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Revised 2015 (Resolution 11)*

ACR–SPR PRACTICE PARAMETER FOR THE SAFE AND OPTIMAL PERFORMANCE OF FETAL MAGNETIC RESONANCE IMAGING (MRI)

PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the practitioner in light of all the circumstances presented. Thus, an approach that differs from the guidance in this document, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in this document when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to the guidance in this document will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of this document is to assist practitioners in achieving this objective.

1 Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing, ___ N.W.2d ___ (Iowa 2013) Iowa Supreme Court refuses to find that the ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures (Revised 2008) sets a national standard for who may perform fluoroscopic procedures in light of the standard’s stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, Stanley v. McCarver, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that “published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation” even though ACR standards themselves do not establish the standard of care.
I. INTRODUCTION

This practice parameter was revised collaboratively by the American College of Radiology (ACR) and the Society for Pediatric Radiology (SPR).

Magnetic resonance imaging (MRI) is a proven, established imaging modality for evaluating fetal anomalies that are not well or completely assessed by sonography [1-6]. MRI is used for problem solving and only in select circumstances for screening. Properly performed and interpreted, MRI not only contributes to diagnosis but also serves as an important guide to treatment, delivery planning, and counseling. However, sonography is the screening modality of choice in the fetus. Fetal MRI should be performed only for a valid medical reason and only after careful consideration of sonographic findings or family history of an abnormality for which screening with MRI might be beneficial.

This practice parameter addresses the use of MRI in fetal diagnosis.

Although MRI is an effective noninvasive diagnostic test for characterizing many fetal abnormalities, its findings may be misleading if not closely correlated with the clinical history and sonographic findings. Adherence to the following practice parameters will enhance the probability of appropriately diagnosing such abnormalities.

II. INDICATIONS

When an anomaly is visualized by ultrasound but the etiology remains uncertain due to the nature of the abnormality, or due to sonographic limitations from fetal lie, maternal body habitus, oligohydramnios, or small field of view, MRI can add additional information that may impact parental counseling, management, and delivery planning [7-15]. Primary indications for MRI include, but are not limited to, the following:

A. Brain and Spine

1. Congenital anomalies of the brain or skull suspected or not adequately assessed by sonography [3,16-39] include, but are not limited to, the following:
   a. Ventriculomegaly
   b. Agenesis of the corpus callosum
   c. Abnormalities of the cavum of the septum pellucidum
   d. Holoprosencephaly
   e. Posterior fossa anomalies
   f. Cerebral cortical malformations or migrational anomalies
   g. Solid or cystic masses
   h. Cephalocele

   In addition, MRI can be helpful in screening fetuses with a family risk for brain abnormalities such as tuberous sclerosis, corpus callosal dysgenesis, or lissencephaly.

2. Vascular abnormalities of the brain suspected or not adequately assessed by sonography [40,41] include, but are not limited to, the following:
   a. Vascular anomalies
   b. Hydranencephaly
   c. Infarctions
   d. Hemorrhage
   e. Monochorionic twin pregnancy complications
3. Congenital anomalies of the spine suspected or not adequately assessed by sonography [7,11,12,27,42-46] include, but are not limited to, the following:
   a. Neural tube defects
   b. Sacrococcygeal teratomas
   c. Caudal regression/sacral agenesis
   d. Sirenomelia
   e. Vertebral anomalies

B. Skull, Face, and Neck

1. Masses of the face and neck suspected or not adequately assessed by sonography [9,31,47-50] include, but are not limited to, the following:
   a. Vascular or lymphatic anomalies
   b. Goiter
   c. Teratomas
   d. Facial clefts

2. MRI can be helpful in assessing airway obstruction that may impact parental counseling, prenatal management, delivery planning, and postnatal therapy [9,47-50].

