ACR–ACOG–AIUM–SRU PRACTICE PARAMETER FOR THE PERFORMANCE OF SONOHYSTEROGRAPHY AND HYSTEROSALPINGO-CONTRAST-SONOGRAPHY (HyCoSy)

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The American College of Radiology will periodically define new practice parameters and technical standards for radiologic practice to help advance the science of radiology and to improve the quality of service to patients throughout the United States. Existing practice parameters and technical standards will be reviewed for revision or renewal, as appropriate, on their fifth anniversary or sooner, if indicated.

Each practice parameter and technical standard, representing a policy statement by the College, has undergone a thorough consensus process in which it has been subjected to extensive review and approval. The practice parameters and technical standards recognize that the safe and effective use of diagnostic and therapeutic radiology requires specific training, skills, and techniques, as described in each document. Reproduction or modification of the published practice parameter and technical standard by those entities not providing these services is not authorized.

PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care[1]. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents in litigation in which the clinical decisions of a practitioner are called into question.

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

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

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1 *Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing, 831 N.W.2d 826 (Iowa 2013) Iowa Supreme Court refuses to find that the "ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures (Revised 2008)" sets a national standard for who may perform fluoroscopic procedures in light of the standard's stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, Stanley v. McCarver, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that "published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation" even though ACR standards themselves do*

not establish the standard of care.

I. INTRODUCTION

The clinical aspects contained in specific sections of this practice parameter (Introduction, Indications and Contraindications, Specifications of the Examination, and Equipment Specifications) were developed collaboratively by the American College of Radiology (ACR), the American Institute of Ultrasound in Medicine (AIUM), the American College of Obstetricians and Gynecologists (ACOG), and the Society of Radiologists in Ultrasound (SRU). Recommendations for Qualifications and Responsibilities of Personnel, Written Requests for the Examination, Documentation, and Quality Control and Improvement, Safety, Infection Control and Patient Education vary among the organizations and are addressed by each separately.

This practice parameter has been developed to assist qualified physicians performing saline infusion sonohysterography (SIS) and hysterosalpingo contrast sonography (HyCoSy); each procedure is addressed separately. Properly performed SIS and HyCoSy can provide information about the uterus, endometrium, and fallopian tubes. Additional studies may be necessary for complete diagnosis. Adherence to the following practice parameter will maximize the diagnostic benefit of each procedure.

SIS, also known as sonohysterography, is a procedure that evaluates the endometrial cavity using the transcervical injection of sterile fluid. Various terms, such as sonohysterography or hysterosonography, have been used to describe this technique. The primary goal of sonohysterography is to visualize the endometrial cavity in more detail than is possible with standard transvaginal ultrasound (US) [1, 2]. The accuracy of SIS approaches hysteroscopy in detecting endometrial abnormalities [3, 4], and exceeds both transvaginal US [5] and hysterosalpingography [6].

HyCoSy, also known as sonosalpingography, is the US evaluation of tubal patency. Tubal patency is demonstrated by instilling contrast into the fallopian tubes via the endometrial cavity, with either direct visualization of fluid flowing through the various tubal segments and out of the tube or the accumulation of fluid in the cul-de-sac. HyCoSy has been demonstrated to have an accuracy essentially equivalent to hysterosalpingogram (HSG) and chromopertubation at laparoscopy [2, 4].

II. INDICATIONS AND CONTRAINDICATIONS

A. SIS

1. Indications include, but are not limited to, evaluation of the following: [1, 3, 5-13]
    i. Abnormal uterine bleeding
    ii. Uterine cavity evaluation, especially relating to uterine leiomyomas, polyps, synechiae, and cesarean scar niches [14]
    iii. Abnormalities detected on transvaginal sonography, including focal or diffuse endometrial or intracavitary abnormalities
    iv. Congenital or acquired abnormalities of the uterus Infertility [15-17]
    v. Recurrent pregnancy loss
    vi. Suboptimal visualization of the endometrium by standard sonography when further evaluation is medically indicated
2. Contraindications
    i. Sonohysterography should not be performed in a woman who is pregnant or who could

be pregnant. In patients with regular cycles, this is usually avoided by scheduling the examination in the follicular phase of the menstrual cycle, after menstrual flow has completely or almost completely ceased and before the patient has ovulated. In a patient with regular cycles, sonohysterography should ideally be performed by the 10th day of the menstrual cycle. While performance of sonohysterography in the early follicular phase should avoid the risk of performing the procedure in a pregnant patient, many patients will have irregular menstrual cycles and thus there may be an over-reliance on timing strictly based on cycle length and last menstrual period. Patients with 21-day cycles may ovulate by day 7 of the cycle. Additionally, first trimester bleeding occurs in up to 25% of pregnancies[18-20]. As a result, there should be a low threshold to utilize urine pregnancy testing prior to performing the procedure.
Sonohysterography should not be performed in patients with active pelvic infection, concern for pelvic inflammatory disease or with an intrauterine device. Active vaginal bleeding is not a contraindication to the procedure but may make the interpretation more challenging [21].

