Standard Operating procedure

FETAL CARDIOLOGY SERVICE – ARRANGEMENTS FOR THE EARLY (PRE-NATAL) DIAGNOSIS OF CONGENITAL HEART DISEASE

SETTING	Division of Women's and Children's Services / Fetal Cardiology Service
FOR STAFF	Medical, nursing, midwifery and diagnostic imaging staff
PATIENTS	Women accessing the services; inclusive of partners or family members

The University Hospitals Bristol NHS Foundation Trust (UH Bristol) Fetal Cardiology Service provides a tertiary level screening and diagnostic service to maternity/obstetric ultrasound departments within the South West and South Wales region. The provision of a timely and accurate diagnosis aims to facilitate informed choice to women and their families diagnosed with fetal Congenital Heart Disease (CHD).

The fetal cardiology service has two key components: a diagnostic service to provide diagnosis, counselling and support to women when a fetal cardiac defect is detected and a screening service is provided to those women at a higher risk of developing fetal CHD.

It is vital that tertiary fetal cardiology services offer evidence based, high quality, standardised care and the following guideline reflects the UH Bristol commitment to providing this level of care. This SOP is intended to be accessed by clinical and administration staff within and allied to the service and has been consulted upon by relevant stakeholders and the Antenatal Working Party.

Service Aims

- To establish normality or the presence of CHD in an accurate and timely manner.
- Arrangements for early (pre-natal) diagnosis of CHD that meet the relevant NHS Fetal anomaly screening.
- To detect the presence of structural, functional or rhythm abnormalities and provide a full and accurate diagnosis.
- To initiate prenatal treatment where applicable.
- To provide non- directive counselling and support services to women diagnosed with fetal CHD.
- To facilitate ongoing pregnancy care to those women wishing to continue their pregnancy following diagnosis of fetal CHD, including arrangements for the delivery at the most appropriate unit.
- To facilitate onward referral and where appropriate ongoing care to those women wishing to end their pregnancy following diagnosis.

- To facilitate onward referral and where appropriate ongoing care to those women wishing to continue their pregnancies but choose palliative care post-delivery.
- To facilitate close liaison with all multidisciplinary team members involved in the woman's care particularly regarding follow up and outcome information.
- To assist in the development of the regional cardiac network as required.
- To develop a robust method of outcome data collection and to undertake regular audit and service assessment.
- To provide high quality patient information to those women accessing the service.
- To facilitate teaching and education on a local and regional level.
- To enter a data sharing agreement with the National Institute for cardiovascular Outcome Research (NICOR) and The National Congenital Anomaly and Rare Disease registration Service.
- To adhere to national standards and protocol as a mandatory requirement (NHS England Congenital heart Disease Standards and Specifications (2016) and the British Congenital Cardiac Association BCCA guidelines 2012)

Fetal Cardiology – Diagnostic & Therapeutic Services

Referral Criteria

Referrals are accepted at any gestational age where there is a suspicion of a fetal cardiac defect, cardiac dysfunction or arrhythmia.

Optimum screening period between 18+0 – 20+6 weeks gestation in line with the fetal Anomaly Screening programme standards **(FASP 2018)**

Referrals are accepted from all Maternity units and other appropriate sources in the South West region. Referrals are also accepted from units in Wales and outside of this region.

Timing of Scan

- Urgent Referrals: See referrals within 3 calendar days and preferably 2 following detection of cardiac abnormality. (NHS England 2016, BCCA 2012).

- Screening Referrals: (for those women at high risk of CHD): 18+0-20+6 weeks of gestation, clinical discretion can be used to with regard to earlier referrals.

Extenuating Circumstances:
Routine referrals received after 20+6 weeks will be seen in the next available clinic unless the referral is urgent (in which case it will be triaged as detailed above).

Patient Contact Regarding Appointment

Women must be informed of the appointment on the same day that the appointment is made. This can be achieved either by telephone, letter or E-mail where applicable.

Appointment Administration

- **Appointment Duration**

Urgent appointments must be a minimum of 45 minutes in duration.

Appointments for multiple pregnancies must be at least 45 minutes per fetus.

Urgent appointments must be booked onto the attending consultant's clinic on Medway. Once attended the follow up must be recorded on Medway to ensure the appointment is listed and charged appropriately.

Routine screening appointments must be booked onto the attending/covering consultant's clinic on Medway. Once attended the follow up must be recorded on Medway to ensure the appointment is listed and charged appropriately. Please refer to the fetal cardiology administration Standard Operating Policy.

