

A03/S(HSS)/a

**NHS STANDARD CONTRACT
FOR PANCREAS TRANSPLANTATION SERVICE (ADULT)**

PARTICULARS, SCHEDULE 2 – THE SERVICES, A – SERVICE SPECIFICATION

Service Specification No.	A03/S(HSS)/a
Service	Pancreas transplantation service (Adult)
Commissioner Lead	
Provider Lead	
Period	12 months
Date of Review	

1. Population Needs

1.1 National/local context and evidence base

There is a huge amount of literature on pancreas transplantation. A number of studies have shown improvement in various complications of diabetes, and survival benefit has been demonstrated in area comparisons in the Netherlands and elsewhere. There are however no randomised controlled trials to demonstrate improved survival.

2. Scope

2.1 Aims and objectives of service

Pancreas transplant services have been commissioned nationally in England since April 2004.

Transplantation of the pancreas is of proven clinical benefit for patients with type 1 diabetes who are undergoing kidney transplantation. It is therefore usually carried out at the same time as the kidney transplant (simultaneous pancreas – kidney transplant or SPK), but can be done as a stand-alone procedure in patients who have previously received a kidney graft (pancreas after kidney or PAK), or as a pancreas transplant alone (PTA) in someone who has not received a kidney transplant.

Pancreas and kidney transplantation

Diabetes is a common cause of end stage renal failure. Diabetics who have a renal

transplantation have poorer outcomes than other transplant patients because of the underlying ongoing disease process.

This Service Specification does not cover kidney transplantation. Whilst dual transplantation (kidney and pancreas) has a slightly increased mortality and morbidity risk in the short term, due to the increased complexity of the operation and the requirement for additional immunosuppression, the long-term benefits far outweigh these additional risks. Transplanting both pancreas and kidney improves 10-year survival in people with diabetes compared to cadaveric kidney transplant alone.

Live donor kidney transplantation has better results than deceased donor kidney transplantation, and evidence suggests the outcomes of live donor kidney transplantation are equal to deceased donor combined kidney and pancreas transplantation at 10 years, with better survival beyond that for patients who have undergone the combined procedure.

Categories of pancreas transplantation

There are three categories of pancreatic transplantation:

Those which aim to improve diabetic control and increase survival of a kidney transplant:

- pancreatic transplantation performed at the same time as a kidney transplant (simultaneous pancreas kidney - SPK)

Those which aim to improve diabetic control alone:

- sequential pancreatic transplantation (pancreas after kidney - PAK); pancreas implanted alone in a diabetic patient who already has a kidney transplant
- pancreatic transplantation alone (PTA) for a patient with type 1 diabetes who has severe and frequent hypoglycaemia, but adequate kidney function.

Pancreas donation

NHS Blood and Transplant commissions live and cadaveric pancreas donation and retrieval. From December 2010, a new procedure has increased the proportion of whole pancreata available to the islet transplantation service. This may affect the number of whole pancreata available to the pancreas transplantation service.

Recipient-organ matching

In the UK, pancreata are distributed to transplant centres through a zonal allocation system. Towards the end of 2010 a national allocation scheme will be introduced aiming to allocate pancreases according to human leukocyte antigen (HLA) match, length of time on the waiting list, degree of sensitisation to HLA antigens, and estimated cold ischaemic time.

Objectives and expected outcomes

The aim of the service is to improve diabetic control through pancreas transplantation for eligible patients who are fit enough to undergo the procedure.

2.2 Service description/care pathway

The service provides:

- assessment
- transplant and,
- follow up

A detailed description is given in the pancreas transplantation service standards.

Organ retrieval and allocation are the responsibility of NHS Blood and Transplant and are excluded from NHS England commissioned service.

Service model and care pathways

Referral

Patients are referred to the pancreas transplant service from nephrologists or diabetologists. Baseline tests are generally performed at the referring hospital prior to the referral.

Assessment

Patients are then seen in a multi-disciplinary clinic for further assessment. Further tests may be indicated; in particular tests to ensure cardiovascular fitness, following which the patient will be presented at the multi-disciplinary teams (MDT) for activation.

On waiting list

This Service Specification does not cover care for patients awaiting pancreas transplantation.

Transplant and recovery

Transplant theatres should be made available at all times, as pancreas transplantation is often done as an emergency procedure.

Post-transplant care

A minority of patients may suffer post-transplant complications including foot problems (relating to their diabetes), infections (due to immunosuppression) and occasional gut and eye problems.

