26 June 2009


Thank you for the opportunity to provide comments on the discussion paper: “Human Tissue Review”

The Eye Bank Association of Australia and New Zealand Inc. (EBAANZ) was formed to promote cooperation, communication, consistency and reliability of service between Eye Banks for the benefit of donors, donor families, ophthalmic surgeons and tissue recipients. All Eye Banks in Australia and New Zealand are members of the Association. Among EBAANZ’s stated purposes are 1) the facilitation of the safety, success and availability of corneal and other ocular tissues required for transplantation in Australia and New Zealand and 2) to provide representation to Government agencies, health entities, community organisations, medical and industry groups as well as the general public in regard to eye donation and corneal transplantation.

Therefore it is most appropriate that our Association provides comments on an issue that is pivotal to the operations and sustainability of Eye Donation and Corneal Transplantation across Australia. Please find attached our comments.

Yours sincerely,

Dr Graeme Pollock
Chair.
Thank you for the opportunity to provide comments on The Human Tissue Review: Discussion Paper.

The Eye Bank Association of Australia and New Zealand Inc. (EBAANZ) was formed to promote cooperation, communication, consistency and reliability of service between Eye Banks for the benefit of donors, donor families, ophthalmic surgeons and tissue recipients. All Eye Banks in Australia and New Zealand are members of the Association. Among EBAANZ’s stated purposes are 1) the facilitation of the safety, success and availability of corneal and other ocular tissues required for transplantation in Australia and New Zealand and 2) to provide representation to Government agencies, health entities, community organisations, medical and industry groups as well as the general public in regard to eye donation and corneal transplantation.

The Terms of Reference for the Human Tissue review covers a wide range of issues including: 1) whether the current items meet Australian legislative requirements, 2) the most appropriate and efficient structure and processes for listing human tissue items, and 3) a cost accounting assessment of the levels of fair and reasonable benefits for items. To provide both a framework for our comments and a reference to our responses to those specific questions raised by the Discussion Paper we felt it appropriate to discuss –

1. the history and the original intent in placing the items on a prostheses list. This helps place things an historical and developmental context.

2. the terminology and classification of human tissue items, the benefits derived, and the risk of commoditisation (incorporating the framework suggested by the NH&MRC Issues Paper: Ethics and the exchange, sale of and profit from Products derived from Human Tissue).

3. considering point 2 above – provide comments on an appropriate structure for the listing of human tissue services and the linkage with Medicare Benefits Scheme informed by the MSAC

4. unique factors influencing the cost of providing a human tissue service and thus those elements affecting the level of benefits in a full cost recovery system

5. specific Questions raised in the Discussion Paper, using the previous comments to provide reference information to the comments. This may involve some repetition in comments.

In regard to the overall process EBAANZ supports:

1. fair, transparent and consistent processes for setting benefits for human tissue services

2. the principle that no profit be derived from trade in human tissue

1. History and original Intent of the Listing

Prior to the wide-spread development of Eye Banks in Australia, ophthalmologists were directly responsible for procuring donor corneas for transplantation. The costs involved in providing this element of the service (surgery, testing etc) were incorporated as part of the benefit listed under the Medicare Schedule Item for corneal transplantation i.e. a component of the Medicare Item Schedule included a benefit for the procurement of the donor cornea. (The original listing came onto a government benefits schedule in 1966).

With the advent of Eye Banks in the 1980’s and early 1990’s this provision from within the MBS was removed. Eye Bank development had become necessary to provide for the growth and additional services involved in providing corneas that were beyond the resources of an individual ophthalmologist or ophthalmic practice. Inherent in this development is that an Eye Bank is not a simple storage and supply unit (and nor is it a manufacturer). Eye Banking activities include:

- hospital development and professional in-service programs designed to maximise the appropriate identification of suitable donors and referral to the Eye Bank
• provision of trained professional staff to approach families to offer the option of donation
• the meticulous screening of donors to assess donor risk, including evaluation of donor medical history and risk factors
• the donation of eye tissue according to established and recognised standards and procedures
• evaluation of corneas by slit-lamp, specular or light biomicroscopy
• fair and equitable distribution of tissue
• donor family support which may include access to bereavement counseling services, information on bereavement literature and associations and facilitation of appropriate and anonymous correspondence between recipients and donor families.

