

Point of view

Valid informed consent: the key to increasing supply of organs for transplantation?

Our society currently faces a critical shortage of organs for transplantation.¹ In 2004, 20% of Australian patients on a transplant waiting list died before receiving a life saving organ.² This situation is replicated in many countries including America where 5,794 people died whilst waiting for an organ transplant in 2000.³ With one-year graft survival rates for most organ transplants of 80 - 90%,⁴ this highly successful medical procedure continues to be curtailed by organ shortages. While this shortage remains an international phenomena, countries such as Spain are applauded for their success in attaining relatively high organ donor rates. In 2002, Spain had the highest rate of organ donation in the developed world with 34 donors per million population (dpmp), as compared to 12.9 dpmp for the U.K and 10.6 dpmp for Australia.²

In Australia, poor donation rates have been attributed to its voluntary system of organ donation (also referred to as the 'Opt-in' system). This system requires the explicit consent of the individual or their next of kin. In contrast, Spain's success rates have largely been attributed to their 'Opt-out' or presumed consent model for organ donation² which is "based on the assumption that silence or inaction implies consent".⁵

Australia, the U.K and many other countries have reached an impasse in the disparity between the supply and demand of transplantable organs.^{6,7} In the search for a sustainable solution to this shortage, heavy-handed and coercive methodologies have emerged. Justification for such approaches has been that 'softer' solutions, which respect autonomy and appeal to an individual's sense of goodwill and altruism, have failed in their aims of encouraging people to donate voluntarily. As a result, countries such as the U.K, which, like Australia, currently rely on voluntary participation, are now being asked to consider presumed consent models as a response to public inaction to register as organ donors.⁵ This approach assumes that people in society are generally ambivalent or have a reluctance to consider the issue of donation for reasons such as a fear of facing their own death.⁶ Such proposals aim to increase the supply of organs by ostensibly coercing competent adults into an inherently altruistic act.

Hence, the two seemingly irreconcilable dilemmas we face are: the need to increase organ donation rates in order to help the sick, and the need to adopt strategies to meet this increase that are ethically sound and balanced against the rights of individuals in society.

In an attempt to respond to growing demand for transplantable organs (both perfused and non-perfused), ethical debate has vacillated between an individual's inherent right of free choice and self-determination (deontological concerns or obligations), versus the utilitarian demand for organs. Subscription to purely teleological ethics is unlikely to provide a sustainable solution to organ shortages since the rights of the individual are rendered subordinate.

Up to this point in time, inability to meet organ demands has led to a number of reactive and 'hard-line' proposals. Some of these include: the use of prisoners for kidneys in exchange for commuted sentences or staying of death sentences,⁸ the replacement of informed consent models with those of presumed consent, the use of anencephalic new born children⁴ and the conscriptive acquisition of all cadaveric organs as rightful property of the state.⁹ In addition, it has been suggested that increasing organ supply is achievable by redefining the concept of death to include those with lesser brain injury,¹⁰ and define death according to neocortical criteria, thus allowing those in Persistent Vegetative States (PVS) to be utilised for organs.⁴ Further to this, the "Communitarian Approach" as described by Etzioni, aims to ensure that people donate their organs through 'moral persuasion' and through 'chiding of those that do not do what is considered right'.¹¹ This approach enforces the notion that donating one's organs is the moral or utilitarian obligation of the individual.

'Opt-out' or presumed consent model

Advocates of the 'Opt-out' or presumed consent model rationalise the need for its use based on poor success rates of voluntary models. In addition, relieving pressure on the family of the deceased by making organ donation routine is considered a major advantage.⁵ Some patrons of this model, based exclusively on utilitarian demand for organs, claim that it is unacceptable that individuals have surviving interests in how their body is treated after they die. They petition that the body of the deceased ought to become property of 'the state', to be used as required to save the lives of the living.⁹ On the other hand, Glannon argues that presumed consent is at best "an ill-informed notion" and at worst "an outright deception".³

The term 'presumed consent' is traditionally used in the health care setting in situations where the individual is deemed incompetent to make informed choices for themselves, thus allowing health care professionals to make paternalistic choices considered to be in the best

interests of the patient.

