The Royal Australasian
College of Physicians

Queensland State Committee

Submission to –

Review of Organ and Tissue Donation Procedures Select Committee - Queensland Parliament

August 2008

Index

Executive Summary

Historically, Queensland has had high organ donation rates in comparison to other states when measured as donors per million population (pmp). However the donation rates have shown a continuous decline in recent years with Queensland now recording its lowest rates since donation commenced in Queensland in1969. A donation agency was established in Queensland in 2000 with the principal aim of improving organ donation rates. No research has been published by the agency so it is difficult to ascertain a reason for this poor performance in its management of donations.

Although there is some debate on the effect of presumed consent on donation rates a number of recent detailed studies have shown positive effects of such legislation. A presumed consent system has the potential to increase the donation rate and thereby benefit not only individuals in need of transplant but also the health system as a whole. It does not necessarily remove autonomy or altruism and places the need for action on the minority rather than the majority. It moves donation into being the societal norm.

Although the Spanish model has improved their donation rate it has had very limited success when transposed to non-Mediterranean cultural settings. Care must be taken when comparisons are made with other countries due to the differing definitions of donors, the much higher donation potential in Spain, their use of older donors, their high organ discard rates and their low transplantation rate in comparison to their organ removal rate. Aspects of the model that were either developed in Spain or imported from other countries have been successfully incorporated into other countries but the model as a whole has in general not succeeded.

Underlying the US model is a number of initiatives. All hospital deaths must be referred for assessment of suitability. Only trained and designated requestors are allowed to discuss donation with the next of kin. A number of regions use in-house coordinators. In the US, hospital units are nursing units (not medical units). All hospitals are subject to death record reviews. Although clinical audits and defined responsibilities are applicable

to Queensland this high cost system may not be. The in-house nurse coordinator model is mismatched with the medical unit model of Critical Care in Queensland.

The most recognised and successful model operating in Europe (and elsewhere) is the Donor Action model. This quality management program is based on best practice from the US, Spain and Eurotransplant and is currently used in over 400 hospitals in 17 countries. It has been successfully in a variety of cultural, legal and health service delivery frameworks. The program is hospital based. It provides the hospital with ownership of the donation process but also places the responsibility for improving donation performance with the hospital. Reported outcomes from this model have shown both an initial and a sustained positive effect on donation rates.

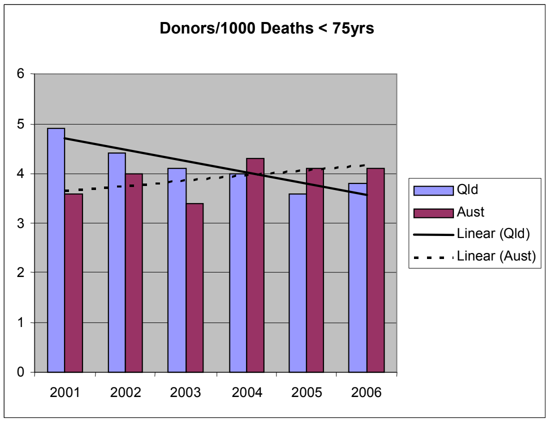
Major Recommendations.

1. ***The introduction of a presumed consent system is supported*.**
2. ***The introduction of the Donor Action Program is strongly recommended.***
3. ***An independent review of the performance, strategic and operational framework and the management of donation in Queensland is strongly recommended.***

Organ and Tissue Donation in Queensland

Historically, Queensland has had high organ donation rates in comparison to other states when measured as donors per million population (pmp). However this has declined dramatically in recent years with Queensland now recording its lowest rates since donation commenced in Queensland in 1969.

