

**SELECTED SPECIALTY
AND STATEWIDE
SERVICE PLANS**

Number Two

**Pancreas
Transplantation**

January 2002

NSW HEALTH DEPARTMENT

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This Selected Specialty and Statewide Service Plan was developed by the Statewide Services Development Branch between 1998 and 2000 with considerable contribution by the specialist clinicians in the field. The Selected Specialty Services Steering Committee provided significant direction to this process.

The Greater Metropolitan Services Implementation Group, under the auspices of the Government Action Plan for Health, then reviewed and ratified this Plan.

The considerable effort of all involved is acknowledged.

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EXECUTIVE SUMMARY

In recognition of the need to plan a number of the more highly specialised health services on a statewide level, NSW Health has undertaken a series of service planning reviews.

The services considered in this series are characterised by one, or a combination of factors, which include:

- a demonstration of a relationship between volume and quality
- the treatment of conditions that are not common
- the need for specialised skills of individual clinicians or team
- the need for highly specialised equipment and/or support services
- the early stage of development of the specialty
- shortages in supply or distribution of the workforce
- high cost infrastructure

Pancreas transplantation is regarded as one of these Selected Specialty and Statewide Services in NSW, and is the second in a series to be released by NSW Health.

Pancreas transplantation was primarily developed as a procedure performed in tandem with a kidney transplant for diabetic patients who had developed end stage renal failure and were considered suitable for renal transplantation. The successful addition of a transplanted pancreas removes the need for ongoing insulin injections resulting in control of blood sugar levels, improved quality of life and the potential for reduction in long term diabetic complications.

The National Pancreas Transplant Unit (NPTU) at Westmead Hospital in NSW is currently funded through the Commonwealth's Nationally Funded Centres (NFC) Program to provide an Australia wide service of up to 15 combined pancreas/kidney transplants per year. The Commonwealth is to advise on the current process for re-assessing funding through this Program. A small number of transplants are also performed at the Monash Medical Centre in Melbourne, supported by State funding. The NFC Program is to be reviewed in 2001.

The waiting list at NPTU has grown significantly over the last two years mostly due to an increased number of interstate referrals. During the first six months of 2000, the NPTU performed ten transplants. Waiting times vary from 24 - 36 months, and are somewhat dependent on donor supply and to some extent on blood group. The majority of organ retrievals are from NSW donors. Combined five-year actuarial survivals for both Australian pancreas transplant units for patient, kidney and pancreas are 88%, 82% and 69% respectively.

It is estimated the NPTU at Westmead will need to perform between 17 and 21 transplants per year by 2001 if the potential Australia wide demand is to be met; NSW residents will make up seven to nine of these. Anticipated demand is unlikely to justify the establishment of further units in NSW or Australia for at least the next five years. Therefore, the NPTU will continue to be the only NSW unit to undertake pancreas transplantation in NSW in this period. A further review will be undertaken in five years, subject to review of donor rates or technological developments.

Contingencies for ongoing support of the program, should there be changes to NFC funding, will be considered. For interstate patients this is likely to be through existing interstate cross border arrangements on a charge per patient, based upon an appropriate breakdown of the components of cost. A funding model for Selected Specialty Services in NSW is currently under development.

1.0 INTRODUCTION

In considering the number and location of highly specialised services, many factors are taken into account. NSW Health considers access, quality of care and service efficiency in these decisions. There are a number of considerations that favour the decision to restrict health care provision to a limited number of sites, or to promote an integrated service network of sites and/or provider groups.

These include:

- When there is reasonable evidence that, up to a certain level, patient outcomes improve as caseloads increase and that care needs to be concentrated to reach this level. This most often occurs with interventions that involve:
 - skills that require substantial training, practice and experience to develop and maintain;
 - large teams, in which the different specialised skills provided by separate team members (including doctors, nurses, technicians and allied health staff) are important, as is the way the team works together;
 - extensive infrastructure requirements, for example diagnostic services with highly specialised equipment and staff skills; and
 - treatment of conditions that are uncommon.
- When there are large infrastructure costs, with unnecessary duplication of services leading to inefficient use of resources. This is especially relevant when attempting to ensure value for money for the public and may occur with interventions that involve:
 - expensive equipment and/or buildings; and
 - substantial investment in staff training and/or recruitment.
- When the medical technologies involved require further research, development and evaluation, and there is an associated need to enhance the diffusion of knowledge in the area. This may include:
 - new or rapidly evolving medical technologies;
 - the need for substantial research infrastructure;
 - the need for research activity to reach "critical mass";
 - widespread enrolment of patients into clinical trials and the associated use of clinical protocols; and
 - a tendency for a lag between scientific knowledge and clinical practice.

As a result, a series of service planning reviews have been undertaken where a number of these criteria have been met.

2.0 CLINICAL TECHNOLOGY REVIEW

2.1. *Development and Rationale for Pancreas Transplantation*

Type I or Insulin Dependant Diabetes Mellitus is a significant health problem which affects up to 80,000 people across Australia. It is due to a failure of the islet cells of the pancreas to produce insulin which is normally released into the blood stream and is required to maintain normal glucose levels. Patients with this form of diabetes require daily insulin injections without which they deteriorate quickly into life threatening ketoacidosis.

There is no cure for diabetes but with regular insulin injections and close diet control most patients can live a relatively normal life. Over the longer term however, people with diabetes are susceptible to the secondary complications of the disease. The most significant of these include renal failure, retinal disease, vascular disease and peripheral neuropathy.

Pancreas transplantation was developed in the United States primarily as a procedure performed in tandem with kidney transplantation for diabetic patients who had developed end stage renal failure and were considered suitable for renal transplantation. Pancreas transplantation is not a treatment option for the majority of diabetic patients because of the potential significant complications associated with immunosuppression following transplantation.

