ACR PRACTICE PARAMETER FOR THE PERFORMANCE OF HYSTEROSALPINGOGRAPHY

The American College of Radiology, with more than 40,000 members, is the principal organization of radiologists, radiation oncologists, and clinical medical physicists in the United States. The College is a nonprofit professional society whose primary purposes are to advance the science of radiology, improve radiologic services to the patient, study the socioeconomic aspects of the practice of radiology, and encourage continuing education for radiologists, radiation oncologists, medical physicists, and persons practicing in allied professional fields.

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

Hysterosalpingography (HSG) consists of radiographic imaging of the cervical canal, uterine cavity, fallopian tubes, and peritoneal cavity during injection of contrast media with fluoroscopic visualization. It should be performed with the minimum radiation exposure necessary to provide sufficient anatomic detail for diagnosis of abnormal findings and delineation of normal and abnormal anatomic structures. Adherence to the following practice parameter will maximize the diagnostic benefit of HSG. An experience-based understanding of the relative merits of other imaging examinations such as sonography, hysterosonography, computed tomography (CT), nuclear medicine, and magnetic resonance imaging (MRI) will result in the selection of the most appropriate test. In each case, the expected gain in information from the diagnostic study should outweigh any potential risk to the patient. Additional diagnostic studies, such as hysteroscopy, may be necessary for complete diagnosis.

II. INDICATIONS AND CONTRAINDICATIONS

A. Indications

HSG is designed to evaluate the uterine cavity and fallopian tubes. The conditions that may require HSG for evaluation include, but are not limited to [1-3]:

1. Infertility
2. Follow-up of sterilization procedures
3. Pelvic pain
4. Irregular menstrual cycles
5. Irregular vaginal bleeding
6. Congenital abnormalities and/or anatomic variants
7. Patients prior to or after tubal surgery, selective salpingography, and tubal recanalization or other intervention
8. Postoperative uterine cavity
9. Patients prior to treatment with assisted reproductive technologies
10. Delineation of submucosal uterine fibroids
11. Thickened or irregular endometrium
12. Sequelae of ectopic pregnancy

B. Contraindications and Cautions

HSG should not be performed on a patient who is pregnant or who could be pregnant. This is usually avoided by scheduling the examination in the follicular phase of the menstrual cycle, after menstrual flow has ceased but before the patient has ovulated, *usually day 7 to 11 of the menstrual cycle*. If the menstrual cycle is irregular, a pregnancy test can be performed before the procedure to confirm a nonpregnant state. Also consider a pregnancy test if the most recent menstrual cycle was atypically light, as this can reflect implantation bleeding. HSG should not be performed when ongoing pelvic infection or active vaginal bleeding is present, although the study can be performed in patients who are chronically spotting. Treatment of known cervical os stenosis should be considered prior to evaluation, as it can make the cannulation of the cervix difficult or impossible. If pelvic infection is of concern, the examination should be rescheduled until the infection is treated. If there is a history of pelvic infection, pretreatment with antibiotics may be indicated (see section IV.A). If there is a history of an allergic-like or unknown reaction to iodinated contrast media, premedication should be considered because there is some intravascular clearance and risk for intravasation and extravasation. If the prior reaction was moderate, the examination may be contraindicated unless no alternative examination is possible. If the prior reaction was severe, the examination is contraindicated in most cases (see the ACR Manual on Contrast Media [4]). When hysterosonography is appropriate to answer the clinical question, it is preferred over HSG to avoid radiation exposure to the patient [5]; see the ACR-ACOG-AIUM-SRU Practice Parameter for the Performance of Sonohysterography and Hysterosalpingo-Contrast-Sonography (HyCoSy) [6].

