Engagement Report for Clinical Commissioning Policies

Unique Reference Number	1782
Policy Title	Open Fetal Surgery to treat fetuses with 'congenital open spina bifida' (the main types of which are myelomeningocoele and myeloschisis)
Accountable Commissioner	Bernie Stocks
Clinical Reference Group	Paediatric Neurosciences
Which stakeholders were contacted to be involved in policy development?	• NHS England Paediatric Neurosciences Spina Bifida Specification Working Group; • Paediatric Neurosciences CRG Members and Stakeholders; • Specialised women's Services CRG Members and Stakeholders; • Belfast Health and Social Care Trust; • British Association of Paediatric Medicine; • British Maternal Fetal Medicine Society; • British Paediatric Neurosurgery Group; • MMC Specification Working Group including SHINE Charity; • Neonatal Operational Delivery Networks – circulated to all in England; • Royal College of Midwives; • Royal College of Obstetricians and Gynaecologists; • Royal College of Obstetric Anaesthetists; • Royal College of Paediatrics and Child Health.
Identify the relevant Royal College or Professional Society to the policy and indicate how they have been	As above

involved	
Which stakeholders have actually been involved?	**Fifteen responses were received in total from:** **Four clinicians responding as individual clinicians rather than in an organisational capacity.** **A patient and public voice representative from the Specialised Women's Services Clinical Reference Group.** **A clinical representative of the Specialised Women's Services CRG.** **Two clinicians who are members of the NHS England Spina Bifida specification Working Group:** (i) King's College Hospital (Neurosurgery Department; Fetal Medicine Unit; Department of Paediatrics) and Evelina/King's Spina Bifida clinic and (ii) Consultant Neuroradiologist, The Portland Hospital; Hon Senior Lecturer,UCL Great Ormond Street Institute of Child Health; Member of NHS England Spina Bifida Specification Working Group. **Birmingham Women's & Children's Hospital NHS Foundation Trust – joint clinician response.** **North Bristol NHS Trust** **British Academy of Childhood Disability** **British Maternal Fetal Medicine Society** **British Paediatric Neonatal Association.** **Children's Hospitals Network, Oxford University and Southampton University Hospitals.** **Leeds Teaching Hospitals Trust** **University Hospitals Plymouth NHS Trust**
Explain reason if there is any difference from previous question	Some consultees did not response to the consultation invite. The British Association of Paediatric Medicine asked for permission to share the draft specification with its members and followers via Twitter – but it was noted that this is more appropriate at public consultation stage as the range of comments could be from a wider group than members of the organisation.
Identify any particular stakeholder organisations that may be key to the policy development that you have approached that have yet to be engaged.	Not applicable (N/A)

Indicate why?	
How have stakeholders been involved? What engagement methods have been used?	SHINE have been represented on the Specification Working Group which has involved 1:1 and group teleconferences and emails of draft documents for comment over a period of months. In addition there are representatives from the Paediatric Neurosciences CRG and Specialised Women's CRGs on the Specification working Group and members of the CRG have commented on the document on two occasions.
What has happened or changed as a result of their input?	Comments were collated into a draft report, circulated to and considered by the members of the NHS England Paediatric Neurosciences Spina Bifida Specification Working Group 'the SWG', including NHS England commissioners. A number of additions and changes have been made to the specification as part of an iterative development process.
How are stakeholders being kept informed of progress with policy development as a result of their input?	Outcomes will be shared with all as part of the public consultation.
What level of wider public consultation is recommended by the CRG for the NPOC Board to agree as a result of stakeholder involvement?	Half of the stakeholders considered 6 weeks to be appropriate and half 12 weeks. However, given the wide scope of comments already received, the Women and Children Programme of Care may wish to consider a different timescale and the likelihood of additional questions from other stakeholders which have not yet been pout forward.
See Stakeholder feedback and SWG comments in Appendix One below.	

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Appendix One: Stakeholder/CRG Feedback

1.1 Question 0:	It is proposed that highly specialised products will go for a period of public consultation. Please select the consultation level that you consider to be most appropriate.		
Organisation Responding	Feedback Received	**PWG response**	**Resulting Action**
1. Olawande Igo, Non Profit Professional.	1 - changes that could reasonably be expected to be broadly supported by stakeholders - up to 6 week consultation - Both 2 - up to 12 weeks consultation to include some additional proactive engagement activities during the live consultation period - Both	Noted	n/a
2. Prof CR Welch, university Hospitals Plymouth NHS Trust.	1 - changes that could reasonably be expected to be broadly supported by stakeholders - up to 6 week consultation	Noted	n/a
3. Alec McEwan, Fetal Medicine Lead, Consultant Obstetrician and subspecialist in Fetal Medicine, Nottingham University Hospital NHS Trust. (responding as an	No response	n/a	n/a

individual clinician).			
4. Dr Kling Chong, Consultant Neuroradiologist, The Portland Hospital; Hon Senior Lecturer, UCL Great Ormond Street Institute of Child Health; Member of NHS England Spina Bifida Specification Working Group.	No response	n/a	n/a
5. Prof. Dr Med Axel Heap, Consultant Neonatologist, North Bristol NHS Trust.	No response	Noted	n/a
6. Lesley Briggs NHS England Specialised Women's Services CRG.	2 - up to 12 weeks consultation to include some additional proactive engagement activities during the live consultation period	Noted	n/a
7. Alison Sims, Children's Hospitals Network, Oxford University and Southampton	No response	n/a	n/a

University Hospitals.			
8. Mr Guirish A Solanki (representative of Paediatric Neurosurgery) and Professor Mark Kilby (Clinical lead of Fetal Medicine), Birmingham Women's & Children's Hospital NHS Foundation Trust.	1 - changes that could reasonably be expected to be broadly supported by stakeholders - up to 6 week consultation	Noted	n/a
9. Dr Thomas Everett, Dept of Fetal Medicine, Leeds Teaching Hospitals NHS Trust – replying as an individual clinician.	1 - changes that could reasonably be expected to be broadly supported by stakeholders - up to 6 week consultation	Noted	n/a
10. Dr Cath Harrison, Leeds Teaching Hospitals NHS Trust – replying as an individual clinician.	No response	n/a	n/a
11. Paul Chumas, Consultant	2 - up to 12 weeks consultation to include some additional proactive engagement activities during the	Noted	n/a

Neurosurgeon, Leeds Teaching Hospitals NHS Trust.	live consultation period		
12. Bas Zebian, King's College Hospital (Neurosurgery Department; Fetal Medicine Unit; Department of Paediatrics) and Evelina/King's Spina Bifida clinic, Member of NHS England Spina Bifida Specification Working Group.	2 - Up to 12 weeks consultation to include some additional proactive engagement activities during the live consultation period	Noted	n/a
13. David Howe, Consultant in FetoMaternal Medicine University Hospitals Southampton; Member of the Specialised Women's Services CRG.	No response	n/a	n/a