However patients with diabetic renal failure who are to undergo renal transplantation are already destined for long term immunosuppression. For these patients the successful addition of a transplanted pancreas removes the need for ongoing insulin injections and results in virtually ideal control of blood sugar levels. Combining this with a successful kidney transplant provides enormous benefits to the patient both medically as well as in terms of independence and quality of life because of the freedom from ongoing dialysis.

There is continued debate as to the risks versus benefits of pancreas transplantation. The surgical procedure is complicated and carries the potential for significant complications as well as the added risk of rejection of the transplanted pancreas. The procedure requires more resources for both the additional surgery as well as the retrieval and preparation of the donated organ.

In addition, pancreas transplantation, in contrast to most other transplant procedures, is not immediately lifesaving as the patient's diabetes can continue to be treated successfully through the use of insulin injections.

Despite the above issues, greater experience with the procedure is resulting in improved outcomes.¹ There is also increasing evidence that the insulin control resulting from a pancreas transplantation can reduce, and sometimes even reverse, the progression of the secondary complications of diabetes.^{2,3} The evidence appears to be strongest for peripheral neuropathy and peripheral vascular disease.

The conclusion appears to be that in experienced units and with careful patient selection, pancreas transplantation can be of significant benefit for a select number of Type I diabetics with end stage renal failure. The procedure however, still remains under close examination as to the benefits versus the risks.

2.2. Indications for Pancreas Transplantation

The vast majority of pancreas transplantation is undertaken on patients with Type I Diabetes complicated by end stage renal failure. Because of the added risks of pancreas transplantation, patient selection is important. There is increasing evidence that improved outcomes are experienced by earlier transplantation of patients before the need for renal dialysis or the development of significant secondary complications of diabetes.⁴

Patients with moderate to severe obesity or with irreversible coronary artery disease have been shown to have worse outcomes.^{5,6} Age is a significant risk factor both in terms of increased surgical complications and the greater likelihood of patients having established secondary diabetic complications. The upper age limit for pancreas transplantation is quoted at 50 years of age.⁴ For this reason pancreatic transplant patients are on average younger than non-diabetic kidney transplant recipients. Table 1 lists the generally accepted indications for pancreas transplantation.

TABLE 1 INDICATIONS FOR PANCREAS TRANSPLANTATION

Absolute	Type I Diabetes Mellitus
	End stage renal failure or functioning renal transplant
	Absent, insignificant or surgically correctable coronary artery disease
	Age less than 50 years
	Non-smoker
Relative	Body weight less than 125% of ideal
	No psychiatric illness

Source: Transplantation Surgery, 1996⁴

2.3. Surgical Techniques

Over the years a number of different approaches to pancreas transplantation have been developed but the one which is currently the most widely accepted is known as simultaneous pancreas/kidney transplantation. Here the patient is transplanted with both a pancreas and kidney from the same donor in a single procedure.

Other methods of pancreas transplantation include pancreas after previous kidney transplantation and pancreas transplantation alone. However early results from both of these procedures have been shown to be inferior to simultaneous pancreas/kidney transplantation which still remains the most widely accepted procedure.⁷

2.4. Outcomes of Combined Pancreas and Kidney Transplantation

For the diabetic end stage renal failure patient, successful pancreas and kidney transplantation is the only treatment available which can provide independence from insulin injections along with restoring renal function. International one-year actuarial survival for simultaneous pancreas and kidney transplant is quoted as 91%, 84% and 77% for patient, kidney and pancreas respectively.⁸

The most significant complications over renal transplantation alone are rejection of the transplanted pancreas and surgical complications from the additional pancreatic transplant procedure. These add greater morbidity and some studies show a greater mortality risk to patients receiving combined pancreas/kidney transplants as opposed to kidney transplant alone.⁹ It should be noted however that statistical analysis of long term pancreas transplant outcomes in Australia suggested that mortality was not increased by the additional procedure¹⁰ (see Section 3.7 of this Plan).

Rejection

The effective treatment of rejection is dependent upon accurate and early diagnosis. However this is problematic in pancreas transplantation because of a lack of specific clinical indicators and the difficulty in obtaining a biopsy of the transplanted organ. Biopsy of the kidney transplant, which is much more easily accessed, is often used as a marker of pancreas rejection.^{4,11} Advancements in the recognition of rejection as well as improvements in immunosuppressive agents have contributed to improved outcomes for pancreas transplant recipients in recent years. However, this has sometimes led to a higher level of immunosuppression which may be reflected in some studies showing a greater incidence of cancer after a combined transplant compared with kidney transplant alone.⁹

Surgical Complications

It is recognised that pancreas transplantation is associated with an increase in surgical morbidity. The most common complications are those associated with the bladder drainage of the transplanted pancreas including recurrent urinary tract infection, duodenal leak and chronic haematuria. Other significant surgical complications include thrombosis of the pancreas, sepsis, cardiac complications and pancreatitis.⁴

Quality of Life

A number of studies have demonstrated objective improvements in quality of life following pancreas transplantation.¹² Studies have included comparisons between diabetic patients receiving kidney alone transplants, pancreas/kidney transplants and patients who underwent pancreas/kidney transplantation and in whom the pancreas graft failed. Improved quality of life indicators have been associated with the pancreas transplant and insulin independence.

2.5. Future Clinical and Technological Advances

The most anticipated advance in the treatment of Type I Diabetes is independent transplantation of the insulin producing islet cells of the pancreas. If this was successfully developed it could replace whole pancreas transplantation. Despite much research into this area there are still a number of major impediments to the success of this new technology.^{8,13} However, more recent indications from Canada appear to indicate an improvement in the level of insulin independence following transplantation, following changes to protocols.

