American College of Radiology ACR Appropriateness Criteria® Second and Third Trimester Screening for Fetal Anomaly

Variant 1: Second and third trimester screening for fetal anomaly. Low-risk pregnancy. Initial imaging.

| Procedure | Appropriateness Category | Relative Radiation Level |
|-------------------------------------------------|--------------------------|--------------------------|
| US pregnant uterus transabdominal anatomy scan | Usually Appropriate | 0 |
| US pregnant uterus transabdominal detailed scan | Usually Not Appropriate | 0 |
| US echocardiography fetal | Usually Not Appropriate | 0 |
| MRI fetal without and with IV contrast | Usually Not Appropriate | 0 |
| MRI fetal without IV contrast | Usually Not Appropriate | 0 |

Variant 2: Second and third trimester screening for fetal anomaly. High-risk pregnancy. Initial imaging.

| Procedure | Appropriateness Category | Relative Radiation Level |
|-------------------------------------------------|-----------------------------------|--------------------------|
| US pregnant uterus transabdominal detailed scan | Usually Appropriate | 0 |
| US echocardiography fetal | May Be Appropriate | 0 |
| MRI fetal without IV contrast | May Be Appropriate (Disagreement) | 0 |
| US pregnant uterus transabdominal anatomy scan | May Be Appropriate (Disagreement) | 0 |
| MRI fetal without and with IV contrast | Usually Not Appropriate | 0 |

<u>Variant 3:</u> Second and third trimester screening for abnormal finding on ultrasound: soft markers. Next imaging study.

| Procedure | Appropriateness Category | Relative Radiation Level |
|-------------------------------------------------|--------------------------|--------------------------|
| US pregnant uterus transabdominal detailed scan | Usually Appropriate | 0 |
| US pregnant uterus transabdominal follow-up | Usually Appropriate | 0 |
| US echocardiography fetal | May Be Appropriate | 0 |
| MRI fetal without IV contrast | Usually Not Appropriate | 0 |
| MRI fetal without and with IV contrast | Usually Not Appropriate | 0 |

<u>Variant 4:</u> Second and third trimester screening for abnormal finding on ultrasound: major anomalies. Next imaging study.

| Procedure | Appropriateness Category | Relative Radiation Level |
|-------------------------------------------------|--------------------------|--------------------------|
| US pregnant uterus transabdominal detailed scan | Usually Appropriate | 0 |
| MRI fetal without IV contrast | Usually Appropriate | 0 |
| US echocardiography fetal | Usually Appropriate | 0 |
| US pregnant uterus transabdominal follow-up | Usually Appropriate | 0 |
| MRI fetal without and with IV contrast | Usually Not Appropriate | 0 |

SECOND AND THIRD TRIMESTER SCREENING FOR FETAL ANOMALY

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Summary of Literature Review

Introduction/Background

Major congenital anomalies occur in 3% to 4% and minor anomalies occur in 7% to 10% of the population [1-3]. Anomalies increase the risk of aneuploidy, syndromes, and poor outcome [2]. Congenital anomalies account for 22.1% of infant deaths, with fetal malformations causing increased morbidity and mortality in the neonatal/postnatal period [3].

Ultrasound (US) is the primary imaging modality for the detection of congenital anomalies and obstetrical problems. It is performed in real-time with high-resolution images. The addition of Doppler for interrogation of blood vessels, transvaginal probes, and 3-D and 4-D US has improved evaluation of fetal anatomy and physiology [4]. The Eurofetus study, a multicenter trial of unselected pregnant women, reported 55% of major malformations could be identified prior to 24 weeks gestation [5]. Diagnostic US is regarded as safe, but it is a form of energy with bioeffects on the tissues, mainly mechanical and thermal effects [6-8]. The highest output is associated with Doppler US and familiarity with safety protocols for output is recommended. Long-term follow-up of children exposed to US in utero has shown no detrimental effects on cognitive or physical development, supporting the safety of US [9], when performed according to recommended standards (see the <u>ACR-SPR-SRU Practice Parameter for Performing and Interpreting Diagnostic Ultrasound Examinations</u> [10]). There are limitations of US, including limited field of view, maternal obesity, fetal position, and oligohydramnios. MRI may be used to complement US evaluations that are suboptimal or to provide additional detail in specific situations [11].

Evaluation of the fetus for congenital anomalies has been closely tied with early detection of genetic conditions, such as an euploidy or genetic syndromes. Amniocentesis has a near 100% detection rate for an euploidy, but there is a risk of pregnancy loss. The rate of pregnancy loss is <.5% at experienced centers [12-14]. Screening with maternal serum markers began in the 1970s to better assess risk of aneuploidy and decrease the risk of fetal loss with invasive testing. By the late 1980s, second trimester screening with maternal serum markers, α -fetoprotein, human chorionic gonadotropin (hCG), unconjugated estriol, and inhibin A was introduced [13]. The second trimester genetic sonogram was used along with maternal serum screening to identify major structural abnormalities and soft markers for aneuploidy. Likelihood ratios were used to adjust trisomy 21 risk when soft markers were identified [15,16]. In the last decade, risk assessment has transitioned into the first trimester, using nuchal translucency measurements obtained with US at 11 to 14 weeks, along with maternal serum analytes to calculate a patients' specific risk for an euploidy, with detection rates of 82% to 87% of fetuses with Down syndrome with a false positive rate of 5% [16-18]. Cell-free fetal DNA in the maternal blood was first identified in the late 1990s and has become a source of fetal genetic material for noninvasive prenatal testing (NIPT). This can be performed after 10 weeks and has a detection rate for trisomy 21 of 99% with a false positive rate of 0.5% in women who receive results. This has been studied extensively in high-risk populations. It can be used with caution in low-risk populations, but it has a higher false positive rate due to decreased pretest probability [17,19]. However, NIPT cannot replace US for detection of anomalies [20].

