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PRACTICE GUIDELINE FOR THE PERFORMANCE OF PERCUTANEOUS INFERIOR VENA CAVA (IVC) FILTER PLACEMENT FOR THE PREVENTION OF PULMONARY EMBOLISM

PREAMBLE

These guidelines are an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the American College of Radiology cautions against the use of these guidelines 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 physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the guidelines, 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 the guidelines when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations on available resources, or advances in knowledge or technology subsequent to publication of the guidelines. However, a practitioner who employs an approach substantially different from these guidelines is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also 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 these guidelines 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 sole purpose of these guidelines is to assist practitioners in achieving this objective.

I. INTRODUCTION

This guideline was revised by a collaborative panel of the American College of Radiology and the Standards of Practice Committee of the Society of Interventional Radiology (SIR)

Pulmonary embolism (PE) continues to be a major cause of morbidity and mortality in the United States. Estimates of the incidence of nonfatal PE range from 400,000 to 630,000 cases per year, and 50,000-200,000 fatalities per year are directly attributable to PE [1-4]. The current preferred treatment for deep venous thrombosis (DVT)

and PE is anticoagulation. However, up to 20% of these patients will have recurrent PE [1, 5 6].

Interruption of the inferior vena cava (IVC) for the prevention of PE was first performed in 1893 using surgical ligation [7]. Over the years, surgical interruption took many forms (ligation, plication, clipping, or stapling), but IVC thrombosis was a frequent complication after these procedures. Endovascular approaches to IVC interruption became a reality in 1967 after the introduction of the Mobin-Uddin filter [8].

Many devices have since been developed for endoluminal caval interruption, and currently several devices designed for permanent placement are commercially available in the United States. In addition to permanent IVC filters, retrievable IVC filters are also available. These filters can be left in place as a permanent implant but also can be removed when the indication for filter placement resolves. (For detailed information regarding each of these filters, the reader is referred to several reviews [9-19].) Selection of a device requires knowledge of the clinical settings in which filters are used, as well as an evaluation of the clot-trapping efficiency and structural integrity of the device, the occlusion rate of the IVC and access vein, the risk of filter movement and filter embolization, and the ease of placement.

Percutaneous caval interruption can be performed as either an outpatient or inpatient procedure. Practically speaking, however, most filter placements will occur in the inpatient population because of ongoing medical therapy for acute thromboembolic disease or underlying illness.

The IVC should be assessed with imaging prior to placement of a filter, and the current preferred method is by vena cavography. Prior to filter selection and placement, the infrarenal IVC length and diameter should be measured, the location and number of renal veins determined, IVC anomalies defined (e.g., duplication), and intrinsic IVC disease such as pre-existing thrombus or extrinsic compression excluded. The ideal placement for the prevention of lower extremity and pelvic venous thromboembolism is the infrarenal IVC. The apex or superior aspect of any filtration device should be at or immediately inferior to the level of the renal veins according to the manufacturer's recommendations. In specific clinical circumstances other target locations may be appropriate.

Percutaneous caval interruption is commonly accomplished through right femoral or right internal jugular vein approaches; however, other peripheral (e.g., antecubital vein) and central venous access sites can be used. Filters can be placed in veins other than the vena cava to prevent thromboembolism. Implant sites have included iliac veins, subclavian veins, superior vena cava,

and inferior vena cava (suprarenal and infrarenal). This paper provides quality improvement guidelines for filter placement within the inferior vena cava because of the limited data available for implantation sites other than the IVC. The patient's clinical condition, the type of filter available, the alternative access sites available, and the expertise of the treating physician should always be considered when the decision to place an IVC filter has been made. Removal of IVC filters may be accomplished in those cases where the indication was for a temporary need.

These guidelines are written to be used in quality improvement programs to assess percutaneous interruption of the IVC to prevent pulmonary embolism. The most important aspects of care are 1) patient selection, 2) performing the procedure, and 3) monitoring the patient. The outcome measures or indicators for these processes are indications, success rates, and complication rates. Outcome measures are assigned threshold levels.