14. Dr Jill Cadwagan, British Academy of Childhood Disability.	2 - up to 12 weeks consultation to include some additional proactive engagement activities during the live consultation period	Noted	n/a
15. Dr Nanda Surabhi, Dr Andrew Breeze - British Maternal and Fetal Medicine Society (BMFMS).	1 - changes that could reasonably be expected to be broadly supported by stakeholders - up to 6 week consultation	Noted	n/a

1.2 Question 1:	To what extent do you consider that the model of care set out in the specification is appropriate?		
Organisation Responding	**Feedback Received**	**PWG response**	**Resulting Action**
1. Olawande Igo Non Profit Professional.	Neonatal Care Units that specialize in intensive care of newborns & Infants' [should be involved where there are complications].	The SWG noted this point and noted that the specification stipulates that neonatal care should occur in a NICU - NICUs are Level 3 regional units. This has been clarified in the service specification.	Additional wording added into specification post-operative pathway map.
2. Prof CR Welch University Hospitals Plymouth NHS Trust.	In many cases the fetal medicine experience at a Fetal Medicine unit is such that referral to a regional centre (RFMU) would be unnecessary, counterproductive. It could delay and confuse patients who have already been fully counselled. For example patients from our centre get more experienced and rapid counselling	The SWG noted this point and noted that there may be some differences in expertise in local and regional services. The purpose of this specification is to determine what will take	Additional wording added to specification.

	(including paediatric neurosurgery) than they could get at our RFMU. “Relevant RFMU” should be replaced with “referring Fetal Medicine Centre”.	place within a Fetal Surgery Centre and in the local/regional units prior to a referral being made. The SWG agreed that women must receive counselling prior to referral to the FSC and be seen by the local/regional paediatric neurosurgeon as appropriate. Wording to be added to the specification to explain – see Section 7.	
	Equally the shared care should be with the referring unit who may have much more experience than the RFMU. In our cases all post-surgical prenatal care and deliveries have been managed at our own unit, in collaboration with the FSC and we would not support that being moved to unit with less experience. In the future and as RFMUs gain experience and insight and as staff change at other units this axis may change.	The SWG agreed that additional wording to be added to the specification Section 1.1, paragraph 1 – the word ‘local’ inserted before Regional Fetal Medicine Units, so reads: ‘The service will be delivered in a shared care pathway together with existing local units/Regional Fetal Medicine Units’.	No further action required.
	It is important to recognise that there are individuals/units around the UK who have been involved in this project for many years internationally and have experience that most RFMUs do not have. This may change as the service matures in the future.	This was noted by the SWG.	No action required.

	Perhaps “grandfather” status needs to be recognised in the early days. These comments apply equally to the flow pathways.	This was noted by the SWG which wishes to provide assurance that those local units which have particular expertise to provide pre- and post-natal services will still do so in conjunction with communications with RFMU’s so that there is a complete communication chain on individual patients and to avoid any issues which may result from a lack of communication. Additional wording to this effect added to RFMU description.	No further action required.
	It is also very important to consider the patient’s postcode, because out of London, their home base may be >100 miles from the RFMU which creates great difficulty for their family support. Prof Deprest’s model and practice over the years his Leuven service has been operating, was to share care with their base unit if the unit had relevant expertise and the willingness to provide the care. It also may facilitate quicker discharge from the FSC, avoiding pressure on beds. The FSC programme described mirrors the service we are used to at Leuven and from the MoMs study so does not require comment.	This was noted by the SWG.	No further action required.

3. Alec McEwan Fetal Medicine lead for Nottingham University Hospitals NHS Trust- responding as an individual clinician.	No response	n/a	No action required.
4. Dr Kling Chong, Consultant Neuroradiologist, The Portland Hospital; Hon Senior Lecturer, UCL Great Ormond Street Institute of Child Health; member of NHS England Spina Bifida Specification Working Group.	No response	n/a	No action required.
5. Prof. Dr Med Axel Heap, Consultant Neonatologist, North Bristol NHS Trust.	No response	n/a	No action required.
6. Lesley Briggs NHS England	Extremely appropriate	The SWG noted this comment.	No action is required.

Specialised Women's Services CRG.			
7. Alison Sims, Children's Hospitals Network, Oxford University and Southampton University Hospitals.	No response	n/a	No action required.
8. Mr Guirish A Solanki (representative of Paediatric Neurosurgery) and Professor Mark Kilby (Clinical lead of Fetal Medicine), Birmingham Women's and Children's Foundation Trust.	Appropriate. The potential role of in-utero surgery for the repair of meningomyelocele has several fetal advantages mainly outlined in the results of the MOMS RCT (N Engl J Med. 2011;364(11):993-1004). This outlined that fetuses with in-utero repair have: □ Lower rates of ventriculoperitoneal shunt placement (potentially leading to lower rates of neurodevelopmental morbidity [40% vs 82%]). □ Improved composite score for mental development and motor function at 30 months (P=0.007) and in improvement in several secondary outcomes, including hindbrain herniation by 12 months and ambulation by 30 months. □ However, this must be 'balanced against' the risks of open surgery by performing a maternal laparotomy and hysterotomy. Such an open operation leads to maternal risks of general anaesthesia, infection, thromboembolic disease and secondary obstetric complications. These obstetric complications include: □ A hysterotomy scars the uterus and leads to	The SWG noted these comments. No action required. The SWG noted these comments and agreed that more information on the risks should be added into the specification. Added into Appendix 3: Example of FSC Patient Information Leaflet for England.	No action required Additional risks added as noted. No further action required.

	potential weakness in future pregnancies with the increased risk of uterine scar rupture, morbidity adherent placenta and repeat caesarean delivery. In the index pregnancy, there are increased risks of prelabour premature ruptured membranes [PPROM](with increased risks of preterm birth). This complication increases the risks of potentially morbid chorioamnionitis and hysterotomy scar weakness, dehiscence and rupture. These are maternal risks which theoretically and practically increase maternal risks of mortality and morbidity in any pregnancy. The 'commissioning brief' focuses upon open fetal surgery (as it is stated that the rates of PPROM are lower. However, over the last 1-3 years, there have been major advances in 'fetoscopic repairs' which have significantly lower risks of maternal morbidities (Obstet Gynecol. 2017;129(4):734-743). These therefore should be considered in the commissioning brief as promising therapies.	The SWG noted this comment and will review the case for fetoscopic repair separately.	No action required at this time.
9. Dr Thomas Everett, Dept of Fetal Medicine, Leeds Teaching Hospitals NHS Trust – replying as an individual clinician.	The model of care set out in this specification is highly detailed and appropriate to the care needed to this highly specialised service. As relatively novel procedure that will be performed of very few fetuses yearly the level of detail and the ability of a providing FSC and RFMU to adhere to these is necessary.	The SWG noted this comment. No action required.	No action required.
10. Dr Cath Harrison, Leeds Teaching Hospitals NHS	Very appropriate	The SWG noted this comment. No action required.	No action required.

