ACR-SIR-SPR PRACTICE PARAMETER FOR THE REPORTING AND ARCHIVING OF INTERVENTIONAL RADIOLOGY PROCEDURES

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 $\frac{1}{2}$. 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.

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, <u>Stanley v. McCarver</u>, 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

This practice parameter was revised collaboratively by the American College of Radiology (ACR), the Society of Interventional Radiology (SIR), and the Society for Pediatric Radiology (SPR).

This practice parameter is intended to improve patient care by improving the consistency of medical record content, written or dictated reports, and image archiving for vascular/interventional radiology procedures (exclusive of breast interventional procedures). For information on breast interventional procedures, see the <u>ACR</u> <u>Practice Parameter for the Performance of Stereotactic-Guided Breast Interventional Procedures</u> or the <u>ACR</u> <u>Practice Parameter for the Performance of Ultrasound-Guided Percutaneous Breast Interventional Procedures</u> [1,2].

These practice parameters will serve the following specific purposes [3]:

- 1. To document medical care
- 2. To be used in quality improvement programs and for credentialing purposes
- 3. To be used in teaching and research
- 4. To document procedures for appropriate coding
- 5. To provide practice parameters for state health codes for image archiving

II. MEDICAL REPORT

A. Nonphysicians and Interpretation

Rendering interpretations of medical imaging studies (preliminary, final, or otherwise) is beyond the scope of practice and is not the intended role of nonphysician members of the healthcare team, including NPRPs, radiologic technologists, nurses, and others, but excluding physicians in training. Nonphysicians should not be permitted to render interpretations of medical imaging studies, whether under physician supervision or as an independent nonphysician healthcare provider. (ACR Resolution 16, adopted 2021)

An interpretation of an imaging procedure is the action of an individual and not defined by the location of their contributions in the report. Interpretations may appear anywhere in a radiology report or elsewhere in the medical record (eg, findings, impression, or otherwise). Nonphysician members of the healthcare team, including radiologic technologists, nurses and others, should not be involved in the interpretation of an imaging examination regardless of where their observations are located in the report or medical record.

An interpretation is not defined by the availability of a report to other healthcare providers, but rather by its content and the nature of intellectual activity which produced it. Specifically, reports and/or notes in the medical record in any stage of completion by a nonphysician when that nonphysician was not directly involved in the acquisition of the medical images being interpreted or procedure which was performed, may all be considered interpretations, depending on their content. Such a report or note is considered an interpretation whether it is a draft (available only to a radiologist), a preliminary report, a final report, or any other written form.

Nonphysicians such as NPRPs and radiologic technologists may provide observations to the radiologist regarding targeted real-time image acquisitions or invasive procedures in which they were involved. Examples include a technologist providing observations from real-time targeted ultrasound or fluoroscopic image acquisitions and an NPRP describing a needle procedure they performed. Observations from a nonphysician who acquired medical images should be provided to the radiologist in a draft form only and should be limited to observations made during the acquisition of images (such as a sonographer worksheet). Observations from a nonphysician who performed or assisted in an invasive procedure may be provided to the radiologist in any portion of the radiology report and/ or medical record and may be in any stage of completion as permitted by local institutional policy. It is not appropriate for nonphysicians to routinely provide observations on imaging studies and/ or procedures when they were not directly involved in the performance of the procedure or acquisition of the images (eg, radiographs, mammography, CT scans, MRI scans, and nuclear imaging). (ACR Resolution 17, Adopted 2021)

II. MEDICAL REPORT

B. Medical Record

A medical record consists of a patient's medical information recorded in either hard copy or electronic format. This information may be recorded in the patient medical chart, nursing reports, radiology records, inpatient or outpatient medical information storage areas, or electronically. The medical record should include, as appropriate, the following information [4]:

- 1. Documentation of preprocedural patient evaluation
- 2. Immediate preprocedure note
- 3. Immediate postprocedure note
- 4. Final procedure report
- 5. Documentation of postprocedure patient follow-up, if applicable

II. MEDICAL REPORT

C.

