

Consultation Report

Topic details

Title of Service Specification:	Open fetal surgery to treat fetuses with open spina bifida
Programme of Care:	Women and Children
Clinical Reference Group:	Paediatric Neurosciences
URN:	170106S

1. Summary

This report summarises the outcome of a public consultation that was undertaken to test the service specification proposal.

2. Background

Spina bifida occurs in early pregnancy (before the sixth week) and around four in 10,000 pregnancies. It is where the spinal column and spinal cord are not properly formed, leaving nerves exposed. The exact cause is unknown. Several factors may be associated with the condition, such as insufficient folate (a B vitamin) in the diet and there are also hereditary factors. Every person with spina bifida is unique, meaning there is a large variety of possible effects, from mild to severe. Typical problems include weakness in the feet or legs, leading to an inability to walk in some children and problems with bladder and bowel control. It can also lead to excess fluid building up in the brain, (a condition called hydrocephalus).

Description of intervention: This specification sets out the proposal for a new NHS England service for the provision of open fetal (in-utero) surgery and supporting medical services in cases where a woman is carrying a baby in the womb which has open spina bifida. Due to the small number of women who could benefit from the intervention and the expertise needed to undertake the intervention, NHS England plans to commission this from up to two Fetal Surgery Centres.

3. Publication of consultation

The service specification proposition was published and sign-posted on NHS England's website and was open to consultation feedback for a period of 30 days from 17 August to 16 September 2018. Consultation comments have then been shared with the Service Specification Working Group to enable full consideration of feedback and to support a decision on whether any changes to the service specification might be recommended.

Respondents were asked the following consultation questions:

- Do you agree that the timing and frequency of communication in the care pathway will support and enable appropriate communication between the Fetal Surgery Centres (FSCs) and the hospitals* with whom these will 'share care' for each woman and her baby in the womb?
- Does the list of questions shown in the 'Template Fetal Surgery Centre patient information leaflet for England' (Appendix 3, page 22) support women to make informed decisions?
- Please detail any other changes that you think should be made to the service specification and explain why the changes are necessary.

4. Results of consultation

Eight responses were received, all in support of the service specification, including the Royal College of Obstetricians and Gynaecologists, clinicians and Shine which is the spina bifida patient support group.

Comments included:

- additional wording to be inserted or in place of existing wording from the patient group which is part of the Specification Working Group;
- comments / suggestions on the number and phasing of units to be commissioned – which will be taken into account when the commissioning plan is drawn up;
- comments / suggestions as to the infrastructure, experience, expertise and availability of the units to be part of the essential criteria for the provider selection process.

Regarding question 1: seven out of eight respondents agreed that the timing and frequency of communication in the care pathway will support and enable appropriate communication between the Fetal Surgery Centres (FSCs) and the hospitals* with whom these will 'share care' for each woman and her baby in the womb? The patient charity Shine, who are part of the Specification Working Group, took the time to do a final read-through of the specification and requested that the wording for actions in local maternity units be modified to include that a referral should be made for all women to a Regional Fetal Medicine Unit for review and counselling there as to the full range of options available, including pre-natal surgery if the inclusion criteria are met, as well as post-natal surgery or termination.

Regarding question 2: seven out of eight respondents agreed that the list of questions shown in the 'Template Fetal Surgery Centre patient information leaflet for England' (Appendix 3, page 22) support women to make informed decisions? The eighth respondent asked for the discussion on surgical options to include fetoscopic (laparoscopic) surgery instead of open surgery. Two respondents went on to give suggested changes including i) that fetoscopic surgery should be discussed as an option instead of open surgery and ii) some suggested amendments to the language to be included in the example patient leaflet for England.

Regarding question 3: four out of eight respondents agreed that the list of questions shown in the 'Template Fetal Surgery Centre patient information leaflet for England' (Appendix 3, page 22) support women to make informed decisions. Four respondents proposed amendments including that:

- i) counselling conversations with women should include that fetoscopic surgery is an alternative to open surgery
- ii) that there should be a single final decision making MDT and 2 site service to ensure equitable access/decision making and surgical approach
- iii) that there would be significant advantages to mother and child if the service was offered on a single site
- iv) a note that the process is very dependent on a highly skilled and motivated team at all points from the referring centre to the FSC...it is not known how many patients will wish to investigate this option or how attitudes will change over time...we should not allow any possibility of dilution of experience in the set up stages; ...that we continue the international precedent of 'organic' growth of a UK service and NHS England must only commission one centre initially and that centre must have developed with direct integration with an existing centre of experience. Once that centre is reaching saturation, the lessons learnt and organisational lessons learnt can be transferred to subsequent start-ups...and the first centre must have sufficient staffing resource to provide a robust 24/7/365 service from its inception, especially with obstetric and neurological surgeons.
- v) to confirm what skills and experience the units will be required to have.
- vi) to confirm why a service is needed given the small number of patients per year.

5. How have consultation responses been considered?

Responses have been carefully considered and noted in line with the following categories:

- Level 1: Incorporated into draft document immediately to improve accuracy or clarity – most comments received were in this category.
- Level 2: Issue has already been considered by the CRG in its development and therefore draft document requires no further change
- Level 3: Could result in a more substantial change, requiring further consideration by the CRG in its work programme and as part of the next iteration of the document
- Level 4: Falls outside of the scope of the specification and NHS England's direct commissioning responsibility – the proposals around including fetoscopic

[laparoscopic] surgery approaches as part of counselling conversations fall under this category as NHS England is commissioning open fetal surgery for spina bifida, not fetoscopic surgery this specification. Any future request to NHS England to develop a clinical commissioning policy for fetoscopic pre-natal surgery spina bifida will be subject to a Clinical Panel review of the available evidence.

6. Has anything been changed in the service specification as a result of the consultation?

Yes, the specification has been amended with regard to agreed Level 1 comments as shown in Appendix 1 below.

These include:

- That there should be a single, final decision making MDT across the units
- That the service should be offered from a single site, that is have the maternal and fetal facilities and staff in a single unit location.
- The recommendation that the Fetal Surgery Centres should be directly integrated with an existing centre of experience.
- Language changes to the Example FSC Patient Information Leaflet for England:
 - In section on Motor, Sensory and Orthopaedic (page 21) change 'deformity' to 'curvature'.
 - In section on Brain Changes (page 22) insert 'physical' to read...'do not necessarily lead to physical problems...'
 - In section on Psychosocial and Sexual (page 22) we suggest adding a sentence to the end: 'Many women with spina bifida are able to have children.'
 - Additional wording added to the specification and leaflet to be more clear on the meaning of 'rest' following surgery: women, to ensure the ongoing safety of the pregnancy and, due to the risk of preterm birth, may be advised to stop work after fetal surgery and restrict daily activities until the baby is born.

7. Are there any remaining concerns outstanding following the consultation that have not been resolved in the final service specification proposal?

No.