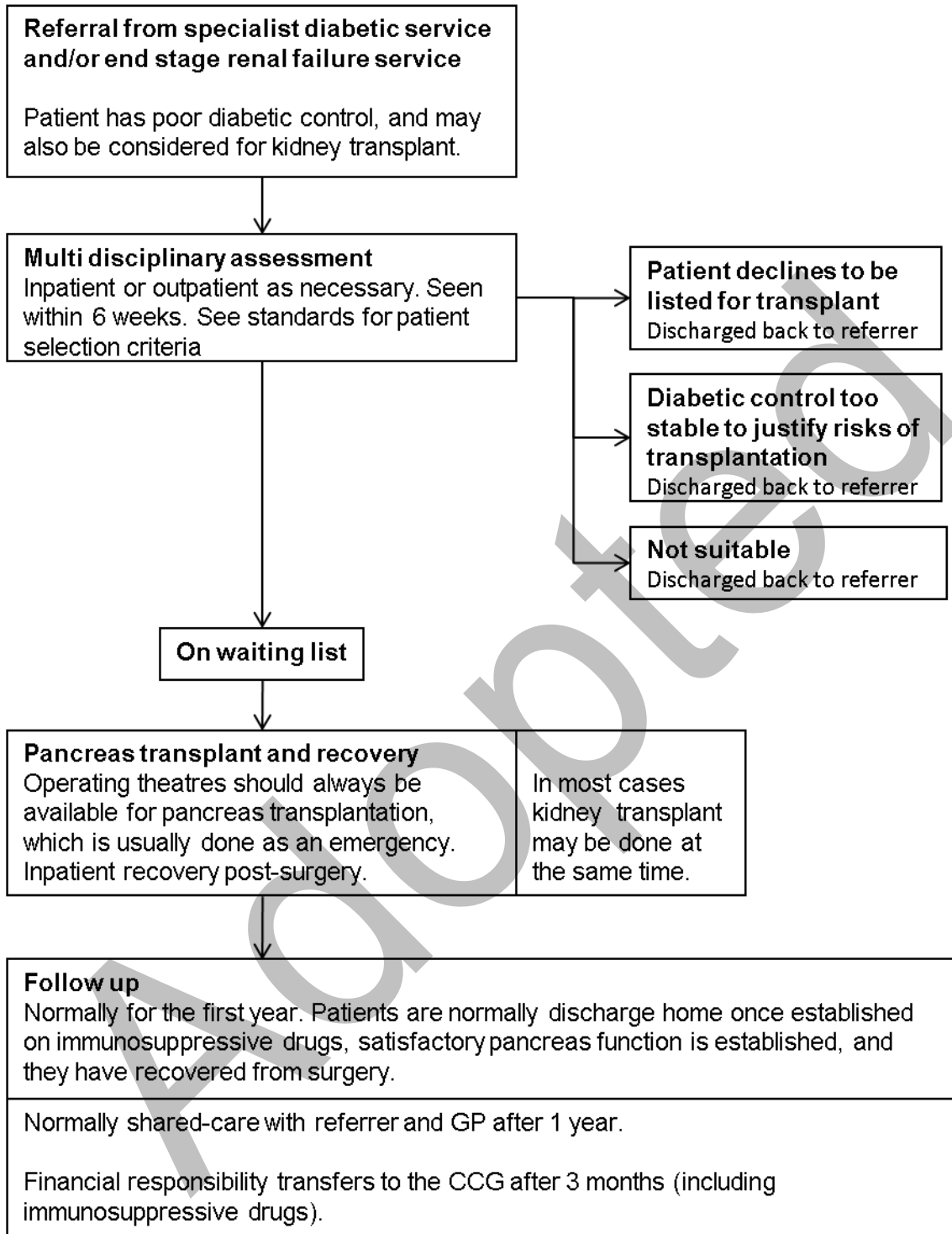
Follow-up

In a very small number of patients, complications may lead to graft failure. In such

cases, they may need to be reassessed by the multidisciplinary team (MDT) for a second transplant to be considered. Patients are normally sent home once established on immunosuppressant drugs, have satisfactory pancreas function, and have recovered from surgery. The transplant centre provider follow up care for the first year, after which shared care may be agreed with the referrer and general practitioner. The designated service includes immunosuppressant medication for the first three months post-transplant, after which time the clinical commissioning group (CCG) takes financial responsibility.

Adopted

Pancreas transplantation care pathway



Days/hours of operation

The service is always open. This includes seven days a week access to a range of diagnostic imaging and histopathology services. Patients should be able to obtain advice by telephone 24 hours a day.

Discharge criteria & planning including any transition arrangements

Discharge criteria

A patient is suitable for discharge when:

- they have been established on the immunosuppressive drugs
- the pancreas (and kidney) is functioning satisfactorily, and
- the patient has recovered from the operation

Discharge process

Patients can usually be discharged home, supported by frequent reviews in outpatient clinics (normally twice weekly initially, decreasing thereafter). In the case of complicated patients referral back to their originating centre may be made for ongoing inpatient care.

2.3 Population covered

NHS England commissions the service for the population of England. Commissioning on behalf of other devolved administrations is reviewed annually, and a current list is available from NHS England commissioners or via the website.

