A02/S(HSS)/b

2013/14 NHS STANDARD CONTRACT
SMALL BOWEL TRANSPLANTATION SERVICE (ADULT)

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

Service Specification No.	A02/S(HSS)/b
Service	Small bowel 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 are no randomised studies to determine the effect of transplantation on patient survival. There is some published data suggesting that for a certain group of patients, transplantation offers a possible survival advantage. There are a number of studies which have demonstrated an improvement in quality of life as a consequence of transplantation, but again these are not randomised controlled high quality studies.

The current report from the International Intestinal Transplant Registry indicates that there have been a total of 2,291 transplants undertaken in 2,061 patients since the registry began in the 1980s. Since the inception of the registry in 1985, the following procedures have been performed:

Table 1 – International activity to 2009

Number of centres	73
Number of transplants (patients)	2,291 (2,061)
Age (mean (SD)	38.8 (12.6)
◆ SBT	937
◆ SB/Liv	736
◆ MVT	
◆ (Si, L,S)	500
Current surviving patients	1184(57%)

When considering which patients should be offered intestinal transplantation, the factors are complex, but can in the main be distilled down to survival advantage and quality of life. Both are influenced by the underlying disease, complications of parenteral nutrition and the aspirations and psychological attitude of the patient. There may also be financial considerations which can vary considerably between countries.

Survival of patients on long term parenteral nutrition (PN)

The survival of patients on home parenteral nutrition (HPN) has been described in a number of studies in world literature. The survival rates range between 86-97% at 1 year, 57-83% at 5 years and 43-71% at 10 years. There are differences in the patient populations in these studies which will have an effect on the quoted survival outcomes. For example, some studies include all patients whilst others exclude patients with an underlying malignancy. A number of other factors have also been shown to have an effect on HPN survival rates. These include the age at the time of commencing PN, underlying aetiology of intestinal failure, residual small bowel length and intestinal failure associated liver disease. With respect to underlying aetiology there is a poorer prognosis for adults with an underlying malignancy, scleroderma and radiation enteritis and in children with short bowel syndrome, intestinal pseudo-obstruction. There is a trend for reduced survival in patients with the shortest length of residual small intestine.

Survival after intestinal transplantation

The survival of intestinal transplantation has improved through the different eras. The improved survival following intestinal transplantation is attributed to the advances in surgical techniques and the medical knowledge of treating and monitoring for rejection and opportunistic infections.

Comparison of survival in HPN and intestinal transplant patients – not an equitable comparison

When comparing survival data for HPN and transplanted patients it is important to note that patients undergoing transplantation are a higher risk group. Many patients are assessed for transplantation because they have developed complications of HPN and those who have other indications often have extensive co-morbidity. Therefore we do not have matched groups for comparison. Ideally we would consider patients with and without transplantation who have no complications of HPN.

This has been addressed in part, over a relatively short period of time, in a study by Pironi and colleagues who pooled data from Europe. This prospective study demonstrated that the three year survival of patients was 94% and 87% in patients who did not meet the transplant criteria used in this study, respectively (p=0.007). Sub-group analysis revealed a survival rate of 85% and 70% at three years in patients who did meet criteria for central venous catheter complications and parenteral nutrition-related liver failure, respectively, but were not transplanted. Survival in the 11 patients receiving an isolated small bowel transplant was 81% at three years. These data do suggest that patients who meet the transplant criteria do have a worse outcome than those that do not meet criteria, although the difference is not large at three years. Survival appears to be poorest for those with liver failure, as expected. It should be noted that this study combined the data for adult and paediatric patients, which is a weakness as there are likely to be significant differences between these two groups.

The information from the study above is helpful but not definitive when considering survival in patients who meet transplant criteria. In particular, the criteria used in the study were an extended criteria of the North American guidelines and do not fully represent the decision-making during assessment for transplantation. For instance the patients selected for transplantation in USA, Italy and UK will all differ because alternative treatments such as PN is variable in its availability, quality and cost to the patients.

2. Scope

2.1 Aims and objectives of service

Small bowel transplantation is a highly specialised treatment for the management of irreversible intestinal failure. There are a number of primary conditions that result in intestinal failure and the treatment options available are limited. Initially the patients are supported with PN but complications secondary to this may result in the need to consider intestinal transplantation.

Intestinal transplantation has evolved from an experimental science in the 1960s into a therapeutic entity in the 2000s. Improved surgical techniques and immunosuppressive therapies have now made it a viable treatment for intestinal failure. Worldwide there are now ~60 centres offering this treatment and to date over 1,000 transplants have been performed.

The small bowel and multi-visceral transplant service was established in the UK in the early 1990s. In the UK, intestinal transplantation was first performed in adults at Cambridge University Hospitals NHS Foundation Trust, Cambridge in 1987 and in children at the Birmingham Children's Hospital NHS Foundation Trust in 1993. The use of the technique in the UK was initially of very low volume but has increased since 2006 due to an improvement in survival figures and an increased awareness of the procedure by referring centres.