The measurement of donors pmp is essentially flawed in that it does not take into account the underlying potential for donation. Studies in the United States have shown that although a region's donation rate, as measured by donors pmp, may be low its actual effectiveness may be high when measured against the number of potential donors (1). That is to say that although the pmp rate is low the conversion of potential donors to actual donors is high. No good measurement of the donation potential in Queensland is available due to a lack of published data but data based on the more accurate measure (donors/1000 deaths < 75yrs) are available from the Australian and New Zealand Organ Donor Registry. These data show that while the overall donation rate in Australia is trending upward the donation rate in Queensland is trending downward (2). Given the inherent fluctuations in donation rates and the relatively small numbers involved even one year snapshots of data provide little information. Trend data provides a more reliable indicator of the true situation.



Tissue donation in Queensland does not seem to be affected by this continuing decline in the organ donation rate. This is most likely due to the larger number of potential tissue donors and the donation systems established by the tissue banks in the early 1990's. Although there has been some integration of these services they remain as tissue-specific banks.

In the context of increasing numbers of patients suffering from end stage renal disease these low organ donation numbers will mean an increasing burden on renal services in this state. It has been shown that in terms of both resource utilisation and patient outcomes renal transplantation is the best form of treatment for end stage renal disease. A continuing decline in organ donation rates will result in an increasing human and resource burden for this state. For the individual it will mean a reduction in both life expectancy and quality of life.

A donation agency was established in Queensland in 2000 with the principal aim of improving organ donation rates. The agency has made some improvement to areas peripheral to donation but the initiatives it has taken in respect of increasing organ donation rates have shown no positive results. Rather, it has overseen a continuous decline in the donation rate. This has occurred in the context of increased human and financial resources to the agency. No research has been published by the agency so it is difficult to ascertain a reason for this poor performance in its management of donations. Clearly the situation requires a major revision of the agency's strategic and operational framework and the management of donations in Queensland.

Presumed Consent

As noted in the Issues Paper there are two forms of presumed consent. A weak presumed consent model, in which the family of the deceased is consulted, and a strong presumed consent model in which there is no consultation with the family. In the European context Austria is the only country that practises the strong model. It also introduced the first presumed consent law, which was enacted by the Empress Marie-Thérése. This decree provided blanket consent to autopsy and for the use of autopsy specimens for medical purposes. In 1978 the Council of Europe recommended a presumed consent approach which allowed for the automatic removal of organs for transplantation from citizens but provided for those who object to register that objection. The objection would be given legal weight and donation would not occur. It would be presumed that those who did not register an objection were in agreement with donation. The 1977 Australian Law Reform Commission Report, ALRC7 – Human tissue transplants (3), considered presumed consent due to a "strong body of opinion in Australia in favour" but due to many opposing such a move concluded that "communities are likely to develop in the near future a much more favourable attitude". It also accurately predicted a shortage of tissue for transplantation with the current consent model.

A number of European countries have since enacted this 'Presumed Consent' legislation. The most noteworthy of these is Belgium. In 1986 the Belgian Parliament passed presumed consent legislation. The law applies to Belgian citizens and foreign nationals who have resided in the country longer than six months. Less than 2% of the Belgian population has registered an objection. An implicit consent law applies in all other cases. In the case of a potential donor where there is no registered objection the family is informed of the intent to proceed to donation. If at this point the family objects to donation then that objection is respected and donation does not occur. This represents an example of a weak presumed consent law. The majority of presumed consent countries (including Spain (1)) practise the weak model in this way. The key point in this model is that the discussions with the family are based on an assumption that donation will occur and that the discussion is not to obtain consent but rather to allow the family to voice an objection.

Although there is some debate on the effect of presumed consent on donation rates a number of recent detailed studies have shown positive effects of such legislation. In a study published in the Journal of Health Economics, Abadie and Gay (4) looked at potential factors affecting donation rates in 22 countries over a ten year period. They found that "when other determinants of donation rates are accounted for, presumed consent countries have roughly 25% - 30% higher donation rates than informed consent countries". They also noted that "families in informed consent countries infer that non-registered individuals had weak preferences for donation … and do not consent" and that "legislative defaults on organ donation may affect the consent decisions of the families, even if they are not enforced". In other words when the default position is an objection to donation (informed consent model), then the default prevails whereas in presumed consent countries where the norm is to donate then donation prevails. This is refected in the current situation in that 90% of Australians support organ donation yet reported consent rates from other States are just over half that number. It should also be noted that although Queensland may report that donation is volunteered in approximately 60% of cases this only relates to those cases where there is consent – it does not represent a consent rate. The Queensland consent rate is unknown as there are no published data. Mossialos, Costa-Font and Rudisill (5) from the London School of Economics analysed the results of a European Union survey (#16,230 respondents) to ascertain the determinants of willingness to donate. Their results showed that respondents living in "countries with presumed consent regulation have a higher willingness to donate". These studies support the gross donation data that presumed consent countries have higher donation rates and show the positive effect of presumed consent legislation on donation rates.