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The American College of Radiology seeks and encourages collaboration with other organizations on the development of the ACR Appropriateness Criteria through representation of such organizations on expert panels. Participation on the expert panel does not necessarily imply endorsement of the final document by individual contributors or their respective organization.

Special Imaging Considerations

Transvaginal US

The transvaginal US scan can be performed to supplement a transabdominal US scan where a fetal body part is close to the cervix and cannot be visualized transabdominally. Transvaginal US at 12 to 16 weeks can improve evaluation of fetal anatomy in obese women [8,10,21,22].

Doppler Imaging

Doppler imaging is used to assess vessels, organs, and supporting structures. It is helpful in the setting of vascular anomalies as well as assessment for the presence of blood flow in fetal masses [4]. Particular caution is warranted when using Doppler mode because of its higher level of energy, especially early in gestation. US should be used only when clinically indicated using the lowest acoustic energy level compatible with accurate diagnosis, the 'as low as reasonably achievable' principle [6-8].

3-D and 4-D US

Both 3-D and 4-D US have been helpful to further evaluate anatomy, especially facial clefts, spine anomalies such as hemivertebra, and midline brain anomalies such as agenesis of the corpus callosum or abnormalities of the posterior fossa [23,24]. In addition, 3-D and 4-D US [25] can be used as an adjunct to fetal echocardiography [26].

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CT has an extremely limited role to play in evaluation of the fetus, predominantly restricted to some cases of skeletal anomalies [27].

Initial Imaging Definition

Initial imaging is defined as imaging at the beginning of the care episode for the medical condition defined by the variant. More than one procedure can be considered usually appropriate in the initial imaging evaluation when:

• There are procedures that are equivalent alternatives (ie, only one procedure will be ordered to provide the clinical information to effectively manage the patient's care)

OR

• There are complementary procedures (ie, more than one procedure is ordered as a set or simultaneously in which each procedure provides unique clinical information to effectively manage the patient's care).

Discussion of Procedures by Variant

Variant 1: Second and third trimester screening for fetal anomaly. Low-risk pregnancy. Initial imaging.

In the developed world, US is usually performed at least once during pregnancy [28]. A review of 11 randomized trials and quasi-randomized trials looked at outcomes for US performed routinely versus selective US at <24 weeks. Although perinatal mortality was not affected, there was increased detection of fetal anomalies, improved detection of multiple gestations, and lower rates of induction for postdates. Long-term follow-up of children exposed to US in utero showed no detrimental effects on cognitive or physical development, supporting the safety of US [9]. There are several systematic reviews and large studies, which report fetal anomaly detection rates between 16% and 56% on US performed prior to 24 weeks [5,8,9]. The rate of detection of lethal anomalies is higher, up to 84% [8,29].

MRI Fetal Without and With IV Contrast

There is no relevant literature to support the use of fetal MRI with and without intravenous (IV) contrast for screening of a fetal anomaly in a low-risk pregnancy.

MRI Fetal Without IV Contrast

There is no relevant literature to support the use of fetal MRI without IV contrast for screening of a fetal anomaly in a low-risk pregnancy.

US Echocardiography Fetal

There is no relevant literature to support the use of fetal echocardiography for screening of a fetal anomaly in a low-risk pregnancy.

US Pregnant Uterus Transabdominal Detailed Scan

There is no relevant literature to support the use of US pregnant uterus transabdominal detailed scan for screening of a fetal anomaly in a low-risk pregnancy.

US Pregnant Uterus Transabdominal Anatomy Scan

The Eunice Kennedy Shriver National Institute of Child Health and Human Development hosted a fetal imaging workshop in December 2012, resulting in a multispecialty panel recommending that at least one US be offered routinely to all pregnant women between 18 and 20 weeks of gestation [8]. The components of the standard fetal examination at 18 to 20 weeks have been agreed upon by several organizations and outlined in the <u>ACR-ACOG-AIUM-SMFM-SRU Practice Parameter for the Performance of Standard Diagnostic Obstetrical Ultrasound</u> [8,30].

A routine diagnostic US may be used in the third trimester, either selectively or in the setting of a late arrival for assessment. Bricker et al [31] reviewed 13 trials with 34,980 patients and showed no evidence of improved antenatal, obstetric, or neonatal outcome or morbidity in those screened in the third trimester versus controls. A study by Manegold et al [32]; however, showed third trimester US to have utility for perinatal management and postnatal follow-up, with 15% of all anomalies found only in the third trimester in a study of 8,074 fetuses.

Variant 2: Second and third trimester screening for fetal anomaly. High-risk pregnancy. Initial imaging.

Detailed fetal anatomic examinations are performed in high-risk pregnancy instances where there is increased risk for anatomic or karyotypic fetal abnormality based on maternal factors (including age, use of in vitro fertilization, drug dependence, infection, or other maternal medical conditions) or abnormality of screening testing (including the quad screen, NIPT, or US findings). The category of high risk also includes family history of genetic disease or abnormality, multi-gestational pregnancies, and teen pregnancies [33]. A German study looked at teenage pregnancies in a database of all pregnancies from 2000 to 2011 and found 638 pregnancies in women <20 years of age, with a total of 9.2% of patients having anomalies or aneuploidy [34].

Obese patients deserve special consideration as rates of congenital anomalies are increased, particularly involving neural tube defects, cardiovascular anomalies, cleft lip or palate, anorectal atresia, hydrocephaly, and limb reduction anomalies [35,36]. Several studies demonstrate decreased detection of fetal anomalies with increasing body mass index (likely related to suboptimal visualization) on routine and detailed examinations [36-40]. An anatomic survey in obese women should be considered at 20 to 22 weeks (about 2 weeks later than women of normal weight), and if incomplete, a repeat follow-up US should be considered in 2 to 4 weeks [8,40-44].

