

E03/S(HSS)/a

**2013/14 NHS STANDARD CONTRACT
FOR LIVER TRANSPLANTATION SERVICE (Children)**

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

Service Specification No.	E03/S(HSS)/a
Service	Liver Transplantation Service (Children)
Commissioner Lead	
Provider Lead	
Period	12 months
Date of Review	

1. Population Needs

1.1 National/local context and evidence base

Adults

There are a large number of conditions which cause liver failure but the commonest reasons among transplanted patients are alcoholic liver disease, hepatitis from viral infections (hepatitis B and C) and fatty liver disease.

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

- Acute liver failure (fulminant hepatic failure).
- Chronic liver failure.
- Metabolic liver disease.
- Liver cancer.
- Other metabolic diseases caused by liver based inborn errors of metabolism.

Children

Indications for paediatric liver transplantation contrast strongly with those for adults. Children are less likely to have suffered the long term physiological consequences of chronic liver disease, highly unlikely to require transplantation for diseases that recur and require re-transplantation such as auto-immune hepatitis, chronic viral hepatitis, alcoholic liver disease and Non-Alcoholic Fatty Liver Disease.

The predominant conditions are biliary atresia, a neonatal biliary disease (40-70% of primary transplants) according to age group, congenital metabolic conditions including alpha-1-antitrypsin deficiency (10-25%) other cirrhosis, mostly non-recurring 5-20%, tumours 5-12%, and acute liver failure (ALF) 10-15%. Even among

patients with ALF the causation is different with the commonest adult cause, drug ingestion especially paracetamol being rarely a cause of transplantation.

Children 6kg to 35kg can benefit from live-related transplant more readily than other recipients because a left lateral segment can be removed with lowest risk estimated as 0.2% mortality in the donor. However, only 44% of paediatric candidates have a donor from their immediate family so this is a limited and still relatively high risk option.

Because the primary diagnoses leading to liver transplantation in children do not recur in the allograft most of the complications of liver transplantation, early and long term, relate to the need for immunosuppression.

Children may be at increased risk of developing significant end-organ damage as a result of increased serum lipid levels, elevated blood pressure, altered glucose metabolism, decreased renal function and diminished bone accretion that occur as complications of therapy. Because most children are Epstein Barr virus naive they are at increased risk of post-transplant lymphoproliferative disease. Liver transplant therefore creates an increasing population of patients who require specialist paediatric care to optimise the outcome.

Evidence Base

NHS Blood and Transplant hold a large database of all transplants in the UK. Outcome data are monitored continuously using CUSUM techniques, and 6 monthly analysis is carried out jointly by the Clinical Effectiveness Unit Royal College of Surgeons clinical effectiveness unit and NHS Blood and Transplant.

Adult

90-day survival after elective liver transplant is over 95% and patients who survive the first 90 days live on average more than 20 years after transplant.

Child

Paediatric data are quoted separately from those for adults. Paediatric transplantation has comparable results with 80-85% 10 year survival excluding newborns. UK Transplant data shows that patients transplanted between the ages of 2 and 9 years have the best long-term patient and graft survival.

2. Scope

2.1 Aims and objectives of service

This specification describes the designated national liver transplant service for adults

and children commissioned by NHS England NHS England do not commission organ retrieval. From April 2009, organ retrieval and allocation has been the responsibility of NHS Blood and Transplant.

The liver is a large and complex organ, which carries out a multitude of functions that are essential to sustain life. Despite considerable research efforts, no practical artificial device is yet available to support or replace a failing liver. Transplantation of the liver is a life saving treatment for patients with liver failure.

There are two categories of patient – ‘super urgent’ patients have sudden liver failure and are likely to die within 48 hours unless transplanted; and ‘elective’.

The objective of the service is to assess, transplant and promote the optimal future health of patients who need liver transplant. This includes the planned transition of a well young person to adult services.

Adults

Eligibility for 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 both (a) are likely to die within 12 months unless transplanted and (b) will survive on average 5 years or more if transplanted.

Children

The criteria agreed by consensus at the Liver Advisory Group are intended to match overall patient numbers to the availability of donated organs, but the situation for children is less clear. Children can benefit from part of an adult donor organ, either reduced or split between two recipients while organs from child donors are in very short supply. Organs suitable for reduction or splitting come from better quality donors placing a further restriction on availability for children.

2.2 Service description/care pathway

The key components of the service are:

- Assessment
- Transplant
- Management of complications
- Follow up

Liver Transplantation Service Standards have been agreed for adults and children. These are updated through the NHS Blood and Transplant Liver Advisory Group.