Staffing

The appointment must be facilitated by designated consultant(s) with a special interest and expertise in fetal cardiology, who have fulfilled the training requirements for fetal cardiology as recommended by the Paediatric Cardiology Scientific Advisory Committee (SAC) or the Association of European Paediatric Cardiologists

The fetal echocardiogram may be completed under the supervision of the attending fetal cardiologist by :

Sonographers
Midwife/sonographers
Specialist radiographers
Doctors in training

Training and Professional Competence

All diagnostic ultrasound fetal echocardiograms must be undertaken by health professionals who are fully trained and competent in the specialty and the safe use of ultrasound.

Those training to undertake fetal echocardiograms must be supervised by fully trained and qualified health professionals.

Multidisciplinary training and education should be supported and provided for health professionals involved in antenatal fetal cardiac screening.

Ultrasound Equipment

The ultrasound equipment used meets national specification guidelines (RCR 2014) and is only operated by qualified health professionals trained in its usage or under the supervision of those

trained in its usage

Health professionals adhere to British Medical Ultrasound Society (BMUS 2009) guidelines for the safe use of diagnostic ultrasound equipment.

Routine maintenance must include disinfecting the ultrasound transducer between patients

Ultrasound equipment must be maintained for working use via internal quality assurance. This is achieved in collaboration with the Radiology and Medical Physics Dept.

Database and Image Storage/Archiving

The women's attendance must be recorded on the UH Bristol Medway system and the cardiology database Heart Suite. All ultrasound findings should be recorded on the Heart Suite database. Formal reports and a digital recording of every scan must be maintained and securely stored for 25 years. Disposal after this time must be confidential.

Mandatory data items for the fetal dataset required by NICOR and are to be completed in HeartSuite system by the consultant who confirms the diagnosis and are to be uploaded to NICOR by the administrative staff within 1 month of the date of diagnosis.

All new diagnosis should be uploaded to the NCARDRS database via the online data collection portal, by the administrative staff within 1 month of the date of diagnosis.

Where a fetal echocardiogram had been undertaken by the cardiac sonographer, the echo should be reviewed by the fetal cardiology consultant on the day the echo has been performed.

Where images are stored for teaching purposes the woman will be informed and consent documented. Information pertaining to the storage of images for teaching purposes will be provided in the patient information leaflets.

Suboptimal Imaging

The ultrasound images must be of an acceptable quality to confirm or exclude abnormalities. Images compromised by fetal or maternal factors must be assessed on an individual basis and further ultrasound investigation is facilitated ideally within the next available clinic or at the attending consultant's discretion.

Audit and Service Assessment

Yearly audit and service assessment must be undertaken using data collected from the Heart Suite database and fetal cardiology records.

Multidisciplinary fetal cardiac meetings will also be held ideally every month.

Patient Information prior to the Scan

Those referred for an urgent appointment must be given adequate information regarding appointment time, location and probable duration (UH Bristol local policy).

Information must be provided in an appropriate format for the woman and partner taking into account language, sensory and cognitive needs. An Interpreter must be considered and arranged prior to the appointment, if required and available.

Consent

Women undergoing a fetal echocardiogram must be well informed to ensure they are able to make an individually appropriate choice and verbal consent to the examination and use of data for research purposes.

Telemedicine

All guidelines stated above must be followed appropriately for telemedicine diagnosis.

Telemedicine must only be undertaken by those adequately trained and competent in its use.

The imaging quality using this medium must be assessed by the attending consultant and further appointments will be arranged at their discretion. A formal report should be generated on Heartsuite.

Once generated the report should be sent to the woman, her referring clinician and/or sonographer and GP. This should be undertaken with the woman's consent.

Care following the Echocardiogram

The findings of the ultrasound examination must be clearly communicated to the woman and if she wishes, those attending with her. This must be undertaken in an appropriate manner for the woman considering language, sensory and cognitive requirements. (NHS FASP 2018). Where necessary cardiac nurse specialist support will be provided. (See Role of the Cardiac Nurse specialist in fetal cardiology SOP)

- **Normal Findings:**

This must be explained to the woman alongside the limitations of fetal echocardiography.

The woman's attendance must be documented in the hand held pregnancy notes if present and a formal report must be generated.

Once generated the report should be sent to the woman, her referring clinician and/or sonographer and GP.

- **Abnormal Findings:**

In the event that a fetal cardiac defect is detected, the woman must be provided with adequate written and verbal information, counselling and support. This must be undertaken in an appropriate manner.

