



## **Open fetal surgery to treat fetuses with ‘open spina bifida’ (children)**

Public consultation guide

**Improving patient outcomes when a woman has a baby in the womb (fetus) with open spina bifida**

**Equality and health inequalities statement:**

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities.

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## 1 About this guide

NHS England is committed to working with a wide range of patients, patient groups and other stakeholders in the development of its commissioning of specialised services. A public consultation is an opportunity to check whether: proposals are right and supported; the public understands their impact and alternatives are identified before decisions are made.

We have launched this consultation to seek views on the proposed new specification 'Open fetal surgery to treat fetuses with 'open spina bifida' (children)', which will run from 17 August to 16 September (30 days). In this document the word fetus is used for a baby when it is still in the womb.

The document has information about the proposed changes to the way services may be provided and also explains how you can share your views with NHS England. At the end of the consultation period, all feedback will be considered and amendments made to the service specification as appropriate.

We recommend that you read this consultation guide alongside the service specification and impact assessment. Both of these documents can be found on the consultation landing page.

## 2 Context

**What is spina bifida?** Spina bifida occurs in early pregnancy (before the sixth week) and is where the spinal column and spinal cord are not properly formed, leaving nerves exposed. It occurs in around 4 in 10,000 pregnancies.

**What causes spina bifida?** The exact cause is unknown. Several factors may be associated with the condition, such as insufficient folate (a B vitamin) in the diet. There are also hereditary factors.

**What does spina bifida mean for my child?** Every person with spina bifida is unique, meaning there is a large variety of possible effects, from mild to severe. Generally, a defect higher up on the spine is associated with more serious consequences. Ultrasound of the baby in the womb can be used to determine the position (height) of the spina bifida defect in the spinal column. This gives doctors information about what problems the child is likely to have. Typically these 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). However it is not possible to predict before birth exactly how severe these problems are going to be.

**About the new service specification:** 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 where a woman is carrying a baby in the womb with 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.

**What is currently available?** When a woman has a baby in the womb that is suspected of having spina bifida, the local maternity hospital will refer her to the regional fetal medicine unit (RFMU) for more testing. If spina bifida is confirmed, the RFMU will talk with the woman and her partner/family about spina bifida, available community resources and provide initial information regarding prenatal and postnatal surgery, including a contact for SHINE, the spina bifida charity. Some women decide to terminate their pregnancy whilst others choose to continue with the pregnancy. When a pregnancy is continued, the baby will have postnatal surgery in the woman's regional paediatric neurosurgery unit shortly after it is born. For more questions and answers about prenatal surgery, see Service Specification page 22 Appendix 3 – Template FSC Patient Information Leaflet for England. NHS England does not currently commission open fetal surgery for babies born with spina bifida, only postnatal surgery

**What is new?** NHS England proposes to commission a new service where the NHS will fund open fetal surgery on babies in the womb instead of the currently available postnatal surgery in those cases where the woman and her baby meet the inclusion criteria for fetal surgery.

**What are the benefits of fetal surgery as compared to postnatal surgery on the baby after it is born?** A clinical trial - the Management of Myelomeningocele (MOMS) trial which is the only evidence-based randomised control trial for this surgery, which was published in the New England Journal of Medicine in 2011, demonstrated that certain women and their baby in the womb could benefit from fetal surgery. The criteria from the MOMS trial were used as the basis of the clinical criteria for this specification by the Open Prenatal Surgery for Open Spina Bifida Specification Working Group.

In the MOMS trial, 77 babies with spina bifida were operated on in whilst they were still in the womb. Their clinical outcomes were compared to 80 babies who had spina bifida surgery after birth. The children who were operated before birth had: i) less severe hindbrain herniation; ii) less need for a shunt operation (a tube to drain hydrocephalus) by one year of age and iii) better leg function at 30 months of age. On further follow-up those babies operated before birth seemed to have better bladder function, but that evidence is not yet conclusive.

**Are there risks from fetal surgery?** Yes there are risks to the woman and to her baby in the womb. Also, any future pregnancies will have further risks, including needing to be delivered by caesarean section.

The specification, including Appendix 3: The Template FSC Patient Information Leaflet for England can be found at:

<https://www.england.nhs.uk/commissioning/spec-services/npc-crg/group-e/e04/>

In 2016, an Open Prenatal Surgery for Open Spina Bifida Specification Working Group was set up including clinicians and commissioners from England and Northern Ireland to develop a specification for open surgery to be commissioned by NHS England. The group set out the following items within the specification:

- inclusion and exclusion criteria for the woman and her baby in the womb, based on those used in the MOMS trial;
- steps for the care pathway for open fetal surgery for spina bifida;
- when and how often the Fetal Surgery Centres (FSCs) should communicate with the local and regional hospitals which are also caring for each woman who is referred to a FSC for assessment. The hospitals with whom the FSCs will share care are the woman's local hospital maternity unit, the regional fetal medicine unit and the regional paediatric neurosurgical unit.
- the risks to the woman and her baby in the womb from open fetal surgery. These are set out in the main body of the specification and in the Template FSC Patient Information Leaflet for England (see Service Specification Appendix 3).