II. DEFINITIONS [20,24]

For the purpose of this guideline, the following definitions apply:

Permanent placement – deployment in those situations where lifelong protection is needed.

Temporary placement – deployment in those situations where time-limited protection is needed.

Procedural success - deployment of a filter such that the filter is judged suitable for mechanical protection against PE.

Procedural failure - the procedure concludes with unsatisfactory filter deployment such that the patient has inadequate mechanical protection against PE.

Death - death directly attributable to the filter placement and documented by clinical findings, imaging, or autopsy.

Recurrent PE - pulmonary embolism occurring after filter placement and documented by pulmonary arteriography, cross-sectional imaging, or significant change in ventilation-perfusion (V/Q) lung scan indicative of recurrent PE, or autopsy.

IVC occlusion - presence of an occluding thrombus in the IVC occurring after filter insertion and documented by ultrasound, CT, MRI, venography, or autopsy.

IVC penetration - penetration of the vein wall by filter hooks with transmural incorporation. For quality improvement reporting purposes, the definition of IVC penetration is filter strut or anchor devices extending more than 3 mm outside the wall of the IVC as

demonstrated by CT, ultrasound, venography, or autopsy. Acute penetration occurring during placement of the filter is considered an insertion problem (see below).

Filter embolization - postdeployment movement of the filter to a distant anatomic site completely out of the target zone.

Filter movement - a change in filter position compared to its deployed position (either cranial or caudal) more than 2 cm as documented by plain film imaging, CT, or venography.

Filter fracture - any loss of structural integrity (i.e., breakage or separation) of the filter documented by imaging or autopsy.

Insertion problems - filter or deployment system related malfunctions such as incomplete filter opening, filter tilt more than 15° from the IVC axis (e.g., non-self-centering filters), misplacement of filter outside the infrarenal IVC when the operator's intent is to place the filter in the infrarenal IVC (e.g., when a portion of the filter is within one iliac vein), or prolapse of filter components. Filter malposition requiring surgical removal is considered an insertion problem complication.

Access site thrombus - occlusive or nonocclusive thrombus developing after filter insertion at the venotomy site.

Other access site complications with clinical sequelae - arteriovenous fistula, hematoma, or bleeding requiring a transfusion, hospitalization (either admission or extended stay), or further treatment for management.

III. INDICATIONS [20–23]

A. Accepted

1. Patients with evidence of pulmonary embolus or IVC, iliac, or femoral-popliteal DVT and one or more of the following:
 - a. Contraindication to anticoagulation.
 - b. Complication of anticoagulation.
 - c. Failure of anticoagulation.
 - i. Recurrent PE despite adequate therapy.
 - ii. Inability to achieve adequate anticoagulation.
2. Massive pulmonary embolism with residual deep venous thrombus in a patient at risk for further PE.
3. Free floating iliofemoral or inferior vena cava thrombus.
4. Severe cardiopulmonary disease and deep-vein thrombosis (DVT) (e.g., cor pulmonale with pulmonary hypertension).

5. Poor compliance with anticoagulant medications.

B. Additional Indications for Selected Patients

1. Severe trauma without documented PE or DVT.
 - a. Closed head injury.
 - b. Spinal cord injury.
 - c. Multiple longbone or pelvic fractures
2. High-risk patients (e.g., immobilized, ICU patients, prophylactic preoperative placement in patients with multiple risk factors for venous thromboembolism).

A retrievable filter should be considered for these indications, especially for pediatric and young adult patients, since the long-term effects and durability of the devices are not precisely known.

C. Suprarenal Filter Placement

1. Renal vein thrombosis.
2. IVC thrombosis extending above the renal veins.
3. Filter placement during pregnancy. Suprarenal placement is also appropriate in women of childbearing age.
4. Thrombus extending above previously placed infrarenal filter.
5. Pulmonary embolism following gonadal vein thrombosis.
6. Anatomic variants: duplicated IVC, low insertion of renal veins.

The threshold for these indications is 95%. When fewer than 95% of procedures are performed for these indications, the process of patient selection will be reviewed according to institutional policy.

