

## SCHEDULE 2 – THE SERVICES

### A. Service Specifications

<b>Service Specification No.</b>	170003/S
<b>Service</b>	Liver Transplantation service (Adults)
<b>Commissioner Lead</b>	
<b>Provider Lead</b>	
<b>Date of Review</b>	

#### 1. Population Needs

##### 1.1 National/local context and evidence base

Liver transplantation is a highly specialised procedure which needs specialised skills and facilities.

A functioning liver is essential to sustain life. No practical, artificial device is currently available to support or replace a failing liver and therefore liver transplantation is the only life-saving therapy available. Liver failure may develop acutely (toxic/viral disease) - rapidly destroying liver cells or alternatively, it may be the result of an insidious chronic inflammatory disease that replaces liver cells with fibrous tissue and disrupts its architecture, resulting in cirrhosis.

The two categories of patients requiring liver transplantation are 'super urgent' patients who have sudden liver failure and are likely to die within 48 hours unless transplanted; and 'elective' patients who have a more insidious course. Eligibility for an elective transplant is set out in criteria agreed by consensus at the Liver Advisory Group of NHS Blood and Transplant. The criteria are set to match the availability of donated organs, but in general require that patients have chronic liver disease and are likely to die within 12 months unless transplanted. Organs from paediatric donors are in very short supply but children can benefit from part of an adult donor organ, split between two recipients (1 adult and 1 child). Organs suitable for splitting can only come from better quality donors.

The indications for liver transplantation can be classified into four broad categories:

1. Acute liver failure (fulminant hepatic failure).
2. Chronic liver failure.

3. Metabolic liver disease (including liver based inborn errors of metabolism)
4. Liver cancer (HCC)

There is clear evidence of a survival benefit for transplanted compared to the 'intention to treat' patients who are on the waiting list for transplantation. Up to 18% of patients die while waiting. Once transplanted, approximately 90% of liver transplant patients are still alive after one year and 71% - 85% alive after five years depending on the disease etiology.

A transplant also offers the opportunity for an improved quality of life and greater social independence. Transplantation is not only beneficial for the individual but also represents value to the greater health economy. In addition, some patients can return to work and therefore have a lower dependency on state support.

- On 31 March 2015, 611 patients were on the active waiting list for a liver transplant in the UK. 842 (2013/14: 880) liver transplants were performed in the financial year 2014/15. In addition, 26 transplants (2013/14: 26) were from living donors.
- There are on-going improvements to the organ donation infrastructure which have resulted in an increase in the number of deceased organ donors. This has mainly been an increase in the number of Donation after Circulatory Death (DCD) donors, but with a small increase in the number of Donation after Brainstem Death (DBD) donors. As a consequence of these national changes, there have been significant increases in transplant activity in the UK over the last few years. These numbers are anticipated to increase further following the launch of a UK strategy in July 2013, 'Taking Organ Transplantation to 2020' ([www.nhsbt.nhs.uk/to2020/](http://www.nhsbt.nhs.uk/to2020/))
- Most patients with chronic liver disease will have been under the care of their local gastroenterologist until their disease becomes "end-stage" or under the care of a specialist hepatologist in a non-transplanting centre. Close liaison with hepatologists at the transplant center will ensure timely referral of these patients for transplant assessment. It is essential that patients who need a transplant are added to the waiting list whilst they are fit enough to survive the operation, but not so early that they are exposed to the risks of a transplant prematurely. The British Society of Gastroenterology has issued guidelines on the referral of patients from peripheral units to liver transplant centres to promote equitable access.
- The process of assessment for transplantation is one of making the most appropriate allocation of a scarce resource. Based upon the principle that donor livers should be placed according to greatest benefit, it is currently recommended that organs should be allocated to patients who have at least 50% chance of surviving five years post transplant. There is no age limit for prospective liver transplant candidates, but comorbidity becomes more common with advancing age and limits the prospects for long term survival in the geriatric population.