All of these functions need to be considered when analysing the appropriateness of a benefits listing and the cost-recovery implications in providing a clinical support service. We re-iterate: Services provided in the provision of a cornea (or other human tissue) for transplant is not a simple and supply unit function; nor does it involve manufacture.

The removal of the services involved in providing a cornea for transplant meant that an alternative method of meeting the costs was required (especially in regard to cost recovery in the private sector). With the increasing complexity and functions provided by an Eye Bank, philanthropic funds were not sufficient to cover costs and the public sector could not fully subsidise the private sector. Eye Banks often did issue service fees for the costs of providing a service directly to the transplanting surgeon although these were usually well sort of full cost recovery. Unfortunately these fees would often be added to the recipient’s account by the ophthalmologist yet the insured recipient was unable to recover this component through their health insurer. Thus, some Eye Banks were at risk of closing because they were no longer financially viable and recipients were unable to recover the cost of the service fee through their private health insurance or through the MBS. Eye Banks were making representations to the Commonwealth Government for assistance in funding to ensure viability and sustainability of eye donation and corneal transplantation in Australia, which was under threat.

At a meeting on 28 July, 1993 held at Sydney Hospital and chaired by Mr Peter Callanan, the then Director of the Health Insurance Section of the Department of Health, Housing, Local Government and Community Services, it was decided to place Human Tissue Items for ophthalmic use on the Table of Prostheses. As with manufactured prostheses items, it was necessary that any listing be associated with a manufacturing license issued by the TGA (which was then developing its regulations in regards to human tissue). The minutes of the meeting indicate that under the prevailing legislative arrangements there was no other avenue in the basic table arrangements whereby benefit could be paid for the collection of corneas when this component had been removed from the MBS.

At the time there was much controversy surrounding this move – all of which related to the classification of Human Tissue Items as prostheses and the use of the TGA manufacturing terms “manufacturer” and “product”. Despite the Listing specifically stating that the - “benefit payable for human donor tissue items is to cover the cost of preparation and handling. There is no charge for the actual donor tissue” – rumours persisted that human tissue was being bought and sold. Today this misunderstanding still exists in some quarters.

2. Commoditisation, Terminology and Classification of Human Tissue and Human Tissue Products

The effect of the terminology – manufacture, product, prostheses – has the effect of commoditising human tissue for transplant and a misunderstanding of the necessary services involved in providing it.

The Doyle Report itself provides a clear example of these effects, the misunderstandings that such terminology can create and the consequences of such misunderstandings –

“I also understand that Part B of the list includes a number of autologous products. These are produced by taking an individual’s tissue, manipulating it in some way and then implanting it in the individual. In my view this is essentially a therapeutic process rather than a manufacturing one, and these items should be excluded from the list”
Unfortunately the Report fails to understand that more than 90% of all the listings in Part B, although not autologous, are subject to the same process – the removal of a tissue item, its manipulation, and its implantation / transplantation (into another person). Indeed this is a therapeutic process, not a manufacturing one. A consequence of this is that under the Doyle recommendations/interpretation, most items currently listed do not meet the criteria for listing as prostheses.

The Issues Paper: ‘Ethics and the exchange, sale of and profit from Products derived from Human Tissue’, also provides a useful definition and distinction between Human Tissue Items and those products derived from Human Tissue (Human Tissue Products) – “Human tissues are all constituent parts of the human body formed by cells. Human tissue products include samples, cellular devices, cell cultures, significantly modified cell cultures and acellular products”. This is significant in the context of the Benefits List as a small proportion of the current Part B listing would fall into the Human Tissue Products category. This has ongoing implications for manufacture, commercialism, profit-making and issues regarding efficacy of the product; all issues that are considered in Part A of the listing.

Therefore an appropriate response would be to list Human Tissue for transplant/implantation as Services, as distinct from Prostheses. This would provide a clear distinction of

- what the benefit raised is actually for and what it includes
- recognise it involves human tissue donation NOT manufacture
- reduce the tendency to commoditise the Service.

