

ACR Appropriateness Criteria[®] Female Infertility

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Abstract

Infertility is defined as the inability to conceive spontaneously after 12 months of routinely unprotected intercourse in patients <35 years of age, and after 6 months in patients ≥35 years of age. Infertility also refers to the inability to achieve a successful pregnancy based on the medical, sexual, and reproductive history; age, physical findings; diagnostic testing; the need for medical intervention; or a combination of these variables for a patient. In the United States, 13% of women 15 to 49 years of age have accessed assisted fertility services and it has been suggested that the rate of infertility has been increasing, without geographic bias. Understanding the initial imaging evaluation is essential to this often complex and/or multifaceted clinical circumstance, which may involve the ovaries, uterus, and fallopian tubes.

The American College of Radiology Appropriateness Criteria are evidence-based guidelines for specific clinical conditions that are reviewed annually by a multidisciplinary expert panel. The guideline development and revision process support the systematic analysis of the medical literature from peer reviewed journals. Established methodology principles such as Grading of Recommendations Assessment, Development, and Evaluation or GRADE are adapted to evaluate the evidence. The RAND/UCLA Appropriateness Method User Manual provides the methodology to determine the appropriateness of imaging and treatment procedures for specific

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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 society representation on expert panels. Participation by representatives from collaborating societies on the expert panel does not necessarily imply individual or society endorsement of the final document.

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The ACR Appropriateness Criteria documents are updated regularly. Please go to the ACR website at <https://www.acr.org/Clinical-Resources/Clinical-Tools-and-Reference/Appropriateness-Criteria> to confirm that you are accessing the most current content.

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Disclaimer: 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.

clinical scenarios. In those instances where peer reviewed literature is lacking or equivocal, experts may be the primary evidentiary source available to formulate a recommendation.

Key Words: Appropriateness Criteria, Appropriate Use Criteria, AUC, fallopian tubes, female infertility, ovaries, polycystic ovarian syndrome, reproductive medicine, uterus

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ACR Appropriateness Criteria® Female Infertility. [Variants 1 to 3](#) and [Tables 1 and 2](#).

Variant 1. Adult 50 years of age or younger. Female infertility. Evaluation of uterus and ovaries. Initial imaging.

Procedure	Appropriateness Category	Relative Radiation Level
US pelvis transabdominal	Usually Appropriate	O
US pelvis transabdominal and US pelvis transvaginal	Usually Appropriate	O
US pelvis transvaginal	Usually Appropriate	O
MRI pelvis without and with IV contrast	May Be Appropriate	O
MRI pelvis without IV contrast	May Be Appropriate	O

Variant 2. Adult 50 years of age or younger. Female infertility. Clinical features or history of polycystic ovary syndrome. Initial imaging.

Procedure	Appropriateness Category	Relative Radiation Level
US pelvis transabdominal and US pelvis transvaginal	Usually Appropriate	O
US pelvis transvaginal	Usually Appropriate	O
US pelvis transabdominal	May Be Appropriate	O
MRI pelvis without and with IV contrast	May Be Appropriate	O
MRI pelvis without IV contrast	May Be Appropriate	O

Variant 3. Adult 50 years of age or younger. Female infertility. Evaluation of the fallopian tubes. Initial imaging.

Procedure	Appropriateness Category	Relative Radiation Level
US pelvis transvaginal	Usually Appropriate	O
US sonohysterography with tubal contrast agent	Usually Appropriate	O
Fluoroscopy hysterosalpingography	Usually Appropriate	☢☢
US pelvis transabdominal	May Be Appropriate	O
US pelvis transabdominal and US pelvis transvaginal	May Be Appropriate (Disagreement)	O
US sonohysterography	May Be Appropriate (Disagreement)	O
MRI pelvis without and with IV contrast	May Be Appropriate	O
MRI pelvis without IV contrast	May Be Appropriate	O

Table 1. 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.

Table 2. Relative radiation level designations

RRL	Adult Effective Dose Estimate Range (mSv)	Pediatric Effective Dose Estimate Range (mSv)
0	0	0
⊕	<0.1	<0.03
⊕⊕	0.1-1	0.03-0.3
⊕⊕⊕	1-10	0.3-3
⊕⊕⊕⊕	10-30	3-10
⊕⊕⊕⊕⊕	30-100	10-30

Note: Relative radiation level (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."