- The assessment process must be objective, fair and equitable. Prognostic models can predict survival without transplant for a few specific liver diseases, as well as survival on the waiting list. Currently both the MELD and UKELD scores are used nationally to list patients (minimal listing criteria = UKELD  $\geq$  49) and to prioritise patients within each unit when a donor organ becomes available. The decision to recommend transplantation should be agreed by the multidisciplinary team (MDT) and include a transplant hepatologist and surgeon and the decision documented. In emergencies, such decisions can be made outside of multidisciplinary team meeting but must be subsequently recorded.
- Patients awaiting an emergency (super-urgent) transplant are placed on a national transplant list and donated livers from the whole of the UK are offered to blood group compatible patients in the order on which they were placed on the list. The detailed protocol for the centre based allocation scheme is found at; <http://www.odt.nhs.uk/transplantation/guidance-policies/>
- Deceased donor livers not used for super-urgent patients and thus offered for adult and paediatric patients registered for an elective liver transplant in the UK are currently allocated by transplant teams in each centre. Donated livers are distributed to the liver transplant centres based on the percentage share of new adult elective registrants at each centre, and any liver retrieved in a particular allocation zone can automatically be used in a patient chosen by the centre. Most centres prioritise those patients with a higher UKELD/MELD score in line with the national policy.
- Long-term follow up of transplant recipients often remains at the transplanting centre but the patients care may transfer from the transplanting centre back to the referring hepatologist at any time post transplant following agreement of the two centres.

## **Evidence**

National standards for live donor liver transplantation – 2005

Guidelines for selection of patients for liver transplant in an era of donor organ shortage: 199 vol 354 (910): 1636-1639.

Minutes of the eleventh meeting of the NHSBT Liver Advisory Group, 23 May 2007, LAG(M)(07)1.

Minutes of the thirteenth meeting of the NHSBT Liver Advisory Group, 14 May 2008, LAG(M)(08)1.

National standards for live donor liver transplantation.

(NHS Blood and Transplant (NHSBT) Activity Report 2014/15.  
[http://www.odt.nhs.uk/pdf/organ\\_specific\\_report\\_liver\\_2015.pdf](http://www.odt.nhs.uk/pdf/organ_specific_report_liver_2015.pdf)

'Taking Organ Transplantation to 2020' ([www.nhsbt.nhs.uk/to2020/](http://www.nhsbt.nhs.uk/to2020/))

Centre based allocation scheme <http://www.odt.nhs.uk/transplantation/guidance-policies/>

## 2. Outcomes

### 2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	Preventing people from dying prematurely	√
Domain 2	Enhancing quality of life for people with long-term conditions	√
Domain 3	Helping people to recover from episodes of ill-health or following injury	√
Domain 4	Ensuring people have a positive experience of care	√
Domain 5	Treating and caring for people in safe environment and protecting them from avoidable harm	√

The service will be expected to provide accurate timely data to the NHSBT and Specialist Commissioners. This will enable NHS England to monitor outcomes. These need to be considered in conjunction with the quality monitoring detailed within this contract.

- Number of deceased donor liver transplants pmp (Domain 1 & 2)
- Median waiting time to transplant (Domain 1 & 2)
- Death on the waiting list (Domain 1 & 2)
- Patients removed from the waiting list due to worsening disease or deteriorating fitness (Domain 1 & 2)
- Cold ischaemic times (Domain 3 & 4)
- Ninety day and 12 month patient mortality and transplant outcome (Domain 1, 3, 4 & 5)
- One and 5 year graft and patient survival for deceased donor transplants (Domains 1 & 2)

The key patient and service outcome measures are:

Transplant recipients (domains 1, 2, 3, 4 and 5)

- Patients are able to make an informed choice and shared decision making

about transplantation

- Medically suitable patients are placed on the transplant list in a timely manner as per the quality requirements in this contract.
- To ensure that the waiting time for a transplant is kept to the minimum and that the pathway and quality requirements as described in the service specification are adhered to.
  - There is effective communication between the patient and the right health care professional throughout the pathway
  - Time in hospital is minimised
  - Complications, side effects and co-morbidity of liver transplantation are minimised
  - Optimal long term function of the transplant

Living donors (domains 1, 2, 3, 4 and 5)

- Donors are able to make an informed choice and shared decision making about live donor hepatectomy
- Living donors are worked up according to national guidelines in a timely manner; including assessment of liver anatomy
- To ensure that the waiting time to proceed to living donor hepatectomy is kept to the minimum, unless the donor or recipient wants to delay.
  - See separate service specification
  - There is effective communication between the donor and the right health care professional throughout the pathway.
  - Time in hospital is minimised
  - Complications, side effects and co-morbidity of living donor hepatectomy are minimised
  - Long term follow-up takes place and is nationally reported

These principles are supported by the national standards and guidelines listed in section 1.2 and 4.1. Transplant centres will deliver outcomes which are not significantly inferior to the national average in terms of, mortality and graft survival, cold ischaemic time and waiting times. Measures for these principles are included within the quality requirement of this contract.