Procedures

There are four procedures performed as part of the intestinal transplant programme:

- intestine alone
  - cadaveric donor;
  - living related donor;
- liver and intestine;
- multi-visceral – liver, intestine and/or stomach and/or pancreas and/or kidney;
- modified multi-visceral - intestine and/or stomach and/or pancreas and/or kidney, but no liver;

  (The addition of the large bowel as part of the composite graft may be an option in the future).

Objectives and expected outcomes

The results of bowel transplantation continue to improve but remain somewhat inferior to other common organ transplants such as liver or kidney transplantation. The recovery time is also significantly longer after intestine transplantation.

All patients receive an artificial opening of the bowel onto the abdominal wall called a stoma. This allows the transplant team to assess how the transplanted bowel is functioning and allows easy access for biopsies and also for endoscopic examination of the transplanted bowel. Sometimes the patient's abdomen cannot be closed immediately and it may take several days to achieve closure. During this time the patient remains on the intensive care unit.

The levels of immunosuppression medicines required after intestinal transplantation are greater than prescribed for other transplants. Acute rejection is commonly seen after transplantation and requires additional treatment with immunosuppression medication, usually with big doses of corticosteroids. Approximately two thirds of patients make a long term recovery and around 90% of these patients are off intravenous feeding. A small proportion of patients develop late rejection several months or years after transplantation and sometimes the bowel transplant needs to

be removed. The service includes those patients requiring repeat transplantations. Intestine transplant patients are also more prone to develop some additional complications including opportunistic viral infections, graft versus host disease, post-transplant lymphoproliferative disease and rare forms of haemolytic anaemia.

The service is commissioned to provide a comprehensive assessment, transplantation and follow up service to eligible patients who are fit enough to undergo the procedure. This service aims to improve the quality and length of life of patients undergoing the procedure, and to have outcome figures at least comparable to the best centres internationally.

2.2 Service description/care pathway

The key components of the service are:

- pre-transplant assessment;
- listing;
- transplant;
- management of complications;
- follow up.

Risk management

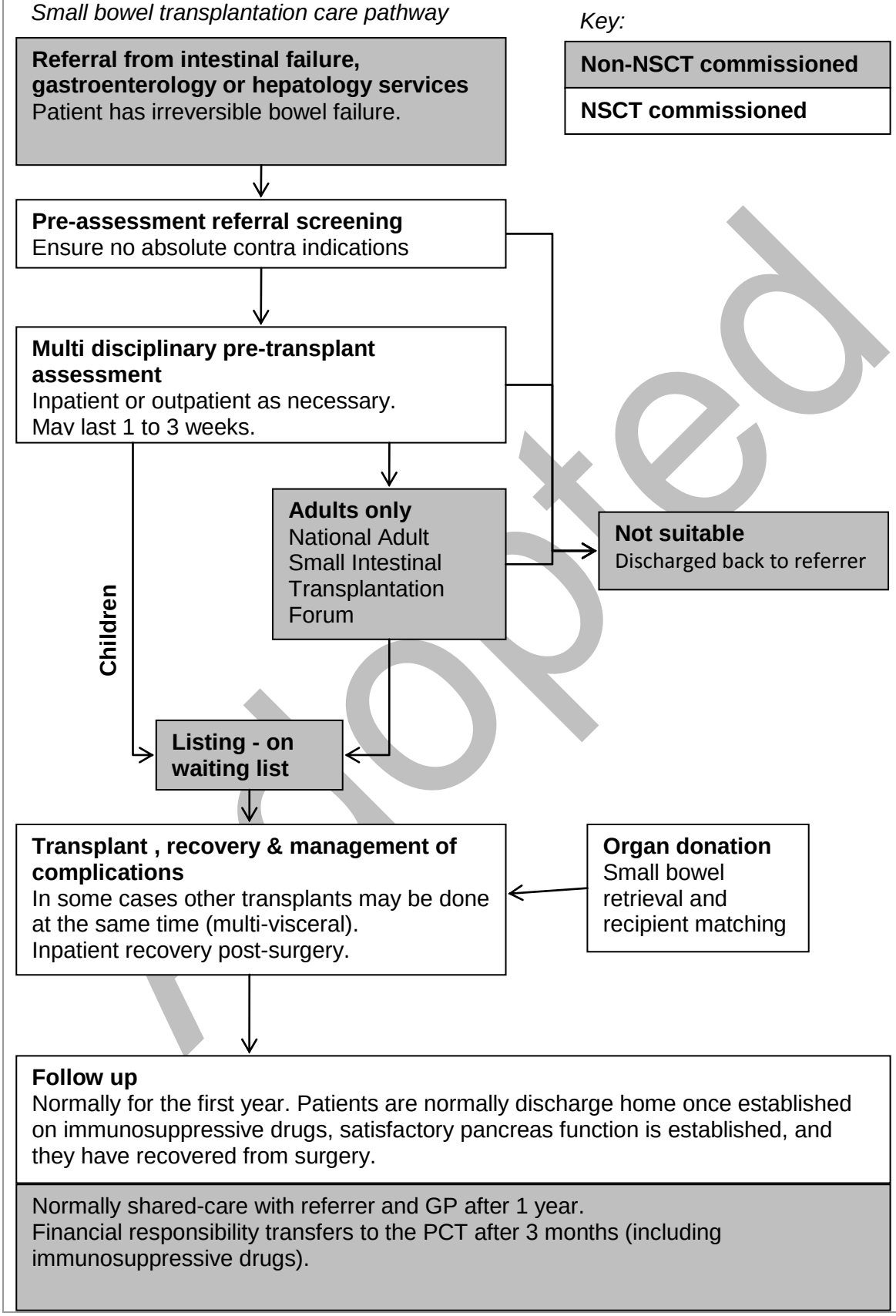
Adult outcomes in the service are monitored continuously by NHS, Blood and Transplant (NHSBT) and discussed at its bowel advisory group (BAG). In the case of adult patients, outcomes and adherence to selection criteria are monitored by the National Adult Small Intestinal Transplantation (NASIT) forum.