There is emerging evidence that anatomic studies performed earlier in gestation with transvaginal imaging may be helpful [36-39]. A recent Canadian publication has demonstrated that performing early anatomic evaluation by transvaginal technique in combination with routine transabdominal study at 18 to 22 weeks can result in completion rates of the anatomic study that are comparable to those in nonobese populations [21]. This method should especially be considered in completion of the anatomic study in the high-risk obese population.

MRI Fetal Without and With IV Contrast

MRI abdomen and pelvis with IV contrast is not recommended for fetal evaluation. There are no documented fetal indications for the use of MRI contrast, but there may be rare instances where contrast is potentially helpful in evaluating maternal anatomy or pathology, to be decided on a case by case basis [45].

MRI Fetal Without IV Contrast

The International Society of Ultrasound in Obstetrics and Gynecology current guidelines recommend that fetal MRI is generally indicated following an US examination in which the information about the abnormality is incomplete. Although MRI is usually reserved for patients with a known or suspected anomaly, MRI can be helpful in screening fetuses with a family risk for brain abnormalities, as well as for assessment of fetal brain development [8,45-47]. If performed, this is ideally done at or after 22 weeks gestation [8], although an MRI performed between 18 to 22 weeks may be of value in certain clinical indications and settings [48].

US Echocardiography Fetal

The decision for the performance of fetal echocardiography, a subspecialized examination, is based on parental and fetal risk factors, as well as abnormal fetal cardiac screening examination. These risk factors include maternal genetic disease or risk, current medical conditions, and chemical exposures, as well as fetal factors such as known or suspected anomaly or cardiac abnormality [49-51].

US Pregnant Uterus Transabdominal Detailed Scan

High-risk patients should have a detailed scan, which is an indication-driven examination performed for a known or suspected fetal anatomic abnormality, known fetal growth disorder, genetic abnormality, or increased risk for a fetal anatomic or genetic abnormality [33,52].

US Pregnant Uterus Transabdominal Anatomy Scan

There is no relevant literature to support the use of US pregnant uterus transabdominal anatomy scan for the second and third trimester screening for fetal anomaly in high-risk patients [33]. However, if the chorionic villous sampling, amniocentesis, or NIPT are normal, then the risk is diminished and a routine scan could be performed [8].

Variant 3: Second and third trimester screening for abnormal finding on ultrasound: soft markers. Next imaging study.

Soft markers are minor sonographic findings that have little or no pathologic significance, but may be associated with an euploidy, most commonly trisomies 21 and 18, and other syndromes or pathologies. Soft markers have been used to recalculate the age-related trisomy risk and decrease the need for invasive testing when identified on the anatomy US examination [8,53,54].

The list of soft markers has changed over time [55]. The most commonly studied soft markers are choroid plexus cysts for trisomy 18 and echogenic intracardiac focus, renal pyelectasis, short humerus and femur, nuchal thickening (\geq 6mm), echogenic bowel, and short or absent nasal bone for trisomy 21 [8,15].

There is literature to suggest that the accuracy of using soft markers to adjust the risk of trisomy 21 may be less than initially reported [56]. In the last decade, risk assessment has transitioned into the first trimester, using nuchal translucency measurements obtained with US at 11 to 14 weeks, along with maternal serum analytes to calculate a patients' specific risk for aneuploidy, with a detection rate for trisomy 21 of 82% to 87% and a false positive rate of 5% [16,17]. Special caution has been suggested when re-evaluating risk based on first trimester nuchal translucency measurements with the presence or absence of soft markers, as these are not likely to be independent [57]. The introduction of first trimester/sequential screening and cell-free fetal DNA (NIPT) has further impacted the relevance of soft markers with several studies demonstrating a greater impact on false positive rates than detection rates [58]. In general, for women who have had karyotype analysis with chorionic villous sampling or amniocentesis, or non-invasive testing with cell-free fetal DNA, the association of soft markers and aneuploidy is no longer relevant and the recommendations presented below do not apply. [8,59]. Of note, it is important to recognize that some soft markers are only important as they relate to aneuploidy risk (eg, echogenic intracardiac focus and choroid plexus cyst), while others, may have additional implications that require additional testing and/or follow-up (eg, pyelectasis, short humerus/femur, echogenic bowel and nuchal thickening) [59-61].

MRI Fetal Without and With IV Contrast

There is no relevant literature to support the use of fetal MRI with and without IV contrast in the evaluation of fetuses with soft markers.

MRI Fetal Without IV Contrast

There is no relevant literature to support the use of fetal MRI without IV contrast in the evaluation of fetuses with soft markers.

US Echocardiography Fetal

While increased nuchal translucency in the first trimester has a well-described association with congenital heart disease, nuchal thickening of ≥ 6 mm in the second trimester has a less clear association. A detailed US study with special attention to the cardiac views is recommended. A fetal echocardiogram can be considered as well [8,17,51,59].

US Pregnant Uterus Transabdominal Follow-up

If one or more required structures are not adequately demonstrated during the detailed fetal anatomic examination, if the study is considered incomplete, or if there is reason for follow-up of an anomaly identified on the screening or detailed examination, the patient may be brought back for a focused follow-up assessment [33]. Even if the fetus is euploid, follow-up US is recommended at 32 weeks for the following soft markers: pyelectasis, short humerus length, short femur length, and echogenic bowel [8,17,59,62,63].

US Pregnant Uterus Transabdominal Detailed Scan

If a soft marker is found on the anatomy scan, a detailed US examination can be performed at the same time to look for additional markers and anomalies, or may be scheduled for the near future. For soft markers that relate only to aneuploidy risk, such as echogenic intracardiac focus and choroid plexus cyst, a detailed scan is optional to be certain the finding is isolated. For other soft markers, such as renal pyelectasis, short humerus and femur, nuchal thickening, echogenic bowel, and short or absent nasal bone, a detailed scan is usually indicated [8,17,52,59,61].