SUMMARY OF LITERATURE REVIEW

Introduction/Background

Infertility is defined as the inability to conceive spontaneously after 12 months of routinely unprotected intercourse in those <35 years of age, and after 6 months in those ≥35 years of age [1]. Infertility also refers to the inability to achieve a successful pregnancy based on the medical, sexual, or reproductive history; age, physical findings; diagnostic testing; the need for medical intervention; or a combination of these variables for a patient [1]. In the United States, 13% of women 15 to 49 years of age have accessed assisted fertility services [2]. It has been suggested that the rate of infertility has been increasing, without geographic bias [3,4]. In addition to infertility, 48.5 million women globally may experience subfertility, which is defined as a delay in conceiving, with the possibility of unassisted reproduction remaining. Both infertility and subfertility may be indications for imaging evaluation because they share common potential etiologies including structural processes impacting the uterus, ovaries, and

fallopian tubes and congenital, posttreatment, and systemic disorders [1].

Infertility is attributed to male factors in about a third of cases and female factors in another third, and the remainder is either unexplained or due to a combination of both [5].

Female-specific causes of infertility include deterioration of oocyte quality with increasing maternal age; ovulatory disorders, most notably polycystic ovarian syndrome (PCOS); tubal factors, such as salpingitis caused by chlamydia infection; endometriosis; and uterine cavity abnormalities interfering with implantation causing an inability to become pregnant or causing recurrent pregnancy loss [6]. Uterine factor infertility may be congenital or acquired, and the true prevalence is unknown due to a lack in consensus agreement in the definition but ranges from 2.1% to 16.7% [7].

This document provides recommendations for initial imaging evaluation of the uterus and ovaries, PCOS, and tubal patency in patients seeking fertility treatment. Although endometriosis may account for up to 50% of infertility cases,

for women with a clinical suspicion of endometriosis and a need for imaging, please refer to the ACR Appropriateness Criteria® topic on “Endometriosis” [8].

Special Imaging Considerations

MR hysterosalpingography (HSG) is an additional technique that can demonstrate tubal patency and may be useful in women in whom both MRI and HSG need to be performed [9]; however, it remains an investigational tool [10]. Another investigational method of tubal evaluation includes virtual CT HSG. Advanced diagnostic ultrasound (US) methods such as the usage of 3-D and 4-D for the evaluation of Müllerian duct anomalies is considered outside the scope of the initial evaluation.

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 wherein each procedure provides unique clinical information to effectively manage the patient’s care).

DISCUSSION OF PROCEDURES BY VARIANT

Variant 1: Adult 50 years of age or younger. Female infertility. Evaluation of uterus and ovaries. Initial imaging

Initial imaging evaluation of the female pelvis in the setting of infertility is essential to assess for structural changes or pathology. This includes evaluation of the uterus to assess for potential Müllerian duct anomalies, focal or diffuse adenomyosis, uterine masses such as fibroids, and endometrial or cervical polyps or masses. Ovarian evaluation may include the size and number of follicles in addition to an evaluation for potential cysts or masses. Abnormalities of the fallopian tubes may also be noted at this time.

MRI Pelvis Without and With IV Contrast. There is no relevant literature regarding the use of pelvic MRI without and with intravenous (IV) contrast as initial imaging in the evaluation of infertility. However, if masses are identified on MRI without IV contrast, contrast is often recommended for further characterization; as such, a unified examination may be considered. Please refer to the

ACR Appropriateness Criteria® topics on “Endometriosis” [8] and the ACR Appropriateness Criteria® topic on “Fibroids” [11] for these specific indications.

MRI Pelvis Without IV Contrast. MRI of the pelvis has been shown to be useful for almost all structural changes pertaining to the female pelvis. With regard to Müllerian duct anomalies, excellent agreement has been demonstrated between MRI and clinical diagnosis [12]. MRI can also be used to assess uterine motion, which has been suggested to impair fertility [13]. With regard to adenomyosis, the specific junctional zone thickness has been shown to be a potential predictor of infertility, and MRI is effective in evaluation of the junctional zone thickness [14]. Masses impacting the uterine cavity, including subserosal and intracavitary fibroids, may be well seen with MRI and have been associated with repeated pregnancy loss and infertility [15]. The ovaries are also well assessed for volume and follicles [16].