Below is a summary from the service standards:

Referral

Patients are referred in for assessment to the transplant centres from regional hepatology services (which may be the same as the transplant centre for local patients). Patients are referred for liver transplantation from GPs or hospital Consultants when their expected mortality without liver transplantation exceeds their expected mortality from the procedure.

Assessment

Unfortunately, there are far more patients who could potentially benefit from liver transplantation than there are donor organs. Thus 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 absolute 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.

Patients will be assessed for suitability for transplant. This has two elements – firstly, to ensure that the patient is fit for operation; and secondly to make a judgement that the patient meets the eligibility criteria for listing.

The assessment process has four possible outcomes.

- The multi-disciplinary team (MDT) recommends a transplant and the patient agrees and is placed on the waiting list.
- 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.
- 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.
- 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.

Waiting list

There are two categories of patient – ‘super urgent’ patients have sudden liver failure and are likely to die within 48 hours unless transplanted; and ‘elective’. Treatment for the underlying condition while waiting for a transplant is not included in the NHSCB specification.

Patients who deteriorate whilst waiting for a liver transplant may become too sick to stand a reasonable chance of surviving the procedure. All patients should be counselled that, in this situation, they might have to be removed from the waiting list

because they are unlikely to survive the operation. Patients deemed unsuitable for transplantation should be informed of their right to seek a second opinion from another transplant centre.

Transplantation and management of complications

Operating theatres should always be available for liver transplantation, which is usually done as an emergency. This service specification includes inpatient recovery post-surgery.

Follow up

The service provides follow up of patients after transplant until mortality, transition to adult services or transfer to other paediatric services. Long-term transplant care should be provided by consultant hepatologists, supported by junior medical staff, in specialist wards and outpatient clinics. This service specification includes the first three months of post transplant drug therapy, after 3 months funding reverts to the patient's Clinical Commissioning Group.

The purposes of follow-up are:

- To monitor and detect technical complications of transplantation at an early stage with a view to correction.
- To monitor, detect and treat non-hepatic, usually immunosuppression related complications.
- To liaise with and educate local services to ensure optimum share-care in keeping with principles of Managed Clinical Networks i.e. as close to home as possible, optimum care and equity of access.
- To promote and develop education and skills in the patient and family in keeping with the principle of the 'Expert Patient' to optimise outcome including quality of life.
- For children - To facilitate change in the family and child towards transition of the patient to Adult Services.

Risk management

90-day outcomes in the service are monitored continuously by NHS Blood and Transplant. Investigations following any alert triggers are carried out under agreed protocols.

Service providers are responsible for managing the logistical arrangements for on-call teams, clinical resources, and recipient coordination.

When surgical teams treat patients who have, or are at risk of having transmissible spongiform encephalopathies (including variant Creutzfeld-Jakob disease, vCJD), there is a risk of contaminating the instruments used during their surgery and hence transmitting the infection to subsequent patients in whom the same instruments are used. Special decontamination measures are required by Department of Health policy. Some instruments cannot be fully decontaminated, in which case policy requires destruction of the instrument. The full guidance is set out at a. Patients with

or at risk of vCJD present to all parts of the NHS and the same precautions are needed. Hence costs of treating patients with this condition, including destruction of surgical instruments where necessary, are included in average costs.

