23 April 2010

Transplant Society of Australia & New Zealand
National Transplantation Project
Suite 11, Level 5
149 Macquarie Street
SYDNEY NSW 2000

Dear Sir/Madam,

ELIGIBILITY GUIDELINES AND ALLOCATION PROTOCOLS – 2ND DRAFT

Thank you again for the opportunity to comment on the revised draft protocols. Members of Gift of Life have had the opportunity to review this draft and comments are included in the attached submission.

Please note that:

- This submission represents the views of Gift of Life Incorporated, and not any individual person.
- It is not confidential.
- You are authorised to publish it on your website if you so wish. Please note that Gift of Life intends to place this submission on its own website.
- You have permission to quote from our submission.

I am sorry that I will not be able to personally attend the consultation session on 30 April, however some members of Gift of Life will attend. I would be pleased to discuss this submission with you at a mutually convenient time.

Yours sincerely,

Anne Cahill Lambert, AM

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SUBMISSION TO

TRANSPLANT SOCIETY OF AUSTRALIA & NEW ZEALAND

ELIGIBILITY GUIDELINES
AND
ALLOCATION PROTOCOLS

2ND DRAFT

23 April 2010

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Introduction

The overall view of Gift of Life is that the latest draft represents a considerable improvement on the version circulated last August. It now conveys more of a nationally consistent (if not entirely uniform) and transparent approach, rather than having the previous strong jurisdictional bias – although there are some notable exceptions. It also contains an evident ethical basis for the approach of eligibility and allocation which seems broadly reasonable. Most sections of the document look more balanced with eligibility/allocation criteria for each organ more clearly set out. We are pleased to see most of the statistical material confined to appendices so that this is a much more readable and coherent document.

It should be noted that many of Gift of Life's previous written comments have not been taken into account; neither have a substantial number of the suggestions made at the targeted consultation session. Gift of Life is unclear as to the reasoning for this. We were advised on 16 February 2010 that a letter outlining specific responses to our comments would be forwarded, but to date no such letter has been received. We are concerned, therefore, that as many of our comments were substantial in terms of equity and transparency, there is no real desire for community and consumer viewpoints to be heard or even adopted. A further copy of our previous submission is attached.

General Comments

There are several overarching comments that are relevant for each organ, viz:

- **Status of Protocols**: the status of the protocols needs to be clarified upfront. There needs to be a clear understanding as to whether these protocols are to be applied by clinicians as formal requirements or merely guidelines. An explicit statement is required as to whether the criteria for inclusion on the transplantation program can be further restricted by individual jurisdictions or clinicians. We consider that protocols should be accepted as formal requirements (Standard Operating Protocol), and jurisdictions should not be allowed to apply more restrictive criteria for patients to access the transplant program.

- **Appeals mechanism**: there has been no enunciation of an appeals mechanism that would befit something as important as being declined listing for transplantation. It is noted that

patients are given the right to know why they are not being listed and that in the case of kidneys, a sub group might review the decision. However, this is hardly an equitable or transparent process. We would like to see a process that exists in each transplant centre that allows patients to appeal their non listing and to have that appeal considered seriously. We would be pleased to make some suggestions about how this would occur.

