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	O
US pregnant uterus transabdominal detailed scan	Usually Not Appropriate	O
US echocardiography fetal	Usually Not Appropriate	O
MRI fetal without and with IV contrast	Usually Not Appropriate	O
MRI fetal without IV contrast	Usually Not Appropriate	O

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	O
US echocardiography fetal	May Be Appropriate	O
MRI fetal without IV contrast	May Be Appropriate (Disagreement)	O
US pregnant uterus transabdominal anatomy scan	May Be Appropriate (Disagreement)	O
MRI fetal without and with IV contrast	Usually Not Appropriate	O

Variant 3: **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	O
US pregnant uterus transabdominal follow-up	Usually Appropriate	O
US echocardiography fetal	May Be Appropriate	O
MRI fetal without IV contrast	Usually Not Appropriate	O
MRI fetal without and with IV contrast	Usually Not Appropriate	O

Variant 4: **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	O
MRI fetal without IV contrast	Usually Appropriate	O
US echocardiography fetal	Usually Appropriate	O
US pregnant uterus transabdominal follow-up	Usually Appropriate	O
MRI fetal without and with IV contrast	Usually Not Appropriate	O

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 ACR–SPR–SRU Practice Parameter for Performing and Interpreting Diagnostic Ultrasound Examinations [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 aneuploidy or genetic syndromes. Amniocentesis has a near 100% detection rate for aneuploidy, 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 aneuploidy, 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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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].

CT

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 ACR-ACOG-AIUM-SMFM-SRU Practice Parameter for the Performance of Standard Diagnostic Obstetrical Ultrasound [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 aneuploidy, 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 (≥ 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]
- ACR-ACOG-AIUM-SMFM-SRU Practice Parameter for the Performance of Standard Diagnostic Obstetrical Ultrasound [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**
O	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."		

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