At the moment, NHS England contract includes provision for the service to treat eligible overseas patients under S2 [Under European Union (EU) regulations, patients can be referred for state funded treatment to another European Economic Area (EEA) member state or Switzerland, under the form S2 (for EU member states) or the form E112 (for Iceland, Norway, Liechtenstein and Switzerland)] referral arrangements. Providers are reimbursed for appropriately referred and recorded activity as part of the NHS England contract.

Trusts performing procedures on EU-based patients outside of S2 arrangements will need to continue to make the financial arrangements directly with the governments involved, separately from their contract with the NHS England.

With regard to S2, the mechanism for recovery of costs has been via the Department for Work and Pensions Overseas Healthcare Team. They are responsible for agreeing reconciliation and recovery of costs with European administrations. These arrangements were implemented in October 2009, though a similar process existed previously. The financial flows are therefore back into the treasury rather than back to trusts.

The report "Allocation of organs to non-UK EU residents" includes a recommendation that the NHS England should take over all arrangements between national EU governments and NHS trusts in England for the provision of liver transplant services for EU-based patients and that these transplants should be undertaken as part of the annual funding contract NHS trusts have with NHS England. This recommendation has not been implemented and is currently being considered by the Department of Health as part of a wider review of eligibility,

allocation and funding of deceased organs donated for transplantation.

2.4 Any acceptance and exclusion criteria

NHS England commissions a range of services for devolved administrations, and these are renegotiated annually.

The provider regularly reviews potential transplant recipients, and works with the wider diabetes community and renal failure services, to ensure appropriate referrals and equity of access for all patients.

As a requirement of race, gender, sexual orientation, and religion and disability equality legislation, providers have a duty to co-operate with the commissioner in undertaking Equality Impact Assessments.

Referral criteria, sources and routes

Patients are referred from diabetic and renal services.

The decision to recommend transplantation is agreed by the transplant surgeon and nephrologist or diabetologist, with input from other members of the MDT.

The assessment process has four possible outcomes:

- the MDT recommends a transplant; the **patient agrees to a transplant** and is placed on the waiting list. (This includes the outcome where the MDT recommends a live donor transplant with the possibility of a subsequent pancreas after kidney transplant)
- the MDT recommends a transplant but the **patient declines or wishes to defer** the decision. The patient is given time and opportunity to revise this decision. He/she may choose to be listed for kidney alone
- the MDT decides that the **patient is currently in a stable condition** that does not justify the risks of transplantation. For SPK, the patient is kept under review for possible reassessment at a later date
- the MDT decides that the **patient is not suitable** for transplantation. The reasons for the decision are explained to the patient, his family and carers. Patients who disagree with the decision are offered the option of a second opinion at another transplant centre. The patient may be found suitable for kidney transplant alone

There is no absolute exclusion criteria.

Response time & detail and prioritisation

Waiting times for transplant are dependent on organ availability. Prioritisation of organ allocation to centres is the responsibility of NHS Blood and Transplant.

2.5 Interdependencies with other services

The key relationships for this service are with diabetic services and services for end stage renal failure.

Organ retrieval and allocation are the responsibility of NHS Blood and Transplant..

Relevant networks and screening programmes

There are a range of renal and diabetic networks but they are not directly applicable to this service.

3. Applicable Service Standards

3.1 Applicable national standards e.g. NICE, Royal College

Providers meet normal NHS governance requirements. Details are set out in the service standards.

4. Key Service Outcomes

Quality Performance Indicator	Threshold	Method of measurement	Consequence of breach	Report Due
90 day graft and patient survival	CUSUM threshold	CUSUM	Response as per protocol agreed between NHSBT and NHS England	Per NHSBT protocol
30-day and one-year graft and patient survival	Significant variation from the national average or, in services with one or two national centres, significant variation from the outcomes achieved in the previous three years	Annual report (September of contract year) with data from previous financial year April to March	Performance notice as set out in Clause 32.4 Review & action plan	Annual report (September of contract year)

5. Location of Provider Premises

Designated provider

Cambridge University Hospitals NHS Foundation Trust
Addenbrooke's Hospital, Box 130, Hills Road, Cambridge. CB2 0QQ

Central Manchester and Manchester Children's University Hospitals NHS
Foundation Trust . Manchester Royal Infirmary, Cobbett House, Oxford Road,
Manchester. M13 9WL

Guy's and St Thomas' NHS Foundation Trust .St Thomas Street, London. SE5 9RS

Imperial College Healthcare NHS Trust. Hammersmith Hospital, Du Cane Road,
London. W12 0HS

Oxford Radcliffe Hospitals NHS Trust . Churchill Hospital, Headington, Oxford. OX3
7LJ

The Newcastle upon Tyne Hospitals NHS Foundation Trust .Freeman Hospital, High
Heaton, Newcastle upon Tyne. NE7 7DN

Adopted