- **Logistics**: we understand that workforce issues might prevail from time to time that would dictate which patient might receive a transplant over another patient. However, in relation to transport and location issues, patients need to be assured that they have as much chance of receiving a transplant, irrespective of their location. So, for example, the cost of moving a patient from rural Australia to the city of transplantation should not be a consideration. We would like to see in each section a clear statement (not in the footnote) that adheres to the principle that all patients have as much chance of receiving a transplant, based on their clinical need. That is, minor administrative processes will not preclude a transplant. Declining patients the opportunity to be transplanted on the basis of their geographical location is discriminatory.
- **Re-transplantation**: There is little or no reference throughout the document to the principles to be applied in relation to second and subsequent transplants. This is a difficult issue but one that consumers and community wish to see addressed.
- **Workforce Issues**: There should be a statement upfront about the technical complexity of organ transplantation and the different competencies required for different procedures. This would help in understanding the reason for clinical need sometimes not being the sole determinant of allocation of organs – that access to well qualified and experienced clinicians in different procedures will also contribute to allocation decisions.
- **Jurisdictional Issues:** the document refers to States. More acceptable terminology is use of the word 'jurisdiction' which assures those who live in the Territories that their needs are not being overlooked.
- **Ownership:** we continue to be concerned that this document will be 'owned' by TSANZ and not jointly by the Authority, the clinicians and consumers. It is appropriate that the Society has taken a leadership role on the development of these criteria and protocol, but it is not appropriate that they be retained as a TSANZ document.
- **Consumer Participation:** We know that an agile and self improving health system relies on genuine consumer engagement and participation and this is one of the key planks of the

current health reform agenda. Logically, these criteria and protocol would be better if consumers had been involved at the outset with the clinicians in a genuine partnership approach. We certainly appreciate the opportunity to comment and to attend targeted consultations. However, this approach is not a partnership model. We are unclear as to whether the revised version has been developed jointly with consumer participation, particularly as most of our comments were ignored. We note that there is no consumer representative on the standing committee, yet if genuine consumer participation is a focus, then a consumer from each of the 'organ groups' would be included.

- **NHMRC Endorsement:** we note that the criteria and protocol ostensibly follow some of the NHMRC processes and are still unclear as to why they will not be submitted through the NHMRC. We understand that they will need to be amended in a timely fashion and it is suggested that the processes of the NHMRC do not support such flexibility. If this is the case, then some other independent 'referee' should be identified to review these criteria and protocols. We are concerned that the opportunity still exists for TSANZ to report to the Authority that it has consulted, for example, with consumers without mentioning that it has ignored all the substantive suggestions.
- **Focus:** the document is focussed on donation from deceased donors (page vi), and it is unclear as to the rationale for this. Some comment should be included as to the reason for this.

Specific Comments

Page vii, second paragraph, second sentence : insert words in red: Allocation of hearts, lungs and livers involves transplant units making a clinical judgement taking into account these criteria and protocols when an organ becomes available . . .

Pages vi-vii: No general appeals mechanisms have been included.

Pages 2-3: Given low organ donor rates in New Zealand, is it appropriate to consider New Zealand patients who are not normally resident in Australia in the same way that Australians are treated? Is it fairer to apply the same criteria to New Zealand patients that exist for other international patients? We accept that systems are in place so that New Zealand is part of the Australian

processes. If it can be demonstrated that mutual benefit is derived then we would agree that they should receive special treatment.

Heart Recipient Suitability Criteria

The inclusion of a life expectancy of ten years (page 4) will almost certainly exclude Aboriginal and Torres Strait Islander patients. Some processes need to be developed to ensure that ATSI patients have as much chance of being listed as any other Australian resident. Dr Dianne Stephens of Royal Darwin Hospital has undertaken considerable work in this area and would be a person who should be consulted.

It is interesting that the abovementioned life expectancy of ten years is considered a criteria, this does not seem to have been a criteria in the case of re-transplant (page 7). The criteria listed in this paragraph are vague and need re-visiting. It is not good enough to 'waste' a heart on re-transplantation unless the prognosis is good, especially if there are others on the waiting list.

There is no appeals mechanism for patients to appeal against their non listing.

Kidney Recipient Suitability Criteria

Gift of Life's experts on kidney transplantation and consumers are disappointed that little has changed in this part of the document.

The reasonable post operative life expectancy of 80% likelihood survival some five years after transplantation follows a utilitarian system, rather than a system that gives a fair go for all Australians. This cut off is purely arbitrary, rather than being scientifically based. It may be logical to ration organs this way, but the community should be involved in the ethical input to this decision. In particular, Aboriginal and Torres Strait Islander patients would again miss out, as would patients who have diabetes. We would prefer to see a cut off point that would allow some flexibility for individual cases. It would be appropriate that where this discretion is exercised, it be formally acknowledged and disclosed (without patient identifiers, of course).

