

National Institute for Health and Care Excellence
IP 949 Open prenatal repair for open neural tube defects in the fetus
IPAC date: 14 November 2019

Co m. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 4 British Maternal & Fetal Medicine Society	1 to 3	I write on behalf of the British Maternal & Fetal Medicine Society. Having reviewed the draft guidance, and the accompanying overview and specialist advisor questionnaires, I approve this as it currently stands.	Thank you for your comments.

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2	Consultee 5 NHS Professional	1.1	Special arrangements: There will only be 1-2 centres offering this service nationally. However, neurosurgical paediatric FU is likely to be regional/local. It is important that neurosurgical FU for all patients with spina bifida (whether they had pre- or post-natal repair) is standardised nationally, so that meaningful comparisons about outcomes can be made. Alternatively, there should be a framework for FU to be done in the specialist centres.	Thank you for your comments. The Interventional Procedures Advisory Committee noted the comment about 1-2 centres offering this procedure nationally. NICE IP programme does not have a remit to determine a national framework or other standards for neurosurgical paediatric follow-up. The guidance does make recommendations about the need for ongoing data collection and identifies key efficacy and safety outcomes.

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3	Consultee 3 British Paediatric Neurosurgery Group	1.3	1.3 I would add teams should have specific experience/expertise in open myelomeningocele repair.	Thank you for your comments. IPAC considered your comment and amended 1.3.
4	Consultee 3 British Paediatric Neurosurgery Group	1.4	1.4 The multidisciplinary team should ALWAYS include include a consultant in fetal medicine, an obstetric surgeon, a paediatric neurosurgeon and an anaesthetist. A radiologist with experience with fetal imaging should also be recommended.	Thank you for your comments. IPAC considered your comment and amended 1.4.
5	Consultee 3 British Paediatric Neurosurgery Group	3.3	3.2 /3.3 Some recognition of the need to monitor long term risks to babies undergoing repair that may or may not be higher or lower than those undergoing standard postnatal repair. These risks would include late spinal cord complications including tethered spinal cord and syringomyelia.	Thank you for your comments. Section 3.3 is the opinion of the specialist advisers and IPAC and not intended to be definitive. IPAC considered your comment and amended 3.3.
6	Consultee 5 NHS Professional	3.3	Key safety outcomes for the mother are: operative morbidity, incisional hernia, and uterine dehiscence "or rupture" in "the current or" subsequent pregnancy.	Thank you for your comments. Section 3.3 is the opinion of the specialist advisers and IPAC and not intended to be definitive. IPAC considered your comment and amended 3.3.

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7	Consultee 1 NHS professional King's College Hospital	3.3	...Key safety outcomes for the mother are: operative morbidity, incisional hernia, uterine dehiscence or rupture during the pregnancy and in subsequent pregnancy and morbidly adherent placenta.	Thank you for your comments. Section 3.3 is the opinion of the specialist advisers and IPAC and not intended to be definitive. IPAC considered your comment and amended 3.3.
8	Consultee 2 NHS Professional	3.3	Key safety outcomes should include uterine dehiscence in the current pregnancy as well as subsequent ones. Placental abruption should be included as a maternal safety outcome. Incisional hernia is not a known or quoted risk of this surgery.	Thank you for your comments. Section 3.3 is the opinion of the specialist advisers and IPAC and not intended to be definitive. Inclusion of 'incisional hernia' as key safety outcome has been supported by other consultees and the committee felt it was a potential complication (see comments 6 and 7). So, the committee decided not to remove this .In response to other comments IPAC amended 3.3.
9	Consultee 2 NHS Professional	3.1	Evidence assessed: the study by Moron 2018 (BJOG 125, 10:1280-1286) is the largest published cohort of open fetal surgery patients (237) and does not seem to be included in this consultation.	Thank you for your comments. The overview of evidence was based mainly on comprehensive systematic reviews and a randomised controlled trial. This large retrospective cohort study (Moron et al 2018) not included in any of the systematic reviews was missed by error. The study has now been added to the overview (Table 2) and the evidence from this study was discussed by the committee.

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10	Consultee 3 British Paediatric Neurosurgery Group	General Comme nts	I agree that there is no good evidence that this procedure is effective and reduces the risk/severity of hindbrain herniation and hydrocephalus. It is arguably better for babies than post-natal repair. The maternal risks, particularly for uterine rupture should be contextualised in comparison with the risk of uterine rupture following caesarean section.	Thank you for your comments. The committee considered that the risks to mother and fetus are covered in section 3.3.

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