Information and Counselling after the diagnosis of a Fetal Cardiac Defect

Counselling must be undertaken in an appropriate environment such as a quiet room separate to the scan room or via telemedicine link. It must be facilitated by designated consultant(s) with a special interest and expertise in fetal cardiology, who have fulfilled the training requirements for fetal cardiology as recommended by the Paediatric Cardiology SAC or the Association of European Paediatric Cardiologists.

The clinician will provide the parents with detailed verbal and written information regarding the fetal cardiac defect (including diagrams where appropriate), surgical and non-surgical options, associated mortality and morbidity data, together with overall long term outlook.

All management options will be explained including continuing the pregnancy, termination of pregnancy and palliative care where appropriate.

Cardiac Nurse Specialists (CNS) will be present during consultation or will contact all prospective parents whose baby has been given an antenatal diagnosis of cardiac disease to provide information and support on day of diagnosis.

Written information and contact numbers for the fetal cardiology team, medical staff within the unit and designated cardiac liaison nurse will be provided.

Written information regarding the condition, pathways discussed, available supports services including contact details of local and national support groups will be provided.

Communication following the diagnosis and counselling

- **Ongoing Care and Management**

Following diagnosis a care plan will be agreed between the fetal cardiology service, the cardiology surgical service, the allied fetal medicine unit, the referring obstetric unit, the neonatal team and paediatricians and the women and family regarding the ongoing care and delivery. This care plan will be updated throughout the pregnancy. Women will be supported throughout this process by specialist consultant and cardiac nurse specialist support.

Due to the complexities of congenital cardiac defects care and delivery location plans will be individualised and updated throughout the pregnancy. The woman and her family will be provided with counselling and information following each fetal cardiology appointment during the pregnancy.

If appropriate the woman and her family will be offered appointments with the paediatric surgical team, neonatologist or clinical geneticist.

Following delivery all outcomes will be recorded on Heart Suite and maternal/child records must be linked (UH Bristol local policy).

- **Continuing Pregnancies**

Following diagnosis a care plan will be agreed between the fetal cardiology service, the cardiology surgical service, the allied fetal medicine unit, the referring obstetric unit, the

neonatal team and paediatricians and the women and family regarding the ongoing care and delivery. This care plan will be updated throughout the pregnancy.

Due to the complexities of congenital cardiac defects, an individualised care plan will be agreed upon with the woman and her partner regarding the preferred location of ongoing care and delivery. These plans will be updated throughout the pregnancy.

The woman and her partner will be provided with counselling and information following each fetal cardiology appointment during the pregnancy.

If appropriate the woman and her partner will be offered appointments with the paediatric surgical team, neonatologist or clinical geneticist.

Following delivery all outcomes must be recorded on Heart Suite and maternal/child records must be linked (UH Bristol local policy). Departments outside of the UH Bristol will be asked to notify us of the relevant clinical outcomes.

Women with a confirmed fetal cardiac defect referred from cardiology units outside of the UH Bristol NHS Trust for delivery and surgical care planning

Women and their partners will be offered an appointment at 32 weeks of pregnancy with fetal cardiology and fetal medicine (UH Bristol local policy).

This appointment aims to finalise delivery care plans and allow fetal medicine assessment of the fetus in terms of inter-uterine growth and wellbeing during the same appointment.

During antenatal appointments a CNS will be present to ensure the women and their families have a preparation conversation with appropriate information provision and visits to the cardiac unit (See CNS protocol).

Palliative Care

Following diagnosis a care plan will be agreed between the fetal cardiology service, the cardiology surgical service, the allied fetal medicine unit, the referring obstetric unit, the neonatal team and paediatricians and the women and family regarding the ongoing care and delivery. This care plan will be updated to reflect the woman's choice to withhold treatment and completed throughout the pregnancy (BCCA 2012).

Termination of Pregnancy

Women who choose to terminate their pregnancy will be referred to either the tertiary fetal medicine unit of if appropriate a local fetal medicine unit to discuss and plan the care and treatment. Should the woman consent to an autopsy this should be completed by a pathologist experienced in CHD.

Counselling post termination or post pregnancy loss should be performed by the obstetric team approximately 6 weeks later. All outcomes must be updated on Heart Suite. Follow up can be offered with the fetal cardiologist to discuss post mortem findings, if the patient wishes.

Women who do not to attend the appointments

Non-attendance is documented within clinic records and on the Medway system. Due to the possible sensitivities surrounding non-attendance a formal letter must be sent to the referring clinician. This letter must be copied for filing. Where appropriate the woman and her family may be contacted to discuss non-attendance.