Transplanted islet cells are more fragile and less likely to survive when implanted separately from the whole pancreas organ. They are also susceptible to immunological destruction therefore recipients still require ongoing immunosuppression.

Research efforts continue into this new technology both at National Pancreas Transplant Unit at Westmead Hospital and the Prince of Wales Hospital in NSW.

The Prince of Wales Hospital Unit is working towards trials of transplantation of insulin producing cells from both humans and pigs with rejection being prevented through monoclonal antibody therapy or encapsulation of the cells. If successful, these initiatives could potentially provide treatment for all people with diabetes, not just those with end stage renal failure. However, it appears unlikely that these new technologies will replace whole pancreas transplantation in the short term. Any expansion of services to include islet transplantation would be subject to the usual technology assessment processes of the Nationally Funded Centre (NFC) Program.

3.0 REVIEW OF CURRENT SERVICE

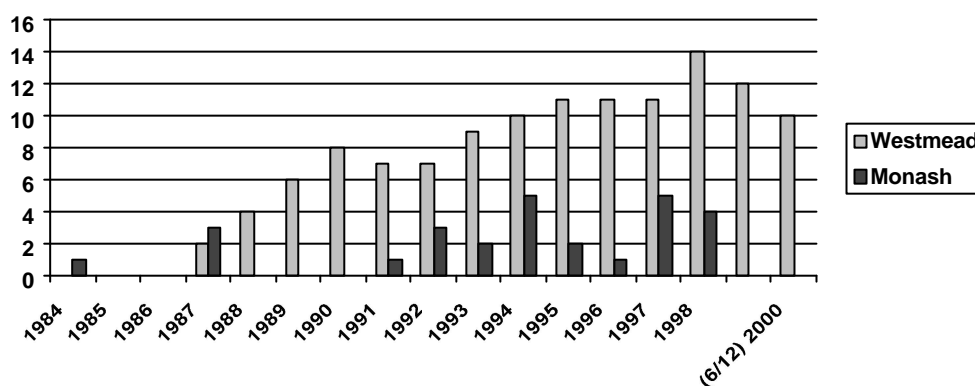
3.1. Delivery Sites

There are only two units that perform routine pancreatic transplants in Australia. These are Westmead Hospital in NSW, known as the National Pancreas Transplantation Unit (NPTU), and the Monash Medical Centre in Melbourne, Victoria. The majority of transplants are performed at Westmead, which receives Commonwealth funding under the NFC Program to provide a national service for pancreas transplantation. The Melbourne unit is supported through State funding and receives most referrals from within Victoria.

3.2. Activity

Activity data for pancreas transplants performed at Westmead and Monash Medical Centre is given in Figure 1. The NPTU performed 122 transplants from 1987 to June 2000. The vast majority of these have been simultaneous pancreas/kidney transplantation from the same donor.

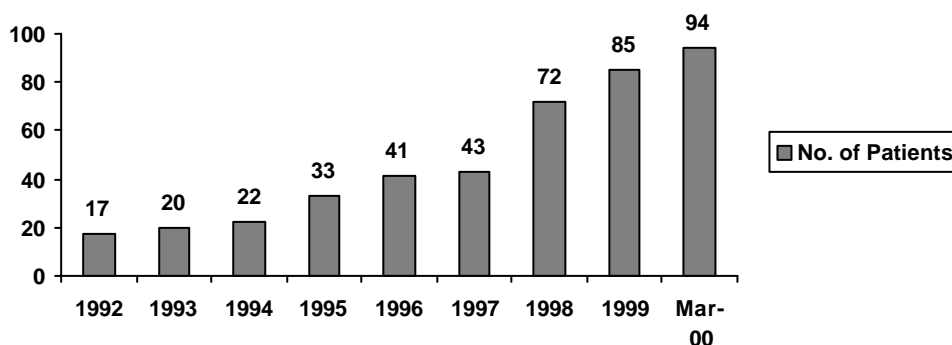
FIGURE 1: ACTIVITY AT AUSTRALIAN PANCREAS TRANSPLANT UNITS¹⁴



3.3. Demand and Waiting List Status at the NPTU

As Westmead is part of the NFC Program, the NPTU accepts referrals for pancreas transplantation from across Australia as well as New Zealand. The average number of patients per year on the waiting list since 1992 is shown in Figure 2.

FIGURE 2: NUMBER OF PATIENTS AWAITING TRANSPLANT¹⁴

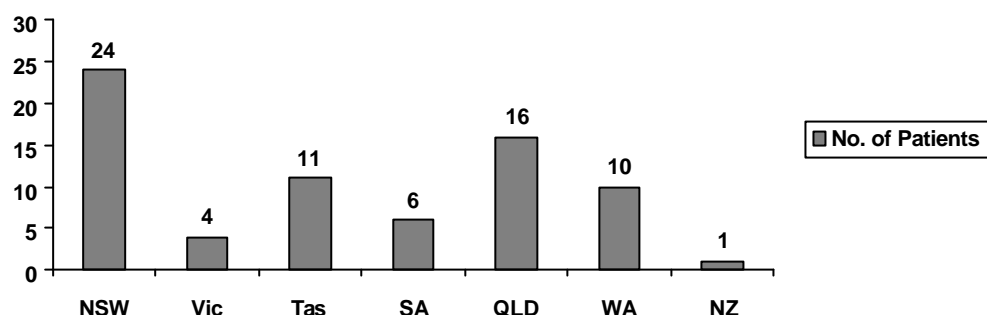


The waiting list as at March 2000 is given in Table 3. A breakdown of patients (1998 data) by their place of residence is shown in Figure 3.

