

Society of Interventional Radiology Clinical Practice Guidelines

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A primary goal of the Society of Interventional Radiology (SIR) is ensuring high quality outcomes and patient safety in vascular and interventional radiology. For more than a decade, SIR, through its Standards Division, has taken a leadership role in improving health care quality through the development of evidence-based standards and clinical practice guidelines for the successful performance of minimally invasive catheter-based interventional radiologic procedures. This supplement serves as a compilation of the Division's published work to date.

The Standards Division has primarily focused on two linked processes: developing a quality improvement program with clinical practice guidelines and developing reporting standards for interventional techniques and devices to ensure that devices used in the practice of interventional radiology are applied safely and appropriately to patients and that patients have timely access to important new technological advances. In addition, the Division has written and contributed to credentialing standards to ensure that practitioners are appropriately trained to perform diagnostic and interventional procedures.

The SIR Standards of Practice Com-

mittee is responsible for the first process, developing the Society's quality improvement guidelines for clinical practice. These documents contain the core of the SIR Quality Improvement Process, a set of indicator thresholds. The indicators for outcomes are effectiveness (success), indications, and complication rates. Interventional radiology practices use these indicator thresholds to examine their outcomes on a regular basis and are encouraged to do so at monthly Quality Assurance meetings.

The second major process is the generation of reporting standards, which are developed by the SIR Technology Assessment Committee. These documents serve as important guidelines for industry and the U.S. Food and Drug Administration (FDA) in the evaluation of new devices during pre-market trials and development. For example, the Society has published a template for evaluation of new endovascular devices. This template is used by industry to design standardized, streamlined protocols (1). SIR Reporting Standards also serve to promote uniform and improved data analysis in the literature. Broad use of these documents improves the ability to compare and assess devices and techniques from article to article. Lack of standardized data analysis has previously been a major problem with the published literature.

The SIR quality improvement and standards program was launched in 1988 with the development of "Guidelines for Establishing a Quality Improvement Program in Vascular and Interventional Radiology." Since that time 20 Quality Improvement Guidelines, 11

Reporting Standards, 4 position statements, and several credentialing criteria have been generated. In addition, the SIR Standards Division has been actively involved in generating international consensus guidelines and multi-society consensus documents, usually providing the only major interventional radiology perspective on vascular medicine.

TYPES OF DOCUMENTS

Quality Improvement Guidelines are systematically developed, evidence-based, consensus documents including definitions, indications, efficacy, success, and complication thresholds that assist medical decision-making (2). Guidelines define an optimal level of patient care and are used to reduce variation in clinical practice between individual physicians or groups of physicians, thus raising the standard of care. Guidelines also assist physicians and other health care providers in managing the huge amount of information that is found at scientific meetings, in journal articles, and in personal clinical experiences. Good practice guidelines should rest on methodical analysis of the scientific evidence, be reproducible and reliable, have clinical applicability for defined patient populations, and be updated periodically to reflect current knowledge and state of practice (3).

As the pace of development and application of new procedures quickens, it is important not only to ensure the safety and efficacy of the procedure, but also to ensure that practitioners performing these diagnostic and interventional procedures have adequate procedural training, skill, and

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Table 1
Criteria for Inclusion of Clinical Practice Guidelines in the National Guidelines Clearinghouse (NGC)

1. The clinical practice guideline contains systematically developed statements that include recommendations, strategies, or information that assists physicians and/or other health care practitioners and patients make decisions about appropriate health care for specific clinical circumstances.
2. The clinical practice guideline was produced under the auspices of medical specialty associations; relevant professional societies, public or private organizations, government agencies at the Federal, State, or local level; or health care organizations or plans. A clinical practice guideline developed and issued by an individual not officially sponsored or supported by one of the above types of organizations does not meet the inclusion criteria for NGC.
3. Corroborating documentation can be produced and verified that a systematic literature search and review of existing scientific evidence published in peer reviewed journals was performed during the guideline development. A guideline is not excluded from NGC if corroborating documentation can be produced and verified detailing specific gaps in scientific evidence for some of the guideline's recommendations.
4. The guideline is English language, current, and the most recent version produced. Documented evidence can be produced or verified that the guideline was developed, reviewed, or revised within the last five years.