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

The examination must be performed under the supervision of and interpreted by a licensed physician, with

the following qualifications:

1. Certification in Radiology, Diagnostic Radiology, or Interventional Radiology/Diagnostic Radiology (IR/DR) by the American Board of Radiology, the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, or the Collège des Médecins du Québec.
   or
2. Completion of a residency program approved by the Accreditation Council for Graduate Medical Education (ACGME), the Royal College of Physicians and Surgeons of Canada (RCPSC), the Collège des Médecins du Québec, or the American Osteopathic Association (AOA), to include documented formal training in the performance, interpretation, and reporting of examinations of the gynecologic system, including HSG. Additionally, the physician should supervise and interpret examinations of the gynecologic system, including HSG, on a regular basis.
   and
3. Radiation physics: The supervising physician must have documented training and understanding of the physics of diagnostic radiology and the equipment needed to produce the images. This should include conventional and digital radiography, fluoroscopy, screen-film combinations, and image processing. In addition, the supervising physician must be familiar with the principles of radiation protection, the hazards of radiation, and radiation monitoring requirements as they apply to both patients and personnel.
   and
4. Disease processes: The supervising physician must be familiar with the disease processes for which the patient is being evaluated and must understand the many manifestations of these diseases, as well as variants of normal anatomy and congenital anomalies.
   and
5. Consultative role: To fulfill a consultative role and be able to interpret the examination, the supervising physician should have training or experience in alternative imaging techniques such as sonography, CT, nuclear medicine, MRI, and vascular imaging.
   and
6. Technique: The supervising physician must have an understanding of and experience in proper imaging technique, imaging sequencing, and the volume and concentration of appropriate contrast material. The physician should be familiar with the various contrast agents available and the indications for the use of each. The physician should also be familiar with timing of the examination with reference to the menstrual cycle.
   and
7. Adverse reactions: The supervising physician must have training in the recognition and treatment of adverse reactions to contrast material (see the ACR Manual on Contrast Media [4]).

   Maintenance of Competence
   All physicians performing HSG procedures who have met the above criteria should perform a sufficient number of these procedures to maintain their skills.

   Continuing Medical Education
   The physician's continuing medical education should be in accordance with the ACR Practice Parameter for Continuing Medical Education (CME) [7].

B. Qualified Medical Physicist

A Qualified Medical Physicist is an individual who is competent to practice independently one or more subfields in medical physics. The American College of Radiology considers certification and continuing education and experience in the appropriate subfield(s) to demonstrate that an individual is competent to practice in one or more subfields in medical physics, and to be a Qualified Medical Physicist. The ACR strongly recommends that the individual be certified in the appropriate subfield(s) by the American Board of Radiology (ABR), the Canadian College of Physics in Medicine, the American Board of Science in Nuclear

Medicine (ABSNM), or the American Board of Medical Physics (ABMP).
A Qualified Medical Physicist should meet the ACR Practice Parameter for Continuing Medical Education (CME) [7].
The appropriate subfield of medical physics for this practice parameter is Diagnostic Medical Physics (previous medical physics certification categories including Radiological Physics, Diagnostic Radiological Physics, and Diagnostic Imaging Physics are also acceptable). (ACR Resolution 17, adopted in 1996 – revised in 2008, 2012, 2022, Resolution 41f)

C. Non-Physician Radiology Provider (NPRP)
NPRPs are all Non-Physician Providers (eg, RRA, RPA, RA, PA, NP, ...) who assist with or participate in portions of the practice of a radiologist-led team (Radiologists = diagnostic, interventional, neurointerventional radiologists, radiation oncologists, and nuclear medicine physicians). The term "NPRP" does not include radiology, CT, US, NM MRI technologists, or radiation therapists who have specific training for radiology related tasks (eg, acquisition of images, operation of imaging and therapeutic equipment) that are not typically performed by radiologists.
The term 'radiologist-led team' is defined as a team supervised by a radiologist (ie, diagnostic, interventional, neurointerventional radiologist, radiation oncologist, and nuclear medicine physician) and consists of additional healthcare providers including RRAs, PAs, NPs, and other personnel critical to the provision of the highest quality of healthcare to patients. (ACR Resolution 8, adopted 2020).

D. Radiologic Technologist
Certification by the ARRT or unrestricted state licensure is required.
Qualifications and performance of technologists should comply with procedure manuals at the imaging facility. Continuing medical education (CME) programs and on-the-job training under the supervision of a qualified physician should be available.

