FAQs and Information for Fetal Medicine Doctors Considering Referral for Open Fetal Surgery to treat fetuses with Open Spina Bifida

1. Inclusion and exclusion criteria

1.1. Criteria (as per NHS England service specification)

- Gestational age <26+0 weeks' gestation
- Normal genetic testing (conventional karyotype or microarray)
- Spinal lesion T1-S1 included (myelomeningocele or myeloschisis)
- Confirmed Chiari type II malformation on prenatal ultrasound and magnetic resonance imaging
- Known maternal HIV, HBV, HBC status for inclusion in the management plan.

1.2. Exclusion Criteria (as per NHS England service specification)

- Multiple pregnancy
- Other fetal anomaly not related to open spina bifida which the MDT review considers is likely to significantly impact on fetal surgery or the short or long term outcome for the baby
- Fetal kyphosis ≥30 degrees
- History of incompetent/weak cervix and/or short cervix <20mm by ultrasound scan in index pregnancy
- Placenta praevia
- Other serious maternal medical conditions which are a contraindication to surgery or general anaesthesia;
- Obesity defined by body mass index of ≥40
- Previous spontaneous singleton delivery <37wks' gestation
- Maternal– fetal Rh isoimmunisation
- Uterine anomalies and previous uterine surgery other than lower segment caesarean section

If there is any uncertainty about whether a patient would be eligible, please discuss with the Fetal Surgery Centre who can discuss this at their multi-disciplinary team meetings.

2. Optimal Timing for Referral

Initial notification of a case from 20 weeks of gestation onwards is helpful to provide sufficient time to counsel families and to plan the assessment and surgery.

3. Optimal Timing for Surgery

23+0 to 25+6 weeks of gestation, as earlier surgery is associated with increased risks of chorioamniotic membrane separation/ Preterm Premature Rupture of the Membranes (PPROM). Outcomes from surgeries performed at or after 26+0 weeks of gestation have not been researched within a clinical trial.

4. Prenatal assessment at the referring centre and at the Fetal Surgery Centre (FSC):

- Referral form to be emailed to spinabifida-fetalsurgery@nhs.net, including details of all investigations and counselling that has been performed locally.
- The referring FMU team will inform the FSC team about any particular issues in relation to the woman/family so that the UCLH FSC Team can make the necessary preparations, for example, if English is not the family's first language.
- Initial patient discussion: the patient will be called by the FSC team to briefly explain the surgery and the process of further review at the FSC to assess if they are suitable.
- First assessment at the FSC: includes complete independent assessment including ultrasound, MRI and fetal medicine consultation. When proceeding to surgery there is an anaesthetic consultation as well.
• Time point: patients can be assessed either well before the ideal surgery date, to allow time for making decisions, or in the days before the anticipated surgery date, if patients find that more practical. This is dependent on patient preferences and practicalities such as travel, gestational age etc.

• Accompanying family members: The patient can be accompanied by one partner or carer. If the woman has children, only a feeding babe in arms may accompany her to the hospital. No other child(ren) should accompany the woman and her partner/carer, and alternative childcare arrangements should be made for the care of these, if any exist.

5. Location of patient assessment and surgery
To maintain and develop an integrated, expert and sustainable service and to comply with the requirements of NHS England Highly Specialised Services, patient assessments and fetal surgery will be equally distributed between the two sites. The patient allocation system to one of the two units for assessment and possible fetal surgery is based both on recognised travel routes for patients and the location of the referring Regional Fetal Medicine Unit (RFMU), as agreed with respective commissioners. The system will also ensure appropriate levels of activity are maintained across the two units and enable continuation of expertise in both providers.

For patients from Wales, this is on the basis of the location of the referring English RFMU, as follows:
• North Wales units, which refer into Alder Hey and Manchester RFMUs will go to Leuven
• Mid Wales units, which refer into Birmingham, will go to Leuven
• South Wales units, which refer into Bristol, will go to UCLH.

UZ Leuven will serve women who live in: North East and North West England (including patients from North Wales referred to Alder Hey and Manchester); Yorkshire and the Humber; Scotland; Northern Ireland; and from these parts of the Midlands: Nottingham, Derby, Burton and Birmingham (including patients from Mid Wales).