C. Thorax

1. Thoracic pathology suspected or not adequately assessed by sonography [51-53] include, but is not limited to, the following:
   a. Congenital lung malformations (including pulmonary airway malformations, bronchogenic cyst, sequestration, and congenital lobar overinflation).
   b. Congenital diaphragmatic hernia
   c. Effusions
   d. Mediastinal masses
   e. Assessment for esophageal atresia

2. MRI can be used for volumetric assessment of fetal lung parenchyma [54-58], particularly in those fetuses at risk for pulmonary hypoplasia secondary to diaphragmatic hernia, oligohydranmios, chest mass, or skeletal dysplasias.

D. Abdominal, Retroperitoneal, and Pelvic

1. Determining the etiology of an abdominal-pelvic cyst
2. Assessing the size and location of tumors such as hemangiomas, neuroblastomas, sacrococcygeal teratomas, and suprarenal or renal masses
3. Assessing complex genitourinary anomalies, such as bladder extrophy, cloacal malformation or extrophy, or complex lower urinary tract obstruction such as prune belly syndrome
4. Assessing renal anomalies in cases of severe oligohydranmios
5. Diagnosing bowel anomalies such as anorectal malformations, or complex bowel obstructions such as with megacystis microcolon hypoperistalsis syndrome [59]

E. Complications of Monochorionic Twins

Delineation of vascular anatomy prior to laser treatment of twins, assessment of morbidity after death of a monochorionic co-twin, and improved delineation of anatomy in conjoined twins are areas where MRI may be useful [60-62] due to its high spatial resolution, contrast resolution, large field of view, and multiplanar imaging
capabilities. This additional information may impact parental counseling, delivery planning, and postnatal management.

F. Fetal Surgery Assessment

When an abnormality is identified that may benefit from fetal surgery, MRI is a useful adjunct in confirming the diagnosis and planning potential surgical options [11,63-67]. It can also be utilized in assessing the fetal brain both before and after surgical interventions [68].

The high risk to mother and fetus of potential in-utero surgery requires accurate assessment of all anomalies. This includes, but is not limited to, the following:

1. Meningomyelocele
2. Sacrococcygeal teratomas
3. Processes obstructing the airway, such as a neck mass or congenital high airway obstruction
4. Complications of monochorionic twins needing surgery
5. Chest masses [69]

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging (MRI) [70].

Individuals interpreting fetal MRI should be familiar with both fetal and neonatal diagnoses as these knowledge bases overlap but can differ, both from each other and from those of the older pediatric and adult populations.

IV. SAFETY GUIDELINES AND POSSIBLE CONTRAINDICATIONS

See the ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging (MRI) [70], the ACR Guidance Document on MR Safe Practices [71], and the ACR Manual on Contrast Media [72].

A. Pregnant patients. For additional information please see the ACR–SPR Practice Parameter for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation [73].

Present data have not conclusively documented any deleterious effects of MR imaging at 1.5T on the developing fetus [74-84]. Therefore, no special consideration is recommended for any trimester in pregnancy. Pregnant patients can be accepted to undergo MR scans at any stage of pregnancy if, in the determination of a level 2 MR personnel-designated attending radiologist [71], the risk-benefit ratio to the patient warrants that the study be performed. The radiologist should review the indications and document them in the radiology report or the patient’s medical record.

There are theoretical RF power considerations that are greater at long exposure times and at a higher specific absorption rate (SAR) [85,86]. Radiologists should be cognizant of the increased power deposition typically accompanying some higher field studies and ensure that they do not exceed established guidelines [87,88].

B. MRI contrast agents should not be routinely administered to pregnant patients. Gadolinium is a pregnancy class C drug, meaning that the safety in humans has not been proven. This document describes fetal MRI, but for completeness we will discuss use of gadolinium contrast agents in pregnancy.