We support the provision of a review mechanism for patients excluded from the transplantation program. However, we consider that the document should specify timelines for undertaking the review when requested and outline in more detail the mechanism for the review. This would provide credibility to patients. Moreover, the second tier review committee to review cases where requested (p. 8) should **not** vary between jurisdictions – patients need to be assured that they have as much chance of a transplant, irrespective of their location. We are supposed to be implementing a national reform agenda that is consistent across the nation.

Liver Recipient Suitability Criteria

One of the exclusion criteria includes malignancy (page 9). Is there a reason that a disease free period could not be included, as per other organs?

There is no appeal mechanism in place for patients who are refused listing. Given the recent case in Western Australia, this would seem to be an important step that would help patients, the community and government understand the rationale behind these criteria. Such an appeal mechanism should include consumers and ethicists.

Lung Recipient Suitability Criteria

Gift of Life is opposed to the inclusion of the sentence as the underpinning criteria on page 11:

> Recent international guidelines were formulated with Australian input, and Australian and New Zealand units broadly follow these recommendations with local interpretation.

The words that cause greatest consternation are 'broadly' and 'local interpretation'. Inclusion criteria should be itemised as should exclusion criteria. Consumers want to be assured that these criteria are the same across the nation, that they are followed, and that there are no local interpretations. Additionally, the international guidelines may well have had Australian input, but it is unclear whether consumer input was sought. If international guidelines are used, they should be itemised in this document.

These criteria are too vague and do not comply with a program of reform that is supposed to be world's best practice and nationally consistent.

Additionally, again there are no appeal mechanisms in place.

Pancreas and Islet

We do not have any specific comments on the criteria other than to note that there is no appeal mechanism in place.

Issues Affecting Allocation of Organs (p. 22)

It would be useful if an initial statement could be included that addresses clinical need as the overriding reason for transplanting patients. As a community awareness group, we go to considerable effort to explain that it is not a matter of taking a ticket in a queue. Rather, allocation of organs is entirely dependent upon clinical need. Geographic location should have nothing to do with such decisions. Perhaps we have been incorrect in our advice to the community?

We therefore strongly oppose the dot point under logistical considerations that suggests the location of recipients may be a factor in considering allocation of organs. As mentioned previously, this is discriminatory.

Reference is made to the State Organ Donation Agency in the second dot point on page 23. In the new world of DonateLife, who are these agencies?

The third dot point on page 23 refers to state-based allocation of kidneys and we reiterate our strong opposition to this approach, based on the premise that a national reform agenda is being implemented that is world's best practice and is nationally consistent.

We are unclear as to why there are not urgent listings for lungs and pancreas (p. 23). Surely patients who are near death who need a lung or pancreas would be offered the next compatible donor organ arising anywhere in Australia and New Zealand? Perhaps there is a clinical reason that would

preclude such an approach – this issue highlights the benefit that may have been obtained if consumers were sitting alongside clinicians while these protocols were being drafted.

General Organ Donor Information

The prerequisites to deceased organ donation may need more explanation in the case of cross border organ donation (page 24). Which laws and regulations should be complied with – the donor hospital's jurisdiction or the recipient hospital's jurisdiction?

Donor Heart Allocation

In section 9.4 on pages 30-31, there is no mention of re-transplantation. Again, the logistical considerations do not exclude geography and are vague.

Donor Kidney Allocation

In the previous draft, an explanation and description was given of the National Organ Matching System (NOMS) and its manager, which has been deleted from this current draft. This is valuable information and should be re-inserted into the document. We regard it as imperative that this document is available to the public and as such it must be written from the viewpoint of the public to understand the issues, principles, protocols and process relating to organ transplantation.