Human Tissue Products however could remain in the Prostheses listing and be subject to the usual Part A Prostheses listing processes, and perhaps still allow for profit-generating etc. rather than just cost-recovery. This would serve to create more transparent and consistent processes.

We suggest:
A new listing, separate from the Prostheses List, should be created for “Listed benefits for Services involved in the provision of Human Tissue Items for transplant or therapeutic purposes.”

We suggest:
Human Tissue Products (as classified using the NH&MRC’s issues paper ‘Ethics and the exchange, sale of and profit from Products derived from Human Tissue’) should be separated and regarded as distinct from Human Tissue services, be listed as Human Tissue Product Prostheses Items, and subject to similar provisions as Part A Items.

3. Linkage with MBS and the MSAC

Each medical act that requires the use of donated human tissue should be linked with the service that provides that human tissue (and vice versa). This could be facilitated by a cross referenced listing on the MBS item to the service items in the new ‘Benefits for Services involved in the provision of Human Tissue Items for transplant or therapeutic purposes’. The efficacy or necessity of the procedure (and thus the human tissue service required for the procedure to be employed) could then be determined through the MSAC process (thus avoiding duplication of assessment).

One pressing issue however is the efficiency of the MSAC process in keeping up to date with the introduction of new or modified procedures. The process of placing new Human Tissue Items on the benefits list has been far more efficient than the updating of the MBS, and thus some items may not currently have a direct association to an MBS item. This situation usually arises through the modification of an existing surgical technique which requires a modification of the human tissue and the service required – rather than a completely new and untested procedure. Currently the surgeon will choose the nearest related MBS item in describing the procedure. However the human tissue item
required for the procedure may currently be listed as a new item (with no associated direct Medicare benefit) and appears to be “orphaned”.

We suggest:
That any “Listed benefits for Services involved in the provision of Human Tissue Items for transplant or therapeutic purposes” be linked with the associated surgical service listed on the MBS.

We wish to highlight that:
If such a linkage was to be implemented then the efficiencies of the process would have to be improved to ensure both schedules (lists) remained in synchrony with one another.

4. Cost of providing a Human Tissue service.

_Services provided in the provision of a cornea (or other human tissue) for transplant is not a simple and supply unit function; nor does it involve manufacture within the “lay” meaning of the word “manufacture”._

A provider of human tissue is not a factory or a manufacturer but a service provider, and the economics, accounting, finance, efficacy and cost-efficiency aspects involved are not the same or equivalent to the Prostheses included in Part A of the Prostheses list (or indeed any manufactured item).

Full cost recovery is essential to maintain the viability of Eye Banks (and other tissue service providers), and for the continued development and growth of these essential services.

Full cost recovery includes operational costs and non-operational costs.

1. Operational costs include the salaries of staff and
   a. Direct contributions to providing, for example, a cornea for transplant
      i. Surgical retrieval and donor coordinator time (including on-call payments)
      ii. Consumables involved in the donation e.g. storage media, medical supplies
      iii. Transport costs, which includes both staff transport to donation sites and tissue distribution to transplant facilities
      iv. Testing services e.g. Microbiology and Virology testing
   b. Indirect costs include:
      i. Facilities – capital cost, maintenance, utilities
      ii. Capital equipment items (e.g. fridges, freezers, microscopes)
      iii. Administrative support
      iv. Quality systems and regulatory issues
      v. Depreciation

2. Non-operational costs include:
   a. Staff training and on-going professional development
   b. Donor hospital staff education and development of donor programs
   c. Public awareness and education
   d. Donor family support
   e. Development of services

The degree to which each of these items impacts on the setting of a benefit depends on a wide range of variables, and few of these remain consistent between service providers. The area of least variation on an income/expenditure basis is within Direct Operational Costs but these only partially
contribute to overall costs, and even here variation will exist depending on jurisdiction in which the Eye Bank is based. The areas of greatest variability are within Indirect Operational Costs, especially in regard to the degree that these cost centres may be provided by government sources or philanthropy, and in Non-operational costs especially in regard to the effects of donor rate and transplantation rate.

