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PRACTICE GUIDELINE FOR THE PERFORMANCE OF IMAGE-GUIDED PERCUTANEOUS NEEDLE BIOPSY (PNB) 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).

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. This guideline outlines the principles for the performance of PNB.

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.

II. DEFINITION

PNB is defined as percutaneous placement of a needle into a suspected abnormal lesion for the purpose of obtaining tissue or cells for diagnosis. Following specimen procurement, the needle is 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. 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 diagnostic examination involving ionizing radiation. If the patient is known to be pregnant, the potential risk to the fetus and clinical benefits of the procedure should be considered before proceeding with this study. 1995, 2005 (Res. 1a)

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 in order to plan and perform it safely and effectively.

The physician performing PNB must fully appreciate the benefits, alternatives, and risks of the procedure. He/she 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 Le College des Medecins du Quebec and has performed at least 35 image-guided PNB procedures as primary operator with outcomes within the quality improvement thresholds of this document.

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 performing interventional radiology procedures, and 6 months of documented formal training in interpreting cross-sectional imaging exam-inations. This training should include the

experience of performing (with supervision) at least 35 image-guided PNBs 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 experience during which the physician was supervised, and during which he/she performed and interpreted at least 35 image-guided percutaneous procedures as primary operator with outcomes within the quality improvement thresholds of this guideline.

   and

4. Substantiation in writing by the director of interventional radiology or the chief 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, 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.

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 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 (Res. 16g)

C. Radiologist Assistant

A 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 (Res. 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 position[1] 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 current ACR policy statements[2] and existing operating procedures or manuals at the interventional radiology facility and/or imaging 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 or have an unrestricted state license with documented training and experience in the imaging modality used for the image-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.

[1]The American College of Radiology approves of the practice of certified and/or licensed radiologic technologists performing fluoroscopy only as a positioning or localizing procedure and then only if monitored by a supervising physician who is personally and immediately available, and the positioning or localizing procedure must have prior written approval by the medical director of the radiology department/service and there be written authority, policy, and procedures for designating radiologic technologists who perform such procedures. 1987, 1997 (Res. 1-E)

[2]The American College of Radiology approves of the injection of contrast material and diagnostic levels of radiopharmaceuticals by certified and/or licensed radiologic technologists and radiologic nurses under the direction of a radiologist or his or her physician designee who is personally and immediately available, if the practice is in compliance with institutional and state regulations. There must be prior written approval by the medical director of the radiology department/service of such individuals; such approval process having followed established policies and procedures and the radiologic technologists and radiologic nurses who have been so approved maintain documentation of continuing medical education related to the materials being injected and to the procedures being performed. 1987, 1997 (Res. 1-H)

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 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. 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 access 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.
    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 time 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.
b. Tight collimation and, when appropriate, shielding (e.g., thyroid, gonadal) 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, 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: emergency defibrillator, oxygen supply and appropriate tubing and delivery systems, suction equipment, tubes for endo-tracheal 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, brady-cardia, and ventricular dysrhythmias should also be readily available.

C. Surgical 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 examination and allow for the proper performance and interpretation of the examination.

Documentation that satisfies medical necessity includes 1) signs and symptoms and/or 2) relevant history (including known diagnoses). The provision of 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 (Res. 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 all state laws and should comply with the ACR Practice Guideline on Informed Consent for Image-Guided Procedures.

2. Procedural care

a. Adherence to the JCAHO 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 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. Postprocedure 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 to exclude bleeding, when indicated.

E. Specifics of the Procedure

1. All invasive image-guided percutaneous needle biopsy procedures are performed for specific indications, and the examination/procedure should therefore 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 Practice Guideline for Reporting and Archiving of Interventional Radiology Procedures.

VII. RADIATION SAFETY IN IMAGING

Radiologists, 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 (Res. 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 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 as needed to higher or lower values, to meet its own quality improvement program needs.

A. Success Rates and Thresholds

Many variables will affect the eventual success of a percutaneous needle biopsy 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, the experience of the institution's pathology staff, the imaging equipment available, and the skill of the operating physician.

Success Rate Thresholds for Identification of Malignant Lesions

Image-Guided PNB	Threshold
Successful biopsy other than lung	80%
Successful lung biopsy	85%

Note: These thresholds may vary depending on the mix of organ systems that 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 (generally overnight) (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 ongoing quality improvement programs.

The complications of percutaneous biopsies are divided into two types: generic and organ-specific. Generic refers to complications that are common to all biopsies. The major generic complications include bleeding, infection, and unintended organ injury. Clinically significant bleeding is infrequent, although there is increased risk in core renal biopsies. 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 surgery or other interventions in less than 2% of patients. Regardless of the organ system in which biopsy is performed; the risk of complication from bleeding is generally higher with large needles than with small needles.

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, and breast biopsies or aspirations. Other complications occur but rarely require therapy. These include hematuria after renal or prostate biopsy and hemoptysis after lung biopsy.

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. Very rare complications, such as hypertensive crisis after adrenal biopsy, pancreatitis, and tumor seeding of the needle track, are not given thresholds. Each major incident should be investigated as appropriate.

Thresholds for Specific Major Complications from Image-Guided PNB

Major Complications	Reported Rate	Suggested Threshold
Bleeding requiring transfusion or intervention:		
Large needle (18-gauge or larger)	5%-10%	10%
Small needle (19-gauge or smaller)	3%	6%
Fine needle (21-gauge or smaller)	0.1%-2.0%	2%
Infection requiring hospitalization or specific therapy:		
All biopsies (sterile)	1%	2%
Prostate biopsy (nonsterile)	2.5%-3.0%	6%
Peritonitis requiring hospitalization or specific therapy:		
Abdominal biopsies	1.5%	2%
Hemoptysis requiring hospitalization or specific therapy:		
Lung biopsies	0.5%	1%
Pneumothorax requiring chest tube placement:		
All biopsies (other than lung)	0.5%	1%
Lung biopsies	5%	10%

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, 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 PNB

Biopsy Location	Threshold
Lung	10%
Other sites	2%

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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.