IV. SPECIFICATIONS OF THE EXAMINATION

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

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

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

A. Patient Preparation
The referring or imaging physician may elect to prescribe prophylactic antibiotics, particularly if there is a history of pelvic inflammatory disease. If dilated and/or obstructed fallopian tubes are diagnosed and the patient is not taking prophylactic antibiotics, consideration should be given to administering antibiotics at the time of the examination. The procedure generally does not require sedation or analgesia; however, cramping may occur during and after the procedure. Therefore, nonopioid pain relief, such as nonsteroidal anti-inflammatory drugs (NSAIDs), should be considered on the day of the procedure [8].

B. Procedure
All air should be removed from the cannula by priming it in the vertical position. The cervical canal or endometrial cavity should be accessed using aseptic technique and an appropriate volume of contrast agent administered under intermittent fluoroscopic observation to demonstrate the anatomic structures to be studied. Typically, 10 to 30 mL is given for water-based contrast media (WBCM) and 2 to 15 mL for oil-based contrast media (OBCM). A balloon catheter aids in reducing leakage of contrast and ensuring an adequate seal. If hydrosalpinx is demonstrated, overdistention of the fallopian tube(s) should be avoided to

reduce risk of rupture.

The contrast medium should be injected slowly to prevent spasm and discomfort and avoid intravasation or rapid intraperitoneal spill, which can obscure findings or complicate interpretation. When using OBCM, use the smallest amount of contrast according to the anatomical area to be visualized. Oil-based contrast injection should be in increments of 2 mL, not to exceed 15 mL, until tubal patency is determined, stopping the injection for excessive discomfort [9]. Additional comfort considerations such as use of warmed or plastic speculum, catheter with stiff introduction sheath as a first line approach rather than a tenaculum, and appropriate lithotomy positioning could be taken. Endocervical and exocervical topical application of lidocaine cream or lidocaine injection applied before the procedure may be effective for pain relief related to cervical manipulation, especially if a tenaculum is used [10,11]. However, it is not helpful with pain due to contrast injection, which is usually the most painful part of the procedure [12].

C. Contrast Agent

Oil-based and various water-based contrast media can be used for HSG, and the relative advantages, disadvantages, and possible therapeutic efficacy [13] of the contrast agent used should be understood. Both agents contain iodine, and therefore premedication or alternative examinations should be considered if the patient has a history of a prior allergic-like or unknown reaction to iodinated contrast (see section II.B). WBCM is more commonly used in the United States. Nonionic low osmolar WBCM is favored due to lower frequency of allergic-like reactions than with ionic and high osmolar contrast media. OBCM carries a small but major risk of pulmonary or cerebral embolism. However, a potential advantage of OBCM is increased fertility rates [14,15]. If an oil-based contrast agent is used, injection should be halted immediately if myometrial or venous intravasation is observed on fluoroscopy [16,17] to reduce the risk of embolism. Thyroid function tests should be checked and be normal prior to administration of OBCM and should be monitored after the procedure. HSG with OBCM may induce subclinical hypothyroidism in the setting of slow contrast clearance and higher iodine concentration [18]. OBCM is contraindicated during breastfeeding due to the risk of inducing neonatal hypothyroidism [19], although breast feeding may be continued if WBCM is used (see the ACR Manual on Contrast Media [4]).

D. Images

Appropriate images should be obtained to demonstrate normal and abnormal findings. Supine frontal views are routinely obtained, and oblique and prone views may be obtained as indicated to show the entirety of the fallopian tube. Magnification is usually indicated for detailed imaging of the fallopian tubes. The endometrial cavity and fallopian tubes are opacified as necessary, typically until peritoneal spill is satisfactorily observed. Waiting a few moments and injecting contrast more slowly may distinguish between lack of tubal filling due to cornual muscle spasm versus tubal obstruction [20,21].

Use of last image hold and/or save grab features is encouraged for saving examination images to reduce radiation exposure. Imaging with the intent of showing tubal opacification should be obtained with full exposure.

Care should be taken to ensure that accurate orientation of the anatomy is annotated by electronic or physical side markers on the images.