Variant 4: Second and third trimester screening for abnormal finding on ultrasound: major anomalies. Next imaging study.

Major congenital anomalies occur in 3% to 4% of the population and minor anomalies occur in 7% to 10% [1-3]. The types of fetal anomalies seen prenatally include, but are not limited to: hydrops fetalis, central nervous system anomalies of the brain and spine [4,64,65], facial anomalies including cleft lip and palate [66,67], genitourinary tract [68-71], cardiac anomalies [50,72-74], thoracic anomalies including congenital diaphragmatic hernias, and congenital pulmonary airway malformation of the lung [11,75], gastrointestinal anomalies such as gastroschisis and omphalocele [4,76], skeletal dysplasia such as achondroplasia [77] and osteogenesis imperfecta syndromes [78], and neoplasms such as neuroblastoma and teratoma [79-81]. Congenital cardiac disease is present in 2 to 15 per 1,000 live births and is a major cause of morbidity and mortality, with half being lethal or requiring surgery [50,82,83].

MRI Fetal Without and With IV Contrast

MRI abdomen and pelvis with IV contrast is not recommended for fetal evaluation. There are no documented fetal indications for the use of MRI contrast, but there may be rare instances where contrast is potentially helpful in evaluating maternal anatomy or pathology, to be decided on a case by case basis [45].

MRI Fetal Without IV Contrast

The International Society of Ultrasound in Obstetrics and Gynecology current guidelines recommend that fetal MRI is generally indicated following an US examination in which the information about the abnormality is incomplete [48]. Under these circumstances, MRI may provide important information that may confirm or complement the US findings and alter or modify patient management [79,84-88]. Fetal MRI is especially helpful for central nervous system anomalies, planning for prenatal and postnatal intervention, and for airway management in fetuses with neck masses [4,8,11]. Other indications for fetal MRI include evaluation of cranial, facial, thoracic, abdominal, retroperitoneal, and pelvic anomalies, as well as complications of monochorionic gestations [89].

Although available data are still inconclusive, MRI for parental reassurance regarding the absence of associated pathologies in fetuses with apparently isolated conditions may be recommended in fetuses with the following sonographic findings: isolated ventriculomegaly, agenesis of the corpus callosum, absent cavum septi pellucidi, and cerebellar or vermian anomalies [48]. If fetal MRI is performed, this is ideally done at or after 22 weeks gestation [8], although an MRI performed between 18 to 22 weeks may be of value in certain clinical indications and settings [48].

US Echocardiography Fetal

The decision for the performance of fetal echocardiography, a subspecialized examination, is based on parental and fetal risk factors, as well as abnormal fetal cardiac screening examination. These risk factors include maternal genetic disease or risk, current medical conditions, and chemical exposures, as well as fetal factors such as known anomaly or cardiac abnormality [49-51].

US Pregnant Uterus Transabdominal Follow-up

If one or more required structures are not adequately demonstrated during the detailed fetal anatomic examination, if the study is considered incomplete, or there is reason for follow-up of an anomaly identified on the screening examination, the patient may be brought back for a focused assessment [33]. Additionally, repeat transabdominal US is also performed for growth, delivery, and postnatal planning/management in the setting of an identified anomaly if the pregnancy is continued.

US Pregnant Uterus Transabdominal Detailed Scan

If an anomaly is seen or suspected on a first trimester US or a second trimester routine US, then a detailed second trimester US (or third trimester detailed US if finding is detected later) is indicated, according to the AIUM Consensus Report on the Detailed Fetal Anatomic Ultrasound Examination [33,52].

Summary of Recommendations

- Variant 1: For initial second and third trimester screening for fetal anomaly in a low-risk pregnancy, US pregnant uterus transabdominal anatomy scan is usually appropriate.
- Variant 2: For initial second and third trimester screening for fetal anomaly in a high-risk pregnancy, US pregnant uterus transabdominal detailed scan is usually appropriate. The panel did not agree on recommending MRI fetal without IV contrast and US pregnant uterus transabdominal anatomy scan for patients in this clinical

scenario, as there is insufficient medical literature to conclude a benefit of these imaging procedures. Therefore, while the performance of these procedures is controversial, their use may be appropriate.

- Variant 3: When soft markers are identified on second and third trimester US anatomy scan, US pregnant uterus transabdominal detailed scan and US pregnant uterus transabdominal follow-up are usually appropriate as next imaging studies. These procedures are complementary and may be selected by the type of soft marker and in certain circumstances performed sequentially, to effectively manage patient care.
- Variant 4: When major anomalies found on second and third trimester US screening, US pregnant uterus transabdominal detailed scan, MRI fetal without IV contrast, US echocardiography, and US pregnant uterus transabdominal follow-up are usually appropriate as next imaging studies. These procedures are complementary (ie, more than one procedure is ordered as a set or simultaneously where each procedure provides unique clinical information to effectively manage the patient's care).

Supporting Documents

The evidence table, literature search, and appendix for this topic are available at https://acsearch.acr.org/list. The appendix includes the strength of evidence assessment and the final rating round tabulations for each recommendation.

For additional information on the Appropriateness Criteria methodology and other supporting documents go to www.acr.org/ac.