Table 1 is an approximate guide. There may be occasions where, due to capacity patients are managed in the alternate FSC.

<table>
<thead>
<tr>
<th>Assessment by +/- treatment at UCLH for patients originating from:</th>
<th>Assessment by +/- treatment at UZ Leuven for patients originating from:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• London: all referring units (including Imperial, Chelsea &amp; Westminster, Guys &amp; St Thomas’, Homerton, King’s, St George’s and Barts)</td>
<td>• North East and North West England: all referring units (including Liverpool, Manchester and Newcastle and including patients from North Wales referred to Alder Hey and Manchester)</td>
</tr>
<tr>
<td>• South East England: all referring units (including Medway)</td>
<td>• Yorkshire and Humber: all referring units (including Leeds and Sheffield)</td>
</tr>
<tr>
<td>• South West England: all referring units (including Plymouth, Cornwall, Devon &amp; Exeter and Bristol (including patients from South Wales)</td>
<td>• Scotland: all referring units</td>
</tr>
<tr>
<td>• East of England: all referring units (including Cambridge and Norfolk &amp; Norwich)</td>
<td>• Northern Ireland: all referring units</td>
</tr>
<tr>
<td>• Wessex: all referring units (including Oxford and Southampton)</td>
<td>• The Midlands: Nottingham, Derby &amp; Burton and Birmingham (including patients from Mid Wales)</td>
</tr>
<tr>
<td>• The Midlands: Leicester, Wolverhampton, Shrewsbury &amp; Telford, North Midlands and Coventry &amp; Warwick</td>
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6. Financial aspects

- Open Fetal surgery for open spina bifida is commissioned by NHS England under a national tariff.
- When the woman is an inpatient for surgery, funding for partner accommodation will be reimbursed by NHS England either adjacent to the FSC or in a nearby, reasonably priced hotel if this is not available.
- NHS England will not fund daily living/subsistence costs such as food apart from when the woman is an inpatient.

- **Travel to UCLH** will not be reimbursed by NHS England apart from eligible patients who can access reimbursement for travel costs from their referring unit via the Hospital Costs Travel Scheme. This will be reimbursed by the referring unit to the patient directly on submission of receipts.

- **Travel to UZ Leuven**, will be reimbursed by NHS England, which will refund the referring FMU the cost of any outward and return reasonable travel costs between the family's home and the UZ Leuven hospital, including flights or ferry or train/Eurostar to and from Brussels airport and onward train travel to Leuven in Belgium for the woman and her partner/carer. The referring team will make and pay for the travel bookings at no cost to the family. The referring provider then invoices NHS England at X24FMARLEY.

  If a family wishes to hire a car during the treatment period, NHS England will fund a Group A car and the cost of fuel between the airport and the accommodation and between the accommodation and the hospital. The Referring Team will reimburse the family on presentation of receipts and invoice NHS England at X24FMARLEY. NHS England will not fund the cost of fuel for other journeys undertaken by the family.

  Whilst in Belgium, NHS England will fund travel between the family’s accommodation and the UZ Leuven hospital. The referring FMU team will reimburse families for travel on presentation of receipts and invoice NHS England at X24FMARLEY noting the service name ‘Open fetal surgery to treat fetuses with open spina bifida’.

  If, in exceptional circumstances, there is a request for accommodation other than that identified by the Leuven FSC Team, this must be agreed by the Leuven FSC Team and NHS England. If a family wishes to use alternative accommodation, they will pay for this directly and the RFMU will reimburse them to the value that the accommodation would have cost if NHS England had paid for this directly, that is up to £120 per night. The RFMU team will invoice NHS England for the accommodation via the NHS England contract or direct at X24FMARLEY.