If a balloon catheter is used for the examination, images should be obtained at the end of the procedure with the balloon deflated to fully evaluate the endometrial cavity and cervical canal [22-24]. Injection of contrast into the cervix as the catheter is pulled out aids in assessing the endocervical canal for abnormalities. Postdrainage images may be obtained if endometrial pathology is suspected.

E. Postprocedure Care

The imaging or referring physician should discuss the HSG findings with the patient. The patient should be instructed to contact the imaging physician or referring physician if the patient develops fever, persistent pain, or unusual bleeding following the procedure. The patient can be told to expect mild pelvic cramping and light vaginal bleeding for one or two days. Advise patients who received oil-based contrast about the risk of hyper-or hypothyroidism following the use of oil-based contrast due to the oil remaining in the body for several months. Instruct the patient to follow up with their physician if they become pregnant or develop any signs of thyroid dysfunction in the months after administration.

V. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [25].

VI. EQUIPMENT SPECIFICATIONS

Equipment performance monitoring should be in accordance with the ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Radiographic Equipment [26] and the ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Fluoroscopic Equipment [27].

Examinations must be performed with fluoroscopic and radiographic equipment meeting all applicable federal, state, and local radiation standards. The equipment should provide diagnostic fluoroscopic image quality and recording capability (radiographs, video, or digital). The equipment should be capable of producing kilovoltage greater than 100 kVp. Fluoroscopy equipment with "last image hold" feature is desirable and can be used for documentation of procedural images. Opacified fallopian tubes should be documented using full exposure X-ray due to potentially subtle findings within fallopian tubes.

Appropriate emergency equipment and medications must be immediately available to treat adverse reactions associated with administered medications. The equipment and medications should be monitored for inventory and drug expiration dates on a regular basis. The equipment, medications, and other emergency support must also be appropriate for the range of ages and sizes in the patient population. Suggested equipment for contrast reactions can be found in the ACR Manual on Contrast Media [4]).

VII. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, non-physician radiology providers**,** radiologic technologists, and all supervising physicians have a responsibility for safety in the workplace by keeping radiation exposure to staff, and to society as a whole, "as low as reasonably achievable" (ALARA) and to assure that radiation doses to individual patients are appropriate, taking into account the possible risk from radiation exposure and the diagnostic image quality necessary to achieve the clinical objective. All personnel who work with ionizing radiation must understand the key principles of occupational and public radiation protection (justification, optimization of protection, application of dose constraints and limits) and the principles of proper management of radiation dose to patients (justification, optimization including the use of dose reference levels). https://www-pub.iaea.org/MTCD/Publications/PDF/PUB1775_web.pdf

Nationally developed guidelines, such as the ACR's Appropriateness Criteria®, should be used to help choose the most appropriate imaging procedures to prevent unnecessary radiation exposure.

Facilities should have and adhere to policies and procedures that require ionizing radiation examination protocols (radiography, fluoroscopy, interventional radiology, CT) to vary according to diagnostic requirements and patient body habitus to optimize the relationship between appropriate radiation dose and adequate image quality. Automated dose reduction technologies available on imaging equipment should be used, except when inappropriate for a specific exam. If such technology is not available, appropriate manual techniques should be used.

Additional information regarding patient radiation safety in imaging is available from the following websites – Image Gently® for children (www.imagegently.org) and Image Wisely® for adults (www.imagewisely.org). These advocacy and awareness campaigns provide free educational materials for all stakeholders involved in imaging (patients, technologists, referring providers, medical physicists, and radiologists).

Radiation exposures or other dose indices should be periodically measured by a Qualified Medical Physicist in accordance with the applicable ACR Technical Standards. Monitoring or regular review of dose indices from patient imaging should be performed by comparing the facility's dose information with national benchmarks, such as the ACR Dose Index Registry and relevant publications relying on its data, applicable ACR Practice Parameters, NCRP Report No. 172, Reference Levels and Achievable Doses in Medical and Dental Imaging: Recommendations for the United States or the Conference of Radiation Control Program Director's National Evaluation of X-ray Trends; 2006, 2009, amended 2013, revised 2023 (Res. 2d).

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

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading *Position Statement on Quality Control & 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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