There are no documented fetal indications for the use of MRI contrast, but there may be rare instances where contrast is considered potentially helpful in assessing maternal anatomy or pathology.
The decision to administer contrast must be made on a case-by-case basis by the covering level 2 MR personnel-designated attending radiologist who will assess the risk-benefit ratio for that particular patient. The decision to administer a gadolinium-based MR contrast agent to pregnant patients should be accompanied by a well-documented and thoughtful risk-benefit analysis. This analysis should be able to defend a decision to administer the contrast agent based on overwhelming potential benefit to the patient or fetus, outweighing the theoretic but potentially real risks of long-term exposure of the developing fetus to free gadolinium ions.

Studies have demonstrated that gadolinium-based MR contrast agents pass through the placental barrier and enter the fetal circulation [89]. From there, they are filtered in the fetal kidneys and then excreted into the amniotic fluid. In this location the gadolinium-chelate molecules are in a relatively protected space and may remain in this amniotic fluid for an indeterminate amount of time before finally being reabsorbed and eliminated. As with any equilibrium situation involving any dissociation constant, the longer the chelate molecule remains in this space, the greater the potential for dissociation of the potentially toxic gadolinium ion from its chelate molecule. It is unclear what impact such free gadolinium ions might have if they were to be released in any quantity in the amniotic fluid. Certainly, deposition into the developing fetus would raise concerns of possible secondary adverse effects. The risk to the fetus with administration of gadolinium-based MR contrast agents remains unknown and may be harmful.

C. It is suggested that pregnant patients undergoing an MRI examination have a discussion with the referring or supervising physician concerning potential risks versus benefits of performing a fetal MRI. At this stage, the preponderance of research studies have failed to discover any reproducible harmful effects of exposure of the mother or developing fetus to the 3T or weaker magnetic fields used in the routine clinical MR imaging process. However, far less is known about the potential effects, if any, of the time varying gradient and/or radiofrequency magnetic fields used during actual scanning to potentiate image generation. Furthermore, the considerable majority of our data to date comes from research involving magnetic fields of 1.5T or less. Thus, we have less information regarding the potential safety issues that may exist at higher field strength systems. These theoretical risks should be carefully balanced against the potential benefits to the patient undergoing a MR examination. A decision as to whether or not to proceed with the requested MRI study will need to be based on a thorough and thoughtful evaluation of the potential and at times unknown risks of the MR examination versus the potential benefits to the patient, as well as the risks associated with declining to do so.

V. SPECIFICATIONS OF THE EXAMINATION

The supervising physician must have an understanding of the indications, risks, and benefits of the examination, as well as alternative imaging procedures. The physician must be familiar with potential hazards associated with MRI. The physician should be familiar with relevant ancillary studies that the patient may have undergone. The physician performing MRI interpretation must have a clear understanding and knowledge of the anatomy and pathophysiology relevant to the MRI examination.

The written or electronic request for fetal MRI examinations should provide sufficient information to demonstrate the medical necessity of the examination and allow for its proper performance and interpretation.

Documentation that satisfies medical necessity includes 1) signs and symptoms and/or 2) relevant history (including known diagnoses). Additional information regarding the specific reason for the examination or a provisional diagnosis would be helpful and may at times be needed to allow for the proper performance and interpretation of the examination.

The request for the examination must be originated by a physician or other appropriately licensed health care provider. The accompanying clinical information should be provided by a physician or other appropriately licensed health care provider familiar with the patient’s clinical problem or question and consistent with the state scope of practice requirements. (ACR Resolution 35, adopted in 2006)
The supervising physician must also understand the pulse sequences to be used and their effect on the appearance of the images, including the potential generation of image artifacts. Standard imaging protocols may be established and varied on a case-by-case basis when necessary. These protocols should be reviewed and updated periodically.

Documentation that satisfies medical necessity includes 1) fetal gestational age and 2) relevant history (including sonographic findings and family history of pertinent abnormalities). Additional information regarding the specific reason for the examination or a provisional diagnosis would be helpful and may at times be needed to allow for the proper performance and interpretation of the examination.