Fetal Cardiology - Screening Services

Referral Criteria

Referrals are accepted for any of the indications cited by the British Congenital Cardiac Association (Appendix 1).

Referrals outside of the BCCA criteria must be discussed with the consultant.

Referrals are accepted from Maternity units in the South West region. Referrals are also accepted from Wales and units outside of this region.

Triage of Referrals

Referrals will be triaged by the consultant team, Fetal Cardiac Nurse specialist and Fetal cardiac sonographer only.

Inappropriate Referrals

Referrals outside of the referral criteria will be identified by the consultant team or cardiac sonographer triaging referrals.

A standard letter will be sent to the referring clinician who will be asked to inform the woman.

Timing of Scan

Women referred for fetal echocardiography screening assessment should ideally be seen between 18+0 – 20+6 weeks of gestation. As per the NHS fetal anomaly screening programme. (FASP 2018).

Referrals received outside of this timeframe (> 20+ 6 weeks gestation) will be offered appointments in the next available Clinic.

Patient Contact Regarding Appointment

Where possible, women must be informed of the appointment at least 2 weeks prior to the appointment. This can be achieved either by telephone or letter where applicable.

Appointment Administration

Routine screening appointments must be booked onto the attending/covering consultant's Fetal clinic on Medway. Once attended, the follow up must be recorded on

Medway to ensure the appointment is listed and charged appropriately.

Appointment Duration

Appointments should ideally be of 45 minutes in duration and attended by either the fetal cardiac sonographer or attending consultant cardiologist.

Appointments for multiple pregnancies must be at least 45 minutes in duration per fetus (UH Bristol local policy).

Urgent appointments must be booked onto the attending consultants on Medway. Once attended the follow up must be recorded on Medway to ensure the appointment is listed and charged appropriately.

Routine screening appointments must be booked onto the attending/covering consultant's clinic on Medway. Once attended the follow up must be recorded on Medway to ensure the appointment is listed and charged appropriately. Please refer to the fetal cardiology administration Standard Operating Policy.

Staffing

The appointment must be facilitated by designated consultant(s) with a special interest and expertise in fetal cardiology, who have fulfilled the training requirements for fetal cardiology as recommended by the Paediatric Cardiology Scientific Advisory Committee (SAC) or the Association of European Paediatric Cardiologists.

The ultrasound fetal echocardiogram may be completed under the supervision of the attending fetal cardiologist by:

Sonographers
Specialist radiographers
Doctors in training

Training and Professional Competence

Multidisciplinary training and education must be supported and provided for health professionals involved in antenatal fetal cardiac screening.

All screening ultrasound fetal echocardiograms must be undertaken by health professionals who are fully trained and competent in the specialty and the safe use of ultrasound.

Multidisciplinary training and education should be supported and provided for health professionals involved in antenatal fetal cardiac screening.

Ultrasound Equipment

The ultrasound equipment used meets national specification guidelines (RCR 2014) and is only operated by qualified health professionals trained in its usage or under the supervision of those trained in its usage

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Where images are stored for teaching purposes the woman will be informed and consent obtained. Information pertaining to the storage of images for teaching purposes will be provided in the patient information leaflets.

Suboptimal Imaging

The ultrasound images must be of an acceptable quality to confirm or exclude abnormality. Images compromised by fetal or maternal factors must be assessed on an individual basis and further ultrasound investigation is facilitated ideally within the next available clinic or at attending consultant's discretion.

Audit and Service Assessment

Yearly audit and service assessment must be undertaken using data collected from the Heart Suite database and fetal cardiology records.

Multidisciplinary fetal cardiac meetings will also be ideally held every month.

Patient Information prior to the Scan

Those referred for a fetal cardiology appointment must be given adequate information regarding appointment time, location and probable duration (UH Bristol local policy).

Information must be provided in an appropriate format for the woman taking into account language, sensory and cognitive needs. An Interpreter must be considered and arranged prior to the appointment, if required.

Consent

Women undergoing a fetal echocardiogram must be well informed to ensure they are able to make an individually appropriate choice and verbal consent to the examination and use of data for research purposes.

Care following the Echocardiogram

The findings of the ultrasound examination must be clearly communicated to the woman and if she wishes, those attending with her. This must be undertaken in an appropriate manner for the woman considering language, sensory and cognitive requirements. (NHS FASP 2018). Where necessary cardiac nurse specialist support will be provided. (See Role of the Cardiac Nurse specialist in fetal cardiology SOP).

- **Normal Findings:**

This must be explained to the woman alongside the limitations of fetal echocardiography.