We acknowledge that the balance between equity and utility in the allocation of organs is a difficult judgment to make (section 10.2). In this regard, we accept the approach that at least 30% of organs are allocated according to patient waiting time. Even so, we consider more detail needs to be included as to the process and timing for applying this principle. We would support this principle being applied on a rolling monthly basis, rather than being reconciled only at the end of the year.

The language at times forgets its broader audience: medical terms or "insider jargon" that are unlikely to be widely understood by the public should be avoided or explained when they are used (for example the term "extended criteria donors").

The document provides a useful explanation as to the reason for the different jurisdictional allocation algorithms (section 10.3). However, this still raises a significant issue as to the merits of this approach. Much of the rationale for this relates to the desire to avoid a situation where too many kidneys are transferred outside a jurisdiction. The fear is that a single common allocation algorithm would see more organs move to those more populous jurisdictions that have not invested in the hospital structures and capacity for transplantations or have not adequately promoted organ donation. However, the retention of a jurisdictional-based approach disadvantages many Australians, particularly those who live in jurisdictions that do not have a transplant centre. Moreover, in the light of the Federal Government's major investment in organ donation promotion and in organ and tissue transplantation - which has already seen an increase in the number of organ transplantations in the lowest performing jurisdiction (NSW) - the need for the current jurisdiction-centric allocation arrangement is now open to serious questioning. While it may be still too early to claim that the Federal Government's investments have totally evened the ground between jurisdictions, Gift of Life suggests that the current two tiered allocation arrangement be terminated within three years — by which time the full benefits of the Federal Government's initiatives will have been felt — and a full national allocation arrangement be established. Some provision would still need to be made for the limited circumstances whether an "emergency" transplant was required as per the current proposed "exceptions". A nationally consistent and transparent approach is preferred that adopts world's best practice. A different approach for each jurisdiction does not fulfil this nationally consistent and transparent approach.

We are all Australians. We have a universal health system. We all pay Australian taxes, including a Medicare levy. Decisions about transplantation being made on the basis of postcode are unfair and discriminatory.

It is also important from the viewpoint of public acceptance and credibility that the transparency of the transplantation process and operation of the protocols be improved. This would be achieved through an independent assurance process (that preserves privacy and patient confidentiality) and which also outlines the occasions and circumstances where the "exceptions" and "urgency transplantations" occurred. As the application of discretion can give rise to community "stories" that can undermine the public acceptance and perceived integrity of the system, it is important that such discretions are fully acknowledged and disclosed.

We wish to reiterate the point that it is very important from the patient / community viewpoint that there is easy public access to information about the estimated average wait times for transplantation by jurisdiction and public disclosure of other relevant information.

It is unclear who comprises the Renal Transplant Advisory Committee (page 32) and whether representation includes consumers and ethicists. We would urge that such representation should be included. It is appropriate that consumers and professionals have numerical equality on any such committee, as it should be on the committee that is formulating these TSANZ protocols.

Donor Liver Allocation

These principles seem reasonable as the liver transplanters seem to have a national approach.

Donor Lung Allocation

The three asterisks at the bottom of page 37 include the term *and other relative contraindications*. These should be itemised or at least an example of such contraindications.

There is no discussion about single or double lung transplants or re-transplants, which is surely an omission.

Thanks

Gift of Life records its appreciation to the following people for their input to this submission:

- Mr Bill Handke
- Dr Tim Mathew
- Mr David O'Leary
- Mr David Parker

** ** **

23 April 2010

GIFT OF LIFE
INCORPORATED

4 September 2009

Transplant Society of Australia & New Zealand
National Transplantation Project
Suite 11, Level 5
149 Macquarie Street
SYDNEY NSW 2000

Dear Sir/Madam,

NATIONAL PROTOCOL FOR ORGAN TRANSPLANTATION ELIGIBILITY AND ALLOCATION CRITERIA

Thank you for the opportunity to comment on the national protocol which has been developed by clinicians of TSANZ for the Australian Organ and Tissue Donation and Transplantation Authority.