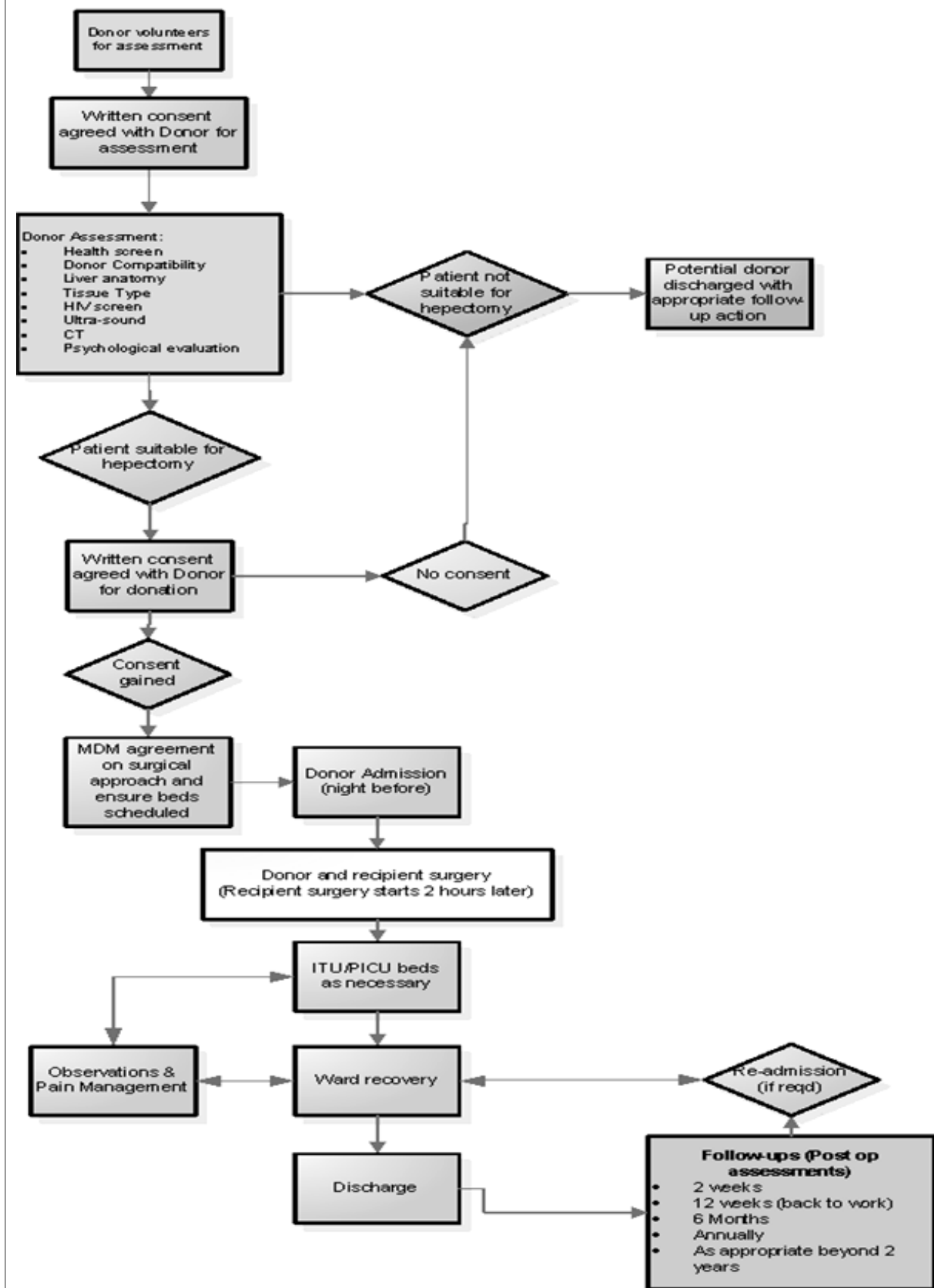
This service specification does not limit the pharmacological treatment options available with regard to transplant care, provided they are met within the existing level of investment. This includes desensitisation due to graft-recipient mismatch.

All providers offering a service to children under 18 years of age should ensure they are compliant with the requirements to safeguard children, and follow current guidance on obtaining consent from children.

The service should be available 24/7.

Adopted

Live Liver Donor Patient Pathway



Discharge

Once deemed fit enough by the transplant team a patient following transplantation is managed as an outpatient using shared care protocols with GPs.

Transition of care from child to adult services

Paediatric patients will need appropriate transitional care as a teenager prior to be transferred to an adult service for long-term follow up.

Follow up after transplantation is life-long in order that disease recurrence, where present, can be identified and treated early, complications of immunosuppression can be monitored and where possible avoided.

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, the NHS England contract includes provision for the service to treat eligible overseas patients under S2 [Under 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 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.

2.4 Any acceptance and exclusion criteria

The Provider has a duty to co-operate with the commissioner in undertaking Equality Impact Assessments as a requirement of race, gender, sexual orientation, religion and disability equality legislation.

Providers of paediatric services have a duty to facilitate legislation and guidelines for

the benefit of children such as the Children Act 1989 and Children Act 2004; The

United Nations Convention on the Rights of the Child 1991; The Education Act 2002; The Protection of Children Act 1999; and Safeguarding Vulnerable Groups Act 2006.

Patients are referred for liver transplantation from GPs or hospital consultants when their expected mortality without liver transplantation exceeds their expected mortality from the procedure.