TABLE 3: WAITING LIST STATUS AS AT MARCH 2000¹⁴

Actively waiting	40
Pending review	47
Under assessment	7
TOTAL	94

FIGURE 3: BREAKDOWN OF WAITING LIST BY PATIENT RESIDENCE¹⁴(1998 DATA)



In total, 290 patients were referred to the NPTU between July 1987 and December 1999. Table 4 summarises the outcome of these referrals from July 1992 to December 1999.

TABLE 4: OUTCOME OF REFERRALS TO NPTU, JULY 1992 - DECEMBER 1999¹⁴

	Number	% of total
Total Patients Assessed (July 1992 – Dec 1999)	235	
Accepted by Unit for Simultaneous Pancreas/Kidney Transplantation:		
- transplanted	92	39%
- on waiting list	43(Active)	18%
- accepted but died on waiting list	7	3.0%
Suitable for Pancreas After Previous Kidney Transplantation and Pancreas Transplantation Alone		
	1	0.4%
Not Suitable for Pancreas Transplant		
	38	16%
Assessed but:		
- renal transplant first	13	5%
- not Type I diabetic	8 (n/suitable)	
Pending investigation		
	41	17%
Total	235	

The number of referrals to the NPTU is increasing. This is likely to be the result of increasing awareness of the program and of the relatively good outcomes being achieved by the Unit. The NPTU estimates that they are now seeing about 30% of all Type I diabetics with end stage renal failure.

Until 1996, the number of procedures funded under the NFC Program was up to ten per year. Following a review of activity and demand by the Australian Health Technology Advisory Committee (AHTAC) in 1996¹⁵ it was recommended this should be increased to 15 per year.

3.4. Patient Flow Analysis of the NPTU

Referral and Assessment

As previously noted, the NPTU at Westmead accepts referrals from across Australia and New Zealand. The general criteria for assessment at Westmead are patients with Type I Diabetes and end stage renal failure who are under 50 years of age, non-smokers and less than 20% overweight.^{15,16}

Most patients are assessed on an outpatient basis and this process takes on average three days. Patients who live some distance from the hospital must be flown to and accommodated near the Unit while the assessment is being done. The initial assessment includes a number of routine investigations including biochemistry, haematology, chest X-ray, ECG and viral screening including HIV.

Specific investigations are performed to detect cardiac disease including a persantin thallium scan. In some cases, patients with coronary artery disease are referred for coronary artery bypass grafting before being admitted onto the waiting list. Investigations are also performed to assess the presence of diabetic complications. These include carotid and femoral artery scans, nerve conduction studies and an ophthalmology review. Other investigations may be required depending upon the presence of intercurrent illnesses in particular respiratory, gastric and urological disorders.

Assessment also includes a formal psychiatric review and assessment of social and family issues which may be relevant to the patient's post-operative care both short and long term.

Admission and Procedure

About 75% of patients who are assessed are accepted onto the waiting list. The waiting time varies widely from three to eighteen months. Patients on the waiting list are required to have further assessments at six and twelve monthly intervals. It has been agreed that a waiting time of 12-18 months achieves a balance between the individual needs of patients and the need to have an adequate pool of patients on the waiting list to take advantage of donor offers.¹⁶

When a potential donor organ becomes available the recipient is admitted to the hospital five hours prior to surgery. Approximately 33% of organs are found to be unsuitable for donation at the retrieval stage in which case the patient is discharged. This occurred three times during 1997. The patients who are called in during these unsuccessful retrievals remain at the top of the waiting list when the next blood group compatible organ becomes available.

Virtually all procedures at the NPTU have been simultaneous pancreas and kidney transplants with organs from the same donor. The surgical procedure involves whole pancreas transplantation with bladder drainage of exogenous secretions. The NPTU has one dedicated pancreas Transplant Surgeon with urological support. They are assisted by a rotating Surgical Registrar with various levels of expertise and experience in pancreas transplant surgery.

Immediate post-operative care is similar to that for renal transplant recipients but with closer monitoring of blood sugar levels. Intensive one-to-one nursing is required for the first 48 hours and may be scaled down after this if the patient's course is satisfactory.

The mean length of stay is now 16 days for a successful transplant. This is longer than for renal transplant recipients mostly due to the period of post-operative paralytic ileus requiring intravenous therapy.

Outpatient Care

Patients are followed up by the NPTU on a daily basis for the first two to three months. The review includes regular pathology testing and assessment of transplant function along with management of their immunosuppression.

Patients from the country or interstate need to reside close to the hospital for the period of this follow up. After this time most patients are returned to the care of their referring physician and will be seen by the NPTU after the first six and twelve months and thereafter annually.

There are a number of social supports in place to assist patients after their discharge from the Unit including a dedicated pancreas transplant patient support group.

3.5. Donor Factors

The Westmead Surgical Transplant Team undertakes the retrieval of almost all donor pancreas organs. The majority of donor organs for the NPTU have come from within NSW and ACT. Most pancreas/kidney transplants come from younger donors being within the 15 - 45 year age group. Organs from potential donors who are older, obese or have intercurrent illnesses tend to be associated with worse outcomes and therefore are generally considered unsuitable.

The number of donors in Australia has been in decline for some years and therefore is the significant constraining factor in responding to demand. Strategies have been put in place in a number of States to improve the donor rates. These strategies will be monitored to determine necessary changes in volume or nature of service delivery.

As previously stated, about 33% of organs are found to be unsuitable at the retrieval stage. After a successful pancreatic organ retrieval, there is a significant amount of bench top preparation required before the organ can be transplanted into the recipient. This is performed at Westmead after the organ is retrieved and can in itself take over two hours. It is probably the most technically demanding part of the transplant procedure for the surgeon.⁴

3.6. *Transplant Co-ordination Network*

The NPTU at Westmead employs a full time Transplant Coordinator who manages both the pancreas/kidney and kidney transplant programs. The Unit is part of a national transplant network for sharing of donor organs between States and intended to ensure equity in organ availability across Australia. When an interstate pancreas/kidney transplant patient receives donor organs a debit is made against the State of origin of the patient. This debit is taken into account when subsequent kidney donor offers are made.

3.7. *Outcomes at the National Pancreas Transplant Unit*

Up to June 2000, 122 pancreas transplants have been undertaken at the NPTU. Analysis of all pancreas transplants to the end of 1997 show five-year actuarial patient, kidney and pancreas survival of 88%, 82% and 69% respectively. These compare favourably with worldwide outcomes.¹⁴

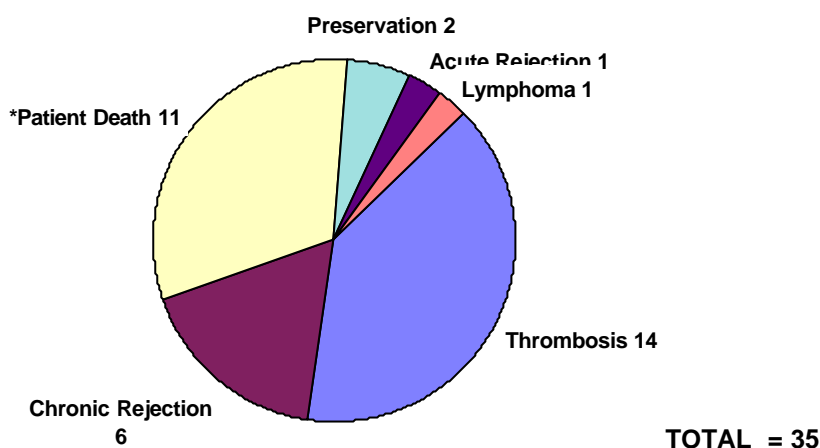
Complications

The causes of graft loss and patient death for Australia wide pancreas recipients up to March 1998 are shown in Figures 4 and 5 respectively. In 11 cases functioning grafts were lost due to patient death.

The most significant surgical complications at Westmead are related to the bladder drainage of pancreas secretions. Previous reports have quoted the rate of these complications to be approximately 75% though severity varies widely between each patient. About 25% of Westmead transplants eventually require re-operation to convert the bladder-drained pancreas to enteric drainage; delayed enteric drainage appears to carry less complications than if performed with the primary procedure⁴. However, recent advances in surgical techniques are causing the Unit to reconsider the use of primary enteric drainage which would eliminate bladder complications.

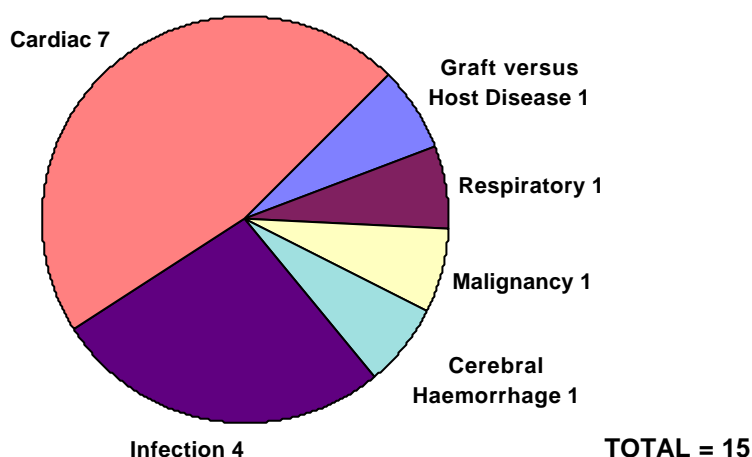
Cardiac complications are a significant cause of mortality in overseas centres. The NPTU at Westmead emphasises careful patient selection and cardiac work-up to reduce the level of cardiac related complications.

FIGURE 4: CAUSES OF PANCREAS GRAFT LOSS AUSTRALIA WIDE¹⁴



* Across Australia 11 functioning grafts have been lost due to patient death

FIGURE 5: CAUSES OF PATIENT DEATH AUSTRALIA WIDE¹⁴



Long Term Outcomes

All patients receiving pancreas/kidney transplants at Westmead receive long term follow up by the Unit. The Unit produces the annual National Pancreas Transplant Registry which includes activity and outcome data from both NPTU at Westmead and the Monash Medical Centre in Melbourne. In addition, Westmead has an active research program into the long term efficacy of pancreas/kidney transplantation.

Westmead has demonstrated excellent long term glucose control for Type I diabetic patients following successful pancreas/kidney transplantation at the Unit.¹⁷

In terms of long term patient and graft survival the 1996 Australian and New Zealand Diabetes and Transplant Registry (ANZDATA) Report presented a comparative statistical analysis of the outcomes of renal transplantation for diabetic patients with end stage renal failure.¹⁰

Data in this report showed that Type I diabetic patients who received a pancreas/kidney transplant had similar patient and graft survival than those who received a kidney transplant alone. Further statistical analysis concluded that having a pancreas transplanted with the kidney was one of only two statistically significant independent predictors of patient survival. The other was related to the occurrence of dialysis before transplantation.

Patient selection is likely to have contributed to these results as well as the fact that the pancreas/renal transplants were done in more recent years. However, these results still support the view that, with appropriate patient selection, combined pancreas transplantation does not increase the risk of mortality.

