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Revised 2008 (Resolution 14)\*

## **ACR–SIR PRACTICE GUIDELINE FOR THE PERFORMANCE OF IMAGE-GUIDED PERCUTANEOUS NEEDLE BIOPSY (PNB) IN ADULTS**

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### **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 of 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 the American College of Radiology (ACR) in collaboration with the Society of Interventional Radiology (SIR).

Image-guided percutaneous needle biopsy (PNB) is an established, effective procedure for selected patients with suspected pathology. Extensive experience documents the safety and efficacy of this procedure. As with any invasive procedure, the patient is most likely to benefit when the procedure is performed in an appropriate environment by qualified physicians [1-3]. This guideline outlines the principles for performing PNB.

For information on breast biopsy, 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](#).

### **II. DEFINITION**

PNB is defined as percutaneous placement of needles into a suspected abnormal lesion or organ for the purpose of obtaining tissue or cells for diagnosis. Following specimen procurement, the needles are removed.

For purposes of this guideline, successful image-guided PNB is defined as the procurement of sufficient material to establish a pathologic diagnosis or guide appropriate patient management.

### III. INDICATIONS AND CONTRAINDICATIONS

#### A. Indications for PNB include, but are not limited to:

1. To establish the benign or malignant nature of a lesion.
2. To obtain material for microbiologic analysis in patients with known or suspected infections.
3. To stage patients with known or suspected malignancy when local spread or distant metastasis is suspected.
4. To determine the nature and extent of certain diffuse parenchymal diseases (e.g., hepatic cirrhosis, renal transplant rejection, glomerulonephritis).

B. There are no absolute contraindications. However, there are relative contraindications and, as for all patients considered for this procedure, the relative 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 PNB include:

1. Significant coagulopathy that cannot be adequately corrected.
2. Severely compromised cardiopulmonary function or hemodynamic instability.
3. Lack of a safe pathway to the lesion.
4. Inability of the patient to cooperate with, or to be positioned for, the procedure.

For the pregnant or potentially pregnant patient, see the [ACR Practice Guideline for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation](#).

### IV. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

#### A. Physician

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

The physician performing PNB must fully appreciate the benefits, alternatives, and risks of the procedure. The physician must have a thorough understanding of imaging anatomy, imaging equipment, radiation safety considerations, and physiologic monitoring equipment, and have access to adequate supplies and personnel to perform the procedure safely.

PNB examinations must be performed under the supervision of and interpreted by a physician who has the following qualifications pertinent to the scope of services provided and the specific privileges sought:

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 the Collège des Médecins du Québec and has performed at least 35 image-guided PNB procedures, 25 of them as primary operator with outcomes within the quality improvement thresholds of this document.  
or
2. Completion of a residency program approved by the Accreditation Council for Graduate Medical Education (ACGME), the Royal College of Physicians and Surgeons of Canada (RCPSC), the Collège des Médecins du Québec, or the American Osteopathic Association (AOA) to include a minimum of 3 months 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 PNBs, 25 of them as primary operator with outcomes within the quality improvement thresholds of this guideline.  
or
3. Physicians whose residency or fellowship training did not include the above may still be considered qualified to perform PNB provided that the following can be demonstrated:

The physician must have at least 2 years of interventional radiology experience during which the physician was supervised, and during which the physician performed and interpreted at least 35 image-guided percutaneous biopsy procedures, 25 of them as primary operator, with outcomes within the quality improvement thresholds of this guideline.

- and
4. Physicians meeting any of the qualifications in 1, 2, and 3 above must also have written substantiation that they are familiar with all of the following:

- a. Indications and contraindications for the procedure.
- b. Periprocedural and intraprocedural assessment, monitoring, and management of the patient and potential complications.
- c. Where applicable, pharmacology of moderate 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, the 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 introduction techniques.
- h. Technical aspects of performing the procedure, including the use of alternative biopsy devices.
- i. Anatomy, physiology, and pathophysiology of the structures being considered for PNB.

The written substantiation should come from the chief of interventional radiology, the director or chief of body imaging or ultrasound, or the chair of the department of the institution in which the physician will be providing these services. Substantiation could also come from a prior institution in which the physician provided the services, but only at the discretion of the current interventional director or chair who solicits the additional input.