US Pelvis Transabdominal. Although transabdominal US and transvaginal US (TVUS) may be performed together for an evaluation of the ovaries, transabdominal US should be relied upon only if the ovaries are not adequately evaluated via a TVUS approach [15]. Additionally, transabdominal US may be preferred over TVUS in select circumstances such as patient discomfort or large uterine fibroids when TVUS may be suboptimal.

US Pelvis Transabdominal and US Pelvis Transvaginal. A combined transabdominal and transvaginal approach is typically used for pelvic US imaging. When TVUS fails to image all the areas of interest, a transabdominal US may be performed [17].

US Pelvis Transvaginal. TVUS is highly effective in the initial assessment of the uterus and ovaries and is the recommendation of multiple societies [18]. This initial evaluation of the uterus may provide information regarding uterine malformations, adenomyosis, synechiae and Asherman syndrome, uterine myomas, and uterine polyps [7]. Ovarian assessment for volume, follicle count, and masses, in addition to evaluation of the fallopian tubes for hydrosalpinx or hematosalpinx, is routinely performed [18]. Color Doppler is not used in isolation; however, it is a relevant part of a complete US pelvis examination and may help in evaluating endometrial cavity findings such as polyps, submucosal fibroids, or synechiae.

Variant 2: Adult 50 years of age or younger. Female infertility. Clinical features or history of polycystic ovary syndrome. Initial imaging PCOS is the most common endocrine disorder of reproductive-aged women. However, the definition and associated ovarian morphology criteria continue to evolve.

Imaging can confirm the findings of polycystic ovarian morphology (PCOM); however, the diagnosis of PCOS requires additional clinical criteria. The recommendations from the 2023 International Evidence-based Guideline for the Assessment and Management of Polycystic Ovarian Syndrome in adults suggest an updated threshold for PCOM of ≥ 20 antral follicles (2-9 mm) in at least one ovary, ≥ 10 mL of ovarian volume (assuming no dominant cyst or corpus luteum), or both. A follicle number per section ≥ 10 should be considered the threshold for PCOM if using older technology or image quality is insufficient to allow for accurate follicle number count [19].

MRI Pelvis Without and With IV Contrast. T2-weighted MRI can be used to determine antral follicle counts and was shown in a study to be superior to TVUS for detecting follicles ≤ 3 mm [20]. To our knowledge, there is no literature supporting the use of contrast-enhanced MRI to assess antral follicle counts [21].

MRI Pelvis Without IV Contrast. MRI may also be used to assess ovarian volume with a slight underestimation in size compared with US (3.15 mL or less) and the ability to detect a higher number of 1 to 3 mm follicles but no difference in detection of follicles > 7 mm [16]. MRI without IV contrast might be useful in the few patients for whom the ovaries are not adequately visualized with US. A study in obese adolescents with suspected PCOS demonstrated that MRI without IV contrast can provide additional information on PCOM if TVUS is unacceptable and transabdominal US is limited [20-22].

US Pelvis Transabdominal. Transabdominal US is often performed in conjunction with TVUS; however, in some settings it may be performed in isolation. The transabdominal approach is generally not suitable to record an accurate follicle count but is considered reliable to determine if the ovarian volume is > 10 mL or to assess for a follicle number per section ≥ 10 in either ovary given the difficulty of assessing follicle counts throughout the entire ovary with this approach. On occasion, with a high superficial location, the ovary may be better seen transabdominally for follicle counts than via the TVUS route but remains less reliable because of lower transducer frequency [18].

US Pelvis Transabdominal and US Pelvis Transvaginal. Although TVUS is the optimal method of evaluating the ovaries, often times transabdominal US assessment will be required due to the positioning of one or both ovaries.

US Pelvis Transvaginal. TVUS is an excellent modality for the assessment of PCOM and the optimal method of

evaluating ovarian volume and follicle number per ovary if the patient is sexually active and if acceptable to the individual being assessed. The recommendations from the international evidence-based guidelines from the international PCOS network suggest using endovaginal US transducers with a frequency bandwidth that includes 8 MHz, the threshold for PCOM on either ovary, a follicle number per ovary of ≥ 20 and/or an ovarian volume ≥ 10 mL on either ovary, ensuring no corpora lutea, cysts, or dominant follicles are present. If using older technology, the threshold for PCOM could be an ovarian volume ≥ 10 mL on either ovary [19].