Safety Considerations in Pregnant Patients

Imaging of the pregnant patient can be challenging, particularly with respect to minimizing radiation exposure and risk. For further information and guidance, see the following ACR documents:

- ACR-SPR Practice Parameter for the Safe and Optimal Performance of Fetal Magnetic Resonance Imaging (MRI) [45]
- ACR-SPR Practice Parameter for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation [90]
- <u>ACR-ACOG-AIUM-SMFM-SRU Practice Parameter for the Performance of Standard Diagnostic Obstetrical Ultrasound</u> [30]
- ACR Manual on Contrast Media [91]
- ACR Manual on MR Safety [92]

Appropriateness Category Names and Definitions

| Appropriateness Category Name | Appropriateness Rating | Appropriateness Category Definition |
|-----------------------------------|---------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Usually Appropriate | 7, 8, or 9 | The imaging procedure or treatment is indicated in the specified clinical scenarios at a favorable risk-benefit ratio for patients. |
| May Be Appropriate | 4, 5, or 6 | The imaging procedure or treatment may be indicated in the specified clinical scenarios as an alternative to imaging procedures or treatments with a more favorable risk-benefit ratio, or the risk-benefit ratio for patients is equivocal. |
| May Be Appropriate (Disagreement) | 5 | The individual ratings are too dispersed from the panel median. The different label provides transparency regarding the panel's recommendation. "May be appropriate" is the rating category and a rating of 5 is assigned. |
| Usually Not Appropriate | 1, 2, or 3 | The imaging procedure or treatment is unlikely to be indicated in the specified clinical scenarios, or the risk-benefit ratio for patients is likely to be unfavorable. |

Relative Radiation Level Information

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, a relative radiation level (RRL) indication has been included for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Patients in the pediatric age group are at inherently higher risk from exposure, because of both organ sensitivity and longer life expectancy (relevant to the long latency that appears to accompany radiation exposure). For these reasons, the RRL dose estimate ranges for pediatric examinations are lower as compared with those specified for adults (see Table below). Additional information regarding radiation dose assessment for imaging examinations can be found in the ACR Appropriateness Criteria. Radiation Dose Assessment Introduction document [93].

| Relative Radiation Level Designations | | | |
|---------------------------------------|----------------------------------------|--------------------------------------------|--|
| Relative Radiation Level* | Adult Effective Dose Estimate Range | Pediatric Effective Dose Estimate Range | |
| 0 | 0 mSv | 0 mSv | |
| € | <0.1 mSv | <0.03 mSv | |
| ⊕⊕ | 0.1-1 mSv | 0.03-0.3 mSv | |
| ♥♥ | 1-10 mSv | 0.3-3 mSv | |
| ❖❖❖❖ | 10-30 mSv | 3-10 mSv | |
| ❖❖❖❖❖ | 30-100 mSv | 10-30 mSv | |

^{*}RRL assignments for some of the examinations cannot be made, because the actual patient doses in these procedures vary as a function of a number of factors (eg, region of the body exposed to ionizing radiation, the imaging guidance that is used). The RRLs for these examinations are designated as "Varies."

References

1. Debost-Legrand A, Laurichesse-Delmas H, Francannet C, et al. False positive morphologic diagnoses at the anomaly scan: marginal or real problem, a population-based cohort study. BMC Pregnancy Childbirth 2014;14:112.

- 2. Estroff JA. Imaging clues in the prenatal diagnosis of syndromes and aneuploidy. Pediatr Radiol 2012;42 Suppl 1:S5-23
- 3. Hill LM. Timing of ultrasound in pregnancy--how often? At what intervals? Semin Perinatol 2013;37:327-33.
- 4. Benson CB, Doubilet PM. The history of imaging in obstetrics. Radiology 2014;273:S92-110.
- 5. Grandjean H, Larroque D, Levi S. The performance of routine ultrasonographic screening of pregnancies in the Eurofetus Study. Am J Obstet Gynecol 1999;181:446-54.
- 6. American Institute of Ultrasound in M. AIUM practice guideline for the performance of obstetric ultrasound examinations. J Ultrasound Med 2013;32:1083-101.
- 7. Abramowicz JS. Fetal Doppler: how to keep it safe? Clin Obstet Gynecol 2010;53:842-50.
- 8. Reddy UM, Abuhamad AZ, Levine D, Saade GR, Fetal Imaging Workshop Invited P. Fetal imaging: executive summary of a joint Eunice Kennedy Shriver National Institute of Child Health and Human Development, Society for Maternal-Fetal Medicine, American Institute of Ultrasound in Medicine, American College of Obstetricians and Gynecologists, American College of Radiology, Society for Pediatric Radiology, and Society of Radiologists in Ultrasound Fetal Imaging Workshop. J Ultrasound Med 2014;33:745-57.
- 9. Whitworth M, Bricker L, Mullan C. Ultrasound for fetal assessment in early pregnancy. Cochrane Database Syst Rev 2015:CD007058.
- 10. American College of Radiology. ACR-SPR-SRU Practice Parameter for Performing and Interpreting Diagnostic Ultrasound Examinations. Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/US-Perf-Interpret.pdf?la=en. Accessed September 30, 2020.
- 11. Hibbeln JF, Shors SM, Byrd SE. MRI: is there a role in obstetrics? Clin Obstet Gynecol 2012;55:352-66.
- 12. The California Prenatal Screening Program. Available at: https://www.cdph.ca.gov/programs/pns/Documents/Provider%20Handbook%20%202009%20WEB.pdf. Accessed September 30, 2020.
- 13. Liau J, Romine L, Korty LA, et al. Simplifying the ultrasound findings of the major fetal chromosomal aneuploidies. Curr Probl Diagn Radiol 2014;43:300-16.
- 14. Ogilvie C, Akolekar R. Pregnancy Loss Following Amniocentesis or CVS Sampling-Time for a Reassessment of Risk. J Clin Med 2014;3:741-6.
- 15. Agathokleous M, Chaveeva P, Poon LC, Kosinski P, Nicolaides KH. Meta-analysis of second-trimester markers for trisomy 21. Ultrasound Obstet Gynecol 2013;41:247-61.
- 16. Bromley B, Shipp TD, Lyons J, Groszmann Y, Navathe RS, Benacerraf BR. What is the importance of second-trimester "soft markers" for trisomy 21 after an 11- to 14-week aneuploidy screening scan? J Ultrasound Med 2014;33:1747-52.
- 17. Committee on Practice Bulletins-Obstetrics CoG, the Society for Maternal-Fetal M. Practice Bulletin No. 163: Screening for Fetal Aneuploidy. Obstet Gynecol 2016;127:e123-37.
- 18. Spencer K, Souter V, Tul N, Snijders R, Nicolaides KH. A screening program for trisomy 21 at 10-14 weeks using fetal nuchal translucency, maternal serum free beta-human chorionic gonadotropin and pregnancy-associated plasma protein-A. Ultrasound Obstet Gynecol 1999;13:231-7.
- 19. Yagel S, Cohen SM, Porat S, et al. Detailed transabdominal fetal anatomic scanning in the late first trimester versus the early second trimester of pregnancy. J Ultrasound Med 2015;34:143-9.
- 20. Merz E. Can Prenatal Testing in the First Trimester be Performed without Ultrasound? Ultraschall Med 2017;38:126-28.
- 21. Glanc P, D'Souza R, Parrish J, Tomlinson G, Maxwell C. Should an Early Anatomy Ultrasound Scan Be Offered Routinely to Obese Pregnant Women? J Obstet Gynaecol Can 2018;40:1288-94.
- 22. Paladini D. Sonography in obese and overweight pregnant women: clinical, medicolegal and technical issues. Ultrasound Obstet Gynecol 2009;33:720-9.
- 23. Hata T, Hanaoka U, Tenkumo C, Sato M, Tanaka H, Ishimura M. Three- and four-dimensional HDlive rendering images of normal and abnormal fetuses: pictorial essay. Arch Gynecol Obstet 2012;286:1431-5.
- 24. Sepulveda W, Ximenes R, Wong AE, Sepulveda F, Martinez-Ten P. Fetal magnetic resonance imaging and three-dimensional ultrasound in clinical practice: applications in prenatal diagnosis. Best Pract Res Clin Obstet Gynaecol 2012;26:593-624.
- 25. Yagel S, Cohen SM, Rosenak D, et al. Added value of three-/four-dimensional ultrasound in offline analysis and diagnosis of congenital heart disease. Ultrasound Obstet Gynecol 2011;37:432-7.
- 26. Manganaro L, Vinci V, Bernardo S, et al. Magnetic resonance imaging of fetal heart: anatomical and pathological findings. J Matern Fetal Neonatal Med 2014;27:1213-9.

