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PRACTICE GUIDELINE FOR SPECIFICATIONS AND PERFORMANCE OF IMAGE-GUIDED PERCUTANEOUS DRAINAGE / ASPIRATION OF ABSCESSSES AND FLUID COLLECTIONS (PDAFC) IN ADULTS

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 developed and written by the Society of Interventional Radiology (SIR) in collaboration with the American College of Radiology (ACR).

Percutaneous drainage/aspiration of abscesses and abnormal fluid collections (PDAFC) has become the diagnostic and therapeutic treatment of choice for a wide variety of fluid collections. The procedures have resulted in reduced morbidity and mortality and have helped to reduce hospital length of stay and hospital costs [1-7].

For information on breast interventional procedures, see the [ACR Practice Guideline for the Performance of Stereotactically Guided Breast Interventional Procedures](#) or the [ACR Practice Guideline for the Performance of Ultrasound-Guided Percutaneous Breast Interventional Procedures](#).

The procedure may be performed with ionizing radiation for image guidance, including fluoroscopy or computed tomography (CT), or nonionizing radiation modalities, including ultrasound (US) and magnetic resonance imaging (MRI). Optimal performance of PDAFC requires knowledge of anatomy and pathophysiology, familiarity with percutaneous techniques (needle, guide-wire, drainage catheter use, etc.), and knowledge of the advantages and disadvantages of one imaging modality versus another for any particular drainage procedure. As with any invasive therapy, the patient is most likely to benefit when the procedure is performed in an appropriate environment and by qualified physicians. This guideline outlines the specifications and principles for the performance of high-quality PDAFC.

This guideline is intended to be used in quality improvement programs to assess percutaneous drainage procedures. The most important processes 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. DEFINITION

Image-guided percutaneous drainage is defined as the placement of a catheter using image guidance to provide continuous drainage of a fluid collection. It includes localization of the collection, and placement and maintenance of the drainage catheter or catheters. It may be performed during a single session or as a staged procedure during multiple sessions.

Percutaneous aspiration is defined as evacuation of a fluid collection using either a catheter or a needle, with removal of the catheter or needle immediately after the aspiration.

III. INDICATIONS AND CONTRAINDICATIONS

Because of variability in the presentation of abscesses and fluid collections, the indications for percutaneous drainage and aspiration must be stated in general terms. The prerequisites for percutaneous aspiration or drainage are an abnormal fluid collection and one of the following: suspicion that the fluid is infected, need for fluid characterization, or suspicion that the collection is producing symptoms sufficient to warrant drainage. The

collection may be detected by physical examination but typically is discovered by an imaging study. Additional studies may be required to confirm the presence or nature of the fluid collection and to evaluate the feasibility of drainage.

Diagnostic aspiration may be the only means of determining that a fluid collection is infected. For instance, while fever, leukocytosis, malaise, anorexia, or other systemic symptoms point to an infection, these signs and symptoms may be absent in elderly, very ill, or immunocompromised patients. If material that appears infected is obtained or if the operator cannot exclude the presence of infection, a drainage catheter may then be placed.

Percutaneous drainage and aspiration may be performed in essentially every organ system. The contraindications are relative and depend on the suitability of surgical alternatives. Common relative contraindications include coagulopathy and necrotic tissue requiring surgical debridement. There is a spectrum of disease complexity. Examples of more complex situations include multiple or multiloculated abscesses; abscess due to Crohn's disease; pancreatic abscesses; drainage route that traverses bowel or pleura; infected clot; and infected tumor [8,9]. Articles have documented curative or partially successful percutaneous drainage in patients with these complex situations [10]. However, one should expect that percutaneous drainage in such cases will have a lower chance of success, be more technically difficult, require longer periods of time for drainage, and have a higher rate of complications. In addition, abscesses in such cases may be more likely to recur. Decisions regarding percutaneous versus surgical drainage of complex collections should be made in concert with other physicians involved in the patient's care.

Patient follow-up and catheter management are integral to the success of the procedure. The radiologist performing the drainage should ensure that appropriate follow-up is performed and maintained until the catheter is removed.

The indications for PDAFC include, but are not limited to:

Threshold – 100%

1. Presence of an abnormal fluid collection with suspicion that the fluid is infected.
2. Need for fluid characterization.
3. Suspicion that the collection is producing symptoms sufficient to warrant drainage.