#### Maintenance of Competence

Physicians must perform a sufficient number of PNBs 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 medical education should be in accordance with the [ACR Practice Guideline on 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 equipment 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 and experience 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 American Board of Radiology (ABR), the Canadian College of Physics in Medicine, 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 Qualified Medical Physicist should meet the [ACR Practice Guideline for Continuing Medical Education \(CME\)](#). (ACR Resolution 17, 1996 – revised 2008, Resolution 7)

#### 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" [4] 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. (ACR Resolution 34, adopted in 2006)

#### 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

position<sup>1</sup> the patient for the image-guided percutaneous procedure and, together with the nurse, monitor the patient during the procedure. 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 policy statements<sup>2</sup> and existing operating procedures or manuals at the facility. The technologist should 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 (ARRT) or have an unrestricted state license with documented training and experience in the imaging modality used for the image-guided percutaneous procedure.

#### E. Diagnostic Medical Sonographer

The sonographer, together with the physician and nursing personnel, should have responsibility for patient comfort and safety. The sonographer should be able to prepare and position the patient for the image-guided percutaneous procedure and, together with the nurse, monitor the patient during the procedure. The sonographer should obtain the imaging data in a manner prescribed by the supervising physician. The sonographer should also perform regular quality control testing of the equipment under supervision of the physicist.

Diagnostic medical sonographers should be certified by the American Registry of Radiologic Technologists (ARRT[S]) or by the American Registry for Diagnostic Medical Sonography (ARDMS) or have an unrestricted state license with documented training and experience in the imaging modality used for the image-guided percutaneous procedure.

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<sup>1</sup>The 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. (ACR Resolution 26, 1987 – revised in 2007, Resolution 12m)

\*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.

<sup>2</sup>See the [ACR Practice Guideline for the Use of Intravascular Contrast Media](#).

#### F. Other Ancillary Personnel

Other ancillary personnel who are qualified and duly licensed or certified under applicable state law may, under supervision by a radiologist or other qualified physician, perform specific interventional fluoroscopic or other image-guided procedures. Supervision by a radiologist or other qualified physician must be direct or personal, and must comply with local, state, and federal regulations. Individuals should be credentialed for specific fluoroscopic and other image-guided interventional procedures and should have received formal training in radiation management and/or application of other imaging modalities as appropriate.

#### G. Nursing Services

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

#### H. Other Licensed Independent Practitioner

In cases where moderate sedation is used or the patient is critically ill, an experienced licensed provider should be present, whose sole responsibility is monitoring of the patient’s vital signs, sedation state, and level of comfort/pain. For moderate sedation, refer to the [ACR–SIR Practice Guideline for Sedation/Analgesia](#).

### V. SPECIFICATIONS AND PERFORMANCE OF THE PROCEDURE

#### A. Imaging Equipment and Facilities

1. The minimum requirements for facilities in which PNB is performed include:
  - a. When fluoroscopic guidance is used, a high-resolution unit with adequate shielding and collimation is desirable. Ability to perform complex angle (e.g., anteroposterior [5], lateral, or oblique) fluoroscopy views is often necessary to ensure proper needle placement. 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.
  - c. When appropriate, computed tomography (CT) and/or CT fluoroscopic capability is desirable to better demonstrate anatomy, particularly in:

- i. Patients with lesions that are difficult to visualize or access with other modalities, or are in unusual or precarious locations.
- ii. Planning the optimal route of biopsy 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 the Patient Care Section below. There should be immediate access to emergency resuscitation equipment. Personnel and equipment to diagnose and treat acute complications should also be available.
- e. For patients undergoing thoracic procedures, a full array of percutaneous catheterization equipment for treatment of pneumothorax should be available.
- f. Access to laboratory facilities should be available with expertise in cytopathology, microbiology, and chemistry. (These resources need not be located in the biopsy facility.)

## 2. Performance guidelines

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

- a. Fluoroscopic times for both X-ray and CT guidance should be kept to a minimum. The operator will use only as much fluoroscopy as is necessary to complete the biopsy, 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 [6].
  - b. Tight collimation and, when appropriate, shielding (e.g., thyroid, gonadal) should be used.
  - c. On units where dose reduction pulsed fluoroscopy is available, its use is recommended.
3. Appropriate emergency equipment and medications must be immediately available to treat adverse reactions associated with administered medications and/or procedural complications. The equipment should be monitored and medications inventoried for drug expiration dates on a regular basis. The

equipment, medications, and other emergency support must also be appropriate for the range of ages and sizes in the patient population.