By imposing a policy of presumed consent for organ donation upon competent individuals, overrides their basic right of autonomy.⁵ The principle of autonomy is based on respect for the individual's right to self-determination, and includes the mandate to decide what happens to one's body after death.^{3,5} The failure to respect individual values and wishes after death could have uncertain implications for the rights of the living. Such a situation could be reasonably construed as the erosion of the rights of the individual if made subordinate to greater societal agendas, such as the need to procure more organs for the sick.

Emergence of proposals to improve organ donation rates, which belie a culture that upholds so highly the right of autonomy, may result in growing intolerance to such paternalistic determinations. It is possible that societal intolerance will manifest in resentment, mistrust and refusal to donate.¹¹

In addition, some proposals aimed at increasing donation rates are motivated by the assumption that for whatever reason, people in society do not wish to do the 'right thing' by actively registering to donate.¹¹ However, repeated surveys in the U.K show that 70% of the population maintain their willingness to become organ donors, but only 15% have formally registered to do so.⁶ It is questionable whether forcing the population to donate through legislation changes will actually foster altruistic motivations and long term goodwill.

To claim that a person 'donates' organs under a presumed consent model is fundamentally contradictory. Organ donation is an act of altruism - a gift from one individual to another,¹² and mandatory procurement under the rule of law, fundamentally alters the nature of this transaction from that of a voluntary act of altruism to one of compliance and acquisition. The giving of one's organs to another can only be considered a gift, since attempts to commodify human organs have been ethically problematic and led to legal prohibition.¹³ To buy or sell human organs and tissues in any form is to diminish human value and dignity which is above that of using body parts as a means to solve a supply and demand problem.¹³

Existing and proposed models of presumed consent are not only inconsistent with the principle of autonomy, but coupled with other proposals with a strong emphasis on teleological considerations, could serve to foster community resentment and mistrust. Ultimately such models will prove counterproductive to their aim of increasing organ donor rates. Models such as Mandated Choice have been suggested as an ethically preferential substitute for presumed consent systems. Mandated choice requires that all competent individuals record an explicit choice in regards to organ donation.¹¹ It has been argued that pressuring people to make this

choice does little to enhance an altruistic willingness to do so, and may foster a recalcitrant indignance and refusal to donate.¹¹ However, a model of mandated choice that embraces all components of informed consent may go some way in alleviating these concerns.

Current 'Opt-in' or informed consent models

Current informed consent models allow individuals to volunteer to donate their organs by actively registering before death, as a 'living will', or via surrogate consent after death. There is concern that this system in its existing form is not meeting current organ demands,^{5,13} and has been the motivating reason for the evolution of hard-line proposals. Originators and supporters of alternative proposals fail to recognise the detrimental subsidiary effects of solutions that lack disclosure and coerce the public into donation. Galea and Pegg, cite anecdotal evidence that refusal to donate rose from 25 - 30% to 50% following enquiries into organ and tissue retention without consent,¹⁴ highlighting the value society places on transparency and informed choices.

In the author's opinion, greater societal confidence and trust in the process of organ donation is achievable by abandoning hard-line proposals and enhancing existing voluntary systems through fully utilising the notion of informed consent.

The notion of valid informed consent

Mitchell, Lowe and McPhee describe the constituents or stages of informed consent as Competence, Disclosure, Understanding, Voluntariness then Consent. Adherence to all stages will render any given consent as 'valid'.⁴

Fully utilising informed consent in the organ donation process has two major advantages. Firstly, it upholds the important ethical principle of autonomy, and secondly, adherence to all constituent stages will allow greater transparency and will augment community trust in the organ donation process. It would be naive to purport that the sole solution to organ shortages lies in this notion alone, but could be argued as an ethically preferable option, which in the long term, is likely to gain greater community support than hard-line and paternalistic strategies.

Competence is a pivotal criterion for informed consent. Competence in the health care context is broadly defined as the capacity to comprehend the nature and consequences of medical procedures.⁴ Precisely assessing and defining competence is complex and difficult to achieve as no objective and absolute criteria exist to do so.⁴ According to Common law there is a general presumption that adults are competent, and hence possess the capacity to make autonomous choices regarding their bodies.⁴ For those in society that are

considered incompetent, it would be ethically objectionable to support any future proposal that would permit paternalistic or surrogate decisions to be made on their behalf regarding organ donation whilst they are living. It would not be in the person's immediate medical best interest to do so. Surrogate decisions are currently made following death in these cases and other instances where the wishes of the deceased are unknown.