Trust – replying as an individual clinician.			
11. Paul Chumas, Consultant Neurosurgeon, Leeds Teaching Hospitals NHS Trust.	Agree with need for 2 services	The SWG noted this comment. No action required.	No action required.
12. Bas Zebian, King's College Hospital (Neurosurgery Department; Fetal Medicine Unit; Department of Paediatrics) and Evelina/King's Spina Bifida clinic, Member of NHS England Spina Bifida Specification Working Group	We agree with the model of care on the whole, however, we believe that the statement regarding insufficient evidence for fetoscopic closure should be revisited in light of recent publications as well as discussions at fetal medicine meetings. It is undeniable that the risks to the mother are significantly less with fetoscopic repair and increasingly clear that the outcomes for the fetus are now almost equivalent to those with the open repair.	The SWG noted this comment. See note above re approach for consideration of evidence base for fetoscopic repair.	No action required at this time.
13. David Howe, Consultant in FetoMaternal Medicine University Hospitals Southampton Member of the	Open fetal surgery is being increasingly requested by parents after an antenatal diagnosis of spina bifida and it should be possible for them to have this treatment in the UK rather than having to travel abroad. There are likely to be only a small number of procedures carried out each year, so it is appropriate that the number of centres providing this treatment should be limited to one or two.	The SWG noted this comment. No further action is required.	No action required.

Specialised Women's Services CRG.			
14. Dr Jill Cadwagan, British Academy of Childhood Disability.	The main point to consider is variation of input from neurology and neurodisability to the existing children with Spina Bifida. Some regions offer MDT comprehensive service, some do not. This model of care shouldn't presume that all centres have on-going input form neurology and neurodisability as MDT service. Model of care is fully adequate.	The SWG noted this point, noting that the pathway for neurology and neurodisability will be via current local and regional paediatric neurosurgical spina bifida clinics as now. It was agreed to include the note in the service specification that there should be referrals made for patients to access any local neurology and neurodisability services as required. Added to specification Section 2.2. The SWG agreed to add the proposed additional questions to specification, Appendix 3: Example FSC Patient Information Leaflet for England: - General developmental impact - How long will my child need to stay in hospital after birth - - What is NICU and will my child have to stay in NICU - What follow up will my child	Added to specification as indicated. No further action required.

		have to have after birth and during the first years of his/her life	
15. Dr Nanda Surabhi, Dr Andrew Breeze, British Maternal and Fetal Medicine Society (BMFMS).	The model of care set out in the specification is based on current practice in leading international fetal surgery centres as is shown in this recent global survey: https://ispdhome.org/ISPD/SIGs/Fetal_Therapy_Map.aspx The care pathway is representative of how referrals in FCS currently work and appears to be appropriate for the UK.	The SWG noted this comment. No action required.	No action required.

1.3 Question 2:	Do the questions that have been indicated for the patient information leaflet [for England] in Appendix 3 [was 2] cover all necessary information areas for a woman to decide on prenatal surgery?		
Organisation Responding	**Feedback Received**	**PWG response**	**Resulting Action**
1. Olawande Igo, Non Profit Professional.	Yes	The SWG noted this comment. No action required.	No action required.
2. Prof CR Welch, University Hospitals Plymouth NHS Trust.	Yes, probably. I assume Fetal Surgery will still only be offered once the patient has decided to continue the pregnancy, as currently internationally recommended, rather than offering it as one of three options (TOP/fetal surgery/conventional postnatal care) at diagnosis. Some mothers.	The SWG noted this point. SHINE the patient charity noted that it is appropriate to mention fetal surgery as part of the options discussions, on condition that (1) it is completely clear that it is only a possibility depending	Actioned. No further action required.

		on meeting the criteria etc. and (2) that potential negative outcomes are articulated at that point (e.g. there may be no improvement in the child's condition, or even other complications resulting in other severe impairment. The SWG added additional wording into the specification Appendix 3- Example FSC Patient Information leaflet fpr England in the specification.	
3. Alec McEwan Fetal Medicine lead for Nottingham University Hospitals NHS Trust- responding as an individual clinician.	No response	n/a	No action required.
4. Dr Kling Chong, Consultant Neuroradiologist, The Portland Hospital; Hon Senior Lecturer, UCL Great	No response	n/a	No action required.

Ormond Street Institute of Child Health; Member of NHS England Spina Bifida Specification Working Group.			
5. Prof. Dr Med Axel Heap, Consultant Neonatologist, North Bristol NHS Trust.	No response.	n/a	No action required.
6. Lesley Briggs Public and Patient Voice Member, NHS England Specialised Women's Services CRG.	I personally feel that the questions indicated are excellent – and cover major concerns. If the woman and her partner were to see this, it would show the common questions which are asked in relation to the surgery, but more importantly these questions could well be a prompt for the couple to raise other concerns they have. Also, importantly, with the patient information leaflet being within the specification it ensures that the advice / information being given to the patient and her partner / carer is up to date, accurate and consistent throughout the centres. I am on the Specialist Women's CRG and have never thought of this aspect being included within the specification but seeing it in practice here it makes complete sense and I see it as the way forward! Ultimately, this would ensure that the patient and her partner are well informed and have information to hand which they will be able to look back through – and, as suggested, contact the centre if any other concerns /	The SWG noted this comment. No action required.	No action required.

	worries arise following the consultation(s).		
7. Alison Sims, Children's Hospitals Network, Oxford University and Southampton University Hospitals.	No response	n/a	No action required.
8. Mr Guirish A Solanki (representative of Paediatric Neurosurgery) and Professor Mark Kilby (Clinical lead of Fetal Medicine), Birmingham Women's and Children's Foundation Trust.	Largely. However it would be helpful for the mother to have some of the items detailed as subquestions feature as separate items. These should include: i. "What are the risks of fetal surgery?": outlining clear maternal and fetal risks. ii. Potential complications of "open fetal surgery" to the fetus and the risks of a premature birth and sepsis. iii. Implications of open fetal surgery for current pregnancy (especially in terms of hysterotomy scar on the uterus, amniotic fluid leak/premature prelabour ruptured membranes and sepsis. Also, the need and risks of uterine rupture and the need for caesarean section delivery. Also, the risks of caesarean section in future pregnancies and the risks of uterine rupture and morbidly adherent placentation. iv. Relative contraindications and the risks arising out of maternal co-morbidities (some of which may be a contraindication for fetal surgery and be in the exclusion criteria)any preceding history of MRSA infections or concurrent existing maternal infections such as MRSA will require treatment prior to surgery A further question could be added: (to underline maternal exclusion criteria) Can any mother with a child diagnosed with spinal bifida	The SWG noted that this point has been addressed via response above point and note that these have been added into the specification, Appendix 3, Example FSC Patient Information Leaflet for England. This question was added to the specification, Appendix	No further action required. No further action required.

	undergo fetal surgery safely? There should also be consideration as to maternal and family emotional and psychological resilience to undergo such challenging therapy with un-certain outcomes for the mother and the baby. Mothers who have the following conditions are at a higher risk and surgery is not recommended □ Insulin-dependent diabetes, gestational diabetes, □ Hypertension or preeclampsia □ Maternal infections with risks of vertical transmission (HIV, hepatitis-B, or hepatitis-C positive). □ Blood related conditions (maternal alloimmunization problem, fetal Rh isoimmunisation, Kell sensitization, neonatal alloimmune thrombocytopenia). □ Body mass index of 35 or more. □ Other medical condition of risk to mother including uterine diseases (previous caesarean maternal fibroids and congenital malformations of the uterus (i.e. didelphis, bicornuate, arcuate, etc.). □ A significant risk of preterm birth including a short cervix <25mm on TV ultrasound □ Presence of cerclage. It would be useful to consider detailing other reasons when surgery is not recommended: □ Multiple gestation pregnancy □ Significant high risk of preterm birth □ Multiple (>1) fetal anomalies that would contra-indicate surgery. □ Abnormal chromosomes [whole and submicroscopic	3: Example FSC Patient Information Leaflet for England. The SWG noted that these points were considered at length as part of the development of the criteria for the specification. No further action required.	No further action required.

	rearrangements](by QF-PCR and chromosomal microarray analysis). o These should be excluded prospectively by amniocentesis (risk of miscarriage of 0.5%). □ Up to what gestational week can the women have fetal surgery (<28 weeks). □ Multiple previous caesarean sections.		
9. Dr Thomas Everett, Dept of Fetal Medicine, Leeds Teaching Hospitals NHS Trust – replying as an individual clinician.	The questions asked are comprehensive. For completion, it may be worth asking and answering the questions: "What will happen if I opt to continue the pregnancy without having fetal surgery?" post-natal would then be offered	The SWG noted this point and added an additional question into specification, Appendix 3: Example FSC Patient Information Leaflet for England.	As set out. No further action required.
10. Dr Cath Harrison, Leeds Teaching Hospitals NHS Trust – replying as an individual clinician.	Yes	The SWG noted this comment. No action required.	No action required.
11. Paul Chumas, Consultant Neurosurgeon, Leeds Teaching Hospitals NHS Trust.	Yes	The SWG noted this comment. No action required.	No action required.
12. Bas Zebian, King's College Hospital (Neurosurgery	Yes	The SWG noted this comment. No action required.	No action required.

Department; Fetal Medicine Unit; Department of Paediatrics) and Evelina/King's Spina Bifida clinic, Member of NHS England Spina Bifida Specification Working Group.			
13. David Howe, Consultant in FetoMaternal Medicine University Hospitals Southampton Member of the Specialised Women's Services CRG.	The information provided in Appendix 2 is helpful. However, the language used needs considerable simplification to make it comprehensible for many parents. For instance there is reference to "ventriculomegaly" with no explanation of what this means. There needs to be more detail about the risks of uterine surgery, both on the current pregnancy with an estimate of the likelihood of severely premature delivery within a few weeks of surgery, and the long term effects on future pregnancies. At present the document does not provide enough discussion about the significant risks associated with such surgery both immediately and in the future.	The SWG noted that the wording in the specification including Appendix 3: Example FSC Patient Information Leaflet for England has been reviewed by a multi-disciplinary team and the SHINE charity. Description of ventriculomegaly reviewed. No Further changes required. This point has also been addressed elsewhere in the document. No further action required.	No further action required.

14. Dr Jill Cadwagan, British Academy of Childhood Disability.	Mostly.	The SWG noted this comment. No action required.	No action required.
15. Dr Nanda Surabhi, Dr Andrew Breeze, British Maternal and Fetal Medicine Society (BMFMS).	Yes	The SWG noted this comment. No action required.	No action required.

1.4 Question 3:	**Do you feel that the appropriate level of liaison for Fetal Surgery Centres to have with their referring Regional Fetal Medicine Units and regional neurosurgery units as part of the shared model of care has been described/included?**		
Organisation Responding	**Feedback Received**	**PWG response**	**Resulting Action**
1. Olawande Igo, Non Profit Professional.	YES- via MDT's	The SWG noted this comment. No action required.	No action required.
2. Prof CR Welch, university Hospitals Plymouth NHS Trust.	No, see comments in section [question] 1	The SWG noted this comment. Response given for previous comments applies.	No further action required.
3. Alec McEwan	No response	n/a	No action required.

Fetal Medicine lead for Nottingham University Hospitals NHS Trust- responding as an individual.			
4. Dr Kling Chong, Consultant Neuroradiologist, The Portland Hospital; Hon Senior Lecturer, UCL Great Ormond Street Institute of Child Health; member of NHS England Spina Bifida Specification Working Group.	No response	n/a	No action required.
5. Prof. Dr Med Axel Heap, Consultant Neonatologist, North Bristol NHS Trust.	No response	n/a	No action required.
6. Lesley Briggs Patient and Public Voice Member, NHS England Specialised Women's Services CRG	Yes	The SWG noted this comment. No action required.	No action required.

7. Alison Sims, Children's Hospitals Network, Oxford University and Southampton University Hospitals.	No response	n/a	No action required.
8. Mr Guirish A Solanki (representative of Paediatric Neurosurgery) and Professor Mark Kilby (Clinical lead of Fetal Medicine), Birmingham Women's and Children's Foundation Trust.	YES. This is essential. It is also essential that there is a local (regional) multidisciplinary hub and spoke referral system. There are 17 tertiary fetal medicine centres in the UK that provide tertiary care and advanced specialist fetal medicine / therapy. These fetal medicine centres, in close collaboration with local neonatal paediatric, neurological and neurosurgical centres should be involved in assessment and counselling prior to referral to the centre potentially performing / offering the fetal surgery itself. We are exploring the possibility of offering this service at Birmingham Women's & Children's Foundation Trust.	The SWG noted this point and noted that current local and regional arrangements for pre and post-operative care will continue to apply. No action required.	No further action required.
9. Dr Thomas Everett, Dept of Fetal Medicine, Leeds Teaching Hospitals NHS Trust – replying as an individual clinician.	Yes	The SWG noted this comment. No action required.	No action required.
10. Dr Cath Harrison, Leeds Teaching Hospitals NHS Trust – replying as an	Yes	The SWG noted this comment. No action required.	No action required.

individual clinician.			
11. Paul Chumas, Consultant Neurosurgeon, Leeds Teaching Hospitals NHS Trust.	Yes	The SWG noted this comment. No action required.	No action required.
12. Bas Zebian, King's College Hospital (Neurosurgery Department; Fetal Medicine Unit; Department of Paediatrics) and Evelina/King's Spina Bifida clinic, Member of NHS England Spina Bifida Specification Working Group.	Yes	The SWG noted this comment. No action required.	No action required.
13. David Howe, Consultant in FetoMaternal Medicine University Hospitals Southampton Member of the Specialised Women's Services CRG.	Yes	The SWG noted this comment. No action required.	No action required.
14. Dr Jill	Yes	The SWG noted this	No action required.

Cadwagan, British Academy of Childhood Disability.		comment. No action required.	
15. Dr Nanda Surabhi, Dr Andrew Breeze, British Maternal and Fetal Medicine Society (BMFMS).	Yes	The SWG noted this comment. No action required.	No action required.

1.5 Question 4:	Do you have any further comments on the proposed document? Yes/No		
Organisation Responding	**Feedback Received**	**PWG response**	**Resulting Action**
1. Olawande Igo, Non Profit Professional.	No	n/a	n/a
2. Prof CR Welch, University Hospitals Plymouth NHS Trust.	No	n/a	n/a
2. Alec McEwan Fetal Medicine	Yes	n/a	n/a

lead for Nottingham University Hospitals NHS Trust- responding as an individual clinician.			
4. Dr Kling Chong, Consultant Neuroradiologist, The Portland Hospital; Hon Senior Lecturer, UCL Great Ormond Street Institute of Child Health; Member of NHS England Spina Bifida Specification Working Group.	No response	n/a	n/a
5. Prof. Dr Med Axel Heap, Consultant Neonatologist, North Bristol NHS Trust.	No response	n/a	n/a
6. Lesley Briggs Public and Patient Voice Member, NHS England Specialised	Yes	n/a	n/a

Women's Services CRG.			
7. Alison Sims, Children's Hospitals Network, Oxford University and Southampton University Hospitals.	Yes	n/a	n/a
8. Mr Guirish A Solanki (representative of Paediatric Neurosurgery) and Professor Mark Kilby (Clinical lead of Fetal Medicine), Birmingham Women's and Children's Foundation Trust.	Yes	n/a	n/a
9. Dr Thomas Everett, Dept of Fetal Medicine, Leeds Teaching Hospitals NHS Trust – replying as an individual clinician.	Yes	n/a	n/a
10. Dr Cath Harrison, Leeds Teaching	Yes	n/a	n/a

Hospitals NHS Trust – replying as an individual clinician.			
11. Paul Chumas, Consultant Neurosurgeon, Leeds Teaching Hospital NHS Trust.	No	n/a	n/a
12. Bas Zebian, King's College Hospital (Neurosurgery Department; Fetal Medicine Unit; Department of Paediatrics) and Evelina/King's Spina Bifida clinic, member of NHS England Spina Bifida Specification Working Group.	Yes	n/a	n/a
13. David Howe, Consultant in FetoMaternal Medicine University Hospitals Southampton	Yes	n/a	n/a

Member of the Specialised Women's Services CRG.			
14. Dr Jill Cadwagan, British Academy of Childhood Disability.	Yes	n/a	n/a
15. Dr Nanda Surabhi, Dr Andrew Breeze, British Maternal and Fetal Medicine Society (BMFMS).	Yes	n/a	n/a

1.6 Question 5:	If your answer to question 4 is 'Yes', please describe below, in no more than 500 words, any further comments on the proposed changes to the document as part of this initial 'sense check'.		
Organisation Responding	**Feedback Received**	**PWG response**	**Resulting Action**
1. Olawande Igo, Non Profit Professional.	N/A	n/a	No action required.
2. Prof CR Welch, University	N/A	n/a	No action required.

Hospitals Plymouth NHS Trust.			
3. Alec McEwan Fetal Medicine lead for Nottingham University Hospitals NHS Trust- responding as an individual clinician.	The results of the MOMS trial are compelling, and have much international support. The reported reduction in the need for shunting/bypass procedures seems highly significant. The data suggesting a functional improvement is, in my opinion, not quite so strong, but is nevertheless significant. The potential for obstetric complications (eg prematurity) and maternal harm (in this pregnancy or a subsequent one) is also real. The need for a vertical incision on the uterus is not without major potential ramifications for the future. I have concerns that even with very good quality, objective and non-biased counselling prenatally, women will focus on this current baby, and the need to do the best for that baby, without weighing up adequately the potential risk for future pregnancies. Are we certain enough as yet about the gains from prenatal surgery to expose women and their future pregnancies to increased risk? Comparing these risks against one another is almost impossible to do, however I am very wary of paternalism. I just feel that truly informed consent in this situation is so difficult; it is all so highly emotive. My experience is that many of the couples choosing to continue pregnancies with a fetus with spina bifida are young and likely to go on and have more children. This procedure will commit the woman to birth by CS every time in all subsequent pregnancies with the increased risk of placenta praevia, abnormal placenta invasion, hysterectomy, uterine rupture and visceral surgical injury. None of these	The SWG noted this point. The SWG considered the points and agreed that the patient should be adequately counselled including being made aware of the risks as well as benefits. See additional wording added to specification, Appendix 3, Example FSC Patient Information Leaflet for England.	No action required. Included as noted. No further action required.

	outcomes are measurable from the MOMS trial. It will be years before we see what price we (actually the women) have paid for the chance of an improved outcome for their child with a neural tube defect. Remember, currently, most fetuses with a neural tube defect are born vaginally, or by lower segment caesarean section if there are obstetric indications. If the evolving data on shunting is to be believed, then this prenatal procedure could lead to a very significant reduction in the need for this procedure. This will have impact on the paediatric neurosurgical workload, but I am not in a position to say by how much. I can say though that this procedure will increase obstetric costs in the affected pregnancy. Who will pay for the procedure; will it come out of the totally inadequate maternity tariff? I would hope there would be specialist commissioning for this. But the costs of caring for a woman with ruptured membranes following the procedure, or for her care if she has a complication such as abruption, will fall on obstetrics. Those fetuses born prematurely, because of complications of the procedure, will be cared for locally, I presume, at massive expense. Most babies with neural tube defects are born vaginally at term. This could alter that distribution significantly. I know that GOSH/UCH are now offering this service, funded by charitable monies. How many centres do we really need doing this in the UK? Complications rates will be lower and outcomes better if it is restricted to centres that do more than a threshold number. It remains to be seen if the GOSH team will cope with demand. I will be	The SWG confirmed that the cost of deliveries is outside the scope of this specification and will be covered as noted, by the maternity tariff. Noted. Noted. The SWG noted this point.	No action required. No action required. No action required. No action required.

	raising it with all my patients, when I see them. We may be deemed 'negligent' if we don't. I suspect the uptake will be quite high. I am not totally up to date with the data. However, I would argue that we restrict ourselves to just one centre in the UK at the moment and that we wait for both obstetric and neurosurgical outcomes, outside of the trial, before 'rolling this out'. Just because we can, doesn't mean that we should.	The commissioning plan for the service notes up to two centres, subject to expertise etcetera.	
4. Dr Kling Chong, Consultant Neuroradiologist, The Portland Hospital; Hon Senior Lecturer, UCL Great Ormond Street Institute of Child Health; Member of NHS England Spina Bifida Specification Working Group.	1. Page 3 – Inclusion and Exclusion criteria Is it case that *all* inclusion criteria need to be satisfied and *none* of the exclusion criteria for cases to proceed or might there be a situation where a balanced judgement could be reached by an MDT for those where the criteria are not suitably satisfied?	The SWG noted this point and added into the specification, Section 2.1 that the FSC's MDT will 'take into account the individual circumstances for each woman and her fetus'.	No further action required.
	2. Page 10 – FSC assessment – Fetal MRI – items 3 and 4; 'exclude anomalies' Although not explicitly stated, the Fetal MRI should include dedicated imaging of the brain and whole spine which is the part that requires a Neuroradiologist (or a Paediatric Radiologist) comfortable with knowledge & skills of the developing brain and the early diagnosis of brain anomalies. 'Fetal MRI' is a generic description and there may be other anomalies which are outside of the skill set of a Neuroradiologist.	Noted. Amendment made. Noted. Amendment made to specification Section 2.1.	No further action required No further action required.
	Page 20 – The figure is that of an adult fully developed spine. A picture of a fetal (or even neonatal) spine may be	The SWG noted that there is no neurological or functional	No action required.

	more appropriate?	difference between the adult and neonatal spine and the current picture will suffice.	
	Page 21 – what 'causes' spine bifida – dietary folate. Just wondering if describing it as an association rather than 'responsible' might be better for the mother to read at this stage.	Noted. Amendment made.	No further action required.
	5. A minor point on semantics – 'Arnold-Chiari malformation' is the same as 'Chiari II malformation'. Strictly speaking there is no 'Arnold-Chiari II malformation' as Arnold did not contribute to the describing of any of the other hindbrain malformations. Because of the general confusion on this subject, I am a supporter of the consensus view to use 'Chari II malformation', as it is often the use of 'Arnold' in the name that creates the confusion.	Noted. Amendment made.	No further action required.
5. Prof. Dr Med Axel Heap, Consultant Neonatologist, North Bristol NHS Trust.	The suggested pathway and underlying evidence is well presented, however unfortunately neglects an important alternative approach, which is fetoscopic treatment of open spina bifida, established , conducted and published on by the German Centre for Fetal Medicine (Prof. Thomas Kohl et al.). The complexity of fetal management has been presented in the Shine supported meeting on fetal treatment of spina bifida in Belfast (publication attached). The endoscopic keyhole strategy was discussed along with the open strategy. In view of maternal morbidity it is evident, that an open approach (hysterotomy + uterotomy) implies a higher morbidity and risk compared	The SWG noted these points and noted that this issue has been addressed elsewhere in this document. No further action required at this time.	No further action required at this time.

	to “keyhole surgery”. Yes I am biased, because I have been involved in developing the less invasive strategy and neonatal management / follow up around it in Germany. Nevertheless I feel that I might need to strongly express my concerns. In view of there is absence of a controlled randomized study comparing both methods, it appears slightly oversimplifying to consider “open fetal surgery” to be the one and only and safe way. Four weeks ago, we have had a patient with fetal diagnosis of SBA in [location removed by commissioner to protect identity of patient], who got informed by both [unit names removed] about the fetal treatment options and decided to go for endoscopic treatment to [name of country removed] in view of potential less maternal morbidity and risk. She follows a number of patients from Northern Ireland. I would like to suggest that least information on both methods should be available to compare the methods and give women a choice within “Europe”. Otherwise I think it is un fair to not mention a less invasive strategy in a situation which implies potential maternal morbidity in a pregnancy which otherwise (without fetal intervention) would run normally. I attach 2 articles on neurodevelopmental follow up and maternal morbidity following fetoscopic treatment.		

	 Degenhardt_et_al-2014-Ultrasound_in_Obs  Verbeek RJ et al DMCN SBA paper 2011  SHINE article Ong S et al 2017.pdf		
6. Lesley Briggs Patient and Public Voice Member, NHS England Specialised Women's Services CRG, Patient and Public Voice representative.	Page 4 – 1. Pre-operative Pathway What sort of time frame are you talking about here - in Cohen et al (2014) a reflective period of 24 hours is recommended - is that long enough for the couple to discuss and think this through? Page 6 – 3. Post-operative pathway (inpatient) Day 1 and 2 – Close Observation Bay / High Dependency Unit	The SWG noted that the wording in the specification will be amended to say 'at least 24 hours'. Added this wording into specification, Table 1: Description of Patient Care Pathway Steps, Row J.	No further action required.
	…ductus arteriosus if using indometacin as tocolysis Should indometacin be INDOMETHACIN?	The SWG took advice and understands that the British National Formulary lists Indometacin as it is spelt in the specification. No change required.	No action required.
	Page 8 – 5. Postnatal Pathway I am extremely glad to see obtaining parental consent for photographs of the baby is highlighted here - as is it an extremely important, but often neglected aspect of medical care. Throughout my work as a patient representative I have always argued that consent for any photography / videos should be done separately and in addition to any other consent - well done!	The SWG noted this point. No action required.	No action required.
	Page 19 – References The first Werner et al (2012) reference needs deleting as	Noted. Amendment made.	No further action

	some details omitted. Metrics Extremely inclusive, covering all aspects of care. This is a well thought-out and developed service specification. It contains all the relevant information – and, crucially, guidance on patient information – to provide care for the patient, her partner and the fetus at what will be a considerably difficult and stressful time. The link to the Shine charity website is fantastic. As a whole, this all makes complete sense and I have no hesitation in offering my support for this to be agreed and put into action – well done!	Noted with thanks. No action required. Noted with thanks. No action required.	required. No action required.
7. Alison Sims, Children's Hospitals Network, Oxford University and Southampton University Hospitals.	From a neurosurgical perspective, at least. It looks complete. It would be advantageous to add that the follow up should be thorough/standardized and mandatory until at least the age of 18.	Noted. Additional wording added to specification Section 2.2 Interdependencies. No further action required.	No further action required.
8. Mr Guirish A Solanki (representative of Paediatric Neurosurgery) and Professor Mark Kilby (Clinical lead of Fetal Medicine),	Any centre that proposes to undertake such work should have a clearly defined multidisciplinary team within a tertiary hospital centre (women's and children's care) able to deliver care to the pregnant women and the unborn child. This should include: 1. Fetal Medicine subspecialists (accredited by the RCOG) and with a track record of providing fetal therapy. 2. Neonatal paediatricians.	The SWG noted these points and noted that they were considered in the development of the specification. No further action required.	No further action required.

Birmingham Women's and Children's Foundation Trust.	3. Paediatric neurologists. 4. Paediatric neurosurgeons. 5. Obstetric Anaesthetists. 6. Paediatric Anaesthetists (5 & 6) working closely as a single team. 7. Psychologists. The team should have access to both clinical and molecular genetics teams to exclude co-morbidities that would contraindicate such therapy. The team should be able to demonstrate the audit and follow up of other fetal therapies. An ongoing, externally validated audit of outcomes (including maternal and perinatal complications) should be centrally registered and audited at regular intervals. The use of LC CUSUM and CUSUM techniques to monitor prospective outcomes and team integrity is mandatory.	Genetics testing will be carried out at the RFMU not the FSC. No action required. The SWG noted this point. This will be part of usual audit processes.	No action required. No action required.
9. Dr Thomas Everett, Dept of Fetal Medicine, Leeds Teaching Hospitals NHS Trust – replying as an individual clinician.	-The term RFMU should be defined. - Post-op Pathway: "Day 1 and 2". Change to "Day 1-2" should be considered. It should be recognised that if the mother is well and stable, transfer to an antenatal ward may be preferable prior to completion of 2 full days on a COB/HDU, which can be active and noisy areas, with high throughput of other women. (This will also align better with Step K; point 5).	Noted. Added to RFMU description at Section 7. No further action required. Noted. Amendment made.	No further action required. Changes made. No further action required.

10. Dr Cath Harrison, Leeds Teaching Hospitals NHS Trust – replying as an individual clinician.	Vital that organisations potentially offering this service have seamless transition between all the specialities involved and must have the ability to carry out surgery at the same site as neonatal intensive care is provided. "True co-location" with all specialities involved being housed in same building must be present. Fetal surgery should be operated on in a unit which has NICU on site.	The SWG noted this point. Wording added to specification Section 2.2 Interdependencies/regional neurosurgery units. No further action required. Noted. Amendments made to specification Section 2.2/FSC infrastructure.	Changes made. No further action required.
11. Paul Chumas, Consultant Neurosurgeon, Leeds Teaching Hospitals NHS Trust.	n/a	n/a	n/a
12. Bas Zebian, King's College Hospital (Neurosurgery Department; Fetal Medicine Unit; Department of Paediatrics) and Evelina/King's Spina Bifida clinic, Member of NHS England Spina Bifida	Further to the answer to question 1 we have included a few points below: The MOMS trial did not report on rates of CSF leaks and the need for further postnatal repair after open fetal repair; it was, however, reported that infants in the prenatal surgery group underwent more procedures for delayed spinal cord tethering. Joyeux et al. (Fetal Diagn Ther 2016) performed a systematic review of outcomes of fetoscopic vs. open prenatal repair and found that perinatal mortality was not significantly different between the 2 groups. They also found that, in centres with larger experience, there was	The SWG noted all of these points and that they have been addressed elsewhere in this document. An approach has been proposed. No further action required at this time.	No further action required at this time.

Specification Working Group	no difference in the need for shunt placement, the need for further untethering of the spinal cord or treatment of Chiari 2. No maternal blood transfusion was required in the fetoscopic group and lower rates of chorioamniotic membrane separation were reported in addition to no uterine dehiscence. They did report higher rates of PROM and higher risk of further surgery postnatally. Although the mean age at birth was 32.9 with the fetoscopic vs. 34.1 with the open, this was a difference of around 1 week. They also highlighted that the reduced risks to the mother applied not just to the current pregnancy but subsequent ones as well. Kabagambe et al. (Fetal Diagn Ther 2018) performed a systematic review and meta-analysis more recently and also found no difference in fetal or perinatal mortality. They also reported no difference in the rates of reversal of hindbrain herniation, preterm birth or chorioamniotic membrane separation. There were no reports of uterine dehiscence with the fetoscopic group. PROM and need for further treatment were higher but they had not taken into account the difference between centres with less experience and those with more – Joyeux et al. had noted a difference between centres with different levels of experience. Kohn et al. (Obstet Gynecol 2018) reported that the fetoscopic technique may permit delivery at advanced gestational ages. Antiel et al. (J Perinatol 2017) surveyed 1200 neonatologists, paediatric surgeons and maternal fetal		

	medicine specialists to examine how they view the benefits and burdens of prenatal closure. Out of 670 respondents 94% would recommend prenatal fetoscopic over open or postnatal closure for a fetoscopic technique that had similar shunt rates but decreased maternal morbidity (both of those outcomes were demonstrated by the systematic reviews above). Furthermore, the topic of prenatal closure was discussed at the most recent British Paediatric Neurosurgery Group Meeting and the advantages of the minimally invasive approach of fetoscopic closure were certainly recognised. Similar discussions have taken place in recent fetal surgery meetings with recognition of these advantages and the promise that fetoscopic closure holds. It is our view with our combined experience and on reviewing the literature that fetoscopic repair should not be excluded from the current service specification. Surgically we have all seen minimally invasive techniques across many specialties initially being treated with scepticism only to become gold standard later. This has been the case with laparoscopic surgery and neuroendoscopic surgery and we can certainly see how this will be the case with fetal surgery for open neural tube defects. Any service specification should consider fetal surgery rather than only open fetal surgery. A smaller point we would like to make is the addition of a specialist in paediatric neuropathic bladders as well as physiotherapists to the multi-disciplinary follow-up of the children. There should also be provisions for following	These points were noted. Amendment made. No further action required.	No further action required.

	these patients up once they reach adulthood as data has always been lacking in that respect.		
13. David Howe, Consultant in FetoMaternal Medicine University Hospitals Southampton Member of the Specialised Women's Services CRG.	The document provides a useful template for the pathway of care but some aspects need further consideration: 1. Most fetal medicine centres now provide fetal MRI, but often this is limited to fetal neurosonography. This may not include local skills in assessing spina bifida, particularly the level of the lesion, and there is even less experience in many centres at assessing non-neurological fetal anomalies on MRI. In Section I), page 10, the document suggests that one role of the MRI is to exclude other anomalies. As discussed above this may not be possible in many RFMUs and many fetal anomalies are better diagnosed using ultrasound. If this is an objective of the MRI it may need to be carried out or repeated in the FSC. 2. The "Description of Pathway" is generally helpful but there is unnecessary and unhelpful detail in many parts and this should be reviewed and simplified. For instance specifying that the mother be fasted overnight and surgery take place in theatre, or that the fetal heart be monitored during surgery by a fetal medicine consultant (delete with expertise of fetal echocardiography is unnecessarily detailed). It is highly unlikely that anywhere would not carry out such surgery in theatre and local practise on fetal monitoring may vary without any consequence for safety. There may be other local variations in practice (e.g. time kept in hospital after surgery) that do not need specification in the document.	The SWG noted these comments, responses are as follows: 1) Specification Table 1: Description of Patient Care Pathway Steps item I) point 3 notes Fetal MRI undertaken at FSC if required. No action required. Noted. Amendments made. No further action required.	No action required. No further action required.
14. Dr Jill Cadwagan,	There is regional, local variation of services offered post-natally.	The SWG noted that the RFMU's already exist as per	No further action required.

British Academy of Childhood Disability.	Consideration should be given to who will be a Regional Fetal Maternity Unit (RFMU) and whether there is paediatric Neurology and Neurodisability resource to support the bid. Similar consideration should be given to National Fetal Surgery Centre (FSC) .In addition to medical resources, therapy resources should also be factored in.	the current provision model – no changes proposed to this and paediatric neurology and neurodisability resources are as current local provision. This scope of this specification is only to replace post-natal surgery for pre-natal surgery for some women and their fetuses. The point regarding neurological and neurorehabilitation needs is taken however and additional wording has been added to the specification to this effect. See specification Section 2.2. In addition the RFMUs and local units will be required to submit date to the FSC's as part of long term follow up to enable the outcomes for the baby/child of the pre-natal surgery to be evaluated.	No further action required.
	It appears that Pre-operative pathway indicates that Individual Patient Requests will lead to a referral to RFMU. Is this feasible?	Removed. No further action required.	No further action required.
	Easy access of RFMU and FSC to Clinical Ethics	The SWG noted that this will	