A. Patient Selection

The physician responsible for the examination should supervise appropriateness of patient selection and preparation and be available in person or by phone for consultation. Patients must be screened and interviewed prior to the examination to exclude individuals who may be at risk by exposure to the MR environment.

Patients suffering from anxiety or claustrophobia may require sedation or additional assistance.

Knowledge of the gestational age of the pregnancy is important for planning the examination and positioning of the surface coil.

Prior to 18 weeks gestational age the fetal MRI study can give limited diagnostic information due to the small size of the fetus and fetal movement. If the examination is limited by early gestational age then it may need to be repeated later. The need for early diagnosis should be balanced against the advantages of improved resolution later in pregnancy, with the choice dependent on the anomalies to be assessed. Fetal motion typically occurs constantly during the examination. However, using single-shot or other rapid acquisition techniques, slices are obtained in less than 1 second, therefore images are only degraded if motion occurs during image acquisition. Sequences may need to be repeated if motion degrades the image of the region of interest.

B. Facility Requirements

Appropriate emergency equipment and medications must be immediately available to treat adverse reactions associated with administered medications. The equipment and medications should be monitored for inventory and drug expiration dates on a regular basis. The equipment, medications, and other emergency support must also be appropriate for the range of ages and sizes in the patient population.

C. Examination Technique

Depending on the size of the uterus and fetal area of interest, either a torso or cardiac phased array surface coil is placed over the gravid uterus. If the patient will not fit into the magnet with a surface coil, then a body coil can be used. The mother lies supine or in the left lateral decubitus position. The maternal foot-first position helps minimize claustrophobia. Maternal sedation is not necessary in the vast majority of cases. Scout images orthogonal to the gravid uterus can be performed.

Fetal MRI single-shot acquisition sequences or other rapid acquisition sequences are employed to limit the effects of fetal motion. A T2-weighted spin-echo single-shot sequence reveals excellent anatomy. Fast acquisition T1-weighted images with gradient-echo sequences are less anatomically discriminating but help to define certain fetal tissue or fluid characteristics, such as fat, hemorrhage, liver, and meconium in bowel. It is preferable to have T1-weighted fast gradient-echo sequences performed during a breath-hold or using respiratory trigger technique. Short tau inversion recovery (STIR) images may provide improved resolution of tissue characteristics when the water contents of structures are similar. Additional sequences such as fluid attenuated inversion recovery
(FLAIR), steady-state free precession (SSFP) sequences (FIESTA, TrueFISP, bFFE), hydrography, BOLD imaging, diffusion-weighted imaging (DWI), and echo planar imaging may be performed as needed.

Field of view should be tailored to fetal (and maternal) size. Overlap of maternal onto maternal anatomy (“wrap-around” or spatial misregistration artifact) is acceptable if fetal structures are well-visualized.

1. Fetal brain
   Imaging sequences should include axial, coronal, and sagittal single-shot T2-weighted images of the fetal brain. Optimal slice thickness is 2 to 3 mm, but in some patients a 4 to 5 mm slice thickness may be needed because of signal-to-noise consideration. The fast T1 gradient echo should be performed in the coronal or axial plane if there is suspicion of fat or hemorrhage. Additional FLAIR sequences may be done to suppress the bright signal of the cerebral spinal fluid in certain cases. The use of DWI to evaluate metabolic or ischemic processes may be performed as needed [90-92].

2. Fetal spine
   Imaging sequences should include axial, coronal, and sagittal single-shot T2-weighted images of the fetal spine. Optimal slice thickness is 2 to 3 mm, but in some patients a 4 to 5 mm slice thickness may be needed because of signal-to-noise consideration. Additional sequences are rarely indicated in the spine evaluation but may include a FLAIR or spoiled fast gradient-echo sequence as noted above regarding brain evaluation. A fast T1 gradient-echo sequence may be performed if there is suspicion of a fat-containing lesion.