IV. RELATIVE CONTRAINDICATIONS

- A. Uncorrectable Severe Coagulopathy
- B. Bacteremia or Untreated Infection

Clinical judgment should be applied in these situations, weighing the theoretical risk of implant infection versus the risk of pulmonary embolism.

V. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

Examinations must be performed under the supervision of and interpreted by a physician who has the following qualifications:

1. Certification in Radiology or Diagnostic Radiology by the American Board of Radiology, the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, or Le College des Medecins du Quebec and must have demonstrated competency in vascular procedures under the supervision of an on-site qualified physician during the performance of at least 25 percutaneous vascular procedures of which at least five were as primary operator for IVC filter placement procedures.
or
2. Completion of an Accreditation Council for Graduate Medical Education (ACGME) approved residency program or an American Osteopathic Association (AOA) approved residency program and a minimum of 6 months training in the performance of percutaneous invasive vascular procedures and interventional radiology or vascular surgery that included the vascular aspects of interventional radiology, including at least 3 months in each of these subspecialty areas with at least 3 months of documented formal training in the performance of invasive catheter angiographic procedures, and must have demonstrated competency in vascular procedures under the supervision of an on-site qualified physician during the performance of at least 25 percutaneous vascular procedures of which at least five were as primary operator for IVC filter placement procedures.
or
3. In the absence of appropriate ACGME approved residency training as outlined in Section V.A.2 above, formal fellowship training in a Radiology Residency Review Committee (RRC) accredited vascular/interventional radiology fellowship program or other postgraduate training that included comparable instruction and experience in vascular interventional procedures. The physician must have at least 2 years experience with demonstrated competency as the primary operator in vascular interventional procedures under the supervision of an on-site qualified physician during which a minimum of 25 percutaneous vascular procedures, including a minimum of five IVC filter placement procedures, were performed with documented success and complication rates that meet the threshold criteria listed below (see section X).
and
4. Substantiation in writing by the director of interventional radiology or the chair of the department of the institution in which the physician will be providing these services that the physician is familiar with all of the following:
 - a. Indications and contraindications for the procedure.
 - b. Periprocedural and intraprocedural assessment, monitoring, and management of the patient.
 - c. Where applicable, pharmacology of moderate or “conscious” sedation medications and recognition and treatment of adverse reactions and complications.
 - d. Appropriate use and operation of fluoroscopic and radiographic equipment, mechanical injectors, rapid film changers, and electronic imaging systems.
 - e. Where applicable, principles of radiation protection, hazards of radiation exposure to both patients and radiologic personnel, and monitoring requirements.
 - f. Where applicable, pharmacology of contrast agents and recognition and treatment of potential adverse reactions.
 - g. Percutaneous needle and catheter introduction techniques.
 - h. Technical aspects of performing the procedure, including the use of alternative catheter and guidewire systems, and filming sequences.
 - i. Anatomy, physiology, and pathophysiology of peripheral and central venous vasculature.
 - j. Postprocedural patient management, especially recognition and initial management of complications.
 - k. Postprocedure management of puncture sites.

Maintenance of Competence

Physicians must perform a sufficient number of percutaneous filter placement procedures to maintain their skills, with acceptable success and complication rates as presented in this document (see Section X). Continued competence should depend on participation in a quality improvement program that monitors these rates.

Continuing Medical Education

The physician’s continuing education should be in accordance with the [ACR Practice Guideline for Continuing Medical Education \(CME\)](#).

B. Qualified Medical Physicist

A Qualified Medical Physicist is an individual who is competent to practice independently in one or more of the subfields in medical physics. The American College of Radiology considers that certification in the appropriate subfield(s) and continuing education demonstrates the competence of the individual. The ACR recommends that the individual be certified in the appropriate subfield(s) by

the American Board of Radiology (ABR) or for MRI, by the American Board of Medical Physics (ABMP) in magnetic resonance imaging physics.

The appropriate subfields of medical physics for this guideline are Diagnostic Radiological Physics and Radiological Physics.

