

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Fetoscopic prenatal repair for open neural tube defects in the fetus

An open neural tube defect (open spina bifida) happens while the baby (fetus) is developing in the womb. Part of the spinal column does not form properly, leaving a gap that allows the spinal cord and nerves to develop outside the body. This may result in the baby being born with spina bifida and can cause lifelong disability. Up to 26 weeks of pregnancy fetoscopic (keyhole) surgery can be done, through the mother's abdomen, to close the gap in the baby's spine. The baby continues to grow and develop until birth. The aim is to prevent further damage to the brain, spinal cord and nerves.

NICE is looking at fetoscopic prenatal repair for open neural tube defects in the fetus.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of specialist advisers, who are consultants with knowledge of the procedure.

This document contains the draft guidance for [consultation](#). Your views are welcome, particularly:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance

- prepare a second draft, which will go through a [resolution](#) process before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 24-10-2019

Target date for publication of guidance: January 2020

1 Draft recommendations

- 1.1 Evidence on the safety and efficacy of fetoscopic prenatal repair of open neural tube defects in the fetus is inadequate in quantity and quality. Therefore, this procedure should only be used in the context of [research](#). This could be in the form of randomised controlled trials or published registry data.
- 1.2 The procedure is technically challenging and should only be done in specialised centres, and only by clinicians and teams with specific training and experience in fetal surgery.
- 1.3 Patient selection should only be done by a multidisciplinary team, which would usually include a consultant in fetal medicine, an obstetric surgeon, a paediatric neurosurgeon and an anaesthetist.
- 1.4 Further research should report details of risks to the fetus and mother (including her subsequent pregnancies), risks to the fetus and long-term disability after birth.

2 The condition, current treatments and procedure

The condition

2.1 Neural tube defects happen because the neural tube doesn't fuse during early embryonic development. Open neural tube defects are those in which the affected region of the neural tube is exposed on the body's surface. The most common neural tube defect is spina bifida where the defect is in the spine. Myelomeningocele (open spina bifida) is the most severe type of spina bifida, in which the baby's spinal canal remains open along several vertebrae in the back. The spinal cord and protective membranes around it push out and form a sac which is exposed on the baby's back. Children born with myelomeningocele may experience motor neurological deficits including muscle weakness and paralysis of the lower limbs, sensory deficit, bowel, bladder and sexual dysfunctions and learning difficulties. The condition can be associated with Chiari II malformation (hindbrain herniation) and hydrocephalus.

Current treatments

2.2 Conventional treatment for myelomeningocele (open spina bifida) is immediate surgical repair of the defect within days of birth to prevent further damage to nervous tissue and reduce the risk of central nervous system infection. The immediate management may also include ventricular-peritoneal shunt placement to relieve hydrocephalus. The condition can also be treated prenatally with the aim of decreasing morbidity in the child.

The procedure

2.3 Fetoscopic prenatal repair is done before 26 weeks of pregnancy. It can be done using local, regional or general anaesthesia and with partial CO₂ insufflation of the uterine cavity. Under ultrasound guidance the paediatric laparoscopy set (a fetoscope/endoscope) is

introduced through a port followed by the introduction of additional ports to allow the passage of instruments. Once the fetus is positioned adequately, the skin around the fetal neural placode/elements is dissected. A biocellulose patch is placed between the neural elements (defect) and the skin. The skin is sutured using interrupted stitches over the patch or, for a large defect, a dermal regeneration patch substitute can be used for repair.

- 2.4 A number of minor variations to the procedure have been described.

3 Committee considerations

The evidence

- 3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 4 sources, which was discussed by the committee. The evidence included 3 systematic reviews and meta-analysis and 1 case report. It is presented in table 2 of the [interventional procedures overview](#). Other relevant literature is in the appendix of the overview.
- 3.2 The specialist advisers and the committee considered the key efficacy outcomes in the baby to be: motor function, hind brain herniation, hydrocephalus, and bowel and bladder function.
- 3.3 The specialist advisers and the committee considered the key safety outcomes in the baby to be: fetal mortality, perinatal death, premature birth, premature rupture of membranes, and cerebrospinal fluid leakage. Key safety outcomes for the mother are: operative morbidity, incisional hernia, and uterine dehiscence in a subsequent pregnancy.

Committee comments

- 3.4 The committee noted that there are 2 variations of the fetoscopic approach: 1 in which the uterus is exteriorised and fetoscopic instruments are used, and 1 in which the entire procedure is done percutaneously in the mother without exteriorising the uterus.
- 3.5 The committee was advised that fetoscopic approaches are being used more commonly than open procedures and that they may have reduced risks for the mother, in particular the risk of uterine rupture in a subsequent pregnancy.
- 3.6 The committee was advised that there is a registry for this procedure. Clinicians are encouraged to submit data to this registry.
- 3.7 The committee noted the need to identify the risks and benefits for both the fetus and mother (including her subsequent pregnancies), and that these need to be discussed during parental counselling by the multidisciplinary team.

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Chair, interventional procedures advisory committee

September 2019

ISBN: