

E12/S/a

**NHS STANDARD CONTRACT
FOR FETAL MEDICINE**

PARTICULARS, SCHEDULE 2 – THE SERVICES, A – SERVICE SPECIFICATION

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| Service Specification No. | E12/S/a |
| Service | Fetal Medicine |
| Commissioner Lead | |
| Provider Lead | |
| Period | 12 months |
| Date of Review | |

1. Population Needs

1.1 National/local context and evidence base

Fetal medicine is the branch of medicine that provides care for the fetus (or fetuses) and mother. This includes the assessment of fetal growth and wellbeing and the diagnosis and management of fetal disorders (including fetal abnormalities) and counselling and support for parents.

Specialised services for women cover rare or complex conditions and / or unusual treatments as well as more common conditions where the severity or uncertainty of the particular case and / or co morbidities necessitates treatment in a specialist centre. A specialist Fetal Medicine Centre is one staffed by subspecialist consultants (i.e. those who have completed subspecialty training in Maternal and Fetal Medicine) who provide a full range of prenatal diagnostic and fetal therapeutic services in collaboration (and co-located) with other specialist services (see below). A few rare and complex therapies are only provided in a more limited number of centres (typically no more than five).

The rationale for these services being specialised is the complexity of the investigations and / or treatment involved requires a sufficient volume of cases to be concentrated in a specialist centre to maintain expertise e.g. management of a potentially correctable fetal malformation. There are less than 20 centres providing specialised Fetal Medicine services in England.

Once the diagnosis is confirmed (and it is not always possible to make a definitive diagnosis) a number of pregnancies will require joint management with other specialties including: medical genetics, radiology, virology, microbiology,

neonatology, paediatric surgery, paediatric cardiology, paediatric nephrology/urology, paediatric neurology, facial cleft services and (specialist) gynaecology. Delivery or termination of pregnancy may be arranged at the woman's local hospital.

2. Scope

2.1 Aims and objectives of service

Aim

The aim of specialised Fetal Medicine services is to provide patient focused high quality evidence-based care to women with complex pregnancies or whose fetus (or fetuses) has a confirmed or suspected disorder. The ability to improve the outcome of some fetal disorders has developed because of advances in prenatal diagnosis and therapy. Fetal medicine is the specialty that focuses on fetal health and its consequences for women and their families.

Objectives of the service:

- To provide a safe and effective care pathway for women and babies with a fetal abnormality or fetal disorder.
- To provide social, economic and psychological benefits for the mother and fetus
- To provide a high level of care and support to local maternity and obstetric services
- To provide continuity of care.

2.2 Service description/care pathway

Specialised fetal medicine services include prenatal diagnosis and fetal therapy as well as pre- and postnatal counselling about future risks and appropriate management strategies, where it takes place in a recognised Fetal Medicine Centre. There are less than 20 specialist Fetal Medicine centres in England. Each specialist Fetal Medicine centre team works closely with obstetric and genetic services as well as neonatal and paediatric services.

Fetal medicine involves the assessment of the unborn fetus mainly by ultrasound. This may allow monitoring of certain conditions, the diagnosis of congenital disorders, in utero (within the womb) therapy, optimisation of time and place of delivery and optimisation of postnatal management. In some cases of serious or potentially serious underlying fetal conditions, termination of pregnancy will be discussed and can also be arranged.

All aspects of advanced fetal medicine are practised in Fetal Medicine Centres. Services include all forms of invasive prenatal diagnosis (including chorionic villus sampling, amniocentesis and fetal blood and urine sampling), management of severely anaemic and thrombocytopenic fetuses with in utero transfusions and

insertion of shunts to allow drainage of over distended organs (e.g. the fetal bladder). A minority of fetal interventions (e.g. fetoscopic laser ablation of placental vessels for twin-twin transfusion syndrome) are available in a more limited number of Fetal Medicine Centres.

Operational Delivery Network

There will be an Operational Delivery Network (ODN) expected for this service area, subject to further definition. ODNs will ensure quality standards and networked patient pathways are in place. They will focus on an operational role, supporting the activity of provider trusts in service delivery, improvement and delivery of a commissioned pathway, with a key focus on the quality and equity of access to service provision. This will allow for more local determination, innovation and efficiency across the pathway. ODNs support the delivery of *Right Care* principles by incentivising a system to manage the right patient in the right place.

2.3 Population covered

The service outlined in this specification is for patients ordinarily resident in England*; or otherwise the commissioning responsibility of the NHS in England (as defined in *Who Pays?: Establishing the responsible commissioner* and other Department of Health guidance relating to patients entitled to NHS care or exempt from charges).

Note: for the purposes of commissioning health services, this excludes patients who, whilst resident in England, are registered with a GP Practice in Wales, but includes patients resident in Wales who are registered with a GP Practice in England.

Specifically, this service is for the following circumstances, which will generate a referral:

- Fetal abnormality suspected / detected during ultrasound screening.
- Pregnancy complicated by a genetic abnormality (suspected recurrence)
- Pregnancy complicated by possible fetal infection
- Severe fetal growth restriction (most commonly presenting before 32 weeks gestation)
- Twin pregnancy with complications
- Triplet and higher order multiple pregnancy

Entry to fetal medicine specialist services is by referral from an obstetrician, GP or midwife.

2.4 Any acceptance and exclusion criteria

Acceptance

Fetal Medicine Services include all care provided by Fetal Medicine Centres including out-reach when delivered as part of a provider network. Centres will also

provide care for other non-specialised cases which fall outwith this specification (e.g. diagnostic testing for Down syndrome) - such cases will form part of the contract with the Clinical Commissioning Groups and would be paid through the maternity pathway payment.

It is also acknowledged that smaller fetal medicine units (staffed by specialists in fetal medicine) may provide elements of specialised care. Where a Trust provides specialised fetal medicine services, as described in this specification, this will only be commissioned by NHS England where the service is compliant with this specification or derogation plans have been discussed and agreed.

If required expertise is not available through the provider network or if the problem is complex then the woman is referred to a specialist Fetal Medicine Centre for a fetal medicine assessment.

Exclusions

- Routine screening for fetal abnormalities and fetal diseases such as rhesus isoimmunisation as well as routine assessment of fetal wellbeing is undertaken by most maternity units and is not a specialised service.
- Chorionic Villus Sampling (CVS) that takes place in a non specialist centre is not a specialised fetal medicine service.
- After the initial screening, if a fetal problem is suspected, further assessment will be required. In some cases, e.g. common fetal abnormalities with a clear prognosis such as anencephaly, assessment typically involving ultrasound scanning will be performed by an obstetrician with a special interest in fetal medicine (Advanced Training Skills Module in Fetal Medicine) at the woman's local hospital.
- The same obstetrician may also manage the pregnancy, this not a specialised service.

The Service

Fetal Medicine services will provide the defined activities outlined below as part of a multidisciplinary team associated with a number of interdependent services (e.g. neonatology, paediatric surgery, paediatric cardiology)

General Specialised Fetal Medicine Services include :

Detailed assessment of fetuses at risk of and / or with abnormalities or dysmorphic syndromes which includes:

- Specialist ultrasound assessment
- Detailed counselling, including explanation of findings which may include specific diagnosis or differential diagnoses and the implications and prognosis for the baby.
- Management planning with the offer of further investigations which include invasive and non-invasive fetal diagnostic tests, e.g. genetic testing on free fetal DNA in maternal serum, parental tests, further imaging such as fetal MRI. Consultation with other disciplines will take place and include information

regarding the implications and outlook for the baby, possible invasive therapeutic procedures and, when appropriate, the option of terminating the pregnancy. Pre- or post-pregnancy counselling for families regarding implications for a future pregnancy.

- Detailed assessment and management planning for fetuses at risk of complications related to maternal red cell or platelet antibodies or some maternal infections
- Detailed assessment and management planning for fetuses at risk due to exposure to teratogen/s (agents that may disturb the development of an embryo or fetus).

Fetal cardiology services:

Detailed assessment of fetuses at risk of and / or with cardiac abnormalities which includes:

- Fetal echocardiography
- Detailed counselling, including explanation of findings which may include specific diagnosis or differential diagnoses and the implications and prognosis for the baby
- Multidisciplinary management planning including offering further investigations (including invasive fetal medicine tests, parental tests) and post pregnancy counselling for families with an affected child regarding implications for a future pregnancy.

Fetuses at risk of cardiac anomaly include where sibling or parent has specific types of congenital heart disease, exposure to specific teratogens, nuchal translucency greater than 3.5mm at 11-14 week ultrasound scan, monochorionic twins and other anomalies e.g. congenital diaphragmatic hernia, exomphalos.

The Small Fetus

Detailed assessment and management planning for fetuses found to be small for gestational age and at risk of preterm birth (either because of suspected intrinsic fetal pathology or growth restriction due to placental dysfunction) before 32 weeks gestation.

Invasive Diagnostic Procedures

CVS (Where this takes place in a designated centre).

Amniocentesis where the procedure is difficult / complex e.g. multiple pregnancy, women with high Body Mass Index, oligohydramnios, where there has been a failure to obtain a sample in the local hospital (note: laboratory activity associated with pre-natal diagnosis of genetic disorders is included the specification for specialised Medical Genetic Services) and fetal blood sampling where further testing is needed to clarify equivocal results from CVS or amniocentesis e.g. mosaicism.

Invasive Therapeutic procedures include:

- Amniotic fluid drainage (amnioreduction)
- Infusion of fluid into the amniotic cavity (amnioinfusion)
- Transfusion therapy for fetal anaemia (alloimmune red cell disease or fetal infection)
- Transfusion therapy for fetal thrombocytopenia (alloimmune platelet disease)
- Intravenous immunoglobulin therapy for alloimmune platelet disease
- Feto-amniotic shunting – pleuroamniotic shunt, vesico-amniotic shunt Cyst aspiration
- Fetoscopic laser ablation in twin to twin syndrome (TTTS) of monochorionic twins
- Fetoscopic tracheal occlusion (FETO) for severe congenital diaphragmatic hernia
- FETO reversal
- Other fetal procedures (e.g. laser therapy for fetal tumours, balloon valvuloplasty)

Invasive procedures relating to termination of pregnancy:

- Multifetal pregnancy reduction
- Fetocide (selective or otherwise)
- Cord occlusion in monochorionic twins
- Intrafetal laser ablation or radiofrequency ablation in twin reversed arterial perfusion (TRAP) sequence
- Late surgical termination of pregnancy (see service specification: Complex gynaecology: Late Termination of Pregnancy)

Assessment and management of complicated twin pregnancies and high order multiple pregnancies (three or more):

- All invasive diagnostic tests in twins or higher order multiple pregnancies
- Antenatal surveillance and management of all triplet and higher order multiple pregnancies
- Dichorionic twins with discordant / concordant anomaly
- Dichorionic twins with a small fetus and/or discordant fetal growth under 32 weeks gestation
- Monochorionic twins between 16-26 weeks gestation at high risk of complications, including TTTS
- Monochorionic twins with discordant nuchal translucency at 11-14 weeks gestation
- Monochorionic twins with a small fetus and/or discordant growth
- Monochorionic twins with discordant / concordant anomaly
- Suspected or confirmed TRAP sequence
- Monochorionic twins where there has been single fetal death.

Infrastructure and multidisciplinary requirements for fetal medicine services:

- A specialist Fetal Medicine centre is one staffed by subspecialist consultants (i.e. those who have completed subspecialty training in maternal and fetal medicine) who provide prenatal diagnostic and fetal therapeutic services in

collaboration (and co-located) with other specialist services. The service will require specialist midwifery support.

- Fetal Medicine Centres work closely with other specialised services such as, neonatology, paediatric surgery, paediatric cardiology, clinical genetics and molecular/cytogenetics.
- The Fetal Medicine service works in partnership with the referring/base multidisciplinary team including, obstetric team, midwives, general practitioners, health visitors, social workers and bereavement counsellors/services to maintain effective communication of information and to ensure good standards of care.

2.5 Interdependencies with other services

Whole System Relationships/ Interdependencies

- Centres that provide this service will also need defined links to other services within the specialised services definition sets.
- Medical genetic services (all ages) - laboratory testing for Down's syndrome, other pre-pregnancy and antenatal genetic problems and pre-implantation genetic diagnosis services.
- Complex child and adolescent gynaecology, neonatal care, paediatric cardiology, paediatric surgery, paediatric endocrinology and paediatric urology/nephrology services.
- The provider will facilitate and develop robust two-way mechanisms for women who require onward referral to other services where required. The provider will also ensure important information is communicated across services (in line with governance policy), including maintaining patient records efficiently.
- It is essential that there is a robust relationship with community provider services to ensure effective two way communication and efficient handover to the general obstetric teams and midwifery teams. It is important that the community provider services are fully aware of the details and individual circumstances for every woman and baby who resides in their community.
- The provider will be expected to liaise with neighbouring Fetal Medicine teams to facilitate repatriation to local services.

Multidisciplinary assessments / imaging / counselling:

Joint working with other specialties e.g. neonatologists, paediatric surgeons, clinical geneticists, paediatric cardiologists, paediatric urologists/nephrologists, paediatric neurologists, radiologists, virologists, microbiologists.

Relevant Networks/ Programmes

The provider will need to participate actively in a range of appropriate networks and screening programmes including the following:

- Maternity and Newborn Networks
- Neonatal Networks
- Newborn Screening Programme

- Genetic Networks

3. Applicable Service Standards

3.1 Applicable national standards e.g. NICE, Royal College

Guidance & Evidence Base

- *Maternity Matters*: Choice, access and continuity of care in a safe service, Department of Health, 2007 sets out the Government's commitment for modern NHS maternity services and provides a national framework for local delivery.
- Specialised Services National Definition Set, Definition No.4, Specialised Services for Women's Health (3rd edition)
- The NHS Fetal Anomaly Screening Programme has produced a number of standards and policies in collaboration with the UK National Screening Committee, which recommend the best working practice for health professionals to work towards within Down's syndrome and Fetal Anomaly screening.