Disclosure: One possible reason people refuse or hesitate to make decisions regarding organ donation, is not because they object (as the 70% in the U.K surveys demonstrated), but rather because they lack the information they feel is necessary to make this choice. Disclosure involves the giving of all relevant information: both benefits and risks.¹⁵ Many campaigns designed to encourage people to donate, focus only on the benefits to organ recipients, highlighting the flawed assumption that the dead cannot be harmed posthumously.⁵ A decision to either donate or not donate based on disclosure of benefits to recipients only, cannot be considered informed and hence is invalid. Effective campaigns should be objective, factual and discuss both benefits and risks of which, in the context of organ donation, it would be reasonable to include such aspects as the emotional or spiritual implications resulting from different procurement options or processes. Campaigns based on motivating the public to donate through guilt alone clearly do not meet this criteria. Comprehensive disclosure by Organ Donor Agencies and health care bodies will provide transparency and serve to foster community trust. Such an approach is likely to diminish suspicion of hidden agendas and biases, thus allowing the individual the freedom to make an altruistic choice if it is their wish to do so.

In addition, while general awareness campaigns are crucial to the cause of increasing organ supplies, they may not seek out individual responses. Detailed information packages specifically sent to all members of the community might elicit not only greater awareness and knowledge regarding organ donation, but enable people to feel that this is a personalised request or invitation.

Understanding is fundamental to one's capacity to make an informed choice. Public understanding regarding organ donation needs to be assessed as an instrument to ascertain why more people do not register to donate. Perhaps the 70% willing to donate in principal have fundamental gaps in their knowledge and understanding that, if addressed, would provide the necessary impetus to register to donate.

Consent given by a patient in the hospital context is assessed by the person seeking this consent. Understanding of the disclosed information is assessed

via conversation and direct questioning. Understanding involves not only the comprehension of disclosed risks, benefits and options, but also the implications of giving consent.¹⁵ A comprehensive survey of the general public would provide valuable insights into the misconceptions or gaps in the public's understanding regarding organ donation. Such information could be utilised in the formation of campaigns designed at increasing public knowledge and cooperation.

Voluntariness is the giving or refusal of consent free from manipulation or coercion. Whilst presumed consent models deny individuals the ability to make voluntary choices, other proposals aimed at increasing organ donation do so through guilt or peer pressure such as the "Communitarian Approach" which relies on moral persuasion and chiding to reach its goal.¹¹ Individuals must feel free from pressured hard-selling, societal shunning, punitive repercussions, and labels such as being a 'free-rider' if they do not make the 'right choice' by agreeing to donate their organs.¹⁶ Emotion-laden appeals from advertising and media campaigns aimed at increasing donor rates constitute weaker forms of control and coercion.¹⁵ Similarly, rational persuasion as to the merits of organ donation by health professionals to surrogate decision-makers at a time of grief may render any agreement non-voluntary.¹⁵

Consent needs to allow equally for agreement or refusal to procurement, as both constitute consent. Processes that favour agreement, but hinder individual's attempts to refuse in any way, are inconsistent with the notion of informed consent, and hence render the consent invalid. Presumed consent models impede individuals freedom to object to donation by requiring these people to actively register not to have their organs procured, whilst leaving some residual doubt as to whether the registering agency will actually maintain this objection and respect it upon their death.^{11,14}

Furthermore, potential donors should be given the ability to choose which procurement option (i.e. brain death, cadaveric, Non-Heart Beating organ Donation - NHBD) they agree to and those they do not. This ability has the advantage of not only upholding a greater degree of autonomy, but is likely to capture the constituency of society that object to one type of organ procurement, but not to all procurement options. Such individuals in the current climate are lost to the process, as they have no choice but to object to organ donation in totality. By permitting greater freedom of choice, individuals that may object to procurement under Brain Death criteria on religious grounds for example, may have no objection to procurement if it were to occur under Cardio-Respiratory criteria (e.g. cadaveric and NHBD). Conversely, recent emergence of non-heart-beating protocols in Australia may provoke uncertainty

and objection by some. Such individuals may instead take preference in agreeing to well established procurement options such as cadaveric and donation under brain death criteria.

