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.
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.

**Objectives**

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) / 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 psychological assessments. The transplant date is set at this meeting.

Transplant surgery (see liver transplantation service specification for more details)
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 normal invoicing channels with NHS England. The NHS is not legally obliged to make payments.
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.

At the moment, NHS England contract includes provision for the service to treat eligible overseas patients under S2* referral arrangements. Providers are reimbursed for appropriately referred and recorded activity as part of 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.

* 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)

2.4 Any acceptance and exclusion criteria

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.

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.

2.5 Interdependencies with other services

Potential donors are likely to be spontaneous volunteers who are relatives of the recipient. The assessment of the potential donor will be vigorous as detailed above.

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. NHS England Donor Expenses Policy and associated forms are available on request to NHS England.

4. Key Service Outcomes

<table>
<thead>
<tr>
<th>Quality Performance Indicator</th>
<th>Threshold</th>
<th>Method of measurement</th>
<th>Consequence of breach</th>
<th>Report Due</th>
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</thead>
<tbody>
<tr>
<td>Donor outcomes</td>
<td>Single event</td>
<td>Complications including post-operative mortality</td>
<td>Response as per protocol agreed between NHS Blood and Transplant and NHS England</td>
<td>Notification to NHS England as per protocol</td>
</tr>
</tbody>
</table>

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).

<table>
<thead>
<tr>
<th>Provider</th>
<th>Address</th>
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<tbody>
<tr>
<td>King’s College Hospital NHS Foundation Trust</td>
<td>Denmark Hill, London. SE5 9RS</td>
</tr>
<tr>
<td>Leeds Teaching Hospitals NHS Trust</td>
<td>St James University Hospital, Beckett Street, Leeds LS9 7TF</td>
</tr>
<tr>
<td>Cambridge University Hospitals NHS Foundation Trust</td>
<td>Addenbrooke’s Hospital, Box 130, Hills Road, Cambridge. CB2 0QQ</td>
</tr>
<tr>
<td>The Newcastle upon Tyne Hospitals NHS Foundation Trust</td>
<td>Freeman Hospital, High Heaton, Newcastle upon Tyne. NE7 7DN</td>
</tr>
<tr>
<td>Royal Free Hampstead NHS Trust</td>
<td>Pond Street, London. NW3 2QG</td>
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