## B. Physiologic Monitoring and Resuscitation Equipment

- 1. Appropriate equipment should be present to allow for monitoring the patient’s heart rate, rhythm, and blood pressure. For facilities using moderate sedation, a pulse oximeter should be available. (See the [ACR–SIR Practice Guideline for Sedation/Analgesia](#).)
- 2. There should be ready access to emergency resuscitation equipment and drugs, to include the following: a defibrillator, oxygen supply and appropriate tubing and delivery systems, suction equipment, tubes for endotracheal intubation, laryngoscope, ventilation bag-valve-mask 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 and checked on a routine basis in compliance with institutional policies.
- 3. Any procedure performed using MRI guidance must have MRI safety compatible emergency resuscitation equipment available.

## C. Acute Care Support

Although complications of PNB 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 PNB should provide sufficient information to demonstrate the medical necessity of the procedure and allow for its proper performance and interpretation.

Documentation that satisfies medical necessity includes 1) signs and symptoms, 2) relevant history (including known diagnoses and/or 3) prior imaging). Additional information regarding the specific reason for the procedure or a provisional diagnosis would be helpful and may at times be needed to allow for the proper performance and interpretation of the procedure.

The request for the procedure 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. (ACR Resolution 35, adopted in 2006)

The requested examination should be specific to body site and side, if appropriate.

#### 1. Preprocedural 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, including an awareness of clinical or medical conditions that may necessitate specific care, such as preprocedure antibiotics or other measures.
  - iii. Possible alternative methods, such as surgery, to obtain the desired diagnostic information or therapeutic result.
- b. Informed consent must be in compliance with all state laws and should comply with the [ACR–SIR Practice Guideline on Informed Consent for Image-Guided Procedures](#).

#### 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 include at least:
    - Correct patient identity.
    - Correct site.
    - Agreement on the procedure to be done.

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

Site marking is not required for interventional procedures when the site of entry is not predetermined and imaging

guidance is used to identify the lesion. The remainder of the universal protocol must still be followed.

- b. During the use of fluoroscopy, the physician should use exposure factors consistent with the ALARA radiation safety guidelines.
- c. Nursing personnel, technologists, and those directly involved in the patient's care during PNB 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. Postprocedural care

- a. Orders for postprocedure patient care should include frequency of obtaining vital signs, discharge instructions, etc.
- b. Specific anatomic considerations
  - i. Thoracic cavity: pulmonary and appropriate imaging assessment for the presence of pneumothorax.
  - ii. Peritoneal and other solid organ biopsies: appropriate imaging and/or laboratory studies to evaluate for acute complications when indicated.

#### E. Specifics of the Procedure

1. All invasive image-guided PNB procedures are performed for specific indications, and they should be tailored accordingly.
2. The physician should be aware of the various types of aspiration and core cutting needles that are available.
3. The physician should be aware of the diagnostic possibilities and request the appropriate laboratory studies.
4. Prior consultation with pathology may be useful in selected cases.

## VI. DOCUMENTATION

Reporting should be in accordance with the [ACR–SIR 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 concept is known as “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; if not, manual techniques should be used to moderate the exposure while maintaining the necessary diagnostic image quality. Periodically, radiation exposures should be measured and patient radiation doses estimated by a medical physicist in accordance with the appropriate ACR Technical Standard. (ACR Resolution 17, adopted in 2006 – revised in 2009, Resolution 11)

## VIII. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

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 appearing under the heading *Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education* on the ACR web page (<http://www.acr.org/guidelines>).

Equipment performance monitoring should be in accordance with the [ACR Technical Standard for Diagnostic Medical Physics Performance Monitoring of Radiological 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 bleeding is one measure of the quality of image-guided PNB, then

values in excess of the defined threshold should trigger a review of policies and procedures within the department to determine the causes and to implement changes to lower the incidence for 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. Each department is urged to alter the threshold to higher or lower values as needed to meet its own quality improvement program needs.