### 3 What we want to achieve?

As NHS England will be commissioning open fetal surgery for spina bifida for the first time, we want to ensure that:

- the care pathway steps will enable and support appropriate levels of communication between the national FSC's and the particular regional and local units which will be sharing care for each woman and her baby in the womb; the Template FSC patient information leaflet for England supports women to make informed decisions.

This new service specification will ensure that where a woman has a baby in the womb with spina bifida and where the inclusion criteria are met, open fetal surgery can then be offered and take place in the right hospital by those with the right skills and experience, using evidence-based techniques.

### 4 Overview of the specification being consulted upon

**What does it cover?** This specification sets out the proposal for a new service for women carrying a baby in the womb with open spina bifida and the provision of open fetal (in-utero) surgery and supporting medical services by up to two Fetal Surgery Centres (FSC's) to reduce the symptoms of this condition.

**What does it not cover?** This specification does not cover the postnatal pathways of care within the regional neurosurgery units.

**What will change?** Currently, where spina bifida is diagnosed whilst the baby is in the womb, for most women (90% or 90 women per year) the baby will go on to have postnatal surgery in a regional paediatric neurosurgery unit in England shortly after birth, as commissioned by NHS England.

## 5 What questions are we asking?

1. Do you agree that the proposed frequency and timing 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 hospitals that the FSC's will communicate with are the regional fetal medicine unit, the regional paediatric neurosurgery unit and the local hospital maternity unit. (These will be a different set of hospitals depending on where each woman lives).

See Service specification, Table 1: Description of Patient Care Pathway Steps (pages 4,5,6,7) for the care pathway table where the proposed level of communication is set out.

2. Do 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?
3. Please detail any other changes that you think should be made to the service specification and explain why the changes are necessary.

## 6 How to give your views

**The consultation period runs from 17 August and will last for 30 days.**

Your views will help NHS England to further shape and refine proposals for the delivery of this service so we can procure the right services from providers who are able to meet the requirements set out in the final service specifications.

- **Complete the online survey:** <https://www.engage.england.nhs.uk/>  
Before completing the survey please read the services specifications which are published on the landing page.
- **Email us:** [england.scengagement@nhs.net](mailto:england.scengagement@nhs.net)
- **Write to us:** Specialised Services; Women and Children's Programme of Care, NHS England, Floor 3B, Skipton House, 80 London Road, London, SE1 6LH.

## 7 Glossary

Fetal surgery	Surgery performed on a baby whilst it is still in the womb/uterus.
FSC	Fetal Surgery Centre
Fetus	The term used for the baby whilst it is still in its mother's womb/uterus. It is only called a baby after birth.
Hindbrain herniation	This is where the lower part of the brain pushes down into the spinal canal.
Hydrocephalus	The brain is surrounded by a clear fluid called cerebral spinal fluid (CSF). In spina bifida, the parts of the brain which are filled with CSF, (lateral ventricles) become enlarged, which can prevent the correct development of the brain.
MOMs	The Management of Myelomeningocele trial was published in the New England Journal of Medicine, March 17 2011 Vol 364, no 11. This was a randomised trial of open fetal surgery as compared to postnatal repair of myelomeningocele. This involved 77 babies with spina bifida being operated on in while still in the womb and who, compared to 80 babies who had spina bifida surgery after birth (postnatal surgery), had: i) less severe hindbrain herniation; ii) less need for a shunt (a draining tube to remove excess fluid from the brain for a condition called hydrocephalus) by the age of one year, iii) better leg function at 30 months of age. On further follow-up those operated before birth seemed to have better bladder function, but that evidence is yet not conclusive.
Open fetal surgery	Whilst the baby is still in the womb, the woman will undergo a surgical procedure where her skin and then her uterus are opened using a surgical incision in the bikini line - this will be slightly wider than the cut used for a caesarean section but is in the same place in the abdomen. The uterus (womb) is then opened to allow the surgeons to access the baby. The spina bifida defect is examined and surgically closed by the paediatric neurosurgeon. The woman's uterus and abdomen are then both closed. The baby will then remain in the womb until approximately 37 weeks, when it will be delivered in the woman's regional fetal medicine unit by caesarean section.
Open spina bifida	The spinal cord and nerve tissue bulge through an open hole or area of thin membrane on the baby's back. Aperta (Latin for open). This form of spina bifida is also called meningocele or myelomeningocele.
RFMU	Regional Fetal Medicine Unit.