	Committee, especially in the preoperative pathway.	be as usual Trust processes for conflict resolution in that situation including view of Multidisciplinary team. No action required.	
	It would be beneficial if the arrangements for research and clinical governance are set up at the same time as the service is developed.	The SWG noted that the audit processes on the outcomes of the service and the clinical governance arrangements will be set up from the outset in the usual way. See new wording added to Specification Section 5.2. No further action required.	No further action required.
15. Dr Nanda Surabhi, Dr Andrew Breeze, British Maternal and Fetal Medicine Society (BMFMS).	We are responding on behalf of BMFMS Fetal Medicine Committee and incorporated responses from key subcommittee members for this response. Our comments are as follows		
	1. We think it is clear that based on the evidence that we have at present, that open fetal surgery should be offered. However, it is likely that we will need to consider fetoscopic repair when there is sufficient data. This will need to be incorporated in counselling, patient choice, and commissioning may be need to be considered for fetoscopic repair, when more evidence is available to support this.	The SWG noted these comments. This point is noted and has been addressed elsewhere in this document. No further action required at this time.	No action required.
	2. Karyotyping prior to the procedure, is an apt	The SWG noted this point	No further action

	recommendation, but may not be acceptable to all women. When women are committed to pregnancy, declining amniocentesis should not preclude them from the eligibility for fetal surgery.	and with clinical and patient representative colleagues have considered the point and noted that the genetic diagnosis is needed to rule out; syndromic congenital abnormality which would contraindicate surgery/is not compatible with life. No further action required.	required.
	3. Fetal MRI and reporting by a Paediatric / Fetal neuro-radiologist, especially commenting on additional intracranial findings (which may not be picked on USS) would be an ideal step, to be incorporated in counselling both at RFM and FCS levels.	The SWG agrees with the need for counselling on this matter. Added to staffing list at RFMU, is already in the MDT for FSC. No further action required.	No further action required.
	There should be explicit discussion whether these findings may or may not get better after surgery, and the impact that an abnormal MRI may have on neurodevelopment. Considering serial MRI as proposed in the document should be complemented by guidance on the next steps, if an MRI is abnormal, pre- or post-surgery.	The SWG noted this point. Wording added to specification, Appendix 3: Example of FSC Patient Information Leaflet for England/Risks of fetal surgery section.	No further action required.
	4. The strength of the proposed pathway is the multidisciplinary nature, accountability of each centre, at different stages of care, and shared care in the best interest of the woman and her unborn baby.	The SWG noted this point. No action required.	No action required.

	5. Ultimately having two centres would make sense, ensuring there are no gaps in the provision of service. However in the short term we should still offer fetal surgery if there is only one centre. Noted – subject to prov sel process	The SWG noted this point. The number of providers will be subject to the provider selection process if the proposed service is approved for commissioning. No action required.	No action required.

1.7 Question 6:	Please declare any conflict of interests relating to this document or service area.		
Organisation Responding	**Feedback Received**	**PWG response**	**Resulting Action**
1. Olawande Igo, Non Profit Professional.	No response	n/a	n/a
2. Prof CR Welch, university Hospitals Plymouth NHS Trust.	None	n/a	n/a
3. Alec McEwan Fetal Medicine lead for Nottingham University	No response	n/a	n/a

Hospitals NHS Trust- responding as an individual clinician.			
4. Dr Kling Chong, Consultant Neuroradiologist, The Portland Hospital; Hon Senior Lecturer, UCL Great Ormond Street Institute of Child Health; Member of NHS England Spina Bifida Specification Working Group.	Member of NHS England Spina Bifida Specification Working Group.	n/a	n/a
5. Prof. Dr Med Axel Heap, Consultant Neonatologist, North Bristol NHS Trust.	I have been involved in developing the less invasive strategy and neonatal management / follow up around it in Germany.	n/a	n/a
6. Lesley Briggs Patient and Public Voice Member, NHS England Specialised	No conflict of interests to declare	n/a	n/a

Women's Services CRG.			
7. Alison Sims, Children's Hospitals Network, Oxford University and Southampton University Hospitals.	N/A	n/a	n/a
8. Mr Guirish A Solanki (representative of Paediatric Neurosurgery) and Professor Mark Kilby (Clinical lead of Fetal Medicine), Birmingham Women's and Children's Foundation Trust.	Guirish A Solanki is an NHS consultant working at Birmingham Women's & Children's Hospital with a long-term interest in surgery for congenital spinal malformations, including dysraphism and spinal bifida. Mr Solanki has national and international academic and clinical collaborations with individuals and or organizations involved in supporting or treating spina bifida. Mr Solanki does not have shares or financial interests in any company or organisation involved in fetal surgery. He declares no known conflict of interest Mark Kilby is the Professor of Fetal Medicine at University of Birmingham and the Clinical lead of Fetal Medicine and Therapy at the Birmingham women's Hospital (within the Birmingham Women's & Children's Foundation Trust). As well as a internationally renowned clinical scientist, he performs 75% of all the fetal therapy at the West Midlands Fetal Medicine Centre (one of the busiest centres in the UK). For in-utero transfusions, the centre receives referrals from the West and east Midlands and for the management of severe twin to twin transfusion syndrome by fetoscopic laser ablation, pregnant patients are referred from the whole of the	n/a	n/a

	Midlands (West and East), the Norther England (West and East) and Northern Ireland. Professor trained an operator in Glasgow, Scotland who refers patients when she is away. Professor Kilby has audited all outcomes and activity since 1997 and is a representative on the National Women's Commissioning Group, Maternity Pathways Development for NHSE and is senior topic advisor for the NICE Guideline development Group on Twin and Triplet Pregnancy. He is also Chairman on the RCOG Subspecialty Training Committee (2015-2018). He is past President of the British Maternal Fetal Medicine Society (2012-2015) and Fellows Councillor for the National RCOG Council (2001-2007 and 2011-2017). He does not have shares or financial interests in any company or organisation involved in fetal surgery. He declares no known conflict of interest.		
9. Dr Thomas Everett, Dept of Fetal Medicine, Leeds Teaching Hospitals NHS Trust – replying as an individual clinician.	None to declare	n/a	n/a
10. Dr Cath Harrison, Leeds Teaching Hospitals NHS Trust – replying as an individual clinician.	None	n/a	n/a

11. Paul Chumas, Consultant Neurosurgeon, Leeds Teaching Hospitals NHS Trust.	We are likely to apply.	n/a	n/a
12. Bas Zebian, King's College Hospital (Neurosurgery Department; Fetal Medicine Unit; Department of Paediatrics) and Evelina/King's Spina Bifida clinic, Member NHS England Spina Bifida Specification Working Group.	No response	n/a	n/a
13. David Howe, Consultant in FetoMaternal Medicine University Hospitals Southampton; Member of the Specialised	I have no conflicts of interest to declare.	n/a	n/a

Women's Services CRG.			
14. Dr Jill Cadwagan, British Academy of Childhood Disability.	None	n/a	n/a
15. Dr Nanda Surabhi, Dr Andrew Breeze, British Maternal and Fetal Medicine Society (BMFMS).	Some sub-committee member responses are from teams that have current UK experience in performing open spina bifida repairs.	n/a	n/a