There are no absolute contraindications. However, there are relative contraindications and, as for all patients considered for this procedure, the relative benefits and risks of the procedure should be weighed carefully. These

relative contraindications should be addressed and corrected or controlled before the procedure, when feasible. The relative contraindications for PDAFC include:

1. Known coagulopathy that cannot be adequately corrected.
2. Inability of the patient to cooperate with, or to be positioned for, the procedure.
3. Known adverse reaction to contrast media when contrast media administration is critical for the performance of the procedure.
4. Hemodynamic instability.
5. Lack of a safe pathway to the lesion.
6. Severely compromised cardiopulmonary function for patients undergoing thoracic interventions when there are risks of further compromise inherent to the procedure.

All imaging facilities should have policies and procedures to reasonably attempt to identify pregnant patients prior to the performance of any examination involving ionizing radiation. If the patient is known to be pregnant, the potential radiation risk to the fetus and clinical benefits of the procedure should be considered before proceeding with the study. (1995, 2005 - ACR Resolution 1a)

IV. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

Image-based diagnosis and treatment planning require integrating the preprocedural imaging findings with the patient's history and physical findings. Therefore, the physician must be clinically informed and understand the specific questions to be answered by PDAFC prior to the procedure in order to plan and perform it safely and effectively.

The physician performing PDAFC must fully appreciate the benefits, alternatives, and risks of the procedure. He/she must have a thorough understanding of imaging anatomy (including congenital and developmental variants), fluoroscopic and ultrasound equipment, radiation safety considerations, and physiologic monitoring equipment and have access to adequate supplies and personnel to perform the procedure safely.

PDAFC procedures must be performed by a physician who has the following qualifications:

1. Certification in Radiology or Diagnostic Radiology by the American Board of Radiology (ABR), the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, or Le College des Medecins du Quebec and has performed with supervision at least 35 image-guided percutaneous procedures as the primary operator.

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 3 months experience performing interventional radiology procedures and 6 months of documented formal training in interpreting cross-sectional imaging examinations. This training should include the experience of performing (with supervision) at least 35 image-guided percutaneous procedures as the primary operator, with outcomes within the quality improvement thresholds of this document.

or

3. Physicians whose residency or fellowship training did not include the above may still be considered qualified to perform PDAFC, provided that the following can be demonstrated:

The physician must have at least 2 years of interventional experience during which the physician was supervised and during which he/she performed and interpreted at least 35 image-guided percutaneous procedures as the primary operator, with outcomes within the quality improvement thresholds of this document.

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. Imaging systems that may be used for guidance during percutaneous procedures.
 - e. Where applicable, principles of radiation protection, hazards of radiation exposure

both to patients and to 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 guide-wire systems.
- i. Anatomy, physiology, and pathophysiology of the structures being considered for PDAFC.

Maintenance of Competence

Physicians must perform a sufficient number of image-guided percutaneous aspirations and drainages to maintain their skills with acceptable success and complication rates as laid out in this guideline. 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 should have the responsibility for overseeing the equipment quality control program and for monitoring fluoroscopy and other cross-sectional imaging studies both upon installation and routinely on an annual basis. Medical physicists assuming these responsibilities should meet the following qualifications:

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 (ACR) considers certification and continuing education in the appropriate subfield(s) to demonstrate that an individual is competent to practice one or more of the subfields in medical physics and to be a Qualified Medical Physicist. The ACR recommends that the individual be certified in the appropriate subfield(s) by the 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

The technologist, together with the physician and nursing personnel, should have responsibility for patient comfort and safety. The technologist should be able to prepare and position¹ the patient for the image-guided percutaneous 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 the current ACR policy statement² and the operating procedures or manuals at the interventional radiology facility and/or imaging facility. The technologist should

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.

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

also perform regular quality control testing of the equipment under supervision of the physicist.

Technologists should be certified by the American Registry of Radiologic Technologists 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.

V. SPECIFICATIONS AND PERFORMANCE OF THE PROCEDURE

A. Imaging Equipment and Facilities

The choice of modality for imaging guidance will depend on the site and characteristics of the collection, the skill and preference of the intervening physician, and the availability of appropriate imaging devices for guidance.