Gift of Life provides the attached comments as a preliminary submission prior to the stakeholder consultation forum on 16 September 2009. We intend to follow up with a further submission once we have had an opportunity to sit with clinicians and hear the background to some of the ideas enunciated in the draft protocols.

Yours sincerely,

Anne Cahill Lambert, AM
President

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PRELIMINARY SUBMISSION TO

TRANSPLANT SOCIETY OF AUSTRALIA & NEW ZEALAND

NATIONAL PROTOCOL FOR ORGAN TRANSPLANTATION ELIGIBILITY AND ALLOCATION CRITERIA

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4 September 2009

GIFT OF LIFE INCORPORATED

Introduction:

Gift of Life Incorporated (GoL) is the peak body for organ donation awareness in the ACT and surrounding districts. Its activities include community education and advocacy and its outreach over the last two years has been well beyond the local area.

It is the only non government organisation of its type in Australia to sit side by side with clinicians and the Territory health authority to provide education and advocacy for organ donor awareness.

Key Issues:

The following issues are a focus for Gift of Life:

1. ***Consumer participation***

As noted, GoL is concerned that this protocol has been developed without in depth consumer participation. It is puzzling that the organ donation and transplantation sector of the health portfolio is not as consultative of its consumers as every other sector of the health system. We hope that when future iterations of this document are developed, there will be an opportunity for genuine consumer engagement at the outset.

2. ***Transparency of allocation processes***

Page one should include that organs and tissues will be allocated not just equitably, but also the process will be transparent and consistent across the country. There is a sense that, from time to time, value judgements are made or judgements are made that are not consistently applied across Australia. We would suggest that a basic principle should be that the exercise of any such value judgements in the allocation of organs are transparent and explained.

GIFT OF LIFE INCORPORATED

3. Exclusion criteria based on age

While GoL is aware that co-morbidities often exist in patients over the age of 65 years and they are not therefore considered for transplantation, nevertheless community and clinicians should have a conversation about this. Ethical issues arise such as:

- a patient over the age of 65 might not have a good prognosis; however
- a young patient with cystic fibrosis, for example, might not have a good prognosis either.

It may be that we agree with the sentiments expressed, but there must be consultation with community on this important matter, together with input from ethicists. For the allocation criteria to have public acceptance, they need to have public credibility and that flows from the community being engaged as an equal partner in the development process.

This issue is one that GoL would like to further explore with broader input from community, clinicians, ethicists and government leaders.

4. Retransplantation and multiple transplantation

Those who have not been transplanted and, for example, have been on dialysis for upwards of seven years, are often concerned about the rate of retransplantation. Their view is that these patients have already had their turn, and it is someone else's turn. However, this view is tempered with the alternate view that a patient who has gone through the trauma of a transplant and who has been advised that retransplantation is an option in the event of rejection has valid claim to a further transplant.

Again, this is a matter that requires more than a passing consideration from clinicians and community. Some in depth structured discussion is required before a decision can be reached on this matter.

5. ***Transplantation of international patients***

GoL supports the endorsement of the Declaration of Istanbul on organ trafficking and transplant tourism. However, supporting patients from countries that have reciprocal Medicare arrangements may sap the pool of available organs.

Again some conversation is required to ensure that patients do not visit Australia from countries that have a low transplant rate with the specific aim of obtaining a transplant that would not occur in their own country of residence. Ethical and community consultation is required on this difficult issue.

6. ***Donor age limitations***

Are there clinical reasons for a heart donor to be up to the age of 50 years, particularly given the social view that 50 is the new 40? Community and ethical conversations are required on this issue, particularly when some consumers would take less than optimal organs if it meant getting out of hospital for a year (or even a week).