Some of the income and expenditure variables which differ, both between and within jurisdictions, include:

1. The degree to which facilities and utilities are provided rent-free by the organisation housing the Service (e.g. University, Hospital or other.)
2. The degree of administrative support provided by the host organisation (e.g. University, Hospital)
3. The amount of Infrastructure support or grant support provided by State Governments. In some instances, for example, this support may be a fixed cash amount in the form of a grant and in other instances a fee-per-service arrangement for providing corneas for public cases within the State Health system.
4. The amount of philanthropic support available (e.g. from Lions Clubs International) to provide for running costs and investment and capital equipment.
5. The degree of support from other services (e.g. organ donation programs, State government investment in donor programs, education, awareness) which may increase donor rates and alleviate the need to the Eye Bank to directly invest in these areas.

The degree to which any of these are provided will have a direct impact on the degree of cost-recovery that needs to be derived from other sources i.e. private insurance benefits listings. All other things being equal, the greater the degree of government funds, grants, philanthropic support and in-kind services provided, the lower the amount that needs to be recovered from other income sources to provide for full cost-recovery.

6. For an Eye Bank one of the greatest variables influencing cost-recovery is the donation and transplantation rates within the Eye Bank’s jurisdiction. Using corneas as an example, cost-recovery is only available through those corneas that are actually transplanted, and the number transplanted will depend on both the number of corneas available for transplant (donor rate) and the ability of the health system to transplant (transplant rate). In general terms, the lower the donor rate, the lower the transplant rate and thus the less the opportunity to generate income. The greatest cost item within an Eye Bank is salaries, which is also the greatest fixed cost. Within the scales of quantum increases of donation and marginal benefit (i.e. a certain number of staff will be required to undertake a minimum and maximum number of donations) a low transplant rate creates the necessity to increase the cost-per-service in order meet cost recovery.

In addition, Eye Donation and Corneal Transplantation are much more cost-sensitive to the vagaries of donation and transplantation rate economics than other tissues.

- Unlike bone (for example) maximum storage times for corneas involve a matter of days rather than a matter of years. This means that processing and testing cannot be batched in order to reduce costs per donor.
- The storage requirements, limited storage time, and sometimes the urgency of transplantation also mean that transport to transplant hospitals can be very expensive. In some instances the cost of transport constitutes more than 80% of the total fee.
- There is seldom the opportunity to transport a number of corneas at a time to reduce costs. In addition a transplant facility cannot hold a “stock” of corneas.
- Unlike bone, where there may be hundreds of potentially transplanted tissues provided by one donor, there are only two eyes provided by one eye donor. Thus increased costs (and the necessary cost recovery) can only be spread across several transplants rather than hundreds. For example the costs of any additional testing of donors (as dictated by the TGA) can only be recovered through several transplants rather than many – thus the percentage increase in a single service fee is much higher than if the cost could be spread across hundreds of transplants.
Full cost recovery is essential to maintain the viability of Eye Banks

By necessity cost recovery must include all the costs involved in providing a service – both operational and non-operational costs

The degree of government support, grants, subsidies, in-kind services and philanthropic support varies both between and within jurisdictions. These have a direct effect on service fee levels – thus differing fees for similar items are both expected and necessary

Service fees for corneas are highly cost-sensitive. The impact of anything that increases expenditure will have a significant and direct impact on services fees (e.g. increased testing requirements, increased transport costs) issued by Eye Banks due to the limited number of transplants available from a single eye donor and the limited storage time available to corneas.

5. Questions posed in the Discussion Paper

Terms of Reference 1

Q1. Are all items on Part B Human Tissue of the Prostheses List consistent with legislation?
   A: All items listed under “Ophthalmic” are consistent with the legislation

Q2. Should autologous items be removed from the Prostheses list?
   A: Given that autologous items are subject to the same processes as other items on the list (i.e. services involved in providing a clinical service rather than a manufacturing process) there seems to be no justification in isolating the autologous service from the services involved in providing an allograft (see section 2)

Q3: What implications are there from the statement – no profit should be derived from trade in human tissue?
   A: Only cost recovery of the cost of services in providing the tissue should be allowed. However, as for all not-for-profit organisations, all costs need to be considered and recovered; including those non-operational costs and forward planning provisions (see section 1 & 3)