The woman's attendance must be documented in the hand held pregnancy notes if present and a formal report must be generated.

Once generated the report should be sent to the woman, her referring clinician and/or sonographer and GP.

- **Abnormal Findings:**

If an abnormality is confirmed the care must follow the pathway outlined in the Fetal Cardiology Diagnostic Services Policy laid out in this document.

Women who do not to attend the appointments

Non-attendance must be documented on Heart Suite and on the Medway system.

Due to the possible sensitivities surrounding non-attendance, a formal letter must be sent to the referring clinician (see Follow up of Non-attender guidelines) This letter must be copied for filing.

Where appropriate the woman and her partner may be contacted to discuss non-attendance.

References

1. NHS England 2016 Congenital heart disease Standards and Specifications NHS England London

2. British Congenital Cardiac Association (BCCA) 2012 Fetal Cardiology BCCA London

3. www.rcr.ac.uk/Publication/Standards-provision-ultrasound-service(last accessed 11/5/17)

4. British Medical Ultrasound Society (BMUS) 2009 Guidelines for the safe use of Diagnostic Ultrasound Equipment BMUS London

5. Information Governance Alliance 2016 Records management NHS Code of Practice for Health and Social Care - published for DOH

6. NHS Fetal Anomaly Screening Programme handbook (2018) Public Health England. London.

7. British Medical Ultrasound Society (BMUS) 2009 Guidelines for the safe use of Diagnostic Ultrasound Equipment BMUS London.

8. National Institute for Clinical Excellence (NICE) 2008 Routine Care for Healthy Pregnant Women NICE London.

9. Fetal Cardiology Handbook (2019) University Hospitals (NHS) Foundation Trust Bristol.

10. Role of cardiac Nurse Specialist within fetal cardiology service Standard Operating procedure (2018) University Hospital Foundation Trust Bristol.

RELATED DOCUMENTS	Fetal Echocardiogram Standard for practice Fetal cardiology non-attenders guideline
AUTHORISING BODY	Paediatric Cardiac Governance Group
QUERIES	Angie Hobbs, Fetal Cardiac Sonographer 0117 342 5394

Appendix 1 Indications for Fetal Echocardiography

Maternal / Familial Indications	Fetal Indications
Maternal congenital heart disease	Suspicion of fetal cardiac abnormality
Maternal metabolic disorders – PKU – Diabetes Mellitus o Type I o Type II/Gestational – only if poorly controlled – HbA1c > 6%	Extra cardiac malformation
Maternal exposure to: – cardiac teratogens – anticonvulsants – lithium – retinoic acid – ACE inhibitors – anticonvulsants – NOT WARFARIN	Chromosomal aberration + genetic syndromes
Maternal Collagen disease –Anti Ro/SSA or Anti La/SSB	Nuchal translucency >99th centile for gestational age (3.5mm)
Maternal viral infection: – Rubella – CMV – Coxsackie – Parvovirus – Toxoplasma	Monochorionic twins
Maternal NSAID after 25 weeks	Fetal arrhythmias
Paternal CHD	Pericardial effusions
Previous child with CHD or congenital heart block	Pleural effusions
First degree relative with CHD	Polyhydramnios
Familial chromosomal or genetic conditions related to CHD	Fetal hydrops
In vitro fertilisation	Other states known to cause fetal cardiac failure: absence of ductus venosus, acardiac twin, twin to twin transfusion, tumours with a large vascular supply, arteriovenous fistulas, fetal anaemia

Monitor pathway

Process	Tool	By whom	Frequency	Review results	Produce action plan	Monitor completed actions	Disseminate learning How will you do this
: Monitor Urgent referrals meet 3 calendar days	Medway and fetal cardiology database	Fetal cardiology administrator & fetal cardiac sonographer	Monthly	Fetal cardiology meeting	Fetal cardiology team leader	Fetal cardiology meeting	Minutes of meeting to cardiac clinical governance and cardiac business meeting.
Monitor Screening referrals	Medway and fetal cardiology database	Fetal cardiology administrator & fetal cardiac sonographer	Monthly	Fetal cardiology meeting	Fetal cardiology team leader	Fetal cardiology meeting	Minutes of meeting to cardiac clinical governance and cardiac business meeting.
Monitor CNS attendance	Medway and fetal cardiology database	Fetal cardiology administrator & fetal cardiac sonographer	Monthly	Fetal cardiology meeting	Fetal cardiology team leader	Fetal cardiology meeting	Minutes of meeting to cardiac clinical governance and cardiac business meeting.