B. HyCoSy

1. Indications include, but are not limited to, evaluation of the following: [15, 16]
    i. Determination of tubal patency in patients desiring fertility [22]
    ii. Confirmation of tubal occlusion after sterilization procedures [23]
2. Contraindications
    i. HyCoSy should not be performed in a woman who is pregnant or who could be pregnant. In patients with regular cycles, this is usually avoided by scheduling the examination in the follicular phase of the menstrual cycle, after menstrual flow has completely or almost completely ceased and before the patient has ovulated. While performance of HyCoSy in the early follicular phase should avoid the risk of performing the procedure in a pregnant patient, many patients will have irregular menstrual cycles and thus there may be an over-reliance on timing strictly based on cycle length and last menstrual period. Patients with 21-day cycles may ovulate by day 7 of the cycle. Additionally, first trimester bleeding occurs in up to 25% of pregnancies [18-20]. As a result, there should be a low threshold to utilize urine pregnancy testing prior to performing the procedure.
    ii. HyCoSy should not be performed in patients with a pelvic infection or unexplained pelvic tenderness that could be due to pelvic inflammatory disease. The presence of a hydrosalpinx is not an absolute contraindication to HyCoSy [24]. Active vaginal bleeding is not a contraindication to the procedure but may make the interpretation more challenging.

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR–SPR–SRU Practice Parameter for the Performance and Interpretation of Diagnostic Ultrasound Examinations [25].

It is strongly recommended that the physician, non-physician radiology provider, or other physician extenders (ie, advanced physician providers, advanced physician clinicians) performing the study has documented formal training in the performance, interpretation, and reporting of US examinations of the female pelvis [26, 27]. Additionally, the physician should supervise and interpret US examinations of the female pelvis on a regular basis and be familiar with techniques of cervical cannulation.

IV. WRITTEN REQUEST FOR THE EXAMINATION

The written or electronic request for SIS and HyCoSy should provide sufficient information to demonstrate the medical necessity of the examination and allow for the proper performance and interpretation of the examination.

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

The request for the examination must be originated by a physician or other appropriately licensed health care provider. The accompanying clinical information should be provided by a physician or other appropriately licensed health care provider familiar with the patient's clinical problem or question and consistent with the state scope of practice requirements. (ACR Resolution 35 adopted in 2006 – revised in 2016, Resolution 12-b)

V. SPECIFICATIONS FOR INDIVIDUAL EXAMINATIONS

A. Patient Preparation
Pelvic organ tenderness should be assessed during the preliminary transvaginal sonogram. If the patient's history or physical examination is concerning for active pelvic inflammatory disease, SIS/HyCoSy should be deferred until the patient is asymptomatic and an appropriate course of treatment has been completed. A pregnancy test is advised when clinically indicated. Patients should be questioned about a latex allergy or a reaction to povidone-iodine or other topical antiseptic (2%-4% chlorhexidine gluconate is a safe alternative [28, 29]) before the use of these products. In patients with regular cycles, a sonohysterogram or HyCoSy should be performed in the early follicular phase, as close to the end of menstrual bleeding as possible.

B. The presence of unusual pain, lesions, or purulent vaginal or cervical discharge may require rescheduling the procedure pending further evaluation or treatment. Routine use of antibiotic prophylaxis is not recommended unless there is history of pelvic inflammatory disease [30].

1. Procedure
    1. SIS
    A transvaginal sonogram should be performed before performing an SIS. The pre-SIS US allows identification of pertinent pelvic anatomy, shows the amount of fluid that is present in the pelvis, may visualize other adnexal or ovarian abnormalities, and allows the unenhanced (with no fluid) assessment of the myometrium and endometrium. This study allows visualization of the orientation and flexion of the uterus, which may assist in placement of the catheters. Before insertion, the catheter should be flushed with sterile fluid to avoid introducing air during the study. After cleansing the external os, the cervical canal and/or uterine cavity should be catheterized using an aseptic technique and normal saline or other contrast fluid instilled slowly by means of manual injection under real-time sonographic imaging. Imaging should include real-time scanning of the endometrium and cervical canal [26, 31].
    2. HyCoSy
    A transvaginal sonogram should be performed before performing HyCoSy. The presence of unusual pain or purulent vaginal or cervical discharge may require rescheduling the procedure pending further evaluation or treatment. The preliminary US allows identification of pertinent pelvic anatomy, shows the amount of fluid that is present in the pelvis, and may visualize other adnexal or ovarian abnormalities. The preliminary study visualizes the orientation and flexion of the uterus, which may assist in placement of the catheters. A SIS can be performed, as described above, immediately before HyCoSy. If performing an SIS, the catheter should be flushed with sterile fluid before insertion. After cleansing the external os, the cervical canal or uterine cavity should be catheterized using an aseptic technique, typically using a balloon