Note.—All of the above criteria must be met for a clinical practice guideline to be included in NGC.

experience. Outcomes-based practice guidelines must be used to monitor results and set a benchmark for expected performance (3). Credentialing standards must be used to monitor training.

Credentialing Standards are recommendations on training and continued competence. Credentials are determined at the hospital level, and while a hospital may rely on outside sources for recommendations, they are not bound by any of these sources. The more reputable the source, the more likely the hospital will choose to abide by the recommendation. Large organizations, such as the American Heart Association (AHA), that have multi-specialty representation tend to be viewed by hospitals as more authoritative and more credible in their recommendations.

The SIR, in its own documents and also in participation with the AHA and the American College of Radiology (ACR), has created recommendations for credentialing for interventional radiology procedures. The ACR recommendations are available through the ACR web site under standards at www.acr.org. These recommendations invariably include performance of a particular number of cases to have adequate training to perform a procedure. For vascular cases, this can lead to ambiguity, since multiple vessels may be catheterized or treated in a single encounter. The official position of SIR regarding numbers is that when these numbers are used for credentialing purposes the number applies to a complete patient encounter regardless of the number of vessels selected or

treated during a given encounter. This can be found with the Credentialing Documents in this supplement (4).

Technology Assessment Documents are reporting standards on how procedures/devices are to be assessed and reported.

Policy Statements are editorial statements clarifying or emphasizing SIR positions, including endorsements or rebuttals of, or comments on documents from outside groups.

METHODOLOGY EMPLOYED

There is increasing concern about the quality, reliability, and independence of practice guidelines (5). In the article by Grilli et al, quality of specialty society guidelines was assessed based on the type of professionals and stakeholders involved in the development process, the strategy to identify primary evidence, and an explicit grading of recommendations according to the quality of supporting evidence (5). The earliest of the SIR standards documents were written by simple consensus. Since 1995, the quality improvement documents have been created using a rigorous scientific and consensus process to ensure that they comply with the criteria set by the AHRQ for documents submitted to the *National Guidelines Clearinghouse (NGC)* (Table 1) (6). It should be noted that documents prior to 2002 are published under the name of the Society of Cardiovascular & Interventional Radiology (SCVIR). Documents since 2002 use the current name: the Society of Interventional Radiology (SIR). In this

supplement, all references to SCVIR have been changed to SIR.

Quality Improvement Documents

These are developed using the following methodology. Standards documents of relevance and timeliness are conceptualized by the members of the Standards of Practice Committee. A recognized expert is identified to serve as the principal author for the standard. Additional authors are assigned dependent upon the magnitude of the project.

An in-depth literature search is performed using 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, success and complication rates, and thresholds.

When the evidence of literature is weak, conflicting, or contradictory, consensus for the parameter is reached by a minimum of 12 committee members using a Modified Delphi Consensus Method (7,8). Consensus is defined as 80% Delphi participant agreement on a value or parameter. 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 members' prac-

Table 2
SIR Classification System for
Complications by Outcome

Minor Complications
A. No therapy, no consequence
B. Nominal therapy, no consequence; includes overnight admission for observation only.
Major Complications
C. Require therapy, minor hospitalization (<48 hours)
D. Require major therapy, unplanned increase in level of care, prolonged hospitalization (>48 hours)
E. Permanent adverse sequelae
F. Death.

tices, and, when available, the SIR HI-IQ® System national database.

The draft document is critically reviewed by members of the Standards of Practice Committee via conference call and/or face-to-face meetings. Once the Committee finalizes the draft it is circulated to the SIR membership for further input/criticism during a 30-day comment period. These comments are reviewed and discussed by the Committee and appropriate revisions made to create the finished standards document. Prior to its publication the document is approved by the SIR Executive Council.

The membership of the SIR Standards of Practice Committee represents experts in a broad spectrum of interventional procedures 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. Technical documents specifying the exact consensus and literature review methodologies as well as the institutional affiliations and professional credentials of the authors of each document are available upon request from the SIR headquarters office (SIR Template).