The continuing education of a Qualified Medical Physicist should be in accordance with the [ACR Practice Guideline for Continuing Medical Education \(CME\)](#). (2006 - ACR Resolution 16g)

C. Registered Radiologist Assistant

A registered radiologist assistant is an advanced level radiographer who is certified and registered as a radiologist assistant by the American Registry of Radiologic Technologists (ARRT) after having successfully completed an advanced academic program encompassing an ACR/ASRT (American Society of Radiologic Technologists) radiologist assistant curriculum and a radiologist-directed clinical preceptorship. Under radiologist supervision, the radiologist assistant may perform patient assessment, patient management and selected examinations as delineated in the Joint Policy Statement of the ACR and the ASRT titled “Radiologist Assistant: Roles and Responsibilities” and as allowed by state law. The radiologist assistant transmits to the supervising radiologists those observations that have a bearing on diagnosis. Performance of diagnostic interpretations remains outside the scope of practice of the radiologist assistant. (2006 - ACR Resolution 34)

D. Radiologic Technologist

1. The technologist, together with the physician and nursing personnel, should be responsible for patient comfort and safety. The technologist should be able to prepare and position¹ the patient for the percutaneous filter placement

¹The American College of Radiology approves of the practice of certified and/or licensed radiologic technologists performing fluoroscopy in a facility or department as a positioning or localizing procedure only, and then only if monitored by a supervising physician who is personally and immediately available*. There must be a written policy or process for the positioning or localizing procedure that is approved by the medical director of the facility or department/service and that includes written authority or policies and processes for designating radiologic technologists who may perform such procedures. (1987, 1997, 2007 - ACR Resolution 12-m)

*For the purposes of this guideline, “personally and immediately available” is defined in manner of the “personal supervision” provision of CMS—a physician must be in attendance in the room during the performance of the procedure. Program Memorandum Carriers, DHHS, HCFA, Transmittal B-01-28, April 19, 2001.

procedure and, together with the nurse, monitor the patient during the examination. The technologist should obtain the imaging data in a manner prescribed by the supervising physician. If intravenous contrast material is to be administered, qualifications for technologists performing intravenous injection should be in compliance with current ACR policy² and existing operating procedures or manuals at the interventional radiology facility and/or imaging facility. The technologist should also perform the regular quality control testing of the equipment under the supervision of the physicist.

2. Technologists should be certified by the American Registry of Radiologic Technologists (ARRT) or have an unrestricted state license with documented training and experience in the imaging modality used for the imaging-guided percutaneous procedure.

E. Nursing Services

Nursing services, when deemed appropriate by the performing physician, are an integral part of the team for pre- and postprocedure patient management and education and are recommended in monitoring the patient during the procedure.

VI. SPECIFICATIONS OF THE EXAMINATION

Several technical requirements are necessary to ensure safe and successful percutaneous filter placement procedures. These include adequate arteriographic equipment and institutional facilities, physiologic monitoring equipment, and support personnel.

A. Equipment and Facilities for Percutaneous Filter Placement

The following are considered the minimum equipment requirements for performing vena cavagrams and percutaneous filter placement. In planning facilities for percutaneous IVC placement, equipment and facilities more advanced than those outlined below may be desired to produce higher quality studies with reduced risk and time of study. In general, the facility should include at a minimum:

1. A high-resolution image intensifier and television chain with standard angiographic filming capabilities including serial 14-inch film changers, and/or large format image intensifiers

²See the [ACR Practice Guideline for the Use of Intravascular Contrast Media](#). (2007 - ACR Resolution 38)

(12-inch or greater) with minimum 1,024-image matrix. Digital angiographic systems are recommended, as they allow for reduced volumes of contrast material and reduced examination times. Images are acquired and stored either on conventional film or digitally on computerized storage media. Imaging and image recording must be consistent with the as low as reasonably achievable (ALARA) radiation safety guidelines. The use of cineradiography or small field mobile image intensifiers is inappropriate for the routine recording of the venacavagram and percutaneous IVC placement, because these methods cause an unacceptably high patient and operator radiation dose. Use of last image hold and pulsed fluoroscopy are recommended for dose reduction.