catheter to avoid backflow of fluid during HyCoSy. Appropriate sterile fluid, with air, contrast, or foam, is instilled slowly by means of manual injection under real-time sonographic imaging [22, 26, 27, 31]. Commercial devices that mix air and saline together to form the air-infused saline for HyCoSy are available. One can produce similar results by filling a 30-cc syringe with 15 cc of saline and 15 cc of air. Pushing the plunger while rocking the syringe up and down effectively infuses air with saline, which is easily seen on US.

2. Contrast Agent
    1. SIS
       Sterile normal saline should be used for sonohysterography.
    2. HyCoSy
       Appropriate sterile fluid, such as normal saline infused with air or appropriate contrast medium that consists of gas-filled microbubbles or foam, should be used for HyCoSy.

3. Analgesics
    1. SIS
       Nonsteroidal anti-inflammatory drugs may benefit some patients during SIS, although data may be conflicting. Evidence supports application of 5% lidocaine-priolocaine cream applied to the cervix to reduce pain with tenaculum placement and insertion of the cannula [32-36].
    2. HyCoSy
       Some authors advocate the use of nonsteroidal anti-inflammatories to reduce pain and potentially reduce tubal spasm, similar with HSG [30, 37], although data may be conflicting. Evidence supports application of 5% lidocaine-priolocaine cream applied to the cervix to reduce pain with tenaculum placement and insertion of the cannula [32-36].

4. Images [38]
    1. SIS
       Precatheterization images should be obtained and recorded in accordance with the ACR-ACOG-AIUM-SPR-SRU Practice Parameter for the Performance of Ultrasound of the Female Pelvis [39].

       It is recommended that fluid be instilled under sonographic guidance, ensuring adequate visualization. A complete survey of the uterine cavity should be performed, with images obtained to document normal and abnormal findings. Images should include sagittal and transverse images of the endometrium, with measurement of each layer of the endometrium in the sagittal plane. Cine sweeps in the sagittal and transverse planes can be obtained as per institutional protocol and PACS storage capabilities. One should also evaluate the endometrium for any asymmetry, irregularity, or presence of focal lesions. 3-D US imaging that includes reconstructions in the coronal plane may be helpful in the evaluation. If an intrauterine balloon is used for the examination, additional images should be obtained at the end of the procedure with the balloon deflated to fully evaluate the endometrial cavity, particularly the cervical canal and lower portion of the endometrial cavity, including a cesarean scar niche or isthmocele, if present.

       The location of any focal lesions should be demonstrated in sagittal and transverse planes, or with 3-D imaging. The size, sonographic characteristics, and depth of penetration into the myometrium, in the case of submucous myomas, should be documented. Fibroids should be documented according to the International Federation of Gynecology and Obstetrics classification system [40]. The use of color Doppler or power Doppler may be helpful in evaluating the vascularity of an intrauterine abnormality.

       Three-dimensional imaging, specifically reconstructed coronal plane imaging, is also useful in the assessment of Müllerian duct anomalies and for preoperative mapping of myomas [41, 42].

2. HyCoSy

Precatheterization images of the pelvis should be obtained and recorded in accordance with the ACR-ACOG-AIUM-SPR-SRU Practice Parameter for the Performance of Ultrasound of the Female Pelvis [39].

It is recommended that fluid be instilled under sonographic guidance, ensuring adequate visualization. If SIS is performed before HyCoSy, images are obtained as described above. Before instilling saline and air or contrast for HyCoSy, the uterus is imaged in a transverse plane, visualizing both cornua simultaneously. Contrast is then instilled under direct US visualization, assessing the passage of contrast through the courses of the fallopian tubes, including the interstitial and isthmic portions, the ampulla, and passage of contrast from the fimbria. Accumulation of contrast in the pelvis is consistent with at least one patent tube. Rotating the patient on each hip may assist in demonstrating tubal patency. Various authors have found power Doppler and 3-D imaging helpful in evaluating tubal patency [43]. The lack of tubal patency should be considered with swirling of air bubbles or contrast in the cornual regions of the endometrium. Tubal spasm may result in a similar appearance [4].

