass: National Bureau of Economic Research, 2004). The authors perform a regression analysis on numerous countries (including Canada) over a 10 year period while accounting for confounding variables (GDP per capita, traffic related fatalities, etc.). The analysis suggests that presumed consent systems increase donation rates by between 25 and 30%. See also Everton Nunes da Silva, Ana Katerina &



- Giacomo Balbinotto Neto,, *The Impact of Presumed Consent Law on Organ Donation: An Empirical Analysis from Quantile Regression For Longitudinal Data* (Rio de Janeiro: Brazilian Association of Graduate Programs in Economics, 2007).
- 23 See Amber Rithalia *et al.*, “Impact of presumed consent for organ donation on donation rates: a systematic review” (2009) 338 *British Medical Journal* 284. This study found that donor availability, transplantation service infrastructure and organization, national wealth/investment in health care and citizen’s attitudes to and awareness of organ donation may all significantly affect donation rate, though the precise role each factor plays is unclear.
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- 25 *Ibid.*
- 26 Carlos Gil-Díaz, “Spain’s Record Organ Donations: Mining Moral Conviction” (2009) 18 *Cambridge Quarterly of Healthcare Ethics* 256.
- 27 *Ibid.* at 257.
- 28 *Supra* note 26 at 258.
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- 44 *Ibid.* at 73.
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- 46 96% of Canadians “very strongly” or “somewhat” approve of organ and tissue donation: Canadian Council for Donation and Transplantation, *Public Awareness and Attitudes on Organ and Tissue Donation and Transplantation Including Donation After Cardiac Death: Final Report* (Edmonton: Canadian Council for Donation and Transplantation, 2005).
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- 48 Sjeff Gevers, Anke Janssen & Roland Friele, “Consent Systems for Post-Mortem Organ Donation in Europe” (2004) 11 *Eur. J. Health L.* 175
- 49 Abadie & Gay, *supra* note 22.
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- 52 *Supra* note 46.
- 53 *Supra* note 8 at 146
- 54 *Ibid.*
- 55 *Supra* note 46. Note also that 90% of respondents believe their wishes will be respected.
- 56 *Ibid.*
- 57 See for example Marsha Exley, Nancy White & Jan Hoot Martin, “Why Families Say No to Organ Donation” (2002) 22:6 *Critical Care Nurse* 44; *supra* note 45.



- 58 R. Matesanz, "A decade of continuous improvement in cadaveric organ donation: the Spanish model" (2001) 21 *Nefrología* 59.
- 59 Directorate-General for Health & Consumers, *Key facts and figures on EU organ donation and transplantation* (Brussels: European Commission, 2007).
- 60 *Supra* note 48.
- 61 *Ibid.*
- 62 *Supra* note 59.
- 63 Beattie *et al.*'s article in this edition contains a discussion on the importance of building consensus to healthcare providers and recent immigrants. See *supra* note 45 at 65.
- 64 *Supra* note 24 at 1043.
- 65 *Supra* note 43 at 46.
- 66 Donate Life New Jersey, *New Jersey Hero Act: Summary*, online: Donate Life New Jersey <<http://www.donatelifenj.org/Professional-Educators/Hero%20Act.pdf>>.

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