

Quality Improvement Guidelines for the Reporting and Archiving of Interventional Radiology Procedures

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THERE is little federal regulatory guidance about the reporting and archiving of interventional procedures. The small body of state regulatory guidance varies considerably from state to state. When state regulations exceed the requirements contained in this document, practitioners are advised to follow the more stringent state regulatory guidelines.

PREAMBLE

The membership of the Society of Interventional Radiology (SIR) (formerly SCVIR) Standards of Practice Committee represents experts in a broad spectrum of interventional pro-

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A complete list of the members of the SIR Standards of Practice Committee is given at the end of this article. From the Department of Radiology (R.A.O.), Northwestern University, Chicago, Illinois; Department of Radiology (M.A.B.), Dartmouth Hitchcock Medical Center, Lebanon, New Hampshire; SUNY Syracuse Health Science Center (J.F.C.), Syracuse; St. Luke's–Roosevelt Hospital Center (C.W.B.), New York, New York; Leesburg, F (M.S.S.); Reading Hospital and Medical Center (D.S.), Reading, Pennsylvania; Inova Alexandria Hospital (K.S.R.), Alexandria, Virginia; Vanderbilt University Hospital (S.G.M), Nashville, Tennessee; and Manuel Maloof Imaging Center (C.A.L.), Emory University School of Medicine, Atlanta, Georgia. **Address correspondence to SIR**, 10201 Lee Highway, Suite 500, Fairfax, VA 22030.

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cedures from both the private and academic sectors of medicine. Generally, Standards of Practice Committee members dedicate the vast majority of their professional time to performing interventional procedures; as such, they represent a valid, broad expert constituency of the subject matter under consideration for standards production.

METHODOLOGY

SIR produces its Standards of Practice documents with use of the following process: Standards documents of relevance and timeliness are conceptualized by the Standards of Practice Committee members. A recognized expert is identified to serve as the principal author for the standard. Additional authors may be assigned depending on the magnitude of the project.

An in-depth literature search is performed with use of electronic medical literature databases. Then, a critical review of peer-reviewed articles is performed with regards to the study methodology, results, and conclusions. The qualitative weight of these articles is assembled into an evidence table, which is used to write the document such that it contains evidence-based data with respect to content, rates, and thresholds.

When the evidence of literature is weak, conflicting, or contradictory, consensus for the parameter is reached by a minimum of 12 Standards of

Practice Committee members with use of a Modified Delphi Consensus Method (Appendix 2) (1). For purposes of these documents, consensus is defined as 80% Delphi participant agreement on a value or parameter.

The draft document is critically reviewed by the Standards of Practice Committee members, in either a telephone conference call or face-to-face meeting. The finalized draft from the Committee is sent to the SIR membership for further input/criticism during a 30-day comment period. These comments are discussed by the Standards of Practice Committee, and appropriate revisions made to create the finished Standards Document. Before its publication, the document is endorsed by the SIR Executive Council.

This standards document aims to provide guidelines to improve consistency of archiving of vascular/interventional radiology procedures and the written/dictated reports. It is our objective to improve patient care by reducing the variation that occurs among different physicians and practices. These standards will serve the following specific purposes:

1. To document medical care;
2. To be used in Quality Improvement Programs and for credentialing purposes;
3. To document procedures for appropriate coding;
4. To provide guidelines to State Health Codes for image archiving.

MEDICAL REPORT

Medical Record

The medical record consists of all recorded medical information, either in written or electronic format. It may be recorded in the patient medical chart, nursing reports, radiology records, inpatient or outpatient medical information storage areas, or on computers. It should include the indication for the procedure and who referred the patient for the procedure. The medical record need not contain all of the information that is stored within a quality improvement program. Contrast agent dose, medications administered, and measures of ionizing radiation exposure (such as total fluoroscopy time) must be part of the permanent medical record. For inserted medical devices, appropriate identifying information, such as the product name, vendor, and lot numbers, must be recorded.

Preprocedural Documentation

The preprocedural documentation provides a baseline record of patient status and documents the indication for the procedure. It should be written in the chart before initiation of conscious sedation or the procedure. Preprocedural documentation should include the following information, depending on the complexity of the procedure:

1. Indication for procedure and brief history;
2. Physical examination findings;
3. Laboratory findings (including noninvasive);
4. Risk stratification, such as the American Society of Anesthesiologists Class;
5. Documentation that informed consent, including risks, benefits, and alternatives, was obtained, or in the case of an emergency, that this was an emergency medical procedure;
6. The diagnostic and/or anticipated treatment plan for each procedure to be performed.