2. Adequate angiographic supplies such as catheters, guidewires, needles, and introducer sheaths.
3. An angiographic injector capable of varying injection volumes and rates with appropriate safety mechanisms to prevent overinjection.
4. An angiography suite that is large enough to allow easy transfer of the patient from the bed to the table and allow room for the procedure table, monitoring equipment, and other hardware such as intravenous pumps, respirators, anesthesia equipment, and oxygen tanks. Ideally, there should be adequate space for the operating team to work unencumbered on either side of the patient and for the circulation of other technical staff in the room without contaminating the sterile conditions.
5. An area within the institution appropriate for patient preparation prior to the procedure and for observation of patients after the procedure. This might be within the radiology department, in a short-stay unit, or in a routine nursing unit. At this location, there should be personnel to provide care as outlined below (Patient Care), and there should be immediate access to emergency resuscitation equipment.

B. Physiologic Monitoring and Resuscitation Equipment

1. Sufficient equipment should be present in the procedure suite to allow for monitoring the patient's heart rate, cardiac rhythm, and blood pressure. For facilities utilizing moderate sedation, a pulse oximeter monitor should be available (see the [ACR Practice Guideline for Adult Sedation/Analgesia](#)).
2. There should be ready access to equipment and drugs for emergency resuscitation. The equipment should include an emergency defibrillator with paper recorder and quick-view capability, oxygen supply and appropriate tubing

and delivery systems, suction equipment, tubes for endotracheal intubation, laryngoscope, ventilation bag-mask-valve apparatus, and central venous line sets. Drugs for treating cardiopulmonary arrest, contrast reaction, vasovagal reactions, narcotic or benzodiazepine overdose, bradycardia, and ventricular arrhythmias should also be readily available. Resuscitation equipment should be monitored on a routine basis in compliance with institutional policies.

C. Support Personnel

1. Radiologic technologists properly trained in the use of the angiographic equipment should assist in performing and imaging the procedure. They should demonstrate appropriate knowledge of patient positioning, arteriographic image recording, angiographic contrast injectors, angiographic supplies including IVC filters, and the physiologic monitoring equipment. Certification as a vascular and interventional radiologic technologist is one measure of appropriate training. The technologist should be trained in basic cardiopulmonary resuscitation and in the function of the resuscitation equipment.
2. If the patient does not receive moderate sedation, one of the staff assisting the procedure should be assigned to periodically assess the patient's status. If the patient is to undergo moderate sedation, a nurse or other appropriately trained individual should monitor the patient as his/her primary responsibility. This person should maintain a record of the patient's vital signs, time and dose of medications given, and other pertinent information (see the [ACR Practice Guideline for Adult Sedation/Analgesia](#)).

D. Surgical support

Although surgical or other emergency treatment is needed infrequently for serious complications after percutaneous filter placement procedures, there should be prompt access to surgical and interventional equipment and to specialists familiar with the management of patients with complications in the unlikely event of a life-threatening complication.

E. Patient Care

The written or electronic request for IVC filter placement for the prevention of pulmonary embolism 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 scope of practice requirements. (2006 - ACR Resolution 35)

1. Preprocedure care

For elective percutaneous filter placement, the following should be documented:

- a. Clinically significant history, including indications for the procedure.
- b. Clinically significant physical examination findings, to include an awareness of clinical or medical conditions that may necessitate specific care.
- c. Clinically indicated laboratory evaluation including, but not limited to, coagulation factors, creatinine, and white blood cell count.

Informed consent must be in compliance with all state laws and the [ACR Practice Guideline on Informed Consent for Image-Guided Procedures](#).

For emergency procedures, a note should be written summarizing the indication for the study, the pertinent history and physical findings, if available, and the proposed procedure.

2. Procedural care

- a. Adherence to the Joint Commission's Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™ is required for procedures in non-operating room settings including bedside procedures. "Time out" must be conducted in the location where the procedure will be done, just before starting the procedure and must:
 - Involve the entire operative team.
 - Use active communication.
 - Be briefly documented, such as in a checklist, and
 - At the least, include:
 - Correct patient identity.
 - Correct side and site.
 - Agreement on the procedure to be done.