Once referred the patient will be assessed by a multidisciplinary team as described in the Service Standards and their cases discussed at an MDT meeting which decides on eligibility for and appropriateness of liver transplantation

There are no absolute exclusion criteria for assessment except as implied by the listing criteria for transplant.

The service is required to meet national wait time targets but wait for transplant is dictated by the availability of a suitable organ.

2.5 Interdependencies with other services

Patients are referred in for assessment to the transplant centres from regional hepatology services (which may be the same as the transplant centre for local patients).

The British Society of Gastroenterology has guidelines on the referral of patients from peripheral units to liver transplant centres

Issues of common interest are discussed among the paediatric staff at the Liver Steering Group of the British Society of Paediatric Gastroenterology, Hepatology and Nutrition (BSPGHAN).

All units have a close but informal relationship with the Children's Liver Disease Foundation, the National Charity that seeks to represent the perspective of children and families with liver diseases.

There is a key relationship with organ retrieval and allocation, which are the responsibility of NHS Blood and Transplant.

There is no relevant national/clinical networks/expert patient programmes or screening programmes.

3. Applicable Service Standards

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

All providers will meet standard NHS governance requirements. All providers will comply with transplantation guidance and policies as agreed by the NHSBT Liver Advisory Group.

In addition, all centres are reviewed at least annually, and are expected to produce a written annual report for NHS England commissioners to demonstrate compliance with the current service standards and requirements for equity of access. Clinical teams are expected to participate actively in clinical networks to improve the national cardiothoracic transplantation service.

Audit requirements are set out in the Service Standards.

4. Key Service Outcomes

Quality Performance Indicator	Threshold	Method of measurement	Consequence of breach	Report Due
Outcomes	Outlier or CUSUM trigger	90 day mortality	Response as per protocol agreed between NHSBT and NHS England	As per protocol
Liver transplantation service for adults and children <ul style="list-style-type: none"> • 90-day mortality • One-year 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	Annual report (September of contract year)

5. Location of Provider Premises

The designated providers are:

Designated 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	Yes	Yes
Leeds Teaching Hospitals NHS Trust St James University Hospital, Beckett Street, Leeds LS9 7TF	Yes	Yes
Cambridge University Hospitals NHS Foundation Trust Addenbrooke's Hospital, Box 130, Hills Road, Cambridge. CB2 0QQ	Yes	No
The Newcastle upon Tyne Hospitals NHS Foundation Trust Freeman Hospital, High Heaton, Newcastle upon Tyne. NE7 7DN	Yes	No
Royal Free Hampstead NHS Trust Pond Street, London. NW3 2QG	Yes	No
University Hospital of Birmingham NHS Foundation Trust Selly Oak Hospital, Raddlebarn Road, Selly Oak, Birmingham, B29 6JD	Yes	No

Providers should formally agree with NHS England any designated liver transplantation service responsibilities they wish to discharge through a 3rd party.

Kings College Hospital NHS Foundation Trust have agreed with NHSE to subcontract some elements of liver transplant assessment and follow up through a formal arrangement with a provider in South West England (Plymouth Hospitals NHS Trust).

Appendix 1

Live liver donation specification (incorporating adult to adult and adult to child donation)

1. Population Needs

1.1 National/local context and evidence base

Description

A healthy adult may donate part of their liver to a patient in need of a liver transplant; the procedure is called a donor hepatectomy. This specification includes adult to adult donation but also the more common adult to child donation.

Individuals who would like to be considered as potential donors must be above the age of legal consent (18 years) and in excellent physical and emotional health.

A donor must be blood group compatible with the recipient.

Evidence base

There is extensive worldwide experience of successful live donor liver transplants.

2. Scope

2.1 Aims and objectives of service

This specification for liver transplant from a live donor only covers aspects related to the donor.

For the recipient, the process and specification is as set out in the Liver Transplantation Service specification.

The objective of the service is to assess potential donors, carry out the donor operation and provide follow up.

2.2 Service description/care pathway

The service is always open.

The first step is for the donor to have a blood test to check compatibility; the clinical team will also need a detailed medical history to evaluate the potential risk to the donor.

The key components of the service are:

- assessment
- surgery - donor hepatectomy
- management of complications
- follow up.

Assessment

At any stage of the assessment the donor may withdraw from the process and the provider may also decide that clinically the donor hepatectomy is too much of a clinical risk to the potential donor.

Stage 1

The first stage is to ensure that the donor's liver is suitable for split transplantation. The donor will formally consent to undertake this assessment stage. This stage includes a general health assessment, screening for various infections, checks on their liver anatomy and a psychological assessments.