  NHS England will fund additional travel insurance for the woman (for any circumstances not related to her pregnancy) and for the woman’s partner/carer. The woman and her partner/carer should arrange the travel insurance themselves and will be reimbursed by the referring team can then invoice NHS England via the NHS England contract or direct at X24FMARLEY. The referring team should confirm that they have seen evidence of the insurance before they make the travel arrangements.
7. **Staying at the FSC for the woman and her partner or carer**

- Patients will be admitted to the hospital the night before surgery. The typical stay is 5-7 postoperative days, initially in the close observation unit on labour ward and then on the antenatal ward.
- The patient’s partner or carer can stay in a single room in the hospital’s family accommodation for the duration of the patient’s stay if there is space available. If space is not available, the FSC’s fetal medicine co-ordinator will make this known to the referring FMU staff who will then need to book and pay for one room for the partner/carer in a reasonably priced hotel nearby as follows:

**For Leuven**, the referring unit team will liaise with the fetal medicine team to check if there is hospital family accommodation available. Following a review of local hotel costs, there is a ceiling value on the nightly room rate of £120 per night for bed and breakfast in a local hotel. The RFMU will book the accommodation either by using an existing CCS framework for travel accommodation/hotels then raise the purchase order in the usual way or use the quotes below which were current as at September 2019 as a guide to the price that should be paid. At the point of booking, the referring unit should note to the hotel that the booking is for a patient/carer of a patient at the UZ Leuven hospital and the usual discounted rates should apply. The referring unit can then invoice NHS England via the NHS England contract or direct at X24FMARLEY noting the service name.

If, in exceptional circumstances, there is a request for accommodation other than that identified by the Leuven FSC Team, this must be agreed by the Leuven FSC Team and NHS England. If a family wishes to use alternative accommodation, they will pay for this directly and the RFMU will reimburse them to the value that the accommodation would have cost if NHS England had paid for this directly, that is up to £120 per night. The RFMU team will invoice NHS England for the accommodation via the NHS England contract or direct at X24FMARLEY.

If a family wishes to hire a car during the treatment period, NHS England will fund a Group A car and the cost of fuel between the airport and the accommodation and between the accommodation and the hospital. The Referring Team will reimburse the family on presentation of receipts and invoice NHS England at X24FMARLEY. NHS England will not fund the cost of fuel for other journeys undertaken by the family.

<table>
<thead>
<tr>
<th>Hotel</th>
<th>Price (Euro) includes hospital patient discount</th>
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<tbody>
<tr>
<td>The Boardhouse Heverlee</td>
<td></td>
</tr>
<tr>
<td>standard</td>
<td>79</td>
</tr>
<tr>
<td>luxe</td>
<td>99</td>
</tr>
<tr>
<td>The Lodge Heverlee</td>
<td></td>
</tr>
<tr>
<td>comfort</td>
<td>128</td>
</tr>
<tr>
<td>Binnenhof Leuven</td>
<td></td>
</tr>
<tr>
<td>standard</td>
<td>112</td>
</tr>
<tr>
<td>Park Inn Radisson Leuven</td>
<td>99</td>
</tr>
</tbody>
</table>

**For UCLH**, there is a ceiling value on the nightly room rate of £150 per night for bed and breakfast. The referring unit team will then invoice NHS England via the NHS England contract or direct at X24FMARLEY noting the service name.

In all cases, the family will be liable to pay for any damage caused by them to the hospital family or hotel accommodation.
8. **Postoperative care and long term follow up**
   - Patients will be expected to return to their referring hospital for antenatal care and delivery.
   - A postoperative protocol and provision of email support by the FSC will be available to units caring for these patients.
   - Following open fetal surgery spina bifida repair, the delivery of this pregnancy and any future pregnancies must be by caesarean section to reduce the risk of rupture.
   - Care and follow up of babies and children born after fetal surgery for spina bifida will be at the regional unit; a suggested post-delivery protocol and email support will be provided.
   - Regional fetal medicine and neuro/paediatric surgery teams are required to provide regular feedback regarding the clinical outcomes of these patients to the fetal surgery centre.
   - We will adhere to the recommendations made by MMC-Maternal Fetal Management Task Force (USA) and the condition of the service contract with NHS England to keep a register of all patients.

9. **Contacts for further information:**
   For further information:
   Spinabifida-fetalsurgery@nhs.net
   www.uclh.nhs.uk/spinabifida-fetalsurgery

10. **Further reading**