NHS
National Services Scotland

National Services Division

Service agreement with:
NHS Greater Glasgow & Clyde

For:
Advanced heart failure

2005/08

1. Introduction

1.1 This agreement is between National Services Division, NHS National Services Scotland, as commissioner, for and on behalf of the Scottish Executive, and NHS Greater Glasgow & Clyde as provider of an advanced heart failure service.

1.2 For cardiac transplantation, this agreement shall cover the period commencing 1 April 2005 to 31 March 2008, with the introduction of cardiac surgery for adults with advanced heart failure from 1 September 2006.

1.3 This agreement is made under the provision of Section 30 of the NHS and Community Care Act 1990.

2. Objective

To provide a comprehensive service for the assessment and management of advanced heart failure for residents of Scotland, which comprises:

- specialist assessment
- adult cardiac transplantation
- cardiac surgery and revascularisation made complex by the presence of advanced heart failure and requiring the multidisciplinary expertise of the national specialist quaternary service.
- follow-up

Notes:

- Lung and heart/lung transplantation are outwith this agreement and are commissioned by NSD from NSCAG centres in England.
- CRT, CRT-D and ICDs are regionally-funded and, while the outcome of assessment may be a recommendation for implantation of a device, this will be funded through regional consortia.
- VADs, either as a bridge to transplant or as a destination therapy, are excluded form this agreement at present until recommendations from the Department of Health and the National Specialised Commissioning Advisory Group [NSCAG], who are operating the UK evaluations, are known.

3. Services to be provided

Advanced heart failure in this context is defined as:

- NYHA class III or IV symptoms with objective documentation of marked functional limitation and poor 12-mo prognosis **despite** optimal medical therapy (peak oxygen consumption <14mL/kg/min, documented progression of heart failure symptoms, clinical instability, or marked serial decline in peak oxygen consumption)

- Recurrent or rapidly progressive heart failure symptoms **unresponsive** to **optimal** dosage of vasodilators, diuretics and inotropic support
- Severe hypertrophic or restrictive cardiomyopathy with NYHA class IV symptoms
- Recurrent symptomatic, life-threatening ventricular arrhythmias **despite** maximal antiarrhythmic therapy by all appropriate conventional medical and surgical modalities (multiple firings from an ICD for documented VT and VF or prolonged periods of documented electromechanical dissociation after ICD conversion of VT or VF)"

3.1 Service specification

3.1.1 The entry point to the national service is:

- referral from a consultant cardiologist for consideration of surgery or cardiac transplantation for the treatment of advanced heart failure

The exit point is:

- discharge to the care of the referring consultant if stable after optimal management
- death

3.1.2 All patients must have:

- clinical evidence of persistent heart failure despite optimum tolerated medical treatment
- documented severe cardiac dysfunction
- no obvious co-morbidities that would compromise the likelihood of benefit

3.1.3 Patients aged 16 or over who are referred for surgery or transplantation will undergo an initial assessment of 3 to 5 days within the unit following which a decision will be made whether or not the patient is suitable for surgery.

3.1.4 During the assessment period the full implications of surgery and its consequences will be explained to the patient and their families or carers prior to the offer of treatment.

3.1.5 If the patient is suitable for transplantation and agrees to the operation, he or she will be registered with the UK Transplant (UKT) as a potential organ recipient. It is essential that the postcode of residence be available for 100% of registered patients.

3.1.6 For transplantation, the provider will make use of the services provided by UKT where appropriate and comply with UKT current UK arrangements for organ distribution. Donor organ retrieval under the current zonal multi organ retrieval arrangements is essential.

3.1.7 Follow-up information should be submitted to UKT immediately post-operatively, again at 3 months follow-up and annually thereafter.

3.1.8 Patients and their families or other carers will be treated with kindness and respect for their dignity and care will be taken to support and reassure them. The hospital environment will be attractive and clean, creating an atmosphere which is calm and welcoming to patients.

3.1.9 The service will be accessible 24 hours a day, 365 days a year.

3.1.10 Shared care protocols must be in place with referring clinicians and GPs for the long term care of the patient. Communication with GPs must be continuous and contact maintained and encouraged - in particular, arrangements for the prescription of immunosuppressive and other life-long medication must be explicit.

3.1.11 Links with GPs will be maintained to monitor patients' availability for transplantation, and to collaborate in post-transplant rehabilitation and clinical management.

3.1.12 Any major change in the way the service is to be provided must be discussed and agreed with the commissioner before implementation. Where changes to the senior clinical team are envisaged, the commissioner must be informed of the succession plan to be operated.