1. The minimum requirements for facilities in which PDAFC is performed include the following:
 - a. When fluoroscopic guidance is used, a high-resolution imaging chain with adequate shielding and collimation is desirable. Ability to perform complex angle (e.g., anteroposterior [AP], lateral, or oblique) fluoroscopy views is often necessary to ensure proper needle placement. Image and written documentation of needle or drainage catheter tip location is essential. Overhead fluoroscopic tube suites are less desirable because of increased radiation exposure to personnel during this procedure.
 - b. When appropriate, availability of ultrasound is desirable. Proper transducer frequency is required to direct and monitor needle placement. This is especially true for diagnostic aspiration of fluid collections in the pleural space, peritoneal cavity, etc.
 - c. When appropriate, CT and/or CT fluoroscopic capability is desirable to better demonstrate anatomy, particularly in:
 - i. Patients with fluid collections that are difficult to access or are in unusual or precarious locations.

- ii. Planning the optimal access route to avoid, when possible, transgression of vital structures.
 - iii. Patients with unusual anatomy.
- d. The facility should provide an area within the institution appropriate for patient preparation and for observation after the procedure. This might be within the radiology department, in a short-stay unit, or in a routine nursing unit as outlined in Patient Care section below. There should be immediate access to emergency resuscitation equipment.
- e. For patients undergoing thoracic procedures, a full array of percutaneous catheterization equipment for treatment of pneumothorax should be available.
- f. Access to a laboratory with expertise in cytopathology, microbiology, and chemistry should be available. (These resources need not be collocated in the facility.)

2. Performance guidelines

When using fluoroscopy for PDAFC, a facility should meet or exceed the following imaging practices:

- a. Fluoroscopic time should be kept to a minimum. The operator will use only as much fluoroscopy as is necessary to achieve aspiration and/or catheter drainage, consistent with the as-low-as-reasonably-achievable (ALARA) radiation safety guidelines. One method to minimize fluoroscopic time is to employ units with “last image hold” capability.
 - b. Tight collimation and, when appropriate, shielding (e.g., thyroid, gonadal, etc.) should be used.
3. An emergency cart containing appropriate medication and resuscitation equipment must be available to treat adverse reactions.

B. Physiologic Monitoring and Resuscitation Equipment

1. Sufficient equipment should be present to allow for monitoring the patient's heart rate, cardiac rhythm, and blood pressure. For facilities using moderate “conscious” sedation, a pulse oximeter should be available. (See the [ACR Practice Guideline for Adult Sedation/Analgesia](#).)
2. There should be ready access to emergency resuscitation equipment and drugs, to include the following: 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 dysrhythmias should also be readily available. Resuscitation equipment should be monitored on a routine basis in compliance with institutional policies.

C. Surgical Support

Although complications of PDAFC only rarely require urgent surgery, some of these procedures should be performed in an environment where surgical intervention can be instituted promptly. Ideally, this would be a facility with adequate surgical, anesthesia, and ancillary support. When these procedures are performed in a freestanding center, detailed protocols for the rapid transport or admission of patients to an acute-care hospital should be formalized in writing.

D. Patient Care

The written or electronic request for PDAFC 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

- a. The physician performing the procedure must have knowledge of the following:
 - i. Clinically significant history, including indications for the procedure.
 - ii. Clinically significant physical examination findings, to include an awareness of clinical or medical conditions that may necessitate specific care.

- iii. Possible alternative methods, such as surgery, to obtain the desired diagnostic information or therapeutic result.
- b. Informed consent must be in compliance with state laws and should comply with the [ACR Practice Guideline on Informed Consent for Image-Guided Procedures](#).

2. Procedural care

- a. Adherence to the Joint Commission 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. During the use of fluoroscopy, the physician should use exposure factors consistent with the as low as reasonably achievable (ALARA) radiation safety guidelines.
- c. Nursing personnel, technologists, and those directly involved in the patient care during PDAFC should have protocols for use in standardizing care. These should include, but are not limited to:
 - i. Equipment needed for the procedure.
 - ii. Patient monitoring.

Protocols should be reviewed and updated periodically.

3. Postprocedure care

- a. Orders for postprocedure patient care should include frequency of monitoring of vital signs, drainage catheter care, discharge instructions, etc.
- b. Specific anatomic considerations

- i. Thoracic cavity: pulmonary assessment for the presence of pneumothorax and to confirm adequate catheter placement.
 - a. If guidance was by fluoroscopy or ultrasound, an upright chest radiograph should be obtained when appropriate.
 - b. If guidance was by CT, a tailored postprocedure scan should be obtained.
- ii. Peritoneal and other cavities: confirmation of appropriate tube placement.
- iii. Postprocedure imaging and follow-up may involve gentle injection of contrast material to confirm tube placement within the abscess/symptomatic fluid collection cavity, and assessing the appropriate setting of fistulae to bowel.
- c. Clinical and imaging follow-up
 - i. Periodic imaging follow-up may be appropriate to facilitate abscess/symptomatic fluid collection resolution.
 - ii. Clinical follow-up only may suffice if patient condition, tube output, and laboratory evidence confirm progressive improvement.