Patients are able to make an informed choice about transplantation (domain 4)

Guideline/standard

- Liver transplantation is the therapy of choice for patients with ESLD disease who are considered fit for major surgery and for chronic immunosuppression
- Specialist Liver Transplant Centres will have written criteria based on the national specialist LAG guidelines for acceptance on to the waiting list. The benefits and potential risks associated with transplantation will be fully

explained both verbally and in writing.

- Both the British liver trust (adults) and children's liver disease foundation (paediatrics) provide detailed publications specifically about liver transplant that should be given to all patients and families.
- Potential transplant recipients will be informed of all donor options including, donation after brain death (DBD) and donation after circulatory death (DCD), split liver transplantation, living donation and newer techniques such as normothermic regional perfusion for category III DCD donors.
- Early provision of culturally appropriate information; discussion with and counselling of patients, relatives and carers about the risks and benefits of transplantation with a clear explanation of tests, procedures and results.
- Support from Clinical Psychology should be offered to meet the needs of patients
- Consent to transplantation will be obtained at the time the patient is accepted for inclusion on the Transplant List, reviewed at least every 3 months and reconfirmed prior to surgery.

Medically suitable patients are placed on the transplant list in a timely manner (domain 2 and 3) based on the minimal listing criteria UKELD score >49 and best practice.

#### Guideline/standard

- Medically suitable patients are placed on the transplant list in a timely manner irrespective of when they present.
- Patients with progressive deterioration in liver function and medically suitable for transplantation will be offered the option of being placed on the transplant list within 1 month of their assessment and acceptance by the Liver MDT.
- To facilitate living donation, information will be provided at an early stage and discussion with potential donors and recipients may be started when the recipient is assessed for acceptance onto the deceased donor list.
- Patients will undergo a surgical assessment prior to being placed on the transplant list.
- People with ESLD on the waiting list will be supported to receive a liver transplant.

Optimise the waiting time for a transplant (domain 1, 2, 3 and 4)

#### Guideline/standards

- Patients in ESLF on the waiting list will have their MELD and UKELD scores reviewed in accordance with NHS BT and BTS guidelines.
- To facilitate living donor transplantation, donor evaluation will start sufficiently early by the transplant unit to allow time for more than one donor to be assessed if necessary. Information will be provided at an early stage and

discussion with potential donors and recipients may be started when the recipient is first assessed. Thereafter, recipient and donor assessment will be tailored according to the rate of decline in recipient liver function to prevent unnecessary investigations, taking into account disease specific considerations and individual circumstances.

- Professional guidelines are required in this area to clarify indications and limitations.
- Consent to transplantation will be obtained at the time the patient is accepted for inclusion on the Transplant List and reviewed at least every 3 months and reconfirmed prior to surgery. Whilst awaiting transplantation, patients will be formally reminded every month, or whenever a change in their condition warrants, of the risks and benefits of the transplant and this will be recorded in the patient records.
- Consent will be re-affirmed at least every 3 months and immediately prior to the transplant; this will be done by an appropriately experienced and trained health care professional.
- Any patient suspended long term from the transplant waiting list will be reviewed as a minimum every 3 months and the outcome of the review communicated to the patient verbally and in writing.

Minimise time in hospital (domain 3 and 5)

#### Guideline/standards

- Timely operating theatre availability to ensure optimal cold ischemia times and it is expected that there will be 24/7 availability of an operating theatre.
- Patients having a deceased donor transplant will be given priority in the operating suite. A dedicated transplant theatre and scrub team should be available immediately.
- Detailed guidelines are available covering all aspects of post-transplant care including immunosuppression and psycho-social support.