3.1.13 The provider unit will incorporate health promotion and patient education into its daily activities.

3.2 Staff and facilities

3.2.1 The provider will employ appropriately trained staff and ensure that such staff are enabled to develop skills and expertise relevant to the service.

3.2.2 The provider will provide medical and support staff to form an organ retrieval team to travel to retrieve donor hearts and lungs when required. The unit will arrange, using UKT services where appropriate, transport for donor organs from the donor hospital to the transplant unit.

3.2.3 A transplant co-ordinator will be provided to support the patient and his or her family and liaise between them and the unit staff. The co-ordinator will make administrative arrangements for transplant operations in liaison with UKT, the donor hospital, the unit, the patient and family/carer.

3.2.4 The provider will ensure the provision of operating facilities at the time needed, for the transplant operation. The theatre is to be provided with appropriate levels of staff with the required expertise and the necessary specialist equipment and other facilities.

3.2.5 The provider will ensure the availability at the time needed, for post operative care of transplant patients in intensive care beds with adequate levels of skilled nursing staff and supervision by cardio-thoracic surgical staff in collaboration with anaesthetic staff.

3.2.6 The unit will make arrangements with the nephrology services for trained staff to consult when appropriate and to provide renal dialysis to transplant patients when required.

3.2.7 General support services which should be available for all stages of surgery will include: radiology/imaging, haematology, blood transfusion, biochemistry, pathology and physiotherapy.

3.2.8 Appropriate specialist laboratory and pathology services are required for monitoring and control of potential rejection of transplanted organs. This must include facilities for heart biopsy and examination of the sample by specialist pathology staff.

3.2.9 The service will include, in addition to normal hospital pharmaceutical requirements, provision of specialist immuno-suppressive and similar drugs to transplanted patients in accordance with practice recommended by the NHS Greater Glasgow & Clyde Drug and Therapeutics Committee and NHS Circular 1992 (GEN)11

3.3 Accommodation

3.3.1 Accommodation for patients referred from outwith Glasgow; and a friend or relative, for a period of up to 4 weeks after operation, and following discharge to allow the patient to attend hospital for outpatient tests will be made available.

4. Referral

Referrals to the service will be accepted from consultant cardiologists and cardiac surgeons and will be expected from all parts of Scotland. Referred patients will be assessed by a clinician of appropriate experience. The resultant opinion regarding clinical management will be provided to the referring clinician and GP within 7 days except where specific test results are awaited.

5. Activity

The agreed annual indicative level of activity for this service is:

15 cardiac transplants
10 complex surgeries
10 lung retrievals

The provider should advise the commissioner if it becomes apparent that activity targets cannot be met or will be exceeded.

6. Quality

6.1 Central guidance

The provider will be expected to comply with all relevant guidance, legislation and statutory instruments. This must include, but is not limited to:

- all appropriate NHS QIS standards.
- SIGN guidelines for heart failure management.
- SIGN guidelines for cardiac arrhythmia in coronary heart disease.
- NSCAG standards for cardiothoracic transplant and advanced heart failure
- the Human Tissue (Scotland) Act 2006
- Health & Safety Executive requirements
- recommendations from the St George's Report
- the recommendations of the Bristol Enquiry report
- the timetable for implementation of the Glennie framework
- guidance on Junior Doctors' Hours
- the EC Working Times Directive
- Disability Discrimination Act 1995
- Race Relations (Amendment) Act 2000

The provider will indicate where meeting these standards is not achievable and agree remedial action with the commissioner.

6.2 NHS Greater Glasgow & Clyde

Baseline quality standards, performance targets and indicators established by NHS Greater Glasgow & Clyde will also be applied to the National Services Division service agreement. These will include:

- increasing value for money by improving efficiency and effectiveness
- delivering a person centred service by providing patients and/or their carers the opportunity to influence planning and decision making and by ensuring that they receive services responsive to their needs
- improving quality through the development and implementation of clinical care protocols, systematic monitoring and ensuring that strategies for research and audit are in place.

6.3 National Services Division

The following additional standards should be applied:

Patient information

This should cover the following subject areas:

- General information about the advanced heart failure service (incorporating the transplant programme)

- Specific information with regards to different treatment strategies provided and recommended by the advanced heart failure service
- Waiting for assessment
- Waiting for transplantation
- Advice on exercise programmes for patients post-treatment
- Comprehensive post-transplant information, e.g. compliance with medication regimes, diet
- Follow-up procedures
- regular bulletin to patients and their family/carers on the waiting list to provide support to long waiting patients and a mechanism to reinforce key messages about maintaining contact and health regimes.
- Information for relatives/carers of all advanced heart failure patients after bereavement.