The donor receives detailed information from the providers liver co-ordinator; this is both verbal and written. The risks involved in the procedure should be discussed from the outset but also emphasised at this stage. A detailed process should be in place at each provider for psychiatric evaluation of the donor, and assurance that the potential risks have been discussed.

A Computed tomography (CT scan) /Magnetic Resonance Imaging (MRI), scan will look at the detailed anatomy of the liver. A blood test will be taken at this stage to see how well the liver and kidneys are functioning; tests will also exclude the presence of any undiagnosed cancer and viruses, including HIV, that can be transmitted between donor and recipient.

Stage 2

At this stage, in some circumstances, a liver biopsy may be necessary and the potential donor's GP will be contacted.

Stage 3

This stage looks at the donor's general fitness to undergo surgery and anaesthesia. Further tests will be carried out to evaluate the donor's heart and lungs. A psychological assessment will also be completed to consider the family, emotional, financial and physical stress of undergoing donor surgery.

Stage 4

At this stage the potential donor will meet with an independent assessor (IA), this

person acts on behalf of the Human Tissue Authority (HTA) and will verify the donor-recipient relationship.

Stage 5

This final stage is a multi-disciplinary team (MDT) review of the case with the IA and psychological assessments. The transplant date is set at this meeting.

Transplant surgery (see the liver transplantation service specification for more detail)

It is possible to split the liver in a variety of ways as there are eight defined liver segments, the most appropriate method will be discussed and agreed with the donor prior to the operations. The most appropriate split will be dependant on the size of the recipient, for example a child will need a much smaller segment than a recipient adult. The donor operation episode from admission to discharge is included in this service.

Surgery will take between three and four hours, post surgery will require a short stay in the high dependency unit (HDU). Most donors can start eating and drinking fluids 2-3 days post surgery and discharge from hospital will be between 5-7 days, assuming there are no complications.

Management of complications

The service includes management of complications clearly related to the donor hepatectomy. Some patients will experience mild jaundice, an ultrasound scan and other test will rule out complications. Complications can arise from the anaesthetic or the surgery. The most common complications are:

- anaesthetic – complications arising from arterial line, central line, epidural catheter
- surgical - complications from bile leak, pulmonary thrombosis.

Occasionally (1:200) the donation leaves insufficient healthy liver and causes liver failure; if the donor fails to recover they may require an emergency liver transplant. The extensive tests prior to surgery aim to minimise this risk.

Follow up

The service includes follow up of patient donors after transplant. Most donors are ready to return to work 4-8 weeks post surgery depending on their type of work. Donors will be reviewed as an outpatient two weeks after discharge and receive regular appointments in the first year post donation. There should be an annual review post surgery for as long as clinically appropriate.

Serious untoward incidents are reportable to NHS England under standard protocols.

Discharge planning

There are two elements to discharge:

- discharge following the donor operation
- discharge from follow up.

Follow up of donors is usually 2 weeks post surgery, regular outpatient appointments in the first year and then annually. This may vary slightly by provider and follow-up 2 years after surgery is at the discretion of the provider.