E. Specifics of the Procedure

1. All invasive image-guided percutaneous procedures involving aspiration of fluid collections with or without percutaneous catheter drainage (PCD) are performed for specific indications, and the examination/procedure should therefore be tailored accordingly.
2. In the setting of image-guided percutaneous aspiration of fluid collections for diagnostic purposes, initial placement of a small needle is advisable unless it is expected that the fluid collection is extremely thick and viscous, which may dictate the use of a larger gauge needle or catheter.
3. The physician should be aware of the technique for definitive drainage with needle/guide-wire/catheter/trocar techniques since diagnostic percutaneous fluid aspiration may lead to therapeutic placement of a percutaneous drainage catheter.
4. The physician performing PDAFC must understand tube maintenance and postprocedure care. This includes the appropriate use of suction or water-seal drainage versus gravity drainage; the need for follow-up imaging, possibly with

contrast injection into a cavity to search for fistulous connections; the possible need for irrigation of the abscess cavity; the occasional need for tube upsizing; and the need for antibiotic therapy, etc.

VI. DOCUMENTATION

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

VII. 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)

VIII. 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.

Equipment performance monitoring should be in accordance with the [ACR Technical Standard for Diagnostic Medical Physics Performance Monitoring of Radiographic and Fluoroscopic Equipment](#).

IX. QUALITY IMPROVEMENT

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 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 refer to a group of indicators for a procedure (e.g., 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. For example, if the incidence of sepsis is one measure of the quality of abscess drainage, then values in excess of the defined threshold (in this case 4%) should trigger a review of policies and procedures within the department to determine the causes and to implement changes to lower the incidence of the complication. 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.

A. Success Rates and Threshold

Success Rates

Successful diagnostic fluid aspiration is defined as the aspiration of material sufficient for diagnosis.

<u>Successful Diagnostic Fluid Aspiration</u>	<u>Threshold</u>
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Drainage of infected collections	95%
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Curative drainage is defined as complete resolution of infection requiring no further operative intervention. Curative drainage has been achieved in more than 80% of patients. Partial success is defined as either adequate drainage of the abscess with surgery subsequently performed to repair an underlying problem or as temporizing drainage performed to stabilize the patient prior to surgery. Partial success occurs in 5%-10% of patients. Failure occurs in 5%-10% and recurrence in 5%-10%. These results are similar for both abdominal and chest drainage procedures. These success rates will depend on the proportion of collections drained in patients with relative contraindications, on the complexity of the collection, and on the severity of the underlying medical problems.

<u>Successful Drainage</u>	<u>Threshold</u>
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(curative and partial success) Drainage of uninfected collections:	85%
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Due to the variability of the types of uninfected collections, the success rate of drainage will be highly variable, and it is not felt that a specific threshold for success can be set.

B. Complication Rates and Thresholds

Complications for PDAFC

Complications occur in approximately 10% of patients. Published complication rates and suggested thresholds include the following:

Specific Major Complication	Reported Rate	Suggested Threshold
Septic shock	1-2%	4%
Bacteremia requiring significant new intervention	2-5%	10%
Hemorrhage requiring transfusion	1%	2%
Superinfection (includes infection of sterile fluid collection)	1%	2%
Bowel transgression requiring intervention	1%	2%
Pleural transgression requiring intervention (abdominal procedures)	1%	2%
Pleural transgression requiring additional intervention (chest procedures)	2-10%	20%

Published rates for individual types of complications are highly dependent on patient selection and are based on series comprising several hundred patients, which is a volume larger than most individual practitioners are likely to treat. Generally the complication-specific thresholds should be set higher than the complication-specific reported rates listed above. 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). In this situation, the overall procedure threshold is more appropriate for use in a quality improvement program. In the above table all values were supported by the weight of literature evidence and panel consensus.

	<u>Overall Procedure Threshold</u>
All major complications resulting from adult PDAFC	10%

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This guideline was revised according to the process described in the ACR Practice Guidelines and Technical Standards book by the Guidelines and Standards Committee of the Commission on Interventional and Cardiovascular Radiology.

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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.