### A. Success Rates and Thresholds

Many variables will affect the eventual success of a PNB procedure. These include the number of samples obtained, the size of the target abnormality, the organ system in which biopsy is performed, the availability of an on-site cytopathologist [7], the experience of the institution’s pathology staff, the imaging equipment available, and the skill of the operating physician.

#### Success Rate Range for Identifying of Malignant Lesions

<u>Image-Guided PNB</u>	<u>Range</u>
Successful biopsy	70% to 90% [5,8-19]

Note: These ranges may vary depending on the mix of organ systems, the size and location of lesions, and the overall condition of patients who are sampled.

### B. Complication Rates and Thresholds

Complications can be stratified on the basis of outcome. Major complications result in admission to the 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 (see Appendix A). The complication rates and thresholds presented refer to major complications, unless otherwise noted. Indicator thresholds may be used to assess the efficacy of quality improvement programs.

The complications of percutaneous biopsies are divided into 2 types: generic and organ-specific. Generic refers to complications that are common to all biopsies. The major generic complications include bleeding, infection, perforation, and unintended organ injury [20]. Clinically significant bleeding is infrequent, although relative bleeding risks increase with increasing needle size, use of cutting needles and vascularity of the organ or lesion biopsied (i.e., renal and liver biopsies, hypervascular lesions) [21,22]. Infection as a result of biopsy is also rare. Injury may occur to the target organ or to a nearby

organ that is traversed by the needle. Injuries of this type require further interventions in fewer than 2% of patients. Organ-specific complications are those that are only associated or most commonly associated with biopsy of a specific organ. For example, pneumothorax is most commonly associated with lung biopsy but can occur during vertebral, rib, liver, spleen, adrenal, kidney, and breast biopsies or aspirations. Other complications may occur, but rarely require therapy. These include hematuria after renal or prostate biopsy, and hemoptysis after lung biopsy. Perforation may be considered organ-specific.

The following set of thresholds lists the reported rates of given complications and a suggested threshold that should prompt a review when exceeded. In addition, there are certain complications that are almost always associated with a single organ [23]. Very rare complications, such as hypertensive crisis after adrenal biopsy, pancreatitis, and tumor seeding of the needle tract [24,25], are not given thresholds. Each major incident should be investigated as appropriate.

### Thresholds for Specific Major Complications Resulting from Image-Guided PNB

Major Complications	Reported Rate	Suggested Threshold
Bleeding requiring transfusion or intervention [15,26-29]:		
Needle size ranges		
19-gauge or larger	5%-10%	10%
20-gauge or smaller	0.1%-2%	2%
Infection requiring hospitalization or specific therapy:		
All biopsies (sterile)	1%	2%
Prostate biopsy [30] (nonsterile)	2.5%-3.0%	6%
Peritonitis requiring hospitalization or specific therapy:		
Abdominal biopsies	1.5%	2%
Hemoptysis requiring hospitalization or specific therapy [11]:		
Lung biopsies	0.5%	2%
Pneumothorax requiring chest tube for biopsies that do not involve entering the lung:		
Nonlung biopsies	0.5%	1%

Lung biopsy: There are special considerations for classifying major versus minor complications requiring chest tube management after lung biopsy resulting in the development of a pneumothorax. Special note is also made that there are lung biopsies during which planned placement of a chest tube is accepted for the successful completion of the procedure. Placement of a chest tube in these settings therefore should not be considered a complication. [11,18,31-36]

Minor Complications (lung biopsy)	Reported Rate	Suggested Threshold
Routine management with chest tube after lung biopsy	5%-10%	20%
➤ Simple overnight hospital stays as part of routine management process.		
➤ Outpatient management in which the catheter is removed within 3 days of insertion.		

Major Complications (lung biopsy)	Reported Rate	Suggested Threshold
Complicated chest tube management after lung biopsy	1%-2%	3%
➤ Unexpected admission for chest tube management.		
➤ Hospitalization > 48 hours for chest tube management.		
➤ Persistent air leak or delay of chest tube removal beyond 3 days.		
➤ Requires catheter change or upsize during the course of management.		
➤ Requires pleurodesis.		

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 larger volume 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 series (e.g., early in a quality improvement program). In this situation, an overall procedural threshold is more appropriate for use in a quality improvement program.

In the above table, all values are supported by the weight of literature evidence and panel consensus.