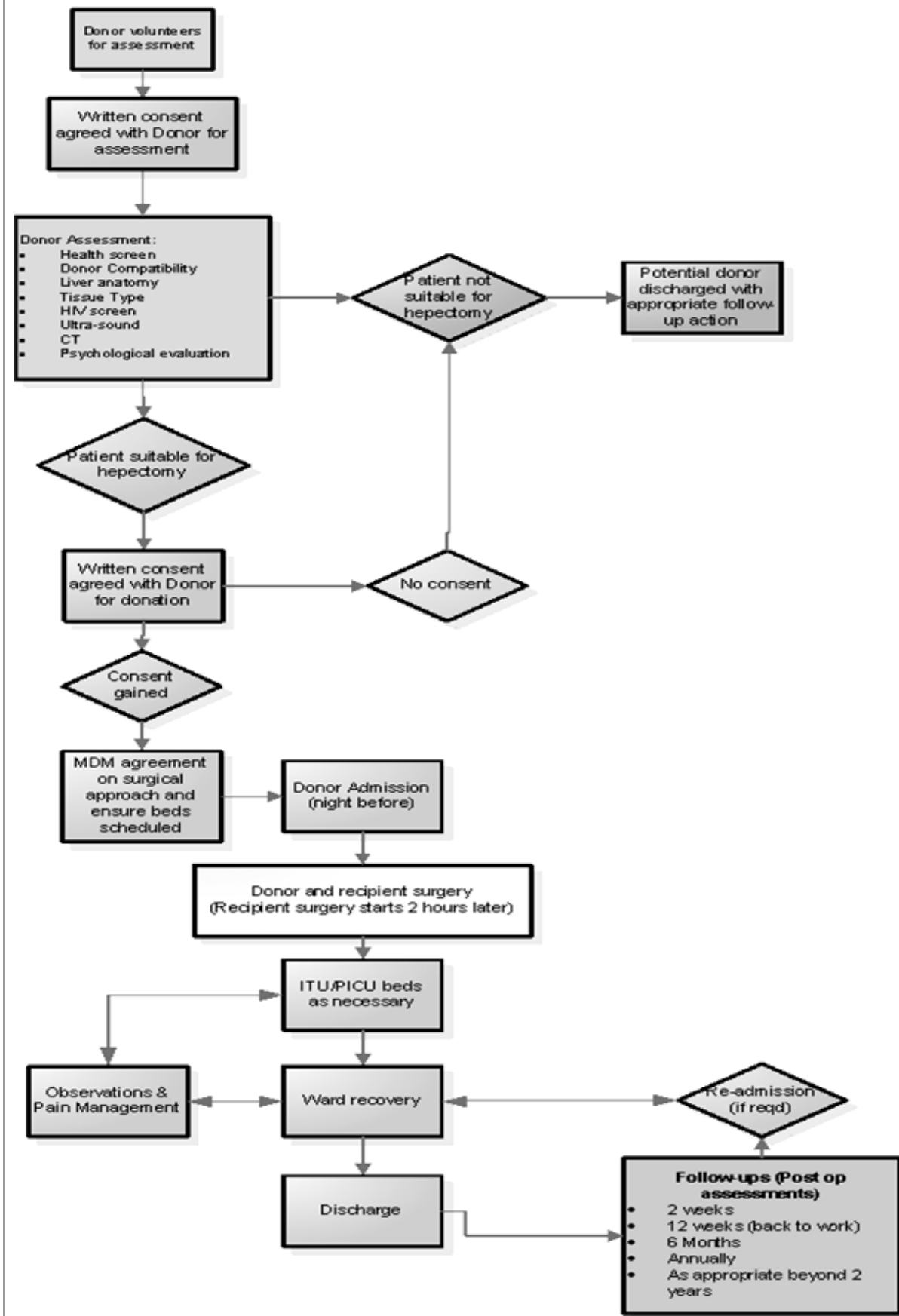
Donor Expenses

The Human Tissue Act 2004 forbids payments or any inducement for the supply of organs. However, it does permit reasonable expenses to a donor for travel, accommodation and loss of earnings incurred if directly attributable to the donation of an organ. These expenses are capped at £7,500 and must be attributable to the donation and be submitted with valid receipts to the provider performing the operation. The expenses claim form and policy are available on request.

Donor expenses should be claimed through and paid for by the provider performing the hepatectomy. The provider should then claim the associated costs through NHS England. The NHS is not legally obliged to make payments.

Adopted

Live Liver Donor Patient Pathway



3. Applicable Service Standards

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

All providers must meet standard NHS governance requirements. Audit requirements are set out in the service standards. Service standards are as per the liver transplantation standards. The NHS England Donor Expenses Policy and associated forms are available on the NHS England website.

4. Key Service Outcomes

Quality Performance Indicator	Threshold	Method of measurement	Consequence of breach	Report Due
Donor outcomes	Single event	Complications including post-operative mortality	Response as per protocol agreed between NHS Blood and Transplant and NHS England	Notification to NHS England as per protocol

5. Location of Provider Premises

Individuals who would like to be considered as potential donors must be aged 18 years or older and in excellent physical and emotional health. Consequently, all providers of live liver donation are adult liver transplant centres, although the livers from live donors are often donated to children and transplanted at child liver transplant centres (see liver transplantation service specification for more details).

Provider
King's College Hospital NHS Foundation Trust Denmark Hill, London. SE5 9RS
Leeds Teaching Hospitals NHS Trust St James University Hospital, Beckett Street, Leeds LS9 7TF
Cambridge University Hospitals NHS Foundation Trust Addenbrooke's Hospital, Box 130, Hills Road, Cambridge. CB2 0QQ
The Newcastle upon Tyne Hospitals NHS Foundation Trust Freeman Hospital, High Heaton, Newcastle upon Tyne. NE7 7DN
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Adopted