It must be noted that presumed consent legislation in isolation will not address the organ shortage problem. The two components of donation are the legislative framework and the clinical organisational structure of the donation process. Neither will achieve maximal results without the other.

The argument that presumed consent removes the ability to make an informed choice and removes the altruistic nature of donation may be seen as simply looking at the issue from a single point of view. It may equally be argued that presumed consent does not remove the opportunity for informed choice but allows it to the same extent as the opt-in model does. Within both systems there is a choice whether or not to donate while the provision of information in both systems is dependent on other factors. The only change that presumed consent makes to the process is that it moves the need for positive action away from those who do wish to make an altruistic commitment to those who do not want to make this same commitment. Donation is legal, it is beneficial to the society as a whole, and it has been embraced by virtually all religions and is acceptable to the majority of the populace therefore it would seem logical for it to be the default legal position. Presumed consent preserves personal autonomy by the provision of the option of registering as a “non donor”. Additionally a presumed consent model moves donation to the position of being the societal norm and the accepted thing to do.

Other Options

Although the type of legislation can have an impact on donation rates the framework within which donation occurs also impacts on results. A number of well recognised frameworks exist with each having both positive and negative aspects.

Spanish Model

The Spanish model is claimed to be the most successful of the donation models. This model does achieve good results but they need to taken in context. They achieve a higher donor rate pmp than any other country but this must be qualified by a number of facts.

The definition of “donor” differs from country to country. The majority of countries define a donor as having at least one organ donated and transplanted whereas the Spanish definition is having at least one organ donated. Therefore there may be “donors” within Spain who would not be classed as donors elsewhere.

Although historically countries have described their donation rate as donors pmp the use of the pmp rate is scientifically flawed (1) as it does not take into account the underlying potential for donation. Baxter (6) , in a study comparing donation rates based on age adjusted, cause specific mortality rates found that “Spain has a potential cadaveric donor pool that is approximately 50% greater than Canada’s”. Another study found that “The high Spanish organ donation rates are largely attributable to increased use of older donors. Utilising similar proportions of older donors in the US would increase the donor pool by almost 40%” (7). This is reflected in the fact that in Spain 25% of donated kidneys are not transplanted as they are medically unsuitable(8) while the number in Australia is <5%. The Spanish model has had a positive effect on their donation rates. It does place them in the higher ranked countries but care must be taken when comparisons are made with other countries due to the differing definitions of donors, the much higher donation potential in Spain, their use of older donors, their high organ discard rates and their low transplantation rate in comparison to their organ removal rate.

The Spanish model relies on full-time medical coordinators. They emphasise that the medical coordinator position must be a full-time position within each hospital for the model to work successfully. This is possible in Spain due to the larger medical workforce but may not be possible in Queensland due to the shortage of Intensive Care Specialists.

Although the Spanish model has improved their donation rate it has had very limited success when transposed to non-Mediterranean cultural settings. Aspects of the model that were either developed in Spain or imported to Spain from the US and other European countries have been successfully incorporated into other countries but the model as a whole has in general not succeeded.