This information should be available in written format and/or in a format that takes account of physical, cultural, educational and mental health needs; however, person-specific communication will also be done verbally by the relevant health care professional.

Discharge procedures

- Clear and appropriate discharge protocols will be established, including liaison with local hospital and primary care teams to facilitate the co-ordination of post-discharge aftercare.

Patient feedback

- There will be effective arrangements in place for monitoring patient and family/carer feedback and, where appropriate, acting on this feedback both during and after episodes of care.

Health promotion and education

- The provider unit will incorporate health promotion and patient education into its daily activities. Particular attention should be given to appropriate advice to patients, staff training and development, monitoring and evaluation, and identifying a lead individual with responsibility for implementing health promotion activities.

6.4 Clinical audit and outcome measurements

a) General

The provider will ensure that the service is clinically and cost effective and that it meets the physical and psychosocial needs of the patients and their carers. They will constantly seek improvement demonstrating this through systematic clinical audit. The provider will regularly monitor all relevant aspects of the service and make the results available to the commissioner.

Documentation should include:

- aggregated and anonymised data reporting clinical care;
- anonymised summaries of regular clinical audit meetings including:
  - the frequency of meetings
  - disciplines attending
  - clinical complaints
  - deaths and complications
  - any service/procedural changes recommended to improve clinical care.

The aim of applying outcome measures within the service agreement is to provide a proxy for the impact of intervention and will look at measures which cover all areas of care.

The provider will measure specific areas of process and outcome as detailed in Annex B. These will include:

- hospital acquired infection
- re-thoracotomy rates (planned or unplanned).

These will be monitored on an ongoing basis by the commissioner who will reserve the right to question the result to anticipate changes to be effected from these results. The provider is also encouraged to develop other outcome indicators as appropriate.

b) Audit

In conjunction with ISD Scotland, the provider is involved in the development and implementation of a national database. Using this database, the provider will audit:

- Time to first consultation from outpatient referral.
- Time to transfer for inpatient management.
- Time to admit for assessment (for outpatients).
- Details of medical therapy optimisation (type and dose of evidence based medication) – comparing baseline at referral to when optimally managed.
- Details of major investigative procedures.
- Percentage of patients recommended for complex pacemaker technologies (as per SIGN guidelines) – comparing baseline at referral to when optimally managed.

For cardiac transplantation the service shall:

- Record re-thoracotomy rates (planned or unplanned).
- Record hospital acquired infection.
- Participate in the Royal College of Surgeons National Intrathoracic Transplant Audit and ensure that the commissioner has access to the results.
- Continue to audit patient information and supporting literature.
- Audit drug utilisation and evaluate post-transplant patients compliance with maintenance therapy, dietary advice and advice on smoking cessation.

The studies will be undertaken during the service agreement period with the results provided to National Services Division as they become available, the objective being to improve the quality and effectiveness of the service.

6.5 Clinical governance

The Chief Executive of NHS Greater Glasgow & Clyde will be accountable for the quality of the clinical service provided. The commissioner expects that robust mechanisms will be put in place to support clinical governance.

7. Teaching and research

The service needs to maintain close liaison with NHS National Education Scotland, Scottish universities and appropriate clinical research bodies to ensure future training and succession planning. The provider will aim to continue the service's commitment to teaching and research in health related areas in the future.

Teaching and research are outwith the funded value of this agreement.

8. Confidentiality

The provider will comply with the provisions of the Caldicott Report. In particular, patient-identifiable information will only be used in clearly defined and monitored circumstances, only when absolutely necessary and should entail the use of the minimum necessary patient-identifiable information.

Access to patient identifiable information will be on a strict need to know basis, everyone in the organisation will be aware of their responsibilities with respect to patient confidentiality and the organisation will ensure that its use of patient-identifiable information is lawful.

National Services Division does not require returns to include patient-identifiable information; information on clinical activity required by NSD must be submitted in anonymised format.

9. Financial arrangements

9.1 Agreement structure

This is a standard agreement under which the provider is entitled to receive an agreed sum.

9.2 Funded value of agreement

The indicative funded value of this agreement is:

2005/06:
2006/07:
~~**2007/08:**~~ [redacted] TBC

9.3 Payment procedure

The agreement sum will be paid monthly in 12 instalments on or around the 19th day of the month. The month 12 payment will bring funding in line with agreed levels.