Whilst this would perhaps constitute a small increase in available organs, it's merits also lie in the subsidiary effects of allowing greater autonomy, transparency, trust and enhancing societal good-will in the organ donation process. Increasing public confidence may hold the key to long term success of organ donor campaigns.

Since July 2005, The Australian Organ Donor Register is now a register of consent and allows the public the option of choosing which organs they are willing to have procured.¹⁷ Again, this option has the advantage of capturing that portion of society who may object to specific organs being procured, but not all organs. Prior to this choice being made available, these people were lost to the system perhaps due to the belief that they had no control over what happens to their body once they agreed to be a donor.

Finally, the concept of consent should be seen to exist along a continuum whereby given consent at one point in time can be withdrawn or changed at any time in the future.

Greater organ donor options may serve to foster community trust and lead to long-term escalation in the number of available organs. Society is likely to gain greater confidence and trust in the organ donation process through enhancement of current informed consent models. This is achievable by providing greater disclosure, assessing understanding and allowing broader freedom of choice.

CONCLUSION

Organ donation is an altruistic gift, not a right of the sick. Ethical principles such as individual autonomy should not be undermined or eroded in reaction to the utilitarian demand for organs. The use of coercive and paternalistic proposals as a sustainable solution to organ shortages is a retrograde philosophy that may inevitably lead to societal resentment and mistrust in the organ donation process and a refusal by many to donate. Such approaches may only serve to ultimately undermine the very aims they espouse of increasing organ supply. Community trust and compliance are achievable by abandoning such philosophies and by upholding autonomy through comprehensive adherence to the constituent stages of informed consent. In doing so, valid informed consent can be achieved, and an ethical

balance between deontological considerations of the individual and utilitarian needs of the sick can be reached.

P. M. McEWEN

Department of Intensive Care, Sir Charles Gairdner Hospital and College of Health, Notre Dame University, Fremantle, WESTERN AUSTRALIA

REFERENCES

1. Biller-Andorno N, Schauenburg H. It's only love? Some pitfalls in emotionally related organ donation. *J Med Ethics* 2001;27:162-164.
2. Australians Donate – The National Body for Organ and Tissue Donation for Transplantation. <http://www.organdonation.org.au/online/docs/statistics>. Retrieved 12th April, 2005.
3. Glannon W. Do the sick have a right to cadaveric organs? *J Med Ethics* 2003;29:153-160.
4. Kerridge I, Lowe M, McPhee J. *Ethics and law for the health professionals* (2nd Ed.) Sydney: The Federation Press 2005.
5. Wilkinson R. Organ donation: The debate. *Nurs Stand* 2000;14:41-43.
6. English V, Sommerville A. Presumed consent for transplantation: A dead issue after Alder Hay? *J Med Ethics* 2003;29:147-154.
7. Bell MDD. Non-heart beating organ donation: old procurement strategy – new ethical problems. *J Med Ethics* 2003;29:176-186.
8. De Castro LD. Human organs from Prisoners: Kidneys for life. *J Med Ethics* 2003;29:171-173.
9. Emson HE. It is immoral to require consent for cadaver organ donation. *J Med Ethics* 2003;29:125-127.
10. Vlatko N. Ethical implications of non-heart-beating organ donation. *Hum Life Rev* 2002;28:107-110.
11. Etzioni A. Organ donation: A Communitarian Approach. *Kennedy Inst Ethics J* 2003;13:1-18.
12. Rucker GM. Organ and tissue donation in the intensive care unit. *CMAJ* 2002;167:1248.
13. De Castro LD. Commodification and exploitation: Arguments in favour of compensated organ donation. *J Med Ethics* 2003;29:142-144.
14. Galea G, Pegg D. The ethics of donation: Changes are necessary and soon. *Lancet* 2003;362:932-934.
15. Mitchell KR, Kerridge IH, Lovat TJ. *Bioethics and Clinical Ethics for Health Care Professionals* (2nd Ed) Australia: Social Science Press 1996.
16. Eaton S. The subtle politics of organ donation: A proposal. *J Med Ethics* 1998;24:166-170.
17. Australian Government Health Insurance Commission. <http://www.hic.gov.au/>. Retrieved 14th April, 2005.