- 27. Gorincour G, Chaumoitre K, Bourliere-Najean B, et al. Fetal skeletal computed tomography: when? How? Why? Diagn Interv Imaging 2014;95:1045-53.
- 28. Makhlouf M, Saade G. Should second trimester ultrasound be routine for all pregnancies? Semin Perinatol 2013;37:323-6.
- 29. National Institute for Health and care Excellence: Antenatal care for uncomplicated pregnancies. Available at: https://www.nice.org.uk/guidance/cg62/resources/antenatal-care-for-uncomplicated-pregnancies-pdf-975564597445. Accessed September 30, 2020.
- 30. American College of Radiology. ACR-ACOG-AIUM-SMFM-SRU Practice Parameter for the Performance of Standard Diagnostic Obstetrical Ultrasound. Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/us-ob.pdf. Accessed September 30, 2020.
- 31. Bricker L, Medley N, Pratt JJ. Routine ultrasound in late pregnancy (after 24 weeks' gestation). Cochrane Database Syst Rev 2015:CD001451.
- 32. Manegold G, Tercanli S, Struben H, Huang D, Kang A. Is a routine ultrasound in the third trimester justified? Additional fetal anomalies diagnosed after two previous unremarkable ultrasound examinations. Ultraschall Med 2011;32:381-6.
- 33. Wax J, Minkoff H, Johnson A, et al. Consensus report on the detailed fetal anatomic ultrasound examination: indications, components, and qualifications. J Ultrasound Med 2014;33:189-95.
- 34. Eckmann-Scholz C, von Kaisenberg CS, Alkatout I, Jonat W, Rajabi-Wieckhorst A. Pathologic ultrasound findings and risk for congenital anomalies in teenage pregnancies. J Matern Fetal Neonatal Med 2012;25:1950-2.
- 35. Stothard KJ, Tennant PW, Bell R, Rankin J. Maternal overweight and obesity and the risk of congenital anomalies: a systematic review and meta-analysis. JAMA 2009;301:636-50.
- 36. Tsai PJ, Loichinger M, Zalud I. Obesity and the challenges of ultrasound fetal abnormality diagnosis. Best Pract Res Clin Obstet Gynaecol 2015;29:320-7.
- 37. Aagaard-Tillery KM, Flint Porter T, Malone FD, et al. Influence of maternal BMI on genetic sonography in the FaSTER trial. Prenat Diagn 2010;30:14-22.
- 38. Best KE, Tennant PW, Bell R, Rankin J. Impact of maternal body mass index on the antenatal detection of congenital anomalies. BJOG 2012;119:1503-11.
- 39. Dashe JS, McIntire DD, Twickler DM. Effect of maternal obesity on the ultrasound detection of anomalous fetuses. Obstet Gynecol 2009;113:1001-7.
- 40. Maxwell C, Dunn E, Tomlinson G, Glanc P. How does maternal obesity affect the routine fetal anatomic ultrasound? J Matern Fetal Neonatal Med 2010;23:1187-92.
- 41. Fuchs F, Houllier M, Voulgaropoulos A, et al. Factors affecting feasibility and quality of second-trimester ultrasound scans in obese pregnant women. Ultrasound Obstet Gynecol 2013;41:40-6.
- 42. Hendler I, Blackwell SC, Bujold E, et al. Suboptimal second-trimester ultrasonographic visualization of the fetal heart in obese women: should we repeat the examination? J Ultrasound Med 2005;24:1205-9; quiz 10-1.
- 43. Hendler I, Blackwell SC, Bujold E, et al. The impact of maternal obesity on midtrimester sonographic visualization of fetal cardiac and craniospinal structures. Int J Obes Relat Metab Disord 2004;28:1607-11.
- 44. Timor-Tritsch IE, Bashiri A, Monteagudo A, Arslan AA. Qualified and trained sonographers in the US can perform early fetal anatomy scans between 11 and 14 weeks. Am J Obstet Gynecol 2004;191:1247-52.
- 45. American College of Radiology. ACR–SPR Practice Parameter for the Safe and Optimal Performance of Fetal Magnetic Resonance Imaging (MRI). Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/mr-fetal.pdf. Accessed September 30, 2020.
- 46. Levine D, Barnes PD, Madsen JR, Li W, Edelman RR. Fetal central nervous system anomalies: MR imaging augments sonographic diagnosis. Radiology 1997;204:635-42.
- 47. Whitby E, Paley MN, Davies N, Sprigg A, Griffiths PD. Ultrafast magnetic resonance imaging of central nervous system abnormalities in utero in the second and third trimester of pregnancy: comparison with ultrasound. BJOG 2001;108:519-26.
- 48. Prayer D, Malinger G, Brugger PC, et al. ISUOG Practice Guidelines: performance of fetal magnetic resonance imaging. Ultrasound Obstet Gynecol 2017;49:671-80.
- 49. American Institute of Ultrasound in M. AIUM practice guideline for the performance of fetal echocardiography. J Ultrasound Med 2013;32:1067-82.
- 50. Rajiah P, Mak C, Dubinksy TJ, Dighe M. Ultrasound of fetal cardiac anomalies. AJR Am J Roentgenol 2011;197:W747-60.
- 51. AIUM Practice Parameter for the Performance of Fetal Echocardiography. J Ultrasound Med 2020;39:E5-E16.