Minimise complications, side effects and co-morbidity (domain 5)

#### Guideline/standards

- Effective preventive therapy to control infections (Cytomegalovirus (CMV), Pneumocystis, Tuberculosis, influenza vaccination as a minimum).
- Any patient transplanted for HCV must have access to current anti-HCV drugs at least 6 months post transplant.
- Appropriate immunosuppression in accordance with national best practice guidance and effective monitoring and treatment to minimise the risks of adverse effects of immunosuppressive treatment.
- Detailed guidelines available covering all aspects of post-transplant care

including immunosuppression, prevention and treatment of cardiovascular disease and prevention and screening for malignancy.

Optimise long term function of the transplant (domain 1 and 2)

Guideline/standards

- Detailed guidelines available covering all aspects of post-transplant care including immunosuppression and monitoring of the transplant

Effective communication between the patient and the right health care professional throughout the pathway (domain 4)

Guideline/standards

- Clear explanation for patients of tests, procedures and results. This applies especially for information and education about immunosuppressive therapy and when patients are called in for a potential transplant that does not happen.
- Specialist advice from the transplant team available for patients with a liver transplant admitted to hospital, whatever the clinical setting
- Communication and care will be based upon the NICE quality standard on 'Patient experience in adult NHS services'. This includes establishing, respecting and reviewing the patients' preferences for sharing information with partners, family members and/or carers.
- Information is available from The British Liver Trust which patients can be signposted to.
- Ensure that the patient's General Practitioner is kept informed throughout the transplant pathway.

### **3. Scope**

#### **3.1 Aims and objectives of service**

- The aim of this service is to provide comprehensive care to patients who either require or who have received a liver transplant. This is underpinned by the National Standards for Liver Transplantation (2005)
- Providers of liver transplant services will ensure that as a minimum the following care is provided:



### Guideline/standard

- Equity of access to transplantation regardless of point of referral and location
- Access to the waiting list will be based on an MDT decision
- Clear and unambiguous care pathways, supported by the provision of culturally appropriate information; specifically in relation to:
- The counselling of patients and relatives/carers regarding the risks and benefits of liver transplantation
- Explanation of tests, procedures and results Information should be available in a variety of formats and given on more than one occasion. It should be evidence-based, clear and understandable, and should be culturally sensitive. When information is given verbally, this should be documented.
- Information given to patients should include their prognosis with and without liver transplantation, and the average waiting time for the operation, based upon local and national audits on transplantation.
- Outcome of assessment and review to be documented in a letter to the patient detailing discussions and agreed shared decision reached, including those patients who are not suitable for a liver transplant
- Information and education about immunosuppressive therapy
- Patients, families and general practitioners should have access to all members of the multidisciplinary team to discuss specific problems or concerns
- A range of psychological and social support services should be offered to meet the needs of patients and families. These should be available at the specialist centre and links to facilitate this at local level should be developed
- Patient support from charities and peer support groups should be encouraged. All patients and families should be provided with information about them.
- There should be formal arrangements for addressing complaints and other comments by patients, families and staff.
- Safe, effective, evidence-based care, delivered through effective pathways of care, in particular through the provision of:
- Detailed recipient assessment (including cardiac assessment) and monthly transplant focussed review whilst on transplant list, including patients with a failing transplant where suitable for further transplantation
- A surgical assessment of each patient prior to being placed on the liver transplant list.
- Detailed living donor assessment when deemed an appropriate option and referral to other centres if this option is not available.
- Detailed discussion and education about DCD and marginal donor usage
- Assessment of suitability for split liver grafting
- Referral of suitable patients for combined heart/lung and liver transplantation.
- Timely operating theatre and relevant staffing availability (surgeon, anaesthetist) to ensure optimal cold ischaemia times.( $<12$  hours for DBD donor and  $<8$  hours for DCD donor transplantation)
- Effective immunosuppressive therapy

- Effective preventive therapy to control infections (CMV)
- Prevention/management of long-term complications and co-morbidities, particularly with respect to cardiovascular disease, renal dysfunction, infection and cancer.
- Additional support to the post-transplant patient transitioning from paediatric services
- Specialist advice from the transplant team available for patients with a liver transplant admitted to hospital, whatever the setting.