- Correct patient position.
- Availability of correct implants and any special equipment or special requirements.

The organization should have processes and systems in place for reconciling differences in staff responses during the "time out."

- b. All patients should have cardiac monitoring continuously during the procedure with intermittent blood pressure monitoring. A record of vital signs should be maintained.
 - c. All patients should have intravenous access for the administration of fluids and medications as needed.
 - d. If the patient is to receive moderate sedation, pulse oximetry should be used. A registered nurse or other appropriately trained personnel should be present, and his/her primary responsibility should be to monitor the patient. A record should be kept of medication doses and times of administration.
- #### 3. Postprocedure care
- a. A procedure note should be written in the patient's chart summarizing the major findings of the study and any immediate complications. This note may be brief if a formal report will be available within a few hours. However, if the typed report is not likely to be on the chart the same day, a more detailed summary of the study should be written in the chart at the conclusion of the procedure. For outpatients a dictated report is sufficient. In all cases, pertinent findings should be communicated to the referring physician in a timely manner.
 - b. All patients should be at bed rest and observed in the initial postprocedure period. The length of this period of bed rest will depend on the site and size of the venotomy and the patient's medical condition.
 - c. During the initial postprocedure period, skilled nurses or other appropriately trained personnel should periodically monitor the puncture site.
 - d. Initial ambulation of the patient must be carefully supervised. The puncture site stability and independent patient function and mobility must be assured.
 - e. The operating physician or a qualified designee should evaluate the patient after the procedure, and these findings should be summarized in a progress note. If conscious sedation was administered prior to and during the procedure, complete recovery from conscious sedation must be documented. The physician or designee should be available for continuing care during hospitalization and after discharge.

The designee may be another physician or a nurse.

F. Selection Criteria for Short-Term Observation

The duration of postprocedure observation must be individualized. Percutaneous IVC filter placement can be performed on some patients with a short period of postprocedure observation (less than 6 hours) prior to discharge to home; others require overnight care. Short-term observation should only be considered when all the following conditions can be met:

1. The patient is capable of independent ambulation prior to the procedure and should demonstrate stable independent ambulation after the procedure. Alternatively, nonambulatory patients should have adequate assistance after discharge to provide care as needed.
2. The patient is capable of following instructions and detecting changes in symptomatology. Alternatively, patients with impaired mental or neurologic status should have adequate assistance after discharge to provide care as needed.
3. The patient is provided with instructions on how to recognize potential complications and how to obtain medical assistance in the event of such complication. A responsible adult is also provided with information regarding recognition of potential complications and is available to transport the patient and be in attendance during the initial night after discharge.
4. The patient is free of concurrent serious medical illness that might contribute to a significantly increased risk of complication.
5. The patient has recovered from the effects of the sedation.

G. Relative Contraindications to Short-Term Observation

Several factors must be considered when determining the length of postprocedure skilled nursing care. Some of the relative contraindications to short-term observation are listed below.

1. Patients with significant risk of contrast media-associated nephrotoxicity that might be prevented by hospitalization and intravenous hydration.
2. Patients with coagulopathies or electrolyte abnormalities that require correction should be hospitalized until stable.
3. Insulin-dependent diabetics who have labile serum glucose levels in the periprocedural period should be hospitalized until stable.
4. Complications occurring during or after IVC filter placement, including large hematoma, anuria, and persistent nausea and vomiting

should prompt observation until symptoms resolve.

5. Patients who exhibit hemodynamic instability or significant arrhythmia during or after the procedure should be hospitalized until stable.
6. Patients who live alone.

The decision for short-term or longer-term postprocedure observation must be individualized, and a patient's care may vary from the above criteria for sound clinical reasons. The decision in each case must be made by the physician who performed the procedure and the referring physician after review of all pertinent data.

VII. DOCUMENTATION

Reporting should be in accordance with the [Practice Guideline for the Reporting and Archiving of Interventional Radiology Procedures](#).

VIII. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, radiologic technologists, and all supervising physicians have a responsibility to minimize radiation dose to individual patients, to staff, and to society as a whole, while maintaining the necessary diagnostic image quality. This is the concept "As Low As Reasonably Achievable (ALARA)".