7. ***South Australia and Northern Territory allocation and retrieval processes for hearts.***

Given that there is apparently a heart transplant unit at Queen Elizabeth Hospital in Adelaide (as itemised on page 3), it is not clear why the organ allocation and distribution for South Australia and the Northern Territory has been left off the table on page 8.

8. Logistical issues

GoL does not agree that logistical issues should be used as an allocation tool. This unfairly favours residents of cities where there are transplant units. Australians generally accept that transplant units cannot be located in every region; but that acceptance is weighted with the expectation that they will have as much chance of receiving an organ irrespective of their location. If logistics are to be included, some way of relocating patients to reside within the city where they are listed will need to be undertaken.

The use of logistics is unfair and discriminates against people who live in regional, rural and remote Australia.

9. Lack of nationally consistent processes, particularly for kidneys.

The submission from the Consumer Committee of Kidney Health Australia is supported by GoL. Suffice to say that GoL would like to see nationally consistent standards across Australia rather than individual arrangements for each jurisdiction. Again, using the principles of equity and transparency, people who need a kidney should not be jeopardised because of their location.

10. Paediatric patients as a priority

It may be that GoL supports the principle of paediatric patients being a priority for transplantation, however some discussion with community and ethicists is again required. What if the paediatric patient does not have a good prognosis, given other disease? A structured and detailed discussion is required.

11. Liver Exclusion Criteria

Again, GoL may be persuaded that exclusion based on psychosocial problems and an unlikely chance of a 50% survival rate post five years may be valid. However, at first blush, this would appear to introduce value judgements. In addition, there is no guarantee in the patient who looks to be a good chance of surviving five years, that such a patient will not reject the liver and die within days, weeks or months. Consumer and ethical consideration is required in this context.

12. Local Interpretation

Local interpretation of international guidelines would appear to be inconsistent (page 26) when the aim of the new organ donation and transplantation process is to have one nationally consistent system. If there are international guidelines that are being followed, these should be itemised within the protocol. Jurisdictional interpretation should not be allowed, given that the aim of the new approach to organ donation is to have nationally consistent processes across Australia.

We would like to see the international guidelines and understand how they are being interpreted.

13. Criteria for Lung Transplantation

The criteria listed on page 27 are far too vague. If international guidelines are used to guide clinicians in either including or excluding patients, then these should be itemised. In addition, the presence of psychological or psychiatric conditions may well be caused

by the need for transplantation and there should be some discussion with consumers and ethicists about the decision to exclude patients with such conditions.

14. Single or Bilateral Lung Transplantation

There is no inclusion of reasons for undertaking single or bilateral transplantation and this would appear to be a gap in the protocol.

15. Other Issues

There is no process itemised for patients to appeal any decision. This would appear to be an important omission.

There was a recent case in Western Australia where clinicians were critical of a patient who had used the local newspaper to call for potential live kidney donors. Comments were made such as "*he can't expect to jump the queue*" and "*he has to wait his turn*" even though quite a few people volunteered to be screened to be a potential donor. While there is an element of the "ick" factor here, nevertheless this patient may not have any family or friends who can be live organ donors. However, if other patients bring a family or friend along to be assessed and matched, they are not usually sent away with their tails between their legs. Again, GoL may possibly agree with the clinicians, but some discussion is required. There are numerous examples of people receiving transplants who may not have received them if the rules were being applied.

Some of the language is unnecessarily complicated, and the protocol would benefit from translation into simple English.

Summary

Gift of Life has raised just some of the issues that are of concern which can be summarised as:

- Lack of nationally consistent standards across all organs and across all jurisdictions;
- Lack of transparency in processes;
- Lack of structured and in depth debate about the ethics involved in some of these issues;
- Shortness of detail in some of the protocols, eg., use of international standards without itemising those standards;
- Lack of appeal mechanisms.

We look forward to the discussion on 16 September 2009 and will further examine these protocols in light of that discussion.

Anne Cahill Lambert, AM

President

GIFT OF LIFE INCORPORATED