Specialist liver transplant centres will have a process/system in place to ensure patients are added to the transplant waiting list based on LAG agreed minimal listing criteria, and registered with NHSBT. In addition, they will ensure that the list is regularly reviewed and updated and prioritization is carried out weekly at an MDT meeting – based on MELD/UKELD score. Liver offers must be received and assessed from NHS Blood and Transplant (NHS BT) in a timely manner, and ensuring the requirements of the European Union (EU) Organ Donation Directive are met. In accordance with the EU Organ Donation Directive, written information relating to organ offers should be reviewed prior to the acceptance or decline of offers.

There will be 24/7 availability of a recipient point of contact and NHSBT standards in accepting or rejecting declining an organ within one hour will be met. Allocation to a particular recipient of an individual donor liver will depend upon a number of factors.

### **Surgical Staffing**

The transplant centre should have at least five consultant surgeons capable of undertaking liver transplantation. All should be members of the MDT. Robust, published duty rotas should be in place to provide continuing consultant cover for surgical transplant activity. Duty rota arrangements should incorporate sufficient flexibility to allow appropriate rest whilst maintaining continuity of care.

Operating theatres should always be available for emergency liver transplantation to ensure there is the capability to accept organs when they become available. Sufficient surgical support staff (surgical trainees and/or trust grade doctors) and operating department staff should be rostered to allow for liver transplant activity out of hours and at weekends but including compliance with the working time directive. There should be explicit consultant involvement in the educational aspects of the retrieval program.

### **Hepatology**

A consultant hepatologist should be available at all times to advise on management of patients with fulminant hepatic failure, and those who develop problems whilst on the waiting list or following transplantation. Long-term transplant care should be provided by consultant hepatologists, supported by junior medical staff, in specialist wards and outpatient clinics. Transplant and non-transplant hepatology centres should share responsibility and arrangements for training junior staff in hepatology according to nationally agreed (and SAC approved) guidelines.

### **Anaesthesia and Intensive Care**

Consultants experienced in the management of liver transplant patients should supervise anaesthesia and intensive care. These consultants should be supported by junior medical staff and represented on the MDT. Sufficient critical care facilities and nursing staff should be available to support the transplant programme and allow emergency admission of patients with fulminant hepatic failure.

### **Diagnostic Support**

The MDT should include a named consultant radiologist with a specific interest in liver imaging and interventional procedures. There should be access to a range of diagnostic imaging on a 7-day basis including ultrasound, CT and MR imaging, and to interventional radiology, including biliary and vascular interventions. There should be robust, published consultant duty rotas to provide for emergency imaging and radiological interventions in liver transplant patients.

### **3.2 Service description/care pathway**

This specification relates specifically to transplantation and in terms of this specification begins when the patient undergoes a 'transplant assessment' (surgical /anaesthetic /medical /psychological) with the sole aim of joining the transplant list. This specification pathway stops when the transplanted patient dies or the 'assessed' patient is not listed or 'de-listed'. Patients and their families should be provided with comprehensive information, and support so that they can make informed decisions about their treatment. This process should start at their first visit to the transplant centre and continue throughout their care at the centre. Information should be available in a variety of formats and given on more than one occasion. It should be evidence-based, clear and understandable, and should be culturally sensitive. When information is given verbally, this should be documented. The patient pathway for transplantation begins with the work up including cardiovascular assessment (CPeT, Stress Echo, Lung Function Tests, Coronary Angiography), cross sectional imaging (CT) and Liver specific imaging (Gadolinium MRI) to assess liver anatomy and the presence of high risk lesions (HCC).

The transplant pathway will be delivered by specialised (tertiary care) liver transplant centres. The infrastructure required will include the necessary resources of staffing (medical, surgical, nursing), intensive care and ward beds, 24 hour access to operating theatres, and the interdependencies described in section 3.5; supported by a multi-disciplinary team (MDT) and a robust clinical governance structure including clinical audit.

### **The Liver Transplant MDT should include:**

a) Clinicians directly responsible for patient care – liver transplant surgeons, hepatologists, transplant anaesthetists/critical care specialists and junior staff in each of these specialties.

All consultant clinicians are expected to have expertise in the management of patients

with liver disease.

- a) Transplant nurses and recipient coordinators.
- b) Dietician, pharmacist, physiotherapist, psychiatric liaison nurse
- c) Clinicians involved in specialist diagnostic services - liver radiology, histopathology and microbiology.