Facilities, in consultation with the medical physicist, should have in place and should adhere to policies and procedures, in accordance with ALARA, to vary examination protocols to take into account patient body habitus, such as height and/or weight, body mass index or lateral width. The dose reduction devices that are available on imaging equipment should be active or manual techniques should be used to moderate the exposure while maintaining the necessary diagnostic image quality. Patient radiation doses should be periodically measured by a medical physicist in accordance with the appropriate ACR Technical Standard. (2006 - ACR Resolution 17)

IX. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION CONCERNS

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 Concerns appearing elsewhere in the ACR Practice Guidelines and Technical Standards book.

These data should be utilized in conjunction with the thresholds described in Section IX below to assess

percutaneous filter placement procedural efficacy and complication rates, and to trigger institutional review when these thresholds are exceeded.

X. QUALITY IMPROVEMENT

A. Success Rates and Thresholds

While practicing physicians should strive to achieve perfect outcomes (e.g., 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 improvement programs. For the purpose of these guidelines, a threshold is a specific level of an indicator that should prompt a review. 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. Thresholds may vary from those listed here; for example, patient referral patterns and selection factors may dictate a different threshold value for a particular indicator at a particular institution. Thus, setting universal thresholds is very difficult, and each department is urged to alter the thresholds as needed to higher or lower values to meet its own quality improvement program needs.

Complications can be stratified on the basis of outcome. Major complications result in admission to a hospital for therapy (for outpatient procedures), an unplanned increase in the level of care, prolonged hospitalization, permanent adverse sequelae, or death. Minor complications result in no sequelae; they may require nominal therapy or a short hospital stay for observation (generally overnight). (See Appendix A.) The complication rates and thresholds below refer to *major* complications.

It is expected that the technical success for percutaneous placed IVC filters will be 97% or better in experienced hands. Therefore, the proposed threshold for review of technical failures should be 3%.

B. Complication Rates and Thresholds

1. Complications

Each currently available filter has been extensively studied as part of the FDA approval process. Few comparative studies have been completed evaluating all filters in one project, and those that have done so have been retrospective analyses. Complication rates are highly variable depending on the filter being studied. For simplicity, these guidelines do not suggest threshold rates for each individual filter; rather filtration devices are considered as a group.

TABLE 1

Complications	Reported Rates (%)	Threshold (%)
Death [7]	0.12	< 1
Recurrent PE [24–29]	0.5–6	5
IVC occlusion [11, 24, 26, 27, 30–34]	2–30	10
Filter embolization [24, 31, 47–56]	2–5	2
Access site thrombosis - major (see Appendix A) [43, 59]	0–6*	1

*Includes reported rates of both major and minor complications.

Published rates for individual types of complications are highly dependent on patient selection and are in some cases based on series comprising several hundred patients, which is a volume larger than most individual practitioners are likely to treat. It is also recognized that a single complication can cause a rate to cross above a complication-specific threshold when the complication occurs within a small patient volume (e.g., early in a quality improvement program).

2. Other trackable events

Because an IVC filter may be implanted as a permanent device (if not retrieved) and can be used in relatively young patients, several other trackable parameters when observed are appropriate to record in a quality improvement program. The following events may or may not be clinically significant in a particular patient. For this reason, thresholds for these events are not included in this document.

TABLE II

Other Trackable Events	Reported Rates (%)
IVC penetration* [7, 24, 26, 30, 34, 35, 46]	0–41
Filter movement* [7, 9,10, 24, 26–28, 33, 36]	0–18
Filter fracture [24, 31]	2–10
Access site thrombus All types [7, 37, 43, 44] Occlusive [42, 43]	0–25 3–10
Other Trackable Events	Reported Rates (%)
Insertion problems [7, 24, 26–29, 31, 33, 37–39]	5–23
Other complications [4,40]	1–15

*Clinically significant penetration and movement are felt to be rare. The rate of clinically significant penetration is undefined in the literature (46,57,58).

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APPENDIX A

Society of Interventional Radiology Standards of Practice Committee Classification of 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.