5. Postprocedure Care

The imaging or referring physician should discuss the SIS and/or HyCoSy findings with the patient. The patient may experience leaking of fluid after the procedure that could be blood-tinged or have a similar color as the cleaning solution. The patient should contact their physician if symptoms such as fever, persistent pain, or unusual bleeding develop following the procedure.

VI. DOCUMENTATION

Adequate documentation is essential for high quality in patient care. There should be a permanent record of the US examination and its interpretation. Comparison with previous relevant imaging studies may prove helpful. Images of all appropriate areas, both normal and abnormal, should be recorded. Variations from normal size should generally be accompanied by measurements. The initials of the operator should be accessible on the images or electronically on the PACS. Images should be labeled with the patient identification, facility identification, examination date, and image orientation. An official interpretation (final report) of the US examination should be included in the patient's medical record. Retention of the US examination images should be based on clinical need and relevant legal and local health care facility requirements.

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [44].

1. SIS

Measurement of the endometrium should be done in the sagittal plane by measuring each layer of the endometrium separately and then adding the results together to obtain the endometrium thickness. One should document whether the layers are uniform and symmetric or if there is asymmetry or irregularities present. Measurement of endometrial polyps and fibroids should be made in three orthogonal planes.

Describing fibroids according to the FIGO classification system can be helpful for surgical planning.

2. HyCoSy

Images should be obtained in the transverse plane, ideally visualizing both uterine cornua simultaneously but may be visualized separately.

Documentation should include the visualization of air bubbles, microbubbles or foam through at least the interstitial portion of the tubes. Detailed visualization of all tubal segments is not always possible due to of overlying bowel loops or fibroids. Any change in the amount of cul-de-sac fluid during the HyCoSy, should be mentioned.

VII. EQUIPMENT SPECIFICATIONS

Equipment performance monitoring should be in accordance with the ACR-AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Real Time Ultrasound Equipment [30].

HyCoSy is usually conducted with a high-frequency transvaginal transducer. The transducer should be adjusted to operate at the highest clinically appropriate frequency under the "as low as reasonably achievable" principle.

Vaginal transducers should be covered by a protective sheath before insertion. Coupling gel should be used. Following the examination, the sheath should be disposed of and the transducer cleaned with a high-level disinfectant. The type of solution and amount of time for cleaning should follow manufacturer and infectious disease control recommendations.

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

Transducers should be cleaned after each use [45].

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

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Writing Committee – members represent their societies in the initial and final revision of this practice parameter

ACR
Bohm-Velez, Marcela MD, Chair
Rodgers, Shuchi K MD

SRU
Andreotti, Rochelle F MD
Shum, Dorothy MD

AIUM
Groszmann, Yvette MD, MPH
Hochberg, Lauri Silver MD

ACOG
Skinner, Bethany MD

Committee on Practice Parameters - Ultrasound
(ACR Committee responsible for sponsoring the draft through the process)

Gabriel, Helena MD, Chair	Adler, Cameron MD
Azadi, Javad MD	Bohm-Velez, Marcela MD
Burgan, Constantine MD	Carnahan, Molly MD
Dahiya, Nirvikar MD	Fu-Yen Lin, Michael MD
Fung, Christopher MD	Gunabushanam, Gowthaman MBBS, MD
Itani, Malak MD	Melany, Michelle MD
Penna, Rupinder MD	Squires, Judy H MD

Committee on Practice Parameters and Technical Standards
(ACR Committee responsible for sponsoring the draft through the process)

Caplin, Drew M MD, Chair

Larson, David B MBA, MD, Chair, Commission on Quality and Safety
Nicola, Lauren MD, Chair, Commission on Ultrasound

Comments Reconciliation Committee

Maltin, Elizabeth MD - CSC, Co-Chair	Moriarity, Andrew MD - CSC, Chair
Andreotti, Rochelle F MD	Bohm-Velez, Marcela MD
Caplin, Drew M MD	Crummy, Timothy MD, MHA - CSC
Gabriel, Helena MD	Groszmann, Yvette MD, MPH
Hochberg, Lauri Silver MD	Larson, David B MBA, MD
Nicola, Lauren MD	Rodgers, Shuchi K MD
Schoppe, Kurt MD - CSC	Shum, Dorothy MD
Skinner, Bethany MD	

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*Practice parameters and technical standards are published annually with an effective date of October 1 in the year in which amended, revised, or approved by the ACR Council. For practice parameters and technical standards published before 1999, the effective date was January 1 following the year in which the practice parameter or technical standard was amended, revised, or approved by the ACR Council.

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