United States

Underlying the US model is a number of initiatives. In the US all hospital deaths must be referred to an Organ Procurement Organisation (OPO) for assessment of suitability for organ and tissue donation - mandated referral. Only trained and designated requestors are allowed to discuss donation with the next of kin and must do so whenever donation is possible. Most States have legislation supporting the primacy of a signed consent (the family cannot overrule the consent) and a number of OPO regions use in-house coordinators. All hospitals are subject to death record reviews and by law must ensure that these requirements are met. It should be noted that in the US, hospital units are nursing units (not medical units) where nurses are in charge and undertake the referrals. Hence in-house coordinators with nursing backgrounds are the model of choice in such a setting.

Although these measures and a national continuous quality improvement program (the Collaborative) have led to improvements and a high donation rate: the donation potential in the US is of a higher order than that in Australia. A lack of data makes accurate comparisons difficult. The US system is fundamentally a cost recovery driven system. All costs incurred in and associated with the procurement of organs and tissues are recovered and passed on to the transplanting hospital. The OPO's are independent not-for-profit organisations and are totally dependent on this cost recovery mechanism to maintain their existence. Hence the costs of providing organs and tissues for transplant are exorbitantly high in comparison to other countries, eg the cost billed to a transplant hospital for one kidney is in the order of US$35,000. This need to maintain income also acts as a driver for donation and is a sizeable component of their success but has on occasion led to some unwanted and well publicised consequences. Although clinical audits and defined responsibilities are applicable to Queensland such a high cost system may not be. The in-house nurse coordinator model is mismatched with the medical unit model of Critical Care in Queensland.

Europe

The most recognised and successful model operating in Europe (and elsewhere) is the Donor Action model. This model is based on best practice from the US, Spain and Eurotransplant and is currently used in over 400 hospitals in 17 countries. Donor Action is a quality management program designed to ISO standards. Following a validated Diagnostic Review, areas of weakness in donation practices are identified and appropriate changes introduced. Corrective measures have been developed in the form of five "Core" Programme Modules which correspond to critical steps in the donation process and can be used together or alone according to specific identified needs. It also incorporates a System Database which is a user-friendly web-based relational database system designed to enter, analyse and report data. The Donor Action System Database is the largest international database of its kind and currently contains over 62,000 Medical Record Review records from nearly 400 hospitals in 17 countries (status July 2008). The program is hospital based. It provides the hospital with ownership of the donation process but also places the responsibility for improving donation performance with the hospital.

Reported outcomes from this model show both an initial and a sustained positive effect. A report on its introduction in 10 countries showed an immediate increase in donation rates of up to 59% and sustained improvements in these rates (9). The introduction of presumed consent legislation saw a dramatic increase in the organ donation rate in Belgium; however, a number of years ago evidence indicated that not all potential donors were referred to the Donor Coordinators and therefore room for further improvement in the system existed . The introduction of elements of the Donor Action program in 2006 saw an increase in the donation rate of 26% in early 2007 (10). This effect has been sustained and improved with the current donor rate in Belgium being 28 donors pmp (11). The National Organ Donor Collaborative currently uses one of the Donor Action modules.

Recommendations.

1. ***The introduction of a presumed consent system is supported***.

2. ***The introduction of the Donor Action Program is strongly recommended.***

3. ***An independent review of the performance, strategic and operational framework and the management of donation in Queensland is strongly recommended.***

Comments on Issues Questions

Do you support the introduction of an opt-out or presumed consent system?

As outlined above a presumed consent system has the potential to increase the donation rate and thereby benefit not only individuals in need of transplant but also the health system as a whole. It has the potential to provide the most effective treatment for renal patients and ease the growing resource demand that is being and will be placed on renal services in Queensland. It will provide other organs and tissues for those in need. A presumed consent system does not necessarily remove autonomy or altruism and places the need for action on the minority rather than the majority. It moves donation into being the societal norm. It should be noted that in the current system where the majority of the population have not registered their position on donation the decision is placed upon the family at a time of great emotional stress.

What requirements for consent to organ and tissue donation should apply?

The next of kin should be kept informed of the donation and asked to confirm a lack of objection from the deceased and themselves (not for consent to the donation).

Should children and people with impaired decision making capacity be part of a presumed consent system?