### Overall Thresholds for all Major Complications Resulting from Image-Guided PNB

Biopsy Location	Threshold
Lung (11,18,31-36)	20%
Other sites	2%

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#### **REFERENCES**

1. Cardella JF, Bakal CW, Bertino RE, et al. Quality improvement guidelines for image-guided percutaneous biopsy in adults: Society of Cardiovascular & Interventional Radiology Standards of Practice Committee. *J Vasc Interv Radiol* 1996;7:943-946.
2. Friedman LS. Controversies in liver biopsy: who, where, when, how, why? *Curr Gastroenterol Rep* 2004;6:30-36.
3. Nikolaidis P, vanSonnenberg E, Haddad ZK, et al. Practice patterns of nonvascular interventional radiology procedures at academic centers in the United States? *Acad Radiol* 2005;12:1475-1482.
4. ACR ASRT joint statement radiologist assistant roles and responsibilities. In: *Digest of Council Actions*. Reston, Va: American College of Radiology; 2007:149.
5. Agarwal PP, Seely JM, Matzinger FR, et al. Pleural mesothelioma: sensitivity and incidence of needle track seeding after image-guided biopsy versus surgical biopsy. *Radiology* 2006;241:589-594.
6. Lucey BC, Varghese JC, Hochberg A, Blake MA, Soto JA. CT-guided intervention with low radiation dose: feasibility and experience. *AJR* 2007;188:1187-1194.
7. Bandyopadhyay S, Pansare V, Feng J, et al. Frequency and rationale of fine needle aspiration biopsy conversion to core biopsy as a result of onsite evaluation. *Acta Cytol* 2007;51:161-167.
8. Agid R, Sklair-Levy M, Bloom AI, et al. CT-guided biopsy with cutting-edge needle for the diagnosis of malignant lymphoma: experience of 267 biopsies. *Clin Radiol* 2003;58:143-147.
9. Aviram G, Greif J, Man A, et al. Diagnosis of intrathoracic lesions: are sequential fine-needle aspiration (FNA) and core needle biopsy (CNB) combined better than either investigation alone? *Clin Radiol* 2007;62:221-226.
10. Gong Y, Sneige N, Guo M, Hicks ME, Moran CA. Transthoracic fine-needle aspiration vs concurrent core needle biopsy in diagnosis of intrathoracic lesions: a retrospective comparison of diagnostic accuracy. *Am J Clin Pathol* 2006;125:438-444.
11. Heck SL, Blom P, Berstad A. Accuracy and complications in computed tomography fluoroscopy-guided needle biopsies of lung masses. *Eur Radiol* 2006;16:1387-1392.
12. Hunter S, Samir A, Eisner B, et al. Diagnosis of renal lymphoma by percutaneous image guided biopsy: experience with 11 cases. *J Urol* 2006;176:1952-1956; discussion 1956.
13. Jaff A, Molinie V, Mellot F, Guth A, Lebret T, Scherrer A. Evaluation of imaging-guided fine-needle percutaneous biopsy of renal masses. *Eur Radiol* 2005;15:1721-1726.
14. Lachar WA, Shahab I, Saad AJ. Accuracy and cost-effectiveness of core needle biopsy in the evaluation of suspected lymphoma: a study of 101 cases. *Arch Pathol Lab Med* 2007;131:1033-1039.
15. Maturen KE, Nghiem HV, Caoili EM, Higgins EG, Wolf JS, Jr., Wood DP, Jr. Renal mass core biopsy: accuracy and impact on clinical management. *AJR* 2007;188:563-570.
16. Paulsen SD, Nghiem HV, Korobkin M, Caoili EM, Higgins EJ. Changing role of imaging-guided percutaneous biopsy of adrenal masses: evaluation of 50 adrenal biopsies. *AJR* 2004;182:1033-1037.
17. Rybicki FJ, Shu KM, Cibas ES, Fielding JR, vanSonnenberg E, Silverman SG. Percutaneous biopsy of renal masses: sensitivity and negative predictive value stratified by clinical setting and size of masses. *AJR* 2003;180:1281-1287.
18. vanSonnenberg E, Goodacre BW, Wittich GR, Logrono R, Kennedy PT, Zwischenberger JB. Image-guided 25-gauge needle biopsy for thoracic lesions: diagnostic feasibility and safety. *Radiology* 2003;227:414-418.
19. Vieillard MH, Boutry N, Chastanet P, Duquesnoy B, Cotten A, Cortet B. Contribution of percutaneous biopsy to the definite diagnosis in patients with suspected bone tumor. *Joint Bone Spine* 2005;72:53-60.