Variant 3: Adult 50 years of age or younger. Female infertility. Evaluation of the fallopian tubes. Initial imaging

Although structural abnormalities of the fallopian tubes may be observed on imaging studies performed to evaluate the ovaries and uterus, dedicated fallopian tube imaging is often warranted in the infertility evaluation to assess fallopian tube patency and function.

Fluoroscopy Hysterosalpingography. HSG is the reference standard in assessing the fallopian tube for patency and structural conditions such as tubal occlusion, salpingitis isthmica nodosa, and hydrosalpinx. HSG uses either a water-soluble contrast medium (WSCM) or an oil-soluble contrast medium (OSCM) [23]. HSG with OSCM results in a higher incidence of non-in vitro fertilization pregnancies when compared with WSCM and, therefore, may be preferred in women < 38 years of age with unexplained subfertility [24]. Recent studies have diminished previous concerns regarding venous intravasation and embolism, showing that the risk of intravasation with OSCM is only slightly greater than with WSCM (4.8% versus 1.3%) and resulted in no further consequences [25]. Additionally, OSCM has a fertility-enhancing effect greater than WSCM. However, it is noteworthy that HSG increases the ongoing rate of pregnancy, regardless of the contrast media used [26].

MRI Pelvis Without and With IV Contrast. MRI may occasionally be useful in the initial assessment of the fallopian tubes if tubal or peritubal disease is suspected and TVUS is nondiagnostic [27]. The use of contrast medium and claustrophobia remain drawbacks to this approach [27].

MRI Pelvis Without IV Contrast. MRI remains an advanced technique for excellent anatomic evaluation of the fallopian tubes, with a high accuracy when compared with surgery (75.6%) [28]. Functional assessment of tubal patency is not possible without the usage of intraluminal contrast. Although there is an association between

congenital fallopian tube diverticula and impaired tubal patency, this is not proven and may lead to incorrect assumptions regarding tubal patency [23].

US Pelvis Transabdominal. A combined transabdominal US and TVUS approach may be employed in pelvic imaging, combining the anatomic overview provided by the transabdominal approach with the greater spatial and contrast resolution of TVUS imaging. Please see the section on “US Pelvis Transabdominal and US Pelvis Transvaginal” for further details. However, the fallopian tubes may not be discretely visible by these standard US studies unless abnormally dilated.

US Pelvis Transabdominal and US Pelvis Transvaginal. A combination of transabdominal and TVUS may be useful, particularly if the size and extent of an ovarian, tubal, or adnexal process extends higher into the pelvis.

US Pelvis Transvaginal. TVUS is the optimal method of evaluating the ovaries and often is very beneficial in the primary evaluation of uterine and adnexal structures. Although only providing indirect evidence of tubal occlusion, this is a highly effective method primary anatomic evaluation [23].

US Sonohysterography. Saline infusion sonohysterography (SIS) performed without a tubal contrast agent may reveal intracavitary processes that impair tubal function or result in obstruction, such as leiomyomas, polyps, synechiae, focal or diffuse adenomyosis, and congenital or acquired abnormalities. The visualization of free fluid in the pelvis after SIS is suggestive that at least one fallopian tube is patent. A study suggests that in patients with PCOS, SIS is an acceptable imaging modality for tubal patency when compared with HSG [29].

US Sonohysterography with Tubal Contrast Agent. US sonohysterography with tubal contrast agents, commonly referred to as hysterosalpingo-contrast sonography (HyCoSy), is often performed after a routine TVUS or SIS [30]. Several types of tubal contrast agents are available. HyCoSy may be performed with a saline infusion mixed 1:1 with air [23]. HyCoSy may also be performed with microbubble contrast; however, this indication has not been FDA approved. Hysterosalpingo-foam sonograph involves the injection of air polymer-type A foam. The foam is FDA approved and nontoxic to an embryo [31]. Additionally, due to its viscosity, the foam remains in the tubes for a minimum of 5 minutes. Intravasation occurs less frequently with foam than microbubble contrast. Microbubble and foam contrast allow for visualization of the entirety of the tube and may have fertility-enhancing

effects; however, further research with a control group is required. One study has suggested that ethiodized oil flushing under US guidance at the time of HyCoSy is feasible and had no major complications, allowing providers to draw upon its described improved fertility rates [32].