- 52. AIUM Practice Parameter for the Performance of Detailed Second- and Third-Trimester Diagnostic Obstetric Ultrasound Examinations. J Ultrasound Med 2019;38:3093-100.
- 53. Ahman A, Axelsson O, Maras G, Rubertsson C, Sarkadi A, Lindgren P. Ultrasonographic fetal soft markers in a low-risk population: prevalence, association with trisomies and invasive tests. Acta Obstet Gynecol Scand 2014;93:367-73.
- 54. Nyberg DA, Luthy DA, Resta RG, Nyberg BC, Williams MA. Age-adjusted ultrasound risk assessment for fetal Down's syndrome during the second trimester: description of the method and analysis of 142 cases. Ultrasound Obstet Gynecol 1998;12:8-14.
- 55. Stefanovic V. Soft markers for an euploidy following reassuring first trimester screening: what should be done? Curr Opin Obstet Gynecol 2015;27:151-8.
- 56. Smith-Bindman R, Chu P, Goldberg JD. Second trimester prenatal ultrasound for the detection of pregnancies at increased risk of Down syndrome. Prenat Diagn 2007;27:535-44.
- 57. Miguelez J, De Lourdes Brizot M, Liao AW, De Carvalho MH, Zugaib M. Second-trimester soft markers: relation to first-trimester nuchal translucency in unaffected pregnancies. Ultrasound Obstet Gynecol 2012;39:274-8.
- 58. Odibo AO, Ghidini A. Role of the second-trimester 'genetic sonogram' for Down syndrome screen in the era of first-trimester screening and noninvasive prenatal testing. Prenat Diagn 2014;34:511-7.
- 59. Norton ME. Follow-up of sonographically detected soft markers for fetal aneuploidy. Semin Perinatol 2013;37:365-9.
- 60. Winter TC, Rose NC. How to Integrate Cell-Free DNA Screening With Sonographic Markers for Aneuploidy: An Update. AJR Am J Roentgenol 2018;210:906-12.
- 61. Society for Maternal-Fetal Medicine . Electronic address pso, Norton ME, Biggio JR, Kuller JA, Blackwell SC. The role of ultrasound in women who undergo cell-free DNA screening. Am J Obstet Gynecol 2017;216:B2-B7.
- 62. Ameratunga DM, Said JM, Reidy K, Palma-Dias R. Perinatal outcomes following the ultrasound diagnosis of echogenic bowel: an Australian perspective. Fetal Diagn Ther 2012;31:179-84.
- 63. Buiter HD, Holswilder-Olde Scholtenhuis MA, Bouman K, van Baren R, Bilardo CM, Bos AF. Outcome of infants presenting with echogenic bowel in the second trimester of pregnancy. Arch Dis Child Fetal Neonatal Ed 2013;98:F256-9.
- 64. D'Addario V, Rossi AC. Neuroimaging of ventriculomegaly in the fetal period. Semin Fetal Neonatal Med 2012;17:310-8.
- 65. Griffiths PD, Morris JE, Mason G, et al. Fetuses with ventriculomegaly diagnosed in the second trimester of pregnancy by in utero MR imaging: what happens in the third trimester? AJNR Am J Neuroradiol 2011;32:474-80
- 66. Manganaro L, Tomei A, Fierro F, et al. Fetal MRI as a complement to US in the evaluation of cleft lip and palate. Radiol Med 2011;116:1134-48.
- 67. Zajicek M, Achiron R, Weisz B, Shrim A, Gindes L. Sonographic assessment of fetal secondary palate between 12 and 16 weeks of gestation using three-dimensional ultrasound. Prenat Diagn 2013;33:1256-9.
- 68. Bornes M, Spaggiari E, Schmitz T, et al. Outcome and etiologies of fetal megacystis according to the gestational age at diagnosis. Prenat Diagn 2013;33:1162-6.
- 69. Capito C, Belarbi N, Paye Jaouen A, et al. Prenatal pelvic MRI: additional clues for assessment of urogenital obstructive anomalies. J Pediatr Urol 2014;10:162-6.
- 70. Devriendt A, Cassart M, Massez A, Donner C, Avni FE. Fetal kidneys: additional sonographic criteria of normal development. Prenat Diagn 2013;33:1248-52.
- 71. Nguyen HT, Benson CB, Bromley B, et al. Multidisciplinary consensus on the classification of prenatal and postnatal urinary tract dilation (UTD classification system). J Pediatr Urol 2014;10:982-98.
- 72. Ganesan S, Brook MM, Silverman NH, Moon-Grady AJ. Prenatal findings in total anomalous pulmonary venous return: a diagnostic road map starts with obstetric screening views. J Ultrasound Med 2014;33:1193-207.
- 73. Jorgensen DE, Vejlstrup N, Jorgensen C, et al. Prenatal detection of congenital heart disease in a low risk population undergoing first and second trimester screening. Prenat Diagn 2015;35:325-30.
- 74. Zhou J, Zhou Q, Zhang M, Zeng S, Peng Q, Tian L. Echocardiographic follow-up and pregnancy outcome of fetuses with cardiac asymmetry at 18-22 weeks of gestation. Prenat Diagn 2014;34:900-7.
- 75. Patenaude Y, Pugash D, Lim K, et al. The use of magnetic resonance imaging in the obstetric patient. J Obstet Gynaecol Can 2014;36:349-63.