Other national guidance is as follows:

- The code: Standards of conduct, performance and ethics for nurses and midwives, Nursing and Midwifery Council. The Code, 2008
- Safer Childbirth: Minimum Standards for the Organisation, Delivery of Care in Labour, Royal College of Obstetricians and Gynaecologists (RCOG), 2007
- Standards for Maternity Care, RCOG, 2008
- Standards for Hospitals Providing Neonatal Intensive and High Dependency Care, British Association of Perinatal Medicine (BAPM), 2001
- Antenatal and Postnatal Mental Health: Clinical Management and Service Guidance, National Institute of Clinical Excellence, clinical guideline 45, 2007
- NHS Operating Framework, Department of Health, 2008
- NHS 2010–2015: from good to great. Preventative, people-centred, productive, Department of Health, 2009
- You're Welcome quality criteria; Making health services young people friendly, Department of Health, 2007
- Getting maternity services right for pregnant teenagers and young fathers, Department of Children Schools and Families and Department of Health, 2008
- Amniocentesis and Chorionic Villus Sampling, Policy, Standards and Protocols, Fetal Abnormality Screening Programme, 2008
- NHS Fetal Anomaly Screening Programme Standards for Screening (2010)

NICE clinical guidelines and quality standards

- Antenatal Care Quality Standard, NICE, 2012
- Multiple pregnancy, NICE, 2011
- Antenatal care: routine care for the healthy pregnant woman, NICE Clinical Guidelines CG62', NICE, 2008
- Diabetes in pregnancy: management of diabetes and its complications from pre-

- conception to the postnatal period, NICE Clinical Guidelines CG63, NICE 2008
- Antenatal and postnatal mental health, NICE Clinical Guidelines CG45, NICE, 2007

NICE interventional procedure guidelines:

- Fetal vesico-amniotic shunt for lower urinary tract outflow obstruction, NICE Interventional Procedures Guidelines IPG 202, NICE, 2006
- Intrauterine laser ablation of placental vessels for treatment of twin-to-twin transfusion syndrome, NICE Interventional Procedures Guidelines IPG 198, NICE, 2006
- Therapeutic amnioinfusion for oligohydramnios during pregnancy (excluding labour) NICE Interventional Procedures Guidelines IPG192, NICE, 2006
- Insertion of pleuro-amniotic shunt for fetal pleural effusion, NICE Interventional Procedures Guidelines IPG 190, NICE, 2006
- Percutaneous laser therapy for fetal tumours, NICE Interventional Procedures Guidelines, IPG180, NICE, 2006
- Percutaneous fetal balloon valvuloplasty for pulmonary atresia with intact ventricular septum, NICE Interventional Procedures Guidelines IPG176, NICE, 2006

Available from the Royal College of Obstetricians and Gynaecologists:

Termination of Pregnancy for Fetal Abnormality in England, Scotland and Wales, RCOG, 2010

Report of a working party

- Management of monochorionic twin pregnancy, (Green-top guideline 51), RCOG, December 2008
- Amniocentesis and chorionic villus sampling (Green-top guideline 8), RCOG 2005
- Ultrasound screening for fetal abnormalities, report of the RCOG Working Party (1997) and Supplement (2000), RCOG 1997 & 2000

4. Key Service Outcomes

- Provide a tertiary service to support women requiring specialist support before, during and after pregnancy.
- Planned and mapped care for women with a fetal medicine problem.
- Social, economic and psychological benefits for families.
- The provider will ensure equity of access including:
 - Vulnerable and hard to reach groups
 - Disadvantaged groups, asylum seekers, refugees, gypsies and travellers
 - Women with learning disabilities
 - Women with physical disabilities
 - Women with translation/interpretation/advocacy issues
- Care and information should be appropriate and the woman's cultural practices

should be taken into account. All information should be provided in a form that is accessible to women, their partners and families, taking into account any additional needs, such as physical, cognitive or sensory disabilities, and people who do not speak or read English.

- Women and their families should always be treated with kindness, respect and dignity. The views, beliefs and values of the woman, her partner and her family in relation to her care and that of her baby should be sought and respected at all times.

Accessibility / Acceptability

- The service will be flexible and responsive, adapting to the individual needs of the baby and family.
- The provider will provide a service that is based on the principle of equal access for all and one that is responsive to diverse needs and is free from stereotyping and discriminatory practices.

Interim for adoption from 01/10/13