SUMMARY OF HIGHLIGHTS

This is a summary of the key recommendations from the variant tables. Refer to the complete narrative document for more information.

■ **Variant 1:** For initial imaging of the uterus and ovaries, US is the most appropriate modality for evaluation, and multiple societies support this recommendation. This is most often optimally assessed with TVUS, and the addition of transabdominal US may be complementary. Transabdominal US in isolation may be used as an alternative procedure when TVUS is not possible; however, it often does not yield the same level of diagnostic confidence. Variables impacting fertility that may be detected include uterine malformations, adenomyosis, synechiae and Asherman syndrome, uterine myomas, uterine polyps and ovarian assessment for volume, follicle count, and masses, along with evaluation of the fallopian tubes for hydrosalpinx or hematosalpinx. This is often optimally performed with TVUS, but transabdominal US may be a useful adjunct based on organ location or as a substitute when TVUS is suboptimal or not possible. MRI of the pelvis without IV contrast is also excellent for the evaluation of structural changes impacting the pelvic organs and may offer additional characterization of the soft tissues; however, unlike US, IV contrast is often required for complete characterization, and data are lacking to support this usage in the initial evaluation of infertility. Endometriosis is a common contributor to infertility and if in question, referring to the ACR Appropriateness Criteria® topic on “Endometriosis” [8] is recommended.

■ **Variant 2:** For the initial imaging of PCOS, ovarian volume and follicle count are the key variables to assess; TVUS is usually appropriate, and transabdominal US maybe be performed in conjunction and may be useful for acquiring ovarian volumes or when the ovary is located more superiorly in the pelvis, or to assess for a follicle number per section ≥ 10 . As such, TVUS and TVUS plus transabdominal US are equivalent procedures. Assessing follicle counts throughout the entire ovary with transabdominal US is usually less reliable because of lower transducer frequency. MRI

without IV contrast might be useful in the few patients for whom the ovaries are not adequately visualized with US. A study in obese adolescents with suspected PCOS demonstrated that MRI without IV contrast can provide additional information on PCOM if TVUS is unacceptable and transabdominal US is limited. Ovarian volume and follicle count on MRI is very comparable to TVUS. There is no literature to support the use of IV contrast to diagnose PCOM.

■ **Variant 3:** Initial evaluation of the fallopian tubes may be stratified by studies that evaluate structural abnormalities (US and MRI) and those that assess structural abnormalities and patency (HSG and HyCoSy). TVUS and the HSG/HyCoSy are complementary procedures and HSG or HyCoSy are equivalent alternatives to one another. Optimally, for the initial evaluation, HSG with water or oil-soluble contrast or HyCoSy with tubal contrast agent will offer the most comprehensive evaluation, noting, however, that HSG evaluates only the endometrial cavity and fallopian tubal lumen and thus has limitations in structural evaluation. TVUS with transabdominal US is often performed in addition to HSG to complete the initial imaging evaluation of the fallopian tubes, potentially noting a dilated tube that may be obstructed or compressed by an obstructing mass. HyCoSy may offer the most comprehensive evaluation of patency and structural abnormalities in an examination. MRI without IV contrast offers excellent structural evaluation of the fallopian tubes and may be useful if US is suboptimal. MRI with IV contrast has no supporting data. SIS evaluates the uterine cavity, and although it does not directly assess the fallopian tubes if there is spill of free fluid in the pelvis, patency of at least one tube may be inferred.

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, please visit <https://www.acr.org/Clinical-Resources/Clinical-Tools-and-Reference/Appropriateness-Criteria>.

GENDER EQUALITY AND INCLUSIVITY CLAUSE

The ACR acknowledges the limitations in applying inclusive language when citing research studies that predates the use of the current understanding of language inclusive of

diversity in sex, intersex, gender, and gender-diverse people. The data variables regarding sex and gender used in the cited literature will not be changed. However, this guideline will use the terminology and definitions as proposed by the National Institutes of Health [33].

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 2). Additional information regarding radiation dose assessment for imaging examinations can be found in the ACR Appropriateness Criteria® Radiation Dose Assessment Introduction document [34].

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