- 76. Brugger PC, Prayer D. Development of gastroschisis as seen by magnetic resonance imaging. Ultrasound Obstet Gynecol 2011;37:463-70.
- 77. Khalil A, Morales-Rosello J, Morlando M, Bhide A, Papageorghiou A, Thilaganathan B. Widening of the femoral proximal diaphysis--metaphysis angle in fetuses with achondroplasia. Ultrasound Obstet Gynecol 2014;44:69-75.
- 78. Benacerraf BB. The Sherlock Holmes approach to diagnosing fetal syndromes by ultrasound. Clin Obstet Gynecol 2012;55:226-48.
- 79. Kul S, Korkmaz HA, Cansu A, et al. Contribution of MRI to ultrasound in the diagnosis of fetal anomalies. J Magn Reson Imaging 2012;35:882-90.
- 80. Lyons K, Cassady C, Mehollin-Ray A, Krishnamurthy R. Current Role of Fetal Magnetic Resonance Imaging in Body Anomalies. Semin Ultrasound CT MR 2015;36:310-23.
- 81. Nemec SF, Horcher E, Kasprian G, et al. Tumor disease and associated congenital abnormalities on prenatal MRI. Eur J Radiol 2012;81:e115-22.
- 82. Small M, Copel JA. Indications for fetal echocardiography. Pediatr Cardiol 2004;25:210-22.
- 83. Liu S, Joseph KS, Lisonkova S, et al. Association between maternal chronic conditions and congenital heart defects: a population-based cohort study. Circulation 2013;128:583-9.
- 84. Amini H, Wikstrom J, Ahlstrom H, Axelsson O. Second trimester fetal magnetic resonance imaging improves diagnosis of non-central nervous system anomalies. Acta Obstet Gynecol Scand 2011;90:380-9.
- 85. Breysem L, Bosmans H, Dymarkowski S, et al. The value of fast MR imaging as an adjunct to ultrasound in prenatal diagnosis. Eur Radiol 2003;13:1538-48.
- 86. Frates MC, Kumar AJ, Benson CB, Ward VL, Tempany CM. Fetal anomalies: comparison of MR imaging and US for diagnosis. Radiology 2004;232:398-404.
- 87. Santos XM, Papanna R, Johnson A, et al. The use of combined ultrasound and magnetic resonance imaging in the detection of fetal anomalies. Prenat Diagn 2010;30:402-7.
- 88. Varavithya V, Phongkitkarun S, Raungrongmorakot K, Rujiwetpongstorn J, Chittacharoen A. The influence of MR imaging on changes in patient counseling in obstetric patients with suspected fetal anomalies by ultrasound. J Med Assoc Thai 2013;96:839-48.
- 89. Bekiesinska-Figatowska M, Herman-Sucharska I, Romaniuk-Doroszewska A, Jaczynska R, Furmanek M, Bragoszewska H. Diagnostic problems in case of twin pregnancies: US vs. MRI study. J Perinat Med 2013;41:535-41.
- 90. American College of Radiology. ACR-SPR Practice Parameter for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation. Available at: https://www.acr.org/media/ACR/Files/Practice-Parameters/pregnant-pts.pdf. Accessed September 30, 2020.
- 91. American College of Radiology. ACR Committee on Drugs and Contrast Media. Manual on Contrast Media. Available at: https://www.acr.org/-/media/ACR/Files/Clinical-Resources/Contrast_Media.pdf. Accessed September 30, 2020.
- 92. American College of Radiology. ACR Committee on MR Safety. ACR Manual on MR Safety. Version 1.0. Available at: https://www.acr.org/-/media/ACR/Files/Radiology-Safety/MR-Safety/Manual-on-MR-Safety.pdf. Accessed September 30, 2020.
- 93. American College of Radiology. ACR Appropriateness Criteria® Radiation Dose Assessment Introduction. Available at: https://www.acr.org/-/media/ACR/Files/Appropriateness-Criteria/RadiationDoseAssessmentIntro.pdf. Accessed September 30, 2020.

The ACR Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those examinations generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the FDA have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.