Paediatric patient outcomes and adherence are monitored by in-house governance procedures within each centre and regular reports are sent to NHSBT and BAG. Investigations following any alert triggers are carried out under agreed protocols. Unlike other areas of transplantation, organ retrieval is not performed by the National Organ Retrieval Service (NORS) and is the responsibility of the implantation centre.

Service model and care pathways

A sequential flow diagram of the integrated service user pathway(s) showing access, exit/ transfer points, potential routes and relationships with other health and/or social care providers is set out below.

Small bowel transplantation care pathway



3. Applicable Service Standards

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

The provider will ensure that practitioners are compliant with continuous professional development requirements.

Quality indicators such as survival figures will be collected by centres and submitted to NASIT and NHS England. The data provided will also be reviewed by the Bowel Advisory Group (BAG) to make recommendations on future management. The provider is expected to action any such recommendations in a timely manner.

By exception providers should alert commissioners to difficulties in succession planning.

See also NHS England Service Standards for the Small Bowel Transplant Service

4. Key Service Outcomes

Quality Performance Indicator	***Threshold***	***Method of measurement***	***Consequence of breach***	***Report Due***
Survival	(CUSUM) threshold	CUSUM	Response as per protocol agreed between NHSBT and NHS ENGLAND (and NASIT for adult patients)	Per NHSBT protocol
90-day and one-year survival of patient and graft	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	By exception annual report (September of contract year)

5. Location of Provider Premises

All providers of the national small bowel transplant service are expected to work collaboratively.

Some aspects of the patient's assessment and follow up can be delivered at other centres particularly where the patient would need to travel large distances to attend the primary transplant centre.

There are no formal contracting arrangements.

The service is provided by four designated centres.

Provider	Adult	Child
Birmingham Children's Hospital NHS Foundation Trust Birmingham Children's Hospital, Steelhouse Lane, Birmingham, B4 6NH	No	Yes
King's College Hospital NHS Foundation Trust Denmark Hill, London. SE5 9RS	No	Yes
Cambridge University Hospitals NHS Foundation Trust Addenbrooke's Hospital, Hills Road, Cambridge CB2 0QQ	Yes	No
Oxford University Hospitals NHS Trust Churchill Hospital, Headington, Oxford. OX3 7LJ	Yes	No

Change Notice for Published Specifications and Products

Developed by Clinical Reference Groups (CRG)/Programme of Care(PoC)

Change of Clinical Reference Group requiring a change to the Published Products

Current Product Name	Small bowel transplantation service (Adult)	**Current Ref No**	A08/S(HSS)/d
Current Programme of Care	Internal Medicine	**Current CRG**	Specialised Colorectal Services

Describe why change required
CRG Discussion identified the service would benefit from being considered by a CRG with a transplant remit

Confirmation that changes been agreed by the relevant CRG Chairs and Accountable Commissioners:			
Name of current CRG Chair: Mark Chapman Agreed: Yes	Name of new/proposed CRG Chair: Graeme Poston Agreed: Yes	Name of current Accountable Commissioner: Ursula Peaple Agreed: Yes	Name of new/proposed Accountable Commissioner: Ursula Peaple Agreed: Yes

New Product Name	Small bowel transplantation service (Adult)	**New Ref No**	A02/S(HSS)/b
New Programme of Care	Internal Medicine	**New CRG**	Hepatobiliary and Pancreas

Date: originally requested June 2013 – new request 2.4.2014

Authorised both CRG Chairs : Mark Chapman and Graeme Poston

Proforma completed by: Ursula Peaple