A presumed consent system should apply to adults who are residents of Queensland. A residency period would need to be established. The existing (informed consent) system should apply to children and adults with impaired decision making capacity.

If presumed consent was to be introduced, what mechanisms should be introduced for people to opt-out?

The ability to register an objection should be made readily available via multiple registration points using existing government offices as well as government agents. A public education campaign must be undertaken prior to the enactment of legislation eg a 12 month campaign was undertaken in Belgium. A Queensland-specific register of objections should be established. It should be maintained and operated by a body independent of and external to the donation and transplant systems. Mechanisms should be developed to ensure the accuracy and completeness of the data. The identity of registrants should be confirmed and the registration witnessed. Access to the data should be restricted to those whose professional duties require access. Access to the data by approved persons should be easy and convenient.

What support would be required for clinical staff if a presumed consent system was introduced?

All clinical staff should receive general training in the concepts and functioning of the system. Key staff in critical care areas should receive additional more detailed training.

If an opt-out or presumed consent system is introduced, should it apply only to transplantation to another person, or also to other purposes such as research?

A presumed consent system should only apply to the transplantation of tissue to another person.

In an opt-out of presumed consent system, should it be possible to opt-out of donating for one purpose, but continue with presumed consent for another purpose?

A presumed consent system should allow for an objection to be registered to specific tissue or tissues while allowing the presumed consent system to apply to tissues not specifically objected to.

If an opt-out or presumed consent system is not introduced, is the current system of consent appropriate?

Whether or not a presumed consent system is accepted, the approach to decision making should be from the perspective that donation is supported rather than the current approach where the assumption is one of non-support.

Should the role of the next of kin or family be different if a person has given written consent to organ or tissue donation?

In line with the intent of the Australian Law Reform Commission Report Recommendations "A competent adult should have the right to give his body or any part of it for the purposes of transplantation or other therapy….His wishes should be paramount. No person (except the coroner in a case within his jurisdiction) should have the power to overrule the decision" (3). The wishes of the deceased should be respected. Although the commonly held belief is that such an action will cause harm to the family, evidence from the US where this is becoming common practice has shown the opposite. Although initially unsettled, the evidence shows such families to be positive and supportive of the decision after the fact (12).

Other strategies to improve organ and tissue donation rates

Given the performance of the Queensland organ and tissue donation agency as outlined above a major revision of the agency's strategic and operational framework and the management of donations in Queensland is strong recommended.

The majority of the initiatives outlined in the national reform package have the potential to improve the organ and tissue donor rate however in order to provide a framework and quality assured system within which these initiatives may be applied, the introduction of the Donor Action Program is strongly recommended.

Some qualifications need to be made regarding some of the national reform package initiatives.

Funding for organ donation specialist doctors and other staff in selected public and private hospitals

> *– Although this initiative is theoretically sound limitations imposed by workforce shortages may impede its implementation.*

Establishment of an independent national authority to coordinate national organ donation initiatives.

> *- This is supported.*

Additional hospital funding for staffing, beds and infrastructure associated with organ donation.

- *This is supported.*

National public awareness and education

– *Public awareness programs promoting an opt-in system have no proven effect on donation rates. There is no evidence to support their use.*

Counselling for potential donor families

– *Such an initiative should not be restricted to the families of donors. The underlying issue is the sudden unexpected death of a family member and as such this type of service should be offered to all families in such a situation.*

The development of protocols to guide paired kidney donation, living donor liver transplantation, donation after cardiac death, clinical 'trigger' checklists and data collection for organ transplants in hospitals.

\- *There is a need to develop a DCD or non-heartbeating donor program. Such a program has the potential to have a significant impact on donation rates. Clinical triggers for organ donation were introduced into Queensland in the late 1980's. Their re-introduction is supported.*

National data collection and reporting.

\- *Local data collection and <u>reporting</u> (in line with national standards) must be introduced*

A new governance structure for the Australian organ, eye and tissue donation and transplantation sector be established to provide cohesive and collaborative advice to Health ministers.

\- *This is supported.*

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