The NPTU is also monitoring the occurrence of long term diabetic complications following pancreas/kidney transplantation. They have recently been successful in demonstrating improvement in peripheral neuropathy in long term prospective studies on their post-pancreatic transplant patients.^{3,18}

Quality of Life

Since 1996 Westmead has formally collected data on quality of life indicators for their pancreas transplant recipients. These results will be analysed once there are adequate patient numbers to produce meaningful statistical results.

3.8. Research Activities

The NPTU has an external peer review, grant funded, pancreas transplantation research program. The program is involved in a broad range of research activities relating to pancreas transplantation.

The Unit reviews the long term outcomes of all patients. This includes monitoring the development of secondary diabetic complications. As already noted, the Unit has published results reporting an improvement in peripheral neuropathy in their post-transplant patients.^{3,18} The Unit also undertakes studies using animal models for the assessment of factors such as long term glucose control, reduction in long term complications¹⁹ and the diagnosis of pancreatic graft rejection.¹¹ They have also been successful in obtaining funding for the study of islet cell transplantation.^{15,20}

4.0 RESOURCE REQUIREMENTS OF PANCREAS TRANSPLANTATION

4.1. Current Funding Arrangements

In March 1992, the Australian Health Ministers' Advisory Council (AHMAC) approved the NPTU at Westmead Hospital as the only NFC for Pancreas Transplantation. Up to ten procedures per year were to be funded under this Program.

AHTAC undertook a scheduled review of the service and released a report in February 1996.¹⁵ This Report recommended the NPTU at Westmead continue to receive funding under the NFC Program for the next three years. It would remain as the only nationally funded pancreas transplant centre and should increase its throughput up to 15 cases per year in order to meet demand.

The review of NFC status was not undertaken in 1999/2000 and NSW is currently seeking advice from the Commonwealth as to the review process.

4.2. Cost of Pancreas Transplantation

The most comprehensive study of the costs of running the National Pancreas Transplant Program at Westmead was performed by the Centre for Health Economics Research and Evaluation (CHERE) and was released in February 1993.¹⁶ The study estimated the average cost of pancreas transplantation on a per patient basis.

The methodology used to estimate costs involved defining six different patient types depending upon the level of treatment provided and then estimating a total cost for each patient group.

The six patient types ranged from those who were assessed but did not receive a transplant through to those undergoing transplantation with a complicated post-operative course. Estimates were then made as to the proportion of each patient type treated by the Unit in a one-year cycle. From this a total annual cost was calculated and this translated to an average cost per transplanted patient.

The study included almost all costs associated with pancreas transplantation including those for direct patient treatment, external costs such as patient transportation and accommodation, overhead costs and capital infrastructure costs.

Although now somewhat dated, Table 5 below, summarises the results of this costing study.

TABLE 5: COSTS OF RUNNING A RENAL TRANSPLANT UNIT

Cost Component	Number of Patients	Cost *
<u>Direct Patient Care Costs:</u>		
<i>Patient Type</i> A	3	\$7,980
B	1	\$3,475
C	1	\$38,032
D	1	\$61,161
E	3	\$196,281
F	5	\$399,030
Total Direct Patient Care Costs	14	\$705,959
Cost Component	Number of Patients	Cost *
<u>Indirect Costs</u>		
External Costs	14	\$99,482
Overhead Costs	14	\$169,657
Capital Costs	14	\$8,875
TOTAL COSTS	14	\$983,973
Cost per Transplanted Patient	10	\$98,397

* costs are as at 1993

Source: CHERE Discussion Paper 13, 1993¹⁶

The study determined that the total cost for ten pancreas/kidney transplantations undertaken over a one-year period to be \$983,973. The average cost per patient was therefore estimated at \$98,397.

According to NSW Health Department inpatient costing pancreas transplantation is costed at \$52,000.²¹ These costs are mostly limited to the inpatient stay and are likely to reflect a large proportion of the variable costs of this component. However, they are likely to exclude a number of the external costs and fixed overheads as well as assessment and follow up costs.

4.3. Factors Influencing Future Costs of the Program

The 1993 CHERE costing study detailed the major factors influencing the cost of pancreas transplantation. These factors need to be reviewed in the context of the current developments in activity and service profile of the Unit. As presented in Table 5, the costs are divided into direct patient care costs and indirect costs which include capital, overhead and external costs. The review of the NFC status of the NPTU at Westmead would enable a more current assessment of costs.

Direct Costs

The most significant cost factors are the direct patient treatment costs which range from \$2,660 for patients who are assessed but not admitted onto the waiting list through to \$79,806 for complicated transplant recipients. The increasing number of patients on the waiting list reflects the fact that the Unit is receiving a higher number of referrals and therefore undertaking an increased number of assessments.

This is most likely related to emerging awareness and acceptance of the program in different States/Territories and it would be reasonable to assume the referral rate will eventually reach a more stable level. However, there will be increased costs in providing more assessments and in maintaining a longer waiting list.

In terms of the costs of the actual procedure it appears the Unit has been operating effectively on NFC funding which approximates the CHERE estimates despite general inflationary pressures. This may be due to improved efficiency as the Unit has become more established. This is demonstrated, for example, through a reduced length of stay. The CHERE study included the costs of long term follow up for six months. The Unit follows up each patient indefinitely on a least an annual basis. As the number of patients who receive pancreas transplant increase the costs of providing this follow up will also increase.

Indirect Costs

The capital and overhead costs are essentially the Unit's fixed costs. AHTAC recommended in its 1996 report that the NPTU could provide up to 15 transplants within its current infrastructure. According to current activity estimates, a significant increase in fixed costs appears unlikely over the next few years.