Immediate Procedure Note

The immediate procedure note is helpful for interim communication to other medical personnel before the fi-

nal report. It should be completed for all patients immediately after the procedure and includes:

1. Identification and brief description of procedure;
2. Operator(s);
3. Results;
4. Complications;
5. Postprocedure monitoring/treatment plan.

Additional information may be included based on complexity of procedure.

Final Report

The final report is required:

1. To transmit procedural information to all members of health care community who may participate in subsequent care of the patient;
2. For legal purposes;
3. For reimbursement.

Specific information included in this report depends on the procedure.

We recommend the following elements:

1. Procedure;
2. Date;
3. Operator(s);
4. Indication;
5. Procedure/technique: a technical description of procedure. This information should include access site (and all attempted access sites), guidance modalities, catheters/guide wires/needles, vessels or organs catheterized, technique, and hemostasis. Each major vessel catheterized for imaging or intervention should be noted specifically. If informed consent was obtained, this should be stated;
6. Complications;
7. Results/findings;
8. Conclusion;
9. Plan, if appropriate.

ARCHIVING OF IMAGES

General Principles

All pertinent imaging data should be saved in permanently retrievable digital or hard-copy format. Examples of pertinent imaging data include the relevant anatomy that will affect patient management, device position, complications, and transient adverse events (such as emboli) that might

have been successfully treated during a given procedure. If ultrasound guidance is used to gain entry into a blood vessel, it is optional to save a sonographic image of this blood vessel.

Documentation of Device Position

The final position of all devices inserted permanently 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 imaging. Benefits of documenting device position should be weighed against ionizing radiation risks of x-ray documentation (eg, in pregnancy).

Angiography

Archived images are crucial to the overall diagnostic and/or therapeutic treatment plan of the patient. Archiving should be similar for cut-film angiography or digital subtraction angiography. For saved digital subtraction angiography runs, an attempt should be made to record at least one image in unsubtracted or partially subtracted format. This image is useful for orientation/localization purposes.

Endovascular Interventions

Predeployment and postdeployment/intervention images should be obtained and archived. Each discrete stage of an endovascular procedure should be documented. Images should detail the position of the device and the effect of the device on the target or nontarget vessel.

Nonvascular Interventions

Images should document the device position and the device's 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. If contrast material is injected for delineation of cavity size, location, or communication with adjacent structures, at least one image obtained 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) under direct imaging guidance, at least one image should be saved with the needle in final position.

Archiving of subsequent needle passes or of the final condition of the accessed structure should be based on the operator's risk stratification. Low-risk procedures may not require additional image archiving. For high-risk procedures, the operator may choose to document all needle passes and the final condition of the accessed structure.

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APPENDIX 1: SIR STANDARDS OF PRACTICE COMMITTEE CLASSIFICATION OF COMPLICATIONS BY OUTCOME

Minor Complications

- A. No therapy, no consequence, or
- B. Nominal therapy, no consequence; includes overnight admission for observation only.

Major Complications

- C. Require therapy, minor hospitalization (<48 h),
- D. Require major therapy, unplanned increase in level of care, prolonged hospitalization (>48 h),
- E. Have permanent adverse sequelae, or
- F. Result in death.

APPENDIX 2: METHODOLOGY

Reported complication-specific rates in some cases reflect the aggregate of major and minor complications. Thresholds are derived from critical evaluation of the literature, evaluation of empirical data from Standards of Practice Committee member practices, and, when available, the SIR HI-IQ system national database.

Consensus on statements in this document was obtained utilizing a modified Delphi technique (1,2).

Technical documents specifying the exact consensus and literature review methodologies as well as the institutional affiliations and professional credentials of the authors of this docu-

ment are available upon request from SIR, 10201 Lee Highway, Suite 500, Fairfax, VA 22030.

The clinical practice guidelines of the Society of Interventional Radiology attempt to define practice principles that generally should assist in producing high quality medical care. These guidelines are voluntary and are not rules. A physician may deviate from these guidelines, as necessitated by the individual patient and available resources. These practice guidelines should not be deemed inclusive of all proper methods of care or exclusive of other methods of care that are reasonably directed toward the same result. Other sources of information may be used in conjunction with these principles to produce a process leading to high quality medical care. The ultimate judgment regarding the conduct of any specific procedure or course of management must be made by the physician, who should consider all circumstances relevant to the individual clinical situation. Adherence to the SIR Quality Improvement Program will not assure a successful outcome in every situation. It is prudent to document the rationale for any deviation from the suggested practice guidelines in the department policies and procedure manual or in the patient's medical record.

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