Documentation of Preprocedural Patient Evaluation

The preprocedural documentation provides a baseline record of patient status and documents the indication for the procedure. It is particularly relevant whenever moderate procedural sedation/analgesia is considered [5] and should be entered in the electronic health record or chart before the procedure. Preprocedural documentation should, as appropriate depending on the complexity and/or clinical urgency of the procedure, include the following information:

- 1. Indication for procedure and brief history
- 2. Findings of targeted physical examination, including baseline vital signs
- 3. Relevant laboratory, imaging study, and other diagnostic findings
- 4. The plan for each procedure to be performed
- 5. Plan for sedation/anesthesia and risk stratification, such as the American Society of Anesthesiologists Physical Status Classification, if it is going to be administered by the performing physician, and assessment of airway anatomy [6], as applicable.
- 6. Documentation of informed consent (consistent with state and federal laws) or, in the case of an emergency, that it was an emergent medical procedure
- 7. Documentation of DNR and DNI status and agreement for blood transfusion.

II. MEDICAL REPORT

D. Updated Immediate Preprocedure Note

The updated immediate preprocedure documentation should be an interval note with any new information developed between the preprocedural evaluation/documentation and the presentation of the patient for the procedure. The physician performing the procedure should provide a note prior to administration of any sedation. In situations where the preprocedural documentation is performed/completed immediately preceding the procedure, the updated immediate preprocedure note is not necessary, as per Joint Commission rules, unless otherwise required by local institution policy.

II. MEDICAL REPORT

E. Immediate Postprocedure Note

Before a patient is transferred to the next level of care, an immediate postprocedure note or a final report should be completed and available. The immediate postprocedure note should include the following, as appropriate:

- 1. Preprocedure diagnosis
- 2. Postprocedure diagnosis
- 3. Procedure(s) performed
- 4. Operator(s) and Assistants
- 5. Medications, including sedation/anesthesia
- 6. Brief description of procedure (eg imaging guidance, access, closure, implants) and findings
- 7. Estimated blood loss
- 8. Specimens removed
- 9. Complications
- 10. Disposition
- 11. Postprocedure monitoring/treatment plan

It is not necessary for the listed items to be recorded in the order given above.

II. MEDICAL REPORT

F. Final Report [7-9]

- 1. A final report is required for the following purposes:
 - a. To transmit procedural information to all members of the health care community who may participate in subsequent care of the patient
 - b. For legal purposes
 - c. For revenue cycle management
- 2. Additional functions of the final report include the following:
 - a. Quality improvement programs and for credentialing purposes
 - b. Data collection for research
 - c. Teaching
 - d. Informing patients and families
- 3. Specific information to be included in this report depends on the procedure. The following elements are recommended, although not all of them may be applicable:

a. Procedure name

- b. Administrative information
 - i. Date
 - ii. Time
 - iii. Facility
- c. Patient information
 - i. Patient Name
 - ii. Medical record number
 - iii. Date of birth
 - iv. Gender
- d. Procedural personnel, as applicable
 - i. Attending physician(s)
 - ii. Fellow physician(s)
 - iii. Resident physician(s)
 - iv. Advanced Practice Provider(s)
 - v. Other assistant(s)
- e. Preprocedure diagnosis
- f. Postprocedure diagnosis
- g. Clinical history
 - i. Diagnosis

- ii. Indications
- iii. Comparison

h. Procedure(s) performed

- i. Procedure details
 - i. Informed consent
 - ii. Time out
 - i. Anesthesia/sedation
 - Type and provider

Local anesthesia dose should be documented in the final report for pediatric patients as per local policy

- iii. Medications and contrast should be documented in the patient's electronic health record as per local policy
- j. Technical details of the procedure
 - i. Patient position
 - ii. Surface antiseptic preparation
 - iii. Patient and provider barrier techniques used (eg, cap, gloves, gown, etc)
 - iv. Imaging guidance for access
 - v. Imaging guidance for procedure
 - vi. Access location/site
 - vii. Access technique
 - viii. Equipment and device utilized
 - ix. Description of the procedure
 - x. Closure and hemostasis technique
 - xi. Specimens removed and laboratory tests that specimens were sent for
 - xii. Estimated blood loss
 - xiii. Radiation doses such as [10,11]:

Skin dose mapping Peak skin dose Reference air kerma, (K_{a·r}) Kerma-area product Fluoroscopy time/number of fluorographic images Dose-length product Volume CT dose index

- k. Complications: Intraprocedural or immediate postprocedural complications, occurrences, or unexpected adverse events
- I. Observations
- m. Impression
- n. Disposition
- o. Treatment and follow-up plan Attestation Supervision
- p. Supplemental information

It is not necessary for the listed items to be recorded in the order given above.