Composition of the MDT can be adjusted according to the needs of different aspects of the service, e.g. assessment, post-operative care, clinico-pathological and audit meetings. A named psychologist/psychiatrist should be accessible to the MDT as appropriate.

### **Care Pathway**

- All patients with decompensated Chronic Liver Failure/ ESLD will be considered for liver transplantation and reasons for not being considered documented. The assessment process has four possible outcomes.
  - a) The MDT recommends a transplant and the patient agrees and is placed on the waiting list.
  - b) 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.
  - c) The MDT decides that the patient is currently in a stable condition that does not justify the risks of transplantation. The patient is kept under review for possible reassessment at a later date.
  - d) 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.
- During the Medical/Surgical assessment, the patient will be provided with appropriate information regarding the transplant pathway.
- Patients will be given the option to attend a patient information session, ideally with expert patients.
- It is expected that for non-complex patients the referral to listing process will be in line with national guidance.
- All patients will undergo a surgical assessment prior to being placed on the transplant list. Patients will be placed on, or removed from the waiting list only after discussion and agreement with the Transplant MDT and the patient themselves according to local practice.
- Complex or borderline patients require a MDT discussion to establish their suitability and/or to plan their management. Surgical issues may also provide insurmountable challenges and the patient will not be listed. Patients will be offered the option of having a second opinion from a transplant clinician in a different transplant centre.
- All patients with Acute Fulminant Liver Failure who meet the LAG accepted FLF criteria will be considered for liver transplantation. It is expected that timely referral by

the regional gastroenterologist or hepatologist to the transplanting centre for urgent assessment will take place and urgent transfer to the regional liver unit will be facilitated by the hepatologist. Any patient developing encephalopathy may need ITU facilities.

### **Transplant listing**

- When patients have completed their assessment and are considered suitable transplant candidates they will be registered with NHSBT onto the transplant list as soon as possible. This task, and the on-going maintenance of the local transplant list, will be the responsibility of the recipient transplant co-ordinator [or other named person]. Patients will be made aware of their activation status.
- Patients listed with HCC must have access to interventional radiology such as TACE and ablation to maintain the tumour within transplant criteria.
- Patients listed with a diagnosis of HCV must have access to anti-viral therapy (AVT) according to their genotype, in line with NICE TA guidance or NHS England policy.

### **Follow up Care**

- All transplant recipients require regular follow up as per the LAG guidelines on the Post-operative care of the liver transplant recipient. Follow-up will be patient focused and units will consider local blood tests and telephone follow-up in addition to clinic visits. This will initially be frequent (2-3 x per week) but will usually become less frequent as time proceeds – often 3-4 x per year. Early follow up is expected to be shared between the transplant surgical team and the transplant hepatologists. Most patients will be followed up at the transplanting centre while for many patients care will be shared between the specialist centres and hepatology services local to the patient. Transplant input will be available when required.
- The care of patients post transplant will be at the mutual agreement of the patient, transplant centre and the patients 'home' liver unit and will vary according to local circumstances. Shared care protocols should be in place in all transplanting units and agreed on an individual basis between the transplanting centre, referring centre and patient's GP.
- NHS England will be the responsible commissioner for immunosuppression prescribing related to liver transplantation. The transplanting centre or specialist centre remains responsible for all follow-up and changes in therapy, and will prescribe immunosuppression required post-transplant. Consideration needs to be given to the availability of generic immunosuppressives and the importance for transplant patients of maintaining consistent supply. Immunosuppressives (both innovator brands and branded generics) will be prescribed by brand and referred to by that brand in all correspondence in tertiary, secondary and primary care, and with all patients themselves (see Medicines and Healthcare products Regulatory Agency guidance).
- The long term care of transplant recipients will include a holistic assessment of the patient's progress along with pre-emptive strategies to minimise future health,

physical and psychological problems. This will include a regular review of their immunosuppressive therapy which will be tailored to prolong the life of their transplant whilst minimising the risk of drug related side effects. In addition patients will have their risk of future cardiovascular disease, renal dysfunction and bone disease assessed with steps taken to minimise such risks. Patients will be made aware of their increased risk of malignancy, in particular skin cancer, and counselled about appropriate changes in their lifestyle. Close links should be established between the transplant centre, local physician and hepatologist for the management of transplant patients postoperatively. Post transplant patients will be encouraged to attend cancer screening programmes if appropriate.