9.4 Basis of funding

The baseline value of the agreement shown above is based on expected price levels. This value may be reviewed throughout the year, with the intention of reconciling expenditure and funding, wherever possible.

Negotiations should, in normal circumstances, only be re-opened where it is apparent that the longer-term trends in service delivery differ significantly from the current plan. The commissioner does, however, reserve the right to re-open formal negotiations with the provider at any point during the term of the agreement if there are material changes in activity and/or expenditure.

(For the purpose of this agreement, material variations in activity and expenditure will be assumed as +/-10%, although breaching this threshold will not automatically trigger a re-opening of negotiations.)

Following receipt of the 9-month statement (see Annex B), the commissioner and provider will meet to agree a final funded value.

The value may also be increased if the commissioner receives additional funding in respect of:

- national pay awards and/or policy
- other statutory changes

9.5 Cost shifting and cross-subsidisation

The provider shall not take action to shift activity or costs to other budgets or to make agreements with other commissioners or providers without prior consent in writing from National Services Division.

The staff and facilities covered by the baseline funding of this agreement should not be used to cross-subsidise local services.

9.6 Purchase and replacement of capital equipment

National Services Division receives a small capital allocation to fund equipment for specialised services. There is an annual process for evaluating equipment needs and agreeing capital funding, but there is no guarantee that this will cover 100% of the needs of all national specialist services.

NHS Greater Glasgow & Clyde must still ensure that the service has a planned programme for the purchase and replacement of vital capital equipment, and remains responsible for all buildings and facilities within the unit. NSD will not contribute towards the cost of major capital building projects or renovations unless it receives specific additional funding from SEHD.

Items of minor capital (under [redacted] including VAT, where appropriate) are considered revenue funding. All minor capital purchases not explicitly included in the indicative baseline should be agreed with the commissioner. Additional funding may be made available for this purpose.

9.7 Charging for other UK residents

UK residents may be treated under this agreement and their activity should be allocated against this agreement and a sum equivalent to the value of that income will be removed from the baseline funding provided by NSD.

The provider will ensure that all non-Scottish residents are charged for at full cost-per-case rates, including fixed costs.

9.8 Other international patients

Treatment of EEA residents through reciprocal health arrangements is the responsibility of the host NHS Board and, as such, is excluded from the baseline of all NSD agreements. [Note: this includes the Republic of Ireland and the Isle of Man.]

Anyone not covered by reciprocal health care agreements are considered private patients and must be able to provide proof of funding (either personal or from their own health system) before any referrals can be accepted. Again, these patients

should be treated within the national service and the costs of their care reflected as income against the NSD-funded baseline.

NSD should be informed before accepting non-UK residents for treatment.

10. Performance monitoring

10.1 Information returns

The provider is responsible for the provision of information to the commissioner and for validity, accuracy and timeliness of all returns and data.

10.2 Right to visit

The commissioner retains the right to visit the service at the provider's convenience and welcomes the opportunity for communication and dialogue throughout the year.

10.3 Reporting timetable

The provider will supply the following reports on the progress of the service agreement:

Report	Date due	Format for report
Monthly report	7th working day of each month	Annex A
Six Month report	31 October	Annex B
Nine month report	31 January	Annex C
Annual report	31 May	Annex D

Notes:
Reports should be sent to: [redacted]
National Services Division, Area 062, Gyle Square, 1 Gyle Crescent, Edinburgh EH12 9EB

Email: [redacted]
Fax:

It is the provider's responsibility to ensure that all reports are received within the agreed timescales. Failure to submit reports on time may impact on NSD's ability to reconcile funding to expenditure.

10.4 Annual review

The service will be reviewed each year in late autumn following receipt of the annual report. The extent of the review will depend on local circumstances.

11. Variations to the agreement

11.1 Variations and notification times

Variations to the agreement will only be made at the mid-year review unless there are exceptional reasons for deviating from this procedure.

Either party will give:

- six months' notice of any proposed changes to the service which require a reduction in staffing
- two months' notice of any other material changes

Variations without notice will be considered in the event of unforeseen circumstances such as:

- the occurrence of a major incident
- emergency treatment needs
- a major outbreak of illness or infection
- industrial action.

11.2 Sub-contracting

No sub-contracting shall be undertaken without the prior agreement in writing of National Services Division.