The external costs are primarily for interstate donor organ retrieval, patient accommodation costs, and travel costs for interstate patients. In the three years to the end of 1997, only one interstate retrieval was undertaken. This suggests a fall in overall retrieval costs compared with the 1993 CHERE study.^{22,23} A more recent study on organ retrieval estimated the average cost for the pancreas retrieval team to be \$4,300 to \$4,900 per retrieval.²⁴ According to this study, the costs of transport varied from \$35 to \$3,400 per retrieval and the overall retrieval costs were higher than the 1993 CHERE study. However, the costs were very dependent upon the location of the retrieval and the mode of transport used.

The number of interstate patients in the CHERE model was six out of ten (60%). These patients incur higher transport and accommodation costs which range from \$6,000 to \$9,000 per patient. During 1997 the Unit undertook six transplants on interstate patients (including one from ACT) out of a total of 11 transplants (55%).

As at March 1998 the number of interstate patients on the waiting list was 48 out of 72 (66%). The current activity is consistent with the assumptions about interstate activity made in the CHERE costing study. However, the trend towards an increasing proportion of interstate patients on the current waiting list is likely to result in an increase in transport costs.

4.4. Cost effectiveness

The cost effectiveness of kidney transplantation for end stage renal failure has been well established.²⁵ However, there is no current consensus of opinion as to the cost effectiveness of combining pancreas transplantation with this procedure.

The costs of kidney transplantation alone were estimated in 1992 to be \$20,000 to \$25,000 for the procedure plus \$5,000 per year for ongoing support.²⁵ The same report suggested that pancreas transplantation added \$40,000 to the procedure cost and \$9,000 to the annual support costs. These figures have not been resolved with the methodology used in the subsequent CHERE costing study.

However, there are many other studies which report that the cost of the combined pancreas/kidney transplant procedure is up twice that of kidney transplantation alone.^{26,27} The main area of contention appears to be comparing the additional surgical costs of pancreas transplantation with the costs of ongoing diabetic management for kidney alone recipients. The major benefits to patients are improved quality of life and the potential for reduction in long term diabetic complications. Although there are studies which support both of these outcomes they are difficult to quantify in terms of economic value.

Following a review of the available literature, the conclusion appears to be that pancreas transplantation is a cost effective option for a select group of Type I diabetic patients with end stage renal failure whose diabetes is difficult to manage and who are more likely to develop early secondary complications. For the rest, the true cost effectiveness of pancreas transplantation is difficult to assess at this stage. It is dependent upon studies into the procedure's ability to prevent long term complications and the subjective quantification of quality of life data.

5.0 PLANNING ISSUES

5.1. *Projections of Future Demand*

The 1996 ANZDATA report¹⁰ showed that during 1995 the incidence of new patients with end stage renal failure secondary to Type I Diabetes was 78; of these 28 were from NSW. This report also shows that the number of new patients has been increasing each year since 1991. The rate of growth is very variable but overall has averaged six to seven patients per year.

The NPTU at Westmead approximates that, according to their suitability criteria for pancreas transplantation, they are now being referred about 30% of all Type I diabetic patients with end stage renal failure. Of these, approximately 75% are admitted onto the waiting list. Based upon current selection criteria and an extrapolation of the ANZDATA figures, the potential demand for pancreas transplantation across Australia can be approximated to range from 22 to 26 cases per year up to the year 2001. This is consistent with the predictions of the 1996 AHTAC review which suggested a potential Australia wide caseload of approximately 25 patients per year.¹⁵

If the Monash Medical Centre in Victoria continues to undertake five procedures per year on their own residents the estimated demand at NPTU will range from 17 to 21 patients per year by the year 2001. Of these the demand from NSW residents will range from seven to nine patients per year.

The above estimates contain many assumptions about the rate of increase in the incidence of end stage renal failure, the rate of selection of suitable patients as well as the activity at Monash Medical Centre. If Monash adjusts their activity to absorb increasing demand from Victoria this would slightly reduce the predictions for Westmead. The establishment of another Australian Pancreas Transplant Unit would also alter these predictions. However there are no indications that this will occur in the near future.

In order to validate these predictions the actual incidence of Type I Diabetes and end stage renal failure will need to be closely monitored. The final level of demand will depend upon the true incidence of end stage renal failure complicating Type I Diabetes as well as the outcome versus risks that the procedure is able to achieve for these patients.

5.2. *Caseload and Unit Size Considerations*

Assessment of the scientific evidence in the 1996 AHTAC review concluded that the caseload of at least ten and preferably 20 per year is required to maintain good patient outcomes¹⁵. These volumes are required in order to maintain expertise not only of the surgical team, but also of services such as imaging and pathology which are required to support the transplant unit. The Westmead Unit's current caseload, which is likely to increase over the next few years, is consistent with these recommendations.

The current infrastructure at Westmead is sufficient to deal with 15 pancreas transplants per year.¹⁵ As the Unit also provides a renal transplant service independent of the pancreas/kidney transplant service the infrastructure required to increase pancreas transplants to 20 per year is unlikely to be significant. In fact a greater throughput may lead to a more effective use of the current resources.

Because of the current throughput the Unit has only one dedicated Pancreas Transplant Surgeon along with some urological support. A Surgical Registrar or Fellow who receives training in pancreatic transplant surgery while attached to the Unit also supports the team. Only having a single transplant surgeon can cause logistical problems particularly with on-call commitments and the ability to take advantage of all organ donor offers.

However, even with an increase in activity to 20 transplants a year, it is unlikely to be sufficient to support a second transplant surgeon. Despite this the Unit needs to ensure there is appropriate backup for the current Surgeon. At present the Unit's Urologist is increasing their skills in transplant surgery which will improve surgical support. The level of expertise of the training Registrar is also an important factor.

5.3. Organ Donation

Increasing organ donation rates is a critical issue for most transplant programs in particular for cardiac and liver transplantation because of the life threatening nature of the patient's condition. For kidney transplantation, the high number of potential recipients has also resulted in efforts to improve the organ donation rate.