Complications are categorized using the definitions listed in **Table 2**. The standards division understands that assignment of a particular event or case as a complication or failure can

be subjective. The division is working on a system to allow more uniform categorization of such events. A series of vignettes has been created describing a range of interventional cases. Principles have been developed to assign events into categories. The cases described in the vignettes were assigned into categories of complication and failure using a consensus process similar to that used to create the quality improvement guidelines. The intent is to create consensus on the principles to be used and to create a library of "events" that will allow more uniform categorization of complications and failures.

Technology Assessment Reporting Standards

The methodology used to create these documents differs from that used to create the quality improvement documents. Reporting standards documents address technology in evolution. The published literature is reviewed to see what definitions have been used historically and where there is a need to have uniform definitions for reporting outcomes of research. When the definitions used in the literature vary, as is frequently the case, a single definition may be recommended in the reporting standards document to allow uniform reporting. Documents are created by a single primary author or multiple authors who may be from multiple specialties. The draft is reviewed by the entire Technology Assessment Committee and frequently reviewed by outside societies, organizations, or government agencies, such as the FDA, who may choose to use these definitions as requirements for clinical trials. The document is approved by the SIR Executive Council prior to its publication.

Credentialing Standards

There are few, if any, publications that have analyzed the learning curve necessary for interventional radiology procedures. Therefore, there is little scientific structure for developing credentialing standards. For this reason, credentialing standards are developed by consensus.

HOW GUIDELINES ARE USED IN PRACTICE

Quality Improvement

Quality improvement documents have been created for many procedures. An institution may choose to focus on selected procedures to analyze outcomes. While practicing physicians should strive to achieve perfect outcomes (eg, 100% success, 0% complications), in practice all physicians will fall short of this ideal to a variable extent. Thus indicator thresholds may be used to assess the efficacy of ongoing quality improvement programs. For the purposes of these guidelines, a threshold is a specific level of an indicator that should prompt a review. "Procedure thresholds" or "overall thresholds" reference a group of indicators for a procedure, eg, major complications. Individual complications may also be associated with complication-specific thresholds. When measures such as indications or success rates fall below a (minimum) threshold, or when complication rates exceed a (maximum) threshold, a review should be performed to determine causes and to implement changes, if necessary (SIR Template).

Reporting Standards

The reporting standards are intended for use in publications of clinical research. They may not be appropriate for use in routine clinical practice, since research requires a far greater amount of detailed reporting than clinical practice. It is intended that the definitions used in the reporting standards become part of the medical literature that is subsequently used to create the standards for quality improvement.

How the Impact of SIR Guidelines is Measured

There is a steady volume of calls and e-mails from SIR members and others asking for practice guidelines and credentialing criteria. The annual average of Web visits to the SIR Clinical Practice Guidelines site is 12,548. In addition, published guidelines are measured by web access in the *Journal of Vascular and Interventional Radiology (JVIR)*. Guidelines frequently appear in the top 10

most frequently cited contents based on hits to articles archived on the site. SIR Standards are used by FDA, state regulatory groups, and most recently have attracted interest in Europe. The British Society of Interventional Radiology has adopted SIR's clinical practice guidelines, and the Cardiovascular and Interventional Radiological Society of Europe (CIRSE) has begun to adapt SIR guidelines for use in Europe. In addition, SIR and CIRSE have agreed to a formal liaison for the development of joint clinical practice guidelines.

CONCLUSION

The purpose of the SIR standards is to improve the quality of patient care. Reporting standards allow research to be reported accurately so that we can reliably determine how well IR procedures work and how they compare to outcomes from other procedures. Credentialing standards provide a guide to ap-

propriate training so that physicians can achieve outcomes in their practice comparable to those reported in the literature. Quality improvement standards allow outcomes to be measured in a practice so that both excellence and problems can be identified. Through such measurement and analysis there is an opportunity to find ways to improve outcomes and have excellence become the norm.

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APPENDIX:

Guidelines can be accessed on line at www.practiceguidelines.org, www.sirweb.org, or www.jvir.org