12. Resolution of disputes

The commissioner and the provider both resolve wherever possible to settle any disputes or disagreements in relation to this service agreement by negotiation.

In the unlikely event that these negotiations fail, the formal disputes procedure as detailed in NHS Circulars FIN (CON) (1992) 1 and FIN (CON) (1993) 4 will apply.

13. Distribution

A copy of this service agreement is to be held by the head of service.

For and on behalf of
The Scottish Executive

Signature [redacted]

Block Capitals DEIRDRE EVANS

Designation DIRECTOR

National Services Division

Date 12 March 2007

For and on behalf of
NHS Greater Glasgow & Clyde

Signature [redacted]

Block Capitals JONATHAN BEST

Designation DIRECTOR - REGIONAL SERVICES

NHS Greater Glasgow & Clyde

Date 11/3/07

Signature .....

Block Capitals .....

Lead Clinician

Date .....

Annex A

Provider: **NHS Greater Glasgow & Clyde**

Service: **Advanced heart failure**

Report format: **Monthly**

Activity

	Planned - current month	*Actual - current month*	*Planned YTD cumulative*	*Actual YTD cumulative*
Advanced HF new OPs				
Advanced HF return OPs				
Advanced HF IP transfer referrals				
Advanced HF IP assessment episodes				
Cardiac biopsies				
Transplants				
Complex surgery				
Post transplant ward stays				
Cardiac Biopsy				
Post transplant OP attendances				
Retrievals - lung				

Comments

- Comment on any major variances from planned activity and on any trends/issues of which the commissioner should be made immediately aware

Annex B

Provider: **NHS Greater Glasgow & Clyde**

Service: **Advanced heart failure**

Report format: **Six month**

1. Activity

In all cases, please state actual activity against planned levels

Assessment by disease:

- Number of patients assessed
- Number of patients assessed by disease
- Number of occupied bed days:
  - ITU
  - Ward
- Number of tx patients on the waiting list
- Number of tx patients dying on the waiting list

Transplantation/surgery:

- Number of transplants performed
- Number of surgical procedures performed
- Number of occupied bed days:
  - ITU
  - Ward
- Number of patients dying within 30 days of operation

Follow-up care:

- Number of patients attending outpatients
- Number of attendances
- Number of re-admissions and LOS
  - ITU
  - Ward

2. Comments

Please provide, as a minimum, commentary on:

- activity YTD
- clinical complications

3. Notification of anticipated problems.

4. Comment on any trends in results of which the commissioner should be aware.

5. Possible developments with potential financial implications for future years.

6. Financial Report:

	value to 30 September	*expenditure to 30 September*	*projected outturn at 31 March*
Detailed breakdown of costs, as per Annex E			
Total			

Please explain variations from the funded value

Annex C

Provider: **NHS Greater Glasgow & Clyde**

Service: **Advanced heart failure**

Report format: **Nine month report**

Activity

No activity report is required.

Financial projections

	agreement value to 31 December	*expenditure to 31 December*	*projected outturn at 31 March*
Breakdown of costs (as per Annex D)			
Total			

Comment on any material variances from planned expenditure.

Forward year baseline

Firm proposals for the forward year baseline:

	current NSD funded value	*proposed baseline*	*variance*
Breakdown of costs (as per Annex D)			
Total			

All variances must be fully explained.
Developments not previously agreed with NSD must be supported by a full business case.

NB *Developments highlighted at this late stage will not normally be considered for funding from 1 April of the following year*

Annex D

Provider: **NHS Greater Glasgow & Clyde**

Service: **Advanced heart failure**

Report format: **Annual report**

1. Introduction

2. Activity Report

- as in six month report but to include NHS Board of residence.

3. Statistics

- average age of patient;
- waiting list information and issues;
- number of patients dying before transplantation and the reason for the death;
- average time between acceptance on the programme and transplantation;
- average length of time between original and re-thoracotomy (as applicable);
- survival data for 6, 12 and 60 months (as applicable);
- wound infection rate;
- hospital acquired infection rate;
- peri-operative deaths;
- organ rejection rates.

The above list may be added at the Unit's discretion.

4. Resources/Facilities

- Staff
- Accommodation
- Equipment

5. Developments

- Accomplished
- In progress
- Plans

6. Quality of Service

7. Finance

	NSD funded value	*Outturn at 31 March*	*variance*
Breakdown of costs			
Total			

8. General Comments/Summary

9. Research/Audit

- audit
- research activities
- teaching activities
- awards/grants/achievements
- publications
- conference attended/papers presented