The availability of pancreas organs for transplantation is not as a significant problem as for other programs due to the relatively low caseload. In 1998 consent for pancreas donation was obtained from 98 potential donors across Australia. Of these 25 were retrieved and 18 transplanted.²³ Donor problems have more commonly occurred due to the logistical problems of only having a single transplant surgeon to undertake retrievals. The other important factor for pancreas transplantation is the preference for younger donors.

So far the majority of transplants at NPTU at Westmead have come from NSW donors. More recently, some interstate transplant surgeons have been able to assist with harvesting of the pancreas organ. This should help with the Unit's ability to utilise interstate organ donors.

Initiatives to improve organ donation rates across Australia will benefit the pancreas transplantation program and these should be encouraged. The 1997 organ donation rate for Australia was 10.3 donors per million population which is one of the lowest rates in industrialised countries. In 1997, funding was allocated in NSW for the establishment of the Coordination Centre for Organ and Tissue Donation as well as the setting up of an Area Health Service network to support and promote organ donation. This new structure was partly based upon that recently used with great success in South Australia which now has the highest rate of organ donation in Australia at 17 donors per million population.²³

Other transplant programs have proposed better coordination of organ retrieval efforts is also required such as a centralised retrieval team consisting of appropriate surgical expertise. The pancreas transplantation unit should be included in these initiatives.

5.4. Funding Arrangements

Currently the NPTU at Westmead is funded through the NFC Program for up to 15 procedures per year. NFC funds are allocated by the Commonwealth to assist in the provision of newly developing, high cost, low volume technologies to Australian residents.

Funding for pancreas transplantation has been approved until the year 2000 when a further review is scheduled. Despite changes in the 1998/1999 Federal Budget regarding the funding of NFC Programs, it appears that the current arrangements for existing NFC Programs will continue.

If NFC funding for the pancreas transplantation program were discontinued in the future, an appropriate funding mechanism would need to be negotiated in order to support this specialty service. This should be determined with reference to recommended funding models for NSW Selected Specialty Services.

It would be beneficial, both in terms of patient outcomes and efficient use of resources, for the NPTU at Westmead to continue to provide an Australia wide service. NSW Health would need to provide funding for an estimated demand of nine patients per year by 2001. According to the 1993 CHERE costing study, the approximate cost for each patient is \$95,800 (calculated by excluding the interstate transport costs from the average cost per patient, at 1993 costs). Because of the low throughput and resource intensive nature of the procedure, a centrally allocated funding arrangement is likely to be the most practical method of funding NSW patients. Any model of this type must ensure that it does not unfairly disadvantage smaller Area Health Services in particular rural Areas. However, current discussions in regard to funding arrangements in NSW will further consider this matter.

The funding for interstate patients would most likely be through existing interstate cross purchasing arrangements on a charge per patient based upon an appropriate breakdown of costs.

6.0 CONCLUSION AND RECOMMENDATIONS

Technology Assessment

Because of the good outcomes being achieved, it is appropriate that pancreas transplantation continue to be available for the relatively low volume of patients for whom it is suitable.

The transplant unit should ensure that selected patients make appropriately informed decisions regarding the option of pancreas transplantation compared with kidney alone transplantation. These decisions should be based upon knowledge of the benefits as well as the potential risks of the additional surgery.

The transplant unit should continue to closely monitor outcomes and complications from the procedure.

Demand Estimates

Based upon ANZDATA trends regarding the incidence of renal failure secondary to Type I Diabetes, and assuming that activity at Monash Medical Centre, Melbourne remains relatively stable, the estimated demand for pancreas transplantation at the NPTU is expected to range from 17 to 21 patients per year by 2001. Of these, the demand from NSW residents will range from seven to nine patients per year by 2001.

Number of Units

In terms of achieving best outcomes and efficient use of resources, the NPTU at Westmead should continue as the sole facility in NSW. It would not be appropriate for a second pancreas transplant unit to be established in NSW in the foreseeable future.

Similarly the estimated demand is unlikely to justify establishment of further units across Australia for at least the next five years and not before a further review of the service is undertaken.

Funding

Based on the 1993 CHERE costing study the estimated cost of pancreas transplantation was approximately \$100,000 with higher costs for interstate residents.

The Unit appears to have operated effectively with the current NFC funding allocation which is similar to the CHERE cost estimates. However, the Unit is experiencing some cost pressures primarily due to increasing numbers of patients being referred for assessment as well as the long term patient follow up costs.

NFC funding is due for review shortly, if the NFC funding is discontinued appropriate funding mechanisms for both interstate and NSW residents would need to be negotiated. This should be done with reference to funding models for NSW Selected Specialty Services. For NSW patients, the most appropriate funding mechanism is a centralised pool of resources allocated to the NPTU at Westmead based upon agreed activity levels. Interstate patients should be charged through appropriate interstate cross purchasing arrangements.

Organ Donation and Retrieval

Though donation rates are not as critical an issue for pancreas transplantation as for other programs, an increase in available organs will benefit the program and initiatives to achieve this in NSW should continue to be supported. In addition, the NPTU should be included in any initiatives to improve the coordination of the organ retrieval network.

Review of this Plan

The Selected Specialty and Statewide Service Plans will be reviewed on a regular basis and it is expected that this Plan will be reviewed with a five year timeframe. However, modification of the Plan may be required following the national review to be undertaken by the Commonwealth later in 2001. In addition, changes in donor rates and technological change will be monitored in order to determine whether a shorter time frame for review is required.

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**Selected Specialty and Statewide Service Plan
NUMBER TWO - PANCREAS TRANSPLANTATION**