II. MEDICAL REPORT

G. Structured Reporting

Structured reporting has gained popularity within the diagnostic radiology community as it may provide referring physicians with more consistent, definitive information, especially with complex examinations (eg, oncology staging) [12,13].

Structured reporting within interventional radiology has been shown to improve institutional compliance, quality, and reimbursement, as well as to help facilitate data collection for research [14,15]. One study suggested that referring physicians preferred reading structured reports compared to free-text reports [15], whereas another study found that interventional radiologists were more compliant and satisfied with structured reporting when they had input into the initial design of the report template, including a (free-text) executive summary and a detailed procedural narrative [16].

Indeed, the benefits of structured reporting within interventional radiology have been initially established [<u>16</u>]. Data fields prompt inclusion of the above required elements of final reporting. Implementation has improved as the templates have automated importing of data into the report and as the templates have become increasingly compatible with existing voice dictation software. Additionally, the interventional radiologist has a vested role in the templates' creation and layout, all of which will help to increase satisfaction and compliance.

III. ARCHIVING OF IMAGES

A. General Principles

All pertinent imaging data should be saved in permanently retrievable digital or hard-copy format. Legal requirements as to the length of time that images should be retained vary from state to state. Examples of pertinent imaging data include the relevant anatomy that will affect patient management, device position, complications, and any transient adverse events (such as emboli) that have been successfully treated during a procedure.

B. Documentation of Device Position

The final position of all devices inserted permanently, temporarily or long term with imaging guidance (eg, stents, endovascular grafts, central venous catheters, inferior vena cava filters, embolic agents, drainage catheters) should be documented with images.

C. Angiography

Archived angiographic images are crucial to the overall diagnostic and/or therapeutic plan of the patient. For saved digital subtraction angiography (DSA) runs, the operator should consider whether archiving native or DSA images might be useful and images should be recorded based on a written local policy and procedure. These images are important for interpreting the orientation and localizing the target organ and vessels. It should be understood that, with the use of rapid-sequence imaging and fluoroscopy, some observations that are described in the report may not be adequately represented by the static images.

D. Endovascular Interventions

Images before and after deployment of endovascular devices should be obtained and archived. Intermediate stages that are pertinent to the performance of the endovascular procedure may also be documented with archived images. Images should detail the position of the device and, when appropriate, the effect of the device on target or nontarget vessels.

E. Nonvascular Interventions

Images of the target organ or fluid collection before the initial access should be obtained. Images should document the device's position and its effect on target and nontarget organs. The final position of drainage catheters within fluid collections, the biliary system, the urinary tract, or the gastrointestinal tract should be

documented. At least one image demonstrating the change of target organ or fluid collection after the drainage catheter should be obtained. If contrast material is injected for delineating cavity size, location, or communication with adjacent structures, at least one image should be archived. If imaging is used to mark a position for subsequent needle entry (eg, ultrasound to mark an entry site for later paracentesis performed without imaging guidance), at least one image of this position should be saved. For needle placement (eg, biopsies, drug delivery, pain management interventions) under direct imaging guidance, at least one image should be saved with the needle in final position at each targeted site. The operator may choose to document every needle pass and the final condition of the accessed structure. At least one image of the target organ or structure after removal of the needle should be archived.

IV. ARCHIVING OF RADIATION DOSE DATA

If technically possible, all radiation dose data recorded by the fluoroscopy unit or CT scanner should be transferred and archived with the images from the procedure [10]. When possible, this should be performed electronically with automatic transfer of the data from the fluoroscopy unit or CT scanner to a picture archiving and communication system (PACS). Archiving of radiation dose data is of particular importance if the procedure is likely to be repeated or if the patient has received a clinically important radiation dose [4].

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