3. Fetal face and neck
   Imaging sequences should include axial, coronal, and sagittal single-shot T2-weighted images of the fetal face and neck. A slice thickness of up to 5 mm should be used with knowledge of signal-to-noise considerations, with earlier gestational age fetuses having thinner slices. The fast T1 gradient-echo sequence should be performed in the appropriate plane if there is suspicion of fat or hemorrhage. STIR images may provide improved resolution of tissue characteristics in masses such as teratoma or in lymphatic anomalies.

   Repetitive sagittal images, including real-time cine, may be needed to visualize fluid in the oropharynx if a lesion of the palate or proximal esophagus is suspected.

4. Fetal thorax
   Imaging sequences should include axial, coronal, and sagittal single-shot T2-weighted images of the fetal thorax. The slice thickness should be up to 5 mm. The fast T1 gradient-echo sequence can be performed in the coronal or sagittal plane to evaluate the liver and meconium in cases of congenital diaphragmatic hernia. STIR images may provide improved resolution of tissue characteristics in lesions such congenital pulmonary airway malformations in some instances [52]. SSFP sequences (FIESTA, TrueFISP) can be used to refine assessment of the heart and vascular masses.

5. Fetal abdomen
   Imaging sequences should include axial, coronal, and sagittal single-shot T2-weighted images of the fetal abdomen. The slice thickness should be up to 5 mm. The fast T1 gradient-echo sequence can be performed in the coronal or sagittal plane to evaluate the liver, meconium, fat, or hemorrhage [93]. STIR images may provide improved resolution of tissue characteristics in lesions of the solid organs, such as kidneys, liver, or adrenal glands. The use of DWI to identify renal tissue may be used as needed. BOLD imaging can be used to screen for hemochromatosis [9,94].
6. **Fetal volumetry**

   Various studies have established MRI-derived volumes and equations for weight [12,95-100]. The most commonly used are lung volumes to predict hypoplasia. Fetal weight has also been estimated. The technique involves adding together measured areas obtained by drawing free-form regions of interest on sequences that allow complete imaging of the volume without motion-induced artifact, and multiplying by slice thickness. Volume assessments should be reserved for specific indications.

7. **Dynamic imaging**

   Studies have demonstrated the utility of multisection balanced steady-state free precession cine sequences to assess fetal limb motion, swallowing, and cardiac motion [101-104].

VI. **DOCUMENTATION**

   Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [105].

VII. **EQUIPMENT SPECIFICATIONS**

   The MRI equipment specifications and performance must meet all state and federal requirements. The requirements include, but are not limited to, specifications of maximum static magnetic strength, maximum rate of change of the magnetic field strength (dB/dt), maximum radiofrequency power deposition (specific absorption rate), and maximum acoustic noise levels.

VIII. **QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION**

   Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education on the ACR website (http://www.acr.org/guidelines).

   Specific policies and procedures related to MRI safety should be in place with documentation that is updated annually and compiled under the supervision and direction of the supervising MRI physician. Guidelines should be provided that deal with potential hazards associated with the MRI examination of the patient as well as to others in the immediate area. Screening forms must also be provided to detect those patients who may be at risk for adverse events associated with the MRI examination.

   Equipment monitoring should be in accordance with the ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Magnetic Resonance Imaging (MRI) Equipment [106].

ACKNOWLEDGEMENTS

This practice parameter was developed according to the process described under the heading The Process for Developing ACR Practice Parameters and Technical Standards on the ACR website (http://www.acr.org/guidelines) by the Committee on Practice Parameters – Pediatric Radiology of the ACR Commission on Pediatric Radiology in collaboration with the SPR.
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*Practice parameters and technical standards are published annually with an effective date of October 1 in the year in which amended, revised or approved by the ACR Council. For practice parameters and technical standards published before 1999, the effective date was January 1 following the year in which the practice parameter or technical standard was amended, revised, or approved by the ACR Council.*