20. Kim KW, Kim MJ, Kim HC, et al. Value of "patent track" sign on Doppler sonography after percutaneous liver biopsy in detection of postbiopsy bleeding: a prospective study in 352 patients. *AJR Am J Roentgenol* 2007;189:109-116.
21. Geraghty PR, Kee ST, McFarlane G, Razavi MK, Sze DY, Dake MD. CT-guided transthoracic needle aspiration biopsy of pulmonary nodules: needle size and pneumothorax rate. *Radiology* 2003;229:475-481.
22. Schubert P, Wright CA, Louw M, et al. Ultrasound-assisted transthoracic biopsy: cells or sections? *Diagn Cytopathol* 2005;33:233-237.
23. Little AF, Ferris JV, Dodd GD, 3rd, Baron RL. Image-guided percutaneous hepatic biopsy: effect of ascites on the complication rate. *Radiology* 1996;199:79-83.
24. Matsuguma H, Nakahara R, Kondo T, Kamiyama Y, Mori K, Yokoi K. Risk of pleural recurrence after needle biopsy in patients with resected early stage lung cancer. *Ann Thorac Surg* 2005;80:2026-2031.
25. Maturen KE, Nghiem HV, Marrero JA, et al. Lack of tumor seeding of hepatocellular carcinoma after percutaneous needle biopsy using coaxial cutting needle technique. *AJR* 2006;187:1184-1187.
26. Gazelle GS, Haaga JR, Rowland DY. Effect of needle gauge, level of anticoagulation, and target organ on bleeding associated with aspiration biopsy. Work in progress. *Radiology* 1992;183:509-513.
27. Manno C, Strippoli GF, Arnesano L, et al. Predictors of bleeding complications in percutaneous ultrasound-guided renal biopsy. *Kidney Int* 2004;66:1570-1577.
28. Nolsoe C, Nielsen L, Torp-Pedersen S, Holm HH. Major complications and deaths due to interventional ultrasonography: a review of 8000 cases. *J Clin Ultrasound* 1990;18:179-184.
29. Smith EH. Complications of percutaneous abdominal fine-needle biopsy. Review. *Radiology* 1991;178:253-258.
30. Littrup PJ WS, Sparschu RA. Prostate biopsy decisions and complications. *Seminars in Interventional Radiology* 1994;11:231-2236.
31. Covey AM, Gandhi R, Brody LA, Getrajdman G, Thaler HT, Brown KT. Factors associated with pneumothorax and pneumothorax requiring treatment after percutaneous lung biopsy in 443 consecutive patients. *J Vasc Interv Radiol* 2004;15:479-483.
32. Gupta S, Krishnamurthy S, Broemeling LD, et al. Small ( $\leq$ 2-cm) subpleural pulmonary lesions: short-versus long-needle-path CT-guided Biopsy--comparison of diagnostic yields and complications. *Radiology* 2005;234:631-637.
33. Tomiyama N, Yasuhara Y, Nakajima Y, et al. CT-guided needle biopsy of lung lesions: a survey of severe complication based on 9783 biopsies in Japan. *Eur J Radiol* 2006;59:60-64.
34. Topal U, Berkman YM. Effect of needle tract bleeding on occurrence of pneumothorax after transthoracic needle biopsy. *Eur J Radiol* 2005;53:495-499.
35. Yamagami T, Kato T, Hirota T, Yoshimatsu R, Matsumoto T, Nishimura T. Duration of pneumothorax as a complication of CT-guided lung biopsy. *Australas Radiol* 2006;50:435-441.
36. Yeow KM, Su IH, Pan KT, et al. Risk factors of pneumothorax and bleeding: multivariate analysis of 660 CT-guided coaxial cutting needle lung biopsies. *Chest* 2004;126:748-754.

## 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.

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\*Guidelines and standards are published annually with an effective date of October 1 in the year in which amended, revised, or approved by the ACR Council. For guidelines and standards published before 1999, the effective date was January 1 following the year in which the guideline or standard was amended, revised, or approved by the ACR Council.

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