Q4: Ramifications of the NH&MRC issues paper in allowing human derived tissue products to generate a profit.
   A: Defining a difference between human tissue and human tissue products allows for a distinction to be made between a human tissue service and a manufactured prosthesis. Human tissue services should ceased to be classified as prostheses and a provision made for “Listed benefits for Services involved in the provision of Human Tissue Items for transplant or therapeutic purposes”. (see section 2). Human tissue products can remain with the other Part A prostheses and be subject to the same processes – including the ability to generate a profit.

Terms of Reference 2

Q1: Is the current structure of Part B of the Prostheses List appropriate? Should there be more categories or subcategories?
A: No. Part B of the Prostheses List should cease to exist and all human items placed in a Human Tissue Service benefits schedule linked to items in the MBS. Thus the structure of the new schedule in regard to categories would resemble the MBS. (see section 2 & 3)

Q2: What are appropriate naming conventions for each of the categories?
A: Should be linked with and following the conventions used in the MBS.

Terms of Reference 3

Q1: What components should be included in the setting of a benefit?
A: Full cost recovery including all operational and non-operational costs (see section 4). To do otherwise would threaten the viability of continued provision of these services. In regard to transport costs, they need to be included as they may form significant component of the total cost – not allowing these will leave the recipient (the insured) having to meet significant out-of-pocket expenses, especially if they the transplant is remote or interstate from the distributing donation service.

Q2: Should similar products have similar benefits? Are there costs specific / unique to a State or Territory that may warrant different benefits?
A: Similar items should not have the same costs. The expenses, government and philanthropic support, in-kind services and transport will vary across jurisdictions (see section 4). This is in contrast to a service that is allowed to generate a profit – for those manufactured products where profit is allowed then similar cost on the listing may be achievable through different organisations being able to accept a different profit margin. However, cost recovery only allows for recouping of actual costs with no room for movement in a non-existent profit. Costs and thus the amount of cost recovery will vary between organisations (and therefore the necessary cost recovery fee will vary between organisations).

Q3: How should financial information be supplied to clearly identify costs associated with specific items?
A: The current system seems appropriate – full financial disclosure on income and expenditure over previous years of operations with the addition of a forward planning component. Additional or remarkable costs identified with specific items (eg. expensive storage requirements or expensive transport requirements) could be readily identified and accounted.

Terms of Reference 4

Q1: What is an appropriate model for assessing (both clinically and financially) human tissue applications?
A: Linkage with the MBS would act as a de-facto clinical assessment of human tissue items provided as a service. Human tissue products could be assessed for efficacy and costs in a similar fashion to Part A prostheses. Financial assessment of the services provided for human tissue applications could remain as currently (as provided in the answer immediately above).

Q2: Are there merits for applying the current arrangements for assessing applications for Part A to assessing applications for Part B of the Prostheses List?
A: For human tissue items – NO. Human tissue items involve only a service and minimal manipulation not manufacture. Thus they are not prostheses and should not be assessed as such.
For human-derived tissue products there may be merit in applying similar arrangements as for assessing Part A applications – however it should be recognised that human-derived tissue products themselves cannot be assessed in the same manner as medical devices or pharmaceutical manufacture (this difference is already recognised by the TGA)

Q3: Should the classes of human tissue defined in the HCT Regulatory Framework guide the level of assessment required for human tissue applications?
A: The framework may provide a useful guideline for discriminating between the classifications of human tissue items and human tissue products – along with some of the proposals put forward by The Issues Paper: ‘Ethics and the exchange, sale of and profit from Products derived from Human Tissue’. The level of assessment should then vary depending upon whether the list is for a “human tissue item service” or for a “human tissue product”.

Q4: Is the Prostheses list the appropriate tool for establishing the benefit to be paid by Private Health Insurers?

A: No. For the services provided in supplying human tissue for transplant a separate and independent list should exist that is linked to the MBS item for performing the therapy that uses the human tissue item. This should be the tool for establishing the benefit to be paid by Private Health Insurers.