- Provision for post transplant donor specific HLA antibody monitoring and investigations of humoral rejection episodes will be part of the transplant service.
- Patients who have recurrent disease (HCV, HBV, HCC, PBC, PSC, AIH) or recurrent cirrhosis post transplant will be identified at an early stage as outlined in this specification to ensure they are prepared for another transplant in a timely manner; or supportive care where appropriate. Patients requiring return to the transplant list will require additional clinical, dietetic and psychological support to minimise the risks and optimise the outcomes for this patient group.
- A consultant level health care professional will be available for every transplant clinic.
- Access to nephrology services if renal dysfunction is diagnosed. The routes to access social work and other support services will be offered to those patients requiring them.

### **Discharge criteria and planning**

- Transplant care will be continuous and extend for the life of the functioning transplant. The day to day care of the transplant recipient will normally transfer at some point within 12 months post transplant from the transplant centre.
- Any transfer of care must be supported by clear communication and documentation between the transplant unit and referring main HBP unit and with the patient fully involved. Patients will already be aware that their day to day care will transfer back to the referring main HPB unit (having been informed pre-transplant) but the exact timing of this transfer will be made clear to the patient with appropriate notice and agreement of the patient.
- Governance and accountability will remain the responsibility of the transplanting centre and requires annual review at the transplanting centre. In addition a clear 'shared care' protocol needs to be in place and any changes in administering immunosuppressive drugs needs to be administered from and in agreement with the main HPB unit at the point of repatriation.

### **3.3 Population covered**

The service outlined in the specification is for patients ordinarily resident in England\*; or otherwise the commissioning responsibility of the NHS in England (as defined in Who Pays?: Establishing the responsible commissioner and other Department of Health

guidance relating to patients entitled to NHS care or exempt from charges).

Specifically this service is for all adult ESLD patients with 'liver decompensation' progressing to liver a transplant assessment and ultimately transplantation. In addition it also covers those patients who already have a functioning liver transplant.

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.

This NHS England contract includes provision for the service to treat eligible patients from overseas under S2 and aligned referral arrangements. Providers are reimbursed for appropriately referred and recorded activity as part of this contract.

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

### **3.4 Any acceptance and exclusion criteria and thresholds**

#### Acceptance Criteria

- Patients with ESLD will often be under the care of a DGH gastroenterologist. The service will accept incoming referrals from the DGH GE as well as regional hepatologists working within the regional hepatology network in which the transplanting centre is based. The service will also accept referrals from other providers of liver transplantation when the referring service does not undertake the specific transplant that the patient requires e.g. Multi-visceral, Lung-Liver, Paediatric, live donor
- When a referral is received the patient will be seen by a transplant hepatologist and a nurse specialist as a preliminary assessment, followed by a formal assessment by all the team members including, transplant surgeons, anaesthetists, recipient co-ordinator and dietician. Following formal MDT discussion the patient will be added to the unit list and given a priority based on the MELD/UKELD score if deemed appropriate.

#### Exclusions

- There are no exclusion criteria for assessment.
- Patients who do not fulfil the minimal listing criteria maybe referred to the LAG review panel for consideration. Currently if 4 out of 7 centres agree the patient may be accepted onto a transplant list. Patients under the age 18 are excluded from this service specification.

### **3.5 Interdependencies with other services/providers**

In this section the episode of care is defined as the inpatient episode for the actual transplant surgery. Optimum delivery of the agreed pathways requires effective working relationships with the following services and organisations, but not limited to:

Co-located services (need to be provided on the same site)

- Hepatology
- HPB surgical services
- Intensive care
- Operating Department
- Anaesthetics
- Radiology (including interventional radiology)
- Pharmacy
- Dietetics
- Clinical Psychology
- Allied Health Professionals (including physiotherapy)

Interdependent services (needed during the spell of care)

- Histocompatibility & Immunogenetics (H&I) laboratory (accredited by Clinical Pathology Accreditation (CPA))
- Histopathology
- Microbiology/Infectious diseases
- The Blood Transfusion Service
- Cardiology – cardiopulmonary assessment and investigations

Related services (preceding or following the spell of care)

- Primary care
- Histocompatibility & Immunogenetics (H&I) laboratory
- Histopathology
- Radiology (including interventional radiology)
- Microbiology/infectious diseases
- Dermatology
- Urology
- Haematology/oncology for management of patients with Post Transplant Lymphoproliferative Disorders
- Paediatric services (transition)
- Young person care workers
- NHS Blood and Transplant (NHSBT) – transplant listing, organ retrieval, offering and allocation, follow-up post-transplant
- Human Tissue Authority – regulatory approval of living donor transplants; and as the competent authority for EU Organ Donation Directive on the Quality and Safety of



## Organs

- Diabetic management of NODAT patients following transplantation
- Medical genetics including laboratory genetics for patients with autosomal dominant polycystic kidney/liver disease
- Palliative care for those that are de-listed / too ill and other patients as needed
- Bereavement services

## 4. Applicable Service Standards

### 4.1 Applicable national standards e.g. NICE

The Provider is expected to deliver in care in accordance with the following standards and guidelines:-

- NICE Quality Standards: Alcoholic Liver Disease Quality Standards
- NICE Quality Standards: Patient Experience in Adult NHS services
- Human Tissue Authority (HTA) Guidance for Transplant Teams and Independent Assessors
- NHS England – Reimbursement of expenses for living kidney donors
- National Standards for Organ Retrieval From Deceased Donors 2010

### 4.2 Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal Colleges)

EU Organ Donation Directive

SaBTO - The Quality and Safety of Human Organs Intended for Transplantation

NHS BT guidelines - <http://www.odt.nhs.uk/transplantation/guidance-policies>

## 5. Applicable quality requirements and CQUIN goals

### 5.1 Applicable quality requirements (See Schedule 4 Parts A-D)

There is a requirement to hold national audit meetings involving all designated centres on an annual basis.

Each centre must assure that:-

1. All practitioners participate in continuous professional development and

networking

2. Patient outcome data is recorded and audited across the service and must be reported to NHSBT
3. All centres must participate in the national audit commissioned by NHS England.

Audit meetings should address:

- Clinical performance and outcome
  - Process-related indicators e.g. efficiency of the assessment process, prescribing policy, bed provision and occupancy, outpatient follow-up etc.
  - Stakeholder satisfaction, including feedback from patients, their families, referring clinician and GPs.
4. Any Serious Untoward Incident must be reported by STEISS and in addition by email to the Public Health Advisor, Highly Specialised Services within 24hours.

## **5.2 Applicable CQUIN goals (See Schedule 4 Part E)**

Please note any contractual levers relating to quality, KPIs, CQUINs will need to be agreed with commissioners and included in the relevant schedules of the contracts.

## **6. Location of Provider Premises**

**The Provider's Premises are located at:**

King's College Hospital NHS Foundation Trust  
Leeds Teaching Hospitals NHS Trust  
Cambridge University Hospitals NHS Foundation Trust  
The Newcastle upon Tyne Hospitals NHS Foundation Trust  
Royal Free London NHS Foundation Trust  
University Hospitals Birmingham NHS Foundation Trust

## **7. Individual Service User Placement**

Not applicable.

## Appendix Two

Quality standards specific to the service using the following template:

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
<b>Domain 1: Preventing people dying prematurely</b>			
30 day and 1 year survival post transplant	CUSUM trigger	NHS BT monitoring	External peer review. Discussion with contracts team to agree further action
<b>Domain 2: Enhancing the quality of life of people with long-term conditions</b>			
5 year survival post transplant	Crosses funnel plot 5% line	NHS BT annual report	Review at annual meeting. Discussion with contracts team to agree further action
<b>Domain 3: Helping people to recover from episodes of ill-health or following injury</b>			
Length of stay post transplant	Length of stay exceed three times the median	Trust PAS system	Review at annual meeting. Discussion with contracts team to agree further action
<b>Domain 4: Ensuring that people have a positive experience of care</b>			
Compliments and complaints	Number of complaints increased by more than 20% on previous year	Trust complaints system	Review at annual meeting
<b>Domain 5: Treating and caring for people in a safe environment and protecting them from avoidable harm</b>			
Never events and SUI	Any signals reported	SUI